

6,666,667 Shares



Common Stock

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This is an initial public offering of shares of common stock of NGM Biopharmaceuticals, Inc. All of the 6,666,667 shares of common stock are being sold by us.

Prior to this offering, there has been no public market for our common stock. The initial public offering price per share is \$16.00.

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "NGM."

We are an "emerging growth company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced public company reporting requirements.

*Investing in our common stock involves a high degree of risk. See "[Risk Factors](#)" beginning on page 12 to read about factors you should consider before buying shares of our common stock.*

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**Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.**

	Per Share	Total
Initial public offering price	\$ 16.00	\$106,666,672
Underwriting discounts and commissions(1)	\$ 1.12	\$ 7,466,667
Proceeds to us, before expenses	\$ 14.88	\$ 99,200,005

(1) We refer you to "Underwriting" beginning on page 203 for additional information regarding total underwriting compensation.

We have granted the underwriters an option to purchase up to an additional 1,000,000 shares at the initial public offering price less the underwriting discounts and commissions.

Merck Sharp & Dohme Corp., a strategic collaborator and existing stockholder, has agreed to purchase 4,121,683 shares of our common stock in a separate private placement concurrent with the completion of this offering at a price of \$16.00 per share. The sale of such shares will not be registered under the Securities Act of 1933, as amended. The completion of this offering is not contingent upon the completion of such concurrent private placement.

In addition, entities affiliated with The Column Group, an existing stockholder, have agreed to purchase 1,875,000 shares of our common stock in this offering at the initial public offering price. The underwriters will receive the same underwriting discount on any shares purchased by these entities as they will on any other shares sold to the public in this offering.

The underwriters expect to deliver the shares against payment in New York, New York on April 8, 2019.

**Goldman Sachs & Co. LLC**

**Citigroup**

**Cowen**

Prospectus dated April 3, 2019

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We have not authorized anyone to provide you with any information other than the information contained in this prospectus or any free writing prospectus we have prepared. We take no responsibility for, and provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only in circumstances and in jurisdictions where it is lawful to so do. The information contained in this prospectus is accurate only as of its date, regardless of the time of delivery of this prospectus or of any sale of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourself about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes included elsewhere in this prospectus. You should also consider, among other things, the matters described under the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included elsewhere in this prospectus. Unless otherwise stated, all references to "us," "our," "NGM," "NGM Biopharmaceuticals," "we," the "Company" and similar designations refer to NGM Biopharmaceuticals, Inc. and its subsidiary.*

### 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, five of which are in clinical testing. Our most advanced product candidate, NGM282, is wholly-owned and will enter Phase 2b development for the treatment of non-alcoholic steatohepatitis, or NASH, in mid-2019. In an ongoing Phase 2 clinical trial, NGM282 has demonstrated the ability to rapidly improve NASH and reverse liver fibrosis at 12 weeks. We have created this portfolio using our research and drug discovery approach that employs unbiased, *in vivo*-based discovery to identify proprietary insights into critical biological processes. We combine this approach with our protein and antibody engineering expertise to find the appropriate modality to enhance each product candidate's therapeutic potential. Our executives, directors and advisors have extensive track records of successfully discovering, developing and delivering to patients first-in-class drugs, which positions us well to maximize the potential of our drug discovery approach.

### Our Collaboration with Merck

In 2015, we entered into a five-year research collaboration, product development and license agreement with Merck Sharp & Dohme Corp., or Merck. On March 15, 2019, Merck exercised its option to extend the collaboration for two additional years to March 2022. At inception, the collaboration included an exclusive worldwide license to our growth differentiation factor 15, or GDF15, receptor agonist program. On March 1, 2019, Merck notified us of its intent to terminate its license to the GDF15 receptor agonist program, effective May 31, 2019. Upon effectiveness of this termination, we will regain full rights to the GDF15 receptor agonist program, which includes NGM386 and NGM395. We expect to decide whether to advance NGM386 and/or NGM395 following our analysis of the results of the NGM386 Phase 1 study. Under the collaboration agreement, we also granted Merck options to take exclusive, worldwide licenses for the programs in our research and development pipeline on a program-by-program basis. Merck generally has a one-time right to exercise its option when a program completes a human proof-of-concept trial. In November 2018, Merck exercised its option to license NGM313, an agonist antibody selectively activating fibroblast growth factor receptor 1c-beta-klotho, or FGFR1c/KLB, as a potential treatment for NASH and type 2 diabetes. The collaboration enables us to develop more product candidates for major indications than we could likely advance on our own, with Merck bearing a majority of the associated cost and risk. We retain an option, when a candidate has advanced to Phase 3 clinical trials, to participate in up to 50% of the

economic return from that candidate if it becomes an approved medicine. Overall, the Merck collaboration provides us with robust research and development support, while we retain our research independence and the option to split costs and profits on product candidates Merck elects to advance. We excluded our fibroblast growth factor 19, or FGF19, program, including NGM282, from the agreement and it remains wholly-owned by us.

### **Our Approach to Drug Discovery and Development**

We pursue drug discovery and development through a multi-step process geared towards translating powerful human biology into first-in-class medicines. Our founding team designed our approach based on many decades of collective experience in successful drug development at other companies, including Amgen, Genentech and Tularik. Our process pairs a research approach that generates novel insights into pathways demonstrating powerful biological effect with the expertise in protein and antibody engineering to transform those insights into product candidates. We then rapidly advance the program to evaluate the effect of these product candidates on biomarkers of disease or target activity in order to enable early demonstration of human proof of concept.

### Our Development Programs

Our most advanced programs have focused on novel discoveries in hormone pathways that regulate cardio-metabolic processes and liver function, including those driving NASH, type 2 diabetes and obesity. We have identified multiple hormone pathways of interest, the most advanced of which are: FGF19, which plays a critical role in controlling bile acid, lipid and glucose metabolism; FGFR1c/KLB, which regulates insulin sensitivity, blood glucose and liver fat; and GDF15, which drives profound metabolic activity by regulating fuel flux and has been considered a challenging therapeutic target. We believe these hormone pathways work through distinct mechanisms and play an important role in metabolic regulation. We are currently advancing seven proprietary product candidates, as summarized below.

PRODUCT CANDIDATE	MECHANISM OF ACTION (Dosing Frequency)	POTENTIAL INDICATIONS	STAGE OF DEVELOPMENT				WORLDWIDE COMMERCIAL RIGHTS	EXPECTED UPCOMING MILESTONES
			Preclinical	Phase 1	Phase 2	Phase 3		
NGM282	FGF19 Analog (Once Daily)	NASH	Phase 2				NGM	Ph 2b (F2/F3) Initiation: Mid-2019 Ph 2b (F4) Initiation: 2H 2019 Interim Ph 2 Data: 2H 2019
NGM313	FGFR1c / KLB Agonistic Antibody (Once Monthly)	NASH, Type 2 Diabetes	Phase 1b				Merck License	Ph 2b Initiation: Late 2019 – Early 2020
NGM120	GFRAL Antagonistic Antibody (Long Acting)	Cancer Anorexia / Cachexia Syndrome (CACS)	Phase 1				Merck Option to License	Ph 1a/1b Initiation: 2H 2019
NGM217	Undisclosed (Long Acting)	Diabetes	Phase 1				Merck Option to License	Ph 1b/2a Initiation: 2020
NGM621	Undisclosed (Long Acting)	Dry Age-Related Macular Degeneration	Preclinical				Merck Option to License	Ph 1 Initiation: 2H 2019
NGM386	GDF15 Analog (Once Daily)	Obesity	Phase 1				NGM <sup>1</sup>	
NGM395	GDF15 Analog (Long Acting)	Obesity	Preclinical				NGM <sup>1</sup>	

<sup>1</sup> Effective May 31, 2019.

We are currently focused on the following programs:

- NGM282 is an engineered variant of the human hormone known as FGF19, which we are developing for the treatment of NASH. Preliminary results from Phase 2 clinical trials have provided clinical proof of concept for a once-daily injection of NGM282 by demonstrating statistically significant reductions in liver fat, liver transaminases and biomarkers of fibrosis, which has translated into improvements on liver histology and fibrosis at 12 weeks. We expect interim data in the second half of 2019 from our ongoing placebo-controlled Phase 2 clinical

trial cohort assessing the histological effects of NGM282 after 24 weeks of treatment. We excluded our FGF19 program, including NGM282, from our Merck collaboration, and it remains wholly-owned by us.

- NGM313 is an agonistic antibody selectively activating FGFR1c/KLB and has the potential as an insulin sensitizer and regulator of lipid homeostasis to be a treatment for NASH and type 2 diabetes. Preliminary data from a Phase 1b proof-of-concept clinical trial in obese, insulin resistant subjects with non-alcoholic fatty liver disease, or NAFLD, demonstrated that a single dose of NGM313 resulted in a statistically significant reduction in liver fat content and improvements in multiple metabolic parameters. Following completion of this proof-of-concept study, Merck exercised its option to license the program in November 2018. We expect Merck to initiate a Phase 2b study of NGM313 in NASH patients in late 2019 or early 2020.
- NGM120 is an antagonistic antibody binding glial cell-derived neurotrophic factor receptor alpha-like, or GFRAL, that is designed to inhibit the effects of elevated GDF15 levels on cancer anorexia/cachexia syndrome, or CACS, and, possibly, cancer. We are currently testing NGM120 in healthy volunteers in a Phase 1 clinical trial to assess its safety, tolerability and pharmacokinetic profile. We expect to initiate a Phase 1a/1b clinical trial of NGM120 in cancer patients in the second half of 2019. Merck has a one-time option to license NGM120 upon our completion of a proof-of-concept study in humans.
- NGM217 is an antibody binding an undisclosed target that is designed to restore pancreatic islet function and increase insulin production in patients with diabetes. NGM217 is in a Phase 1 study in adults with diabetes, where we are assessing its ability to increase levels of C-peptide, a biomarker of insulin production. We expect to initiate a Phase 1b/2a proof-of-concept clinical trial in adults with diabetes in 2020. Merck has a one-time option to license NGM217 upon our completion of a proof-of-concept study in humans.
- NGM621 is an antibody binding an undisclosed target that is designed to decrease levels of a protein implicated in the dry form of age-related macular degeneration, or dry AMD. NGM621 is in investigational new drug, or IND, enabling studies, and we expect to begin a Phase 1 safety, tolerability and pharmacokinetics study in patients with geographic atrophy, or GA, an advanced form of dry AMD, in the second half of 2019. Merck has a one-time option to license NGM621 upon our completion of a proof-of-concept study in humans.
- NGM386 and NGM395 are engineered variants of the human hormone known as GDF15, which were being developed with Merck under the collaboration for the treatment of obesity. Merck licensed our GDF15 receptor agonist program in 2015 and completed the conduct of a Phase 1 study of NGM386 in overweight or obese but otherwise healthy adults. Preliminary data from the study indicated that NGM386 treatment for 28 days was generally well-tolerated but did not result in significant body weight loss in obese subjects. On March 1, 2019, Merck notified us of its intent to terminate its license to the program, effective May 31, 2019. Upon effectiveness of this termination, we will regain full rights to the GDF15 receptor agonist program, which includes NGM386 and NGM395. We expect to decide whether to advance NGM386 and/or NGM395 following the completion of our detailed analysis of the results of the NGM386 Phase 1 study.

### **Our Strategy**

Our strategy is to leverage our biology-centric drug discovery approach to uncover novel mechanisms of action and generate proprietary insights that will enable us to move rapidly into proof-of-concept studies and deliver to patients first-in-class medicines. Key elements of our strategy are:

- *Establish NGM282, our wholly-owned compound, as the leading treatment for NASH patients with moderate to advanced fibrosis*
- *Leverage our collaboration with Merck to advance our pipeline*
- *Grow our pipeline and extend our therapeutic areas of focus*
- *Build capabilities to deliver medicines to patients in areas of high unmet medical need*
- *Strengthen our position as a leading drug discovery and development company*

### **Risks Associated with Our Business**

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors" immediately following this prospectus summary. Some of those risks are:

- we have incurred net losses every year since our inception, expect to incur significant and increasing operating losses and may never be profitable;
- we may need to acquire additional capital to finance our operations, which may not be available to us on acceptable terms, or at all;
- substantially all of our revenue for recent periods has been received from a single collaboration partner;
- we currently have no approved products or product revenue, and we will need to successfully complete preclinical and clinical testing of our product candidates before we can seek regulatory approval and potentially generate commercial sales;
- our future success depends in part on our ability to attract and retain highly skilled employees, including members of our current senior management team, especially Dr. Jin-Long Chen, and our scientific advisors;
- clinical trials of our product candidates may fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or otherwise produce positive results;
- we depend on our collaboration with Merck and may depend on collaborations with additional third parties for the development and commercialization of our product candidates;
- the regulatory approval processes of the U.S. Food and Drug Administration, or FDA, and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable;
- our success depends upon our ability to obtain, maintain, defend and enforce intellectual property protection for our products and technologies, and we may not be able to protect our intellectual property rights throughout the world;
- our principal stockholders, including Merck, and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval;

- 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; and
- 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.

#### **Concurrent Private Placement**

Merck, a strategic collaborator and existing stockholder, has agreed to purchase, 4,121,683 shares of our common stock in a separate private placement concurrent with the completion of this offering at a price of \$16.00 per share. The sale of such shares will not be registered under the Securities Act of 1933, as amended, or the Securities Act. The completion of this offering is not contingent upon the completion of such concurrent private placement.

#### **Corporate History and Information**

We were incorporated in Delaware in December 2007 and commenced operations in 2008. Our principal executive offices are located at 333 Oyster Point Blvd., South San Francisco, CA 94080-7014, and our telephone number is (650) 243-5555. Our website address is <http://www.ngmbio.com>. The information contained in, or that can be accessed through, our website is not part of this prospectus.

NGM and the NGM logo are our trademarks. Each of the other trademarks, trade names or service marks appearing in this prospectus belong to their respective holders.

#### **Implications of Being an Emerging Growth Company**

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act. We will remain an emerging growth company until the earliest to occur of: the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; the date we qualify as a "large accelerated filer," with at least \$700 million of equity securities held by non-affiliates; the issuance, in any three-year period, by us of more than \$1.0 billion in non-convertible debt securities; and the last day of the fiscal year ending after the fifth anniversary of our initial public offering. As a result of this status, we have taken advantage of reduced reporting requirements in this prospectus and may elect to take advantage of other reduced reporting requirements in our future filings with the SEC. In particular, in this prospectus, we have provided only two years of audited consolidated financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected to avail ourselves of this exemption and, as a result, will not be subject to the same implementation timing for new or revised accounting standards as for other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult.



**The Offering**

Common stock offered by us	6,666,667 shares
Concurrent private placement to Merck	Merck has agreed to purchase 4,121,683 shares of our common stock in a separate private placement concurrent with the completion of this offering at a price of \$16.00 per share.
Common stock to be outstanding after the offering and the concurrent private placement to Merck	64,993,706 shares
Underwriters' option to purchase additional shares of common stock	1,000,000 shares
Use of proceeds	<p>We estimate that our net proceeds from this offering, excluding the proceeds from the concurrent private placement to Merck, will be approximately \$95.7 million, or approximately \$110.6 million if the underwriters exercise in full their option to purchase additional shares of our common stock, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Additionally, our net proceeds from the concurrent private placement to Merck will be approximately \$65.9 million.</p> <p>We intend to use the net proceeds from this offering to fund development of the NGM282 program and related product candidates, to fund the development of our other programs, including our early-stage drug discovery programs and pre-commercialization activities, and for working capital and other general operating expenses. See "Use of Proceeds" for more detailed information.</p>
Directed share program	At our request, the underwriters have reserved up to 5% of the shares being offered by this prospectus for sale at the initial public offering price to certain of our directors, officers, employees, business associates and related persons. The number of shares available for sale

Risk factors	to the general public will be reduced by the number of directed shares purchased by participants in the program. Any directed shares not purchased will be offered by the underwriters to the general public on the same basis as all other shares offered.  See "Risk Factors" beginning on page 12 and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Proposed symbol on the Nasdaq Global Select Market	"NGM"

The number of shares of our common stock outstanding after the offering and the concurrent private placement to Merck is based on 54,205,356 shares of our common stock outstanding as of December 31, 2018 (including convertible preferred stock then outstanding on an as-converted basis), and excludes:

- 9,806,689 shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2018 at a weighted-average exercise price of \$5.86 per share;
- 1,550,250 shares of our common stock issuable upon the exercise of stock options granted after December 31, 2018 at an exercise price of \$12.06 per share;
- 19,637 shares of our common stock (on an as-converted basis) issuable upon exercise of an outstanding Series A convertible preferred stock warrant at an exercise price of \$2.00 per share, which automatically net exercised into shares of our Series A convertible preferred stock that are convertible into 16,380 shares of our common stock on February 3, 2019;
- 17,874,624 shares of our common stock reserved for future issuance under our amended and restated 2018 Plan, or the Restated 2018 Plan, which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance under this benefit plan;
- 1,000,000 shares of our common stock to be reserved for future issuance under our 2019 Employee Stock Purchase Plan, or the ESPP, which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance under this benefit plan; and
- 36,751 shares of our common stock reserved for future issuance under our NGM Biopharmaceuticals Matching Plan, or the 401(k) Matching Plan, as of December 31, 2018.

Except as otherwise noted, we have presented the information in this prospectus based on the following assumptions:

- the conversion, in accordance with our existing amended and restated certificate of incorporation, of all shares of convertible preferred stock outstanding as of December 31, 2018 into 47,267,466 shares of our common stock, which will occur immediately prior to the completion of this offering;
- the one-for-two reverse stock split for our common stock and a proportional adjustment to the conversion ratio of our convertible preferred stock effected on March 22, 2019;

- no exercise by the underwriters of their option to purchase up to an additional 1,000,000 shares of our common stock in the offering;
- no exercise of outstanding stock options; and
- the filing and effectiveness of our amended and restated certificate of incorporation with the Secretary of State of the State of Delaware and the adoption of our amended and restated bylaws, each of which will occur upon the completion of the offering.

Entities affiliated with The Column Group, an existing stockholder, have agreed to purchase 1,875,000 shares of our common stock in this offering at the initial public offering price. The underwriters will receive the same underwriting discount on any shares purchased by these entities as they will on any other shares sold to the public in this offering.

**Summary Consolidated Financial Data**

The following tables summarize our financial data and should be read together with the sections titled “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes included elsewhere in this prospectus.

We have derived the summary consolidated statement of operations data for the years ended December 31, 2017 and 2018 from our audited consolidated financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in the future.

	Year Ended December 31,	
	2017	2018
	(in thousands, except share and per share amounts)	
Related party revenue	\$ 77,141	\$ 108,665
Operating expenses:		
Research and development	79,736	95,714
General and administrative	14,830	17,265
Total operating expenses	<u>94,566</u>	<u>112,979</u>
Loss from operations	(17,425)	(4,314)
Interest income	2,358	3,622
Other income (expense), net	(152)	199
Net loss before taxes	(15,219)	(493)
Benefit from income taxes	(1,060)	—
Net loss	<u>\$ (14,159)</u>	<u>\$ (493)</u>
Net loss per common share, basic and diluted(1)	<u>\$ (2.37)</u>	<u>\$ (0.08)</u>
Weighted average shares used to compute net loss per common share, basic and diluted(1)	<u>5,961,767</u>	<u>6,383,751</u>
Pro forma net loss per common share, basic and diluted (unaudited)(1)		<u>\$ (0.01)</u>
Weighted average shares used to compute pro forma net loss per common share, basic and diluted (unaudited)(1)		<u>53,651,217</u>

(1) See Note 2 to our consolidated financial statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma basic and diluted net loss per share and the number of shares used in the computation of the per share amounts.

	As of December 31, 2018 (in thousands)		
	Actual	Pro Forma(1)	Pro Forma As Adjusted(2)
<b>Consolidated balance sheet data:</b>			
Cash, cash equivalents, and short-term marketable securities	\$ 206,633	\$ 206,633	\$ 368,280
Working capital (excluding deferred revenue)	192,096	192,096	353,743
Total assets	246,085	246,085	407,732
Total liabilities	59,406	59,208	59,208
Convertible preferred stock warrant liability	198	—	—
Convertible preferred stock	294,874	—	—
Accumulated deficit	(147,193)	(147,193)	(147,193)
Total stockholders' equity (deficit)	(108,195)	186,877	348,524

- (1) The pro forma column reflects the automatic conversion of all outstanding shares of our convertible preferred stock into shares of our common stock immediately prior to the completion of this offering and the reclassification to additional paid-in capital of our Series A convertible preferred stock warrant liability in connection with the conversion of our outstanding Series A convertible preferred stock warrant into a common stock warrant upon the completion of this offering.
- (2) The pro forma as adjusted column further reflects the receipt of the net proceeds from the sale of 10,788,350 shares of common stock in this offering and the concurrent private placement to Merck at the initial public offering price of \$16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

## RISK FACTORS

*Investment in our common stock involves a high degree of risk and uncertainty. You should carefully consider each of the risks and uncertainties described below before you decide to buy our common stock. You should also refer to the other information in this prospectus, including our consolidated financial statements and related notes. If any of the following risks and uncertainties materialize, our business, financial condition, liquidity and results of operations could be materially and adversely affected. This could cause the trading price of our common stock to decline, and you could lose all or part of your investment.*

### **Risks Related to Our Financial Results and Capital Needs**

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

We are a 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 period since commencing operations in early 2008. Our net loss was \$14.2 million and \$0.5 million for the years ended December 31, 2017 and 2018, respectively. As of December 31, 2018, we had an accumulated deficit of \$147.2 million.

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

During 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 NGM282, for any Merck licensed programs that we opt to co-develop and for any programs that Merck does not opt to develop and that we choose to develop, such as NGM386 and/or NGM395, for which Merck has given us notice of its intent to terminate the license and that we are considering whether to advance pending study results. Under the Merck collaboration, Merck provides us with reimbursement for research and development activities of at least \$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 17, 2022 and has the right to extend it again through March 17, 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. See “Business—Our Collaboration with Merck.”

***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 NGM282, NGM386 and NGM395, advance in clinical development. We believe that the net proceeds from this offering and the concurrent private placement to Merck, together with our existing cash, cash equivalents and short-term marketable securities and funding we expect to receive under our existing collaboration agreement, 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 and clinical studies 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 this 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 and EMA for the development of NASH 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 no 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. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials.

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 NGM282, in Phase 1 clinical trials for NGM313 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 greater 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 NGM282 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 an ongoing, Phase 2 clinical trial of NGM282 in NASH. Until the final cohort of the NGM282 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 NGM282 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 studies 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 NGM282 for NASH and PBC, an active Clinical Trials Notification, or CTN, in Australia for NGM120 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 also could 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

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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 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 and EMA for the development of NASH 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;

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- 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

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of Phase 3 and commercial supplies of NGM282. 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. See the section titled "Business—Intellectual Property—Licensing Arrangements" for more information regarding this agreement. 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 studies may be required to evaluate the safety profile of our product candidates. The following serious adverse events were reported in our Phase 1 and five Phase 2 clinical trials of NGM282: 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 PSC and intervertebral discitis. Preliminary reporting from our completed Phase 1 and Phase 1b clinical trials of NGM313 showed that there were no reported serious adverse events except for a single incident each of cholecystitis and rectal bleeding due to hemorrhoids, both of which were deemed by the investigators to be unrelated to treatment with NGM313.

Significant increases in serum levels of low density lipoprotein, or LDL, cholesterol were observed in clinical trials of NGM282 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 NGM282'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 NGM282 in trials we have conducted in patients with cholestatic liver disease, such as primary biliary cholangitis and primary sclerosing cholangitis.

One subject in the NGM282 Phase 2a clinical trial in type 2 diabetes developed antibodies against NGM282 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 NGM282 Phase 2 extension clinical trial in PBC were confirmed to have antibodies against NGM282. These subjects have not demonstrated any biochemical or clinical safety signals that were different from observations in subjects that did not generate antibodies against NGM282. 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, NGM282, is a modified version of a human hormone that has been associated with liver cancer in rodent testing.***

NGM282 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 NGM282 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 NGM282 in type 2 diabetes after we analyzed the results of the Phase 2a clinical trial of NGM282 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 NGM282 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 mouse ortholog for FGF19 share a sequence identity of approximately 50%, which means that the results of these studies of NGM282 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 NGM282 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 FGF19 in rodents. We believe that NGM282 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 NGM282.

***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 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. See the section titled "Executive and Director Compensation—Other Elements of Compensation—Agreements with our Named Executive Officers" and "Executive and Director Compensation—Other Elements of Compensation—Potential Payments Upon Termination or Change of Control" for further discussion. 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. During the initial term of the Merck collaboration, 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/MedImmune, Bayer, Bristol-Myers Squibb, Eisai,

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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, Conatus, 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 studies 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 NGM282 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; GS-0976, an ACC inhibitor, GS-9674, an FXR agonist, and selonsertib, an ASK1 inhibitor, 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; elobixibat, an IBAT-inhibitor from Albireo; a Galectin-3 inhibitor from Galectin; a synthetic

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conjugate of cholic acid and arachidic acid from Galmed; an FXR agonist from Metacrine; FXR agonists from Novartis; a mitochondrial pyruvate complex modulator from Ciriuz; a PPAR delta agonist from CymaBay; and a PPAR alpha/delta agonist from Genfit. The foregoing competitive risks apply to NGM282 and NGM313 and any variants of NGM282 we may commercialize or, in the case of NGM313, Merck and we may commercialize, including the second-generation, half-life extended version of FGF19 we are currently developing.

If NGM386 or NGM395 were approved for the treatment of obesity, these products would face competition from currently approved and marketed products, including *Saxenda* (liraglutide), *Contrave* (bupropion and naltrexone), *Qsymia* (phentermine and topiramate extended-release), *Belviq* (lorcaserin HCL) and *Xenical* (orlistat). Further competition could arise from products currently in development, including Lilly's LY3298176 (dual GLP-1/GIP receptor agonist). To the extent any of our product candidates are approved for cardio-metabolic indications, particularly obesity, the commercial success of our products will also depend on our ability to demonstrate benefits over the then-prevailing standard of care, including diet and exercise. Finally, morbidly obese patients sometimes undergo the gastric bypass procedure, with salutary effects on the many co-morbid conditions of obesity. Some of these programs have been advanced further in clinical development than our clinical programs or have already received regulatory approval.

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 in May 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. Congress will likely consider other legislation to replace elements of the Affordable Care Act. On December 14, 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, then-President Obama signed into law the Budget Control Act of 2011, 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. 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;

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- 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;

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- 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 facility has been 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, NGM386, NGM395, NGM120, NGM217 and NGM621 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.***

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 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 their operations, but did not affect our internal operations. 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 on collaborations with additional third parties for the development and commercialization of our product candidates in the future. 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 NGM282. In November 2018, Merck exercised its option to license NGM313. On March 1, 2019, Merck notified us of its intent to terminate its license to the GDF15 receptor agonist program, including NGM386 and NGM395, effective May 31, 2019. On March 15, 2019, Merck exercised its option to extend the collaboration for an additional two years, from March 2020 through March 17, 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 of providing sales representatives to co-detail the product candidates that Merck elects to advance in the United States. See "Business—Our Collaboration with Merck." 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 NGM282. 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 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 choose not to renew its agreement with us 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 on or 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. During the initial term of the Merck collaboration, 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 initial term of the collaboration or, if Merck 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. On March 1, 2019, Merck notified us of its intent to terminate 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.

We have contracted with third parties for the manufacture of NGM282, NGM313, NGM386, NGM395, NGM217, NGM120 and NGM621 bulk drug substance and drug product, and for the labeling and distribution of drug product for these candidates for use in our clinical trials. We believe our current drug substance contractors have the scale, the systems and the experience to supply our Phase 2 and Phase 2b clinical trials for NGM282, our collaborator's Phase 1 and Phase 2b clinical trials for NGM313, our Phase 1 clinical trials for NGM217 and NGM120 and our planned Phase 1 clinical trial for NGM621.

Other than a long-term supply agreement with Lonza for NGM282, we have not contracted with alternate suppliers in the event the organizations we are currently utilizing are unable to scale production, or if we otherwise experience any problems with them. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may be delayed in the development of our product candidates.

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 NGM282, NGM386, NGM395, NGM217, NGM120 and NGM621 to the extent we advance these product candidates and will rely on our collaborator 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 amounts of our expenditures 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 NGM282, 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 NGM282, is excluded from this provision, notwithstanding that both NGM282 and NGM313 signal 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 NGM282, 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 NGM282, 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;

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- 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 NGM282 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 EU. The EU 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 NGM282 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 NGM282 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 NGM282 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 studies;
- 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 NGM282 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 NGM282 is approved by the FDA based on a surrogate endpoint pursuant to accelerated approval regulations (Subpart H and 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 NGM282 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 NGM282, NGM313, NGM386, NGM395 and NGM120, 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 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 NGM282 molecule, including the half-life extended variant of FGF19 that we are developing, NGM313, NGM386, NGM395, NGM120 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, or 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. For a description of our patent portfolio, see the section titled "Business—Intellectual Property—Patents and Other Proprietary Rights."

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. We expect to seek extensions of patent terms for our issued patents, where available. This includes in the United States 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, or 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 has 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 technology 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 NGM282, NGM313, NGM386, NGM395, NGM217, NGM120 and NGM621 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 NGM282, NGM313, NGM386, NGM395, NGM217, NGM120 and NGM621 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 reasons, 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, or 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 and our collaborator do not believe that NGM386 and/or NGM395 would be commercially launched until after expiration of the patent. In addition, we and our collaborator 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, the indication for which we are presently pursuing regulatory approval for NGM386 and NGM395. We plan to appeal this decision 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. The deadline for Genentech's response to opposition is April 2019. Thereafter, the EPO's summons to oral proceedings is expected in the range of July to September 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 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.

The patent landscape around our NGM282, NGM313, NGM386, NGM395, NGM217, NGM120 and NGM621 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 NGM282, NGM313, NGM386, NGM395, NGM217, NGM120 and NGM621 product candidates. However, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates and technologies. 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 AG, or 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.



See the section titled “Business—Intellectual Property—Licensing Arrangements” for more information regarding this agreement. 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, in our activities we also rely substantially on trade secrets, 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 but 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 that we hold rights to 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 this Offering and Ownership of Our Common Stock**

***We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.***

Prior to this offering, no market for shares of our common stock existed and an active trading market for our shares may never develop or be sustained following this offering. We determined the initial public offering price for our common stock through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using shares of our common stock as consideration.

***The market price of our stock may be volatile, and you could lose all or part of your investment.***

The trading price of our common stock following this offering is likely 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 and elsewhere in this prospectus, 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;

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- 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.

### ***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.***

Our management will have broad discretion in the application of the net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. You will not have the opportunity, as part of your investment decision, to assess whether we are using the proceeds appropriately. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

***Our principal stockholders, including Merck, and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

Prior to this offering and the concurrent private placement to Merck, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 77.3% of our voting stock and, upon completion of this offering and the concurrent private placement to Merck, and reflecting the purchase in this offering of 1,875,000 shares of our common stock by entities affiliated with The Column Group. That same group will hold approximately 80.2% of our outstanding voting stock (assuming no exercise of the underwriters' option to purchase additional shares, no exercise of outstanding options and no purchases of shares in this offering by any of this group), in each case assuming the conversion of all outstanding shares of our convertible preferred stock into shares of our common stock in connection with this offering. In particular, after this offering and the concurrent private placement, Merck will own approximately 19.9% of our voting stock and entities affiliated with The Column Group will own approximately 23.7% of our voting stock. After this offering and the concurrent private placement to Merck, this group of stockholders will have the ability to control us through this ownership position even if they do not purchase any additional shares in this offering. However, 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. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

***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) the last day of the fiscal year following the fifth anniversary of this offering; (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 with frequency 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. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Newly Issued Accounting Pronouncements.”

In particular, in May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes the revenue recognition requirements in ASC 605, *Revenue Recognition*. The core principle of ASU 2014-09 is that an entity should recognize revenue to depict the transfer of promised 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. As an “emerging growth company,” the JOBS Act allows us to delay adoption of new or revised accounting standards applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act with respect to ASU 2014-09 and anticipate adopting ASU 2014-09 effective January 1, 2019, under the modified retrospective method. While we have not completed our final assessment of the impact, the adoption of ASU 2014-09 may have a material effect on our consolidated financial statements.

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

As a public company, we will incur significant legal, accounting 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 will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002, 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 will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will increase our net loss. For example, we expect these rules and regulations to 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.

We are not currently required to comply with the SEC’s rules that implement Section 404 of the Sarbanes-Oxley Act, or Section 404, and are therefore not yet required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with certain of these rules, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. This assessment will need to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will need to continue to dedicate internal resources, outside consultants and continue to execute a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes, as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements and we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future.

***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. After this offering, we will have outstanding 64,993,706 shares of common stock based on the number of shares outstanding as of December 31, 2018, assuming: (i) no exercise of the underwriters' option to purchase up to 1,000,000 additional shares; and (ii) the conversion of all outstanding shares of our convertible preferred stock into 47,267,466 shares of common stock upon the completion of this offering. This includes the shares that we sell in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates, and the private placement to Merck. Substantially all of the shares of our common stock not sold in this offering (including shares issuable upon exercise or conversion of existing securities and shares issuable to Merck in the concurrent private placement) will be locked up as a result of securities laws or lock-up agreements but will be able to be sold after this offering as described in the section titled "Shares Eligible for Future Sale." Moreover, after this offering, holders of an aggregate of 47,267,466 shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the section titled "Underwriting."

***If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

The initial public offering price is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of \$10.64 per share, based on the initial public offering price of \$16.00 per share. Further, investors purchasing common stock in this offering will contribute approximately 22% of the total amount invested by stockholders since our inception, but will own only approximately 10% of the shares of common stock outstanding.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less than the price offered to the public in this offering when they purchased their shares including the exercise of stock options granted to our employees. As of December 31, 2018, options to purchase 9,806,689 shares of our common stock at a weighted average exercise price of \$5.86 per share were outstanding, and all options are currently exercisable. The exercise of any of these options would result in additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of a liquidation.

***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.***

Upon completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. 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 collaboration 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 that will become effective upon the completion of this offering, 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, or the 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 which 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 collaboration agreements 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. See the section titled “Business—Our Collaboration with Merck” for more information.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws, Delaware law or our collaboration 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 to be in effect upon the completion of this offering will provide 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 to be in effect upon the completion of this offering will provide 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, the Court of Chancery of the State of Delaware recently 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 contingent.

***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.***

The trading market for our common stock will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company or if they cease to cover our company, the trading price for our stock would likely be negatively impacted. In the event that securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or

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unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections titled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” contains forward-looking statements. We may, in some cases, use words such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials;
- our or our partners’ ability to obtain and maintain regulatory approval for NGM282, NGM313, NGM386, NGM395, NGM120, NGM217, NGM621 and any of our future product candidates, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our belief that NGM282 will have a superior therapeutic profile in NASH patients with moderate to advanced fibrosis based on clinical data showing reduced liver fat content, liver aminotransferase levels and fibrosis marker levels;
- our belief in the impact of our product candidate side effects and our ability to effectively manage these side effects;
- our belief that NGM313 will have a superior therapeutic profile in NASH patients with early stage fibrosis based on clinical data showing reduced liver fat content and liver aminotransferase levels, along with improved measures of insulin sensitivity;
- the renewal of our collaboration agreement with Merck and Merck’s decision to exercise its option to license certain programs upon our completion of a proof-of-concept study in humans;
- our ability to obtain funding for our operations;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract additional collaborators with development, regulatory and commercialization expertise;
- current and future agreements with third parties in connection with the commercialization of NGM282, NGM313, NGM386, NGM395, NGM217, NGM120 and NGM621, or any other future approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates, as well as the reimbursement coverage for our product candidates;
- regulatory developments in the United States and foreign countries;
- the performance of third-party suppliers and manufacturers;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific or management personnel;
- our estimates regarding future expenses, revenue, capital requirements and needs for additional financing;

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- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act;
- our use of the net proceeds from this offering; and
- our expectations regarding our ability to obtain, maintain, protect and enforce intellectual property protection for our product candidates.

These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail under the section titled "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

## INDUSTRY AND MARKET DATA

This prospectus contains estimates, projections and other information concerning our industry and our business, including estimated market size, projected growth rates and the prevalence of certain medical conditions. Unless otherwise expressly stated, we obtained this industry, business, market, medical and other information from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources.

This industry, business, market, medical and other information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information and cannot assure you of its accuracy or completeness. Although we are responsible for all of the disclosure contained in this prospectus and we believe the market position, market opportunity, market size and medical information included in this prospectus is reliable, such information is inherently imprecise. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors" and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

In some cases, we do not expressly refer to the sources from which data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

## USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately \$95.7 million, or approximately \$110.6 million if the underwriters exercise their option to purchase additional shares in full, from the sale of the shares of common stock offered by us in this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. Additionally, we estimate that our net proceeds from the concurrent private placement to Merck will be \$65.9 million.

The principal purposes of this offering are to obtain additional capital to support our operations, to establish a public market for our common stock and to facilitate our future access to the public equity markets. We anticipate that we will use the net proceeds of this offering, together with our existing cash, cash equivalents and short-term marketable securities, for the following purposes:

- approximately \$95.0 to \$105.0 million to fund the further development of the NGM282 program and related product candidates;
- approximately \$45.0 to \$55.0 million to fund the development of our other programs, including our early-stage drug discovery programs and pre-commercialization activities; and
- the remainder for working capital and general operating expenses.

We expect to decide whether to advance NGM386 and/or NGM395 following our analysis of the results of the NGM386 Phase 1 trial.

We may also use a portion of the remaining net proceeds to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However, we have no current commitments or obligations to do so.

We believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term marketable securities and the funding we expect to receive under the initial term of our existing agreement with Merck, will be sufficient to fund our operations through 2020, or through 2021 with the additional proceeds from the concurrent private placement to Merck. In particular, we expect that these funds will allow us to complete our ongoing Phase 2 and planned Phase 2b clinical trials and begin preparation for Phase 3 clinical trials of NGM282 for NASH.

Following this offering, we will require substantial capital to complete clinical development, seek regulatory approval of and, if approved, commercialize NGM282 and our other programs. For each

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compound subject to our agreement with Merck, Merck has a one-time option to obtain an exclusive, worldwide license. If Merck chooses to exercise its option with respect to a compound, from that point forward all development costs relating to that compound 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 will incur additional expenses for the development of any compound for which Merck does not exercise its option, for which Merck elects to terminate its license, such as NGM386 and NGM395, or for which we elect to exercise our worldwide cost and profit sharing option. We may seek additional funds through public or private equity, debt financings or other sources, including strategic collaborations. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including the progress of our clinical trials and other development efforts for our product candidates and other factors described in the section titled "Risk Factors," as well as the amount of cash we use in our operations. As a result, our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds of this offering. In addition, we might decide to postpone or not pursue clinical trials or preclinical activities if the net proceeds from this offering and the other sources of cash are less than expected.

Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.

## **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.



## CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term marketable securities, and our capitalization as of December 31, 2018, as follows:

- on an actual basis;
- on a pro forma basis, giving effect to (1) the automatic conversion of all our outstanding convertible preferred stock as of December 31, 2018 into an aggregate of 47,267,466 shares of our common stock in connection with the completion of this offering, (2) the conversion of our Series A convertible preferred stock warrant as of December 31, 2018 into 19,637 shares of our common stock in connection with the completion of this offering, and (3) the filing and effectiveness of our amended and restated certificate of incorporation, which will occur upon the completion of this offering; and
- on a pro forma as adjusted basis, giving effect to the pro forma adjustments discussed above and giving further effect to the receipt of the estimated net proceeds from the sale of 10,788,350 shares of common stock in this offering and the concurrent private placement to Merck at the public offering price and private placement purchase price of \$16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma information below is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with the sections titled "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes included elsewhere in this prospectus.

	As of December 31, 2018 (in thousands, except share amounts)		
	Actual	Pro Forma	Pro Forma As Adjusted
Cash, cash equivalents and short-term marketable securities	\$ 206,633	\$ 206,633	\$ 368,280
Convertible preferred stock warrant liability	\$ 198	\$ —	\$ —
Convertible preferred stock, \$0.001 par value; 96,268,206 shares authorized, 47,267,466 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	294,874	—	—
Stockholders' equity (deficit):			
Preferred stock, \$0.001 par value; no shares authorized, issued and outstanding, actual; 10,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, \$0.001 par value; 129,000,000 shares authorized, 6,937,890 shares issued and outstanding, actual; 400,000,000 shares authorized, 54,224,993 shares issued and outstanding, pro forma; 65,013,343 issued and outstanding, pro forma as adjusted	7	54	65
Additional paid-in capital	39,258	334,283	495,919
Accumulated other comprehensive loss	(267)	(267)	(267)
Accumulated deficit	(147,193)	(147,193)	(147,193)
Total stockholders' equity (deficit)	(108,195)	186,877	348,524
Total capitalization	\$ 186,877	\$ 186,877	\$ 348,524

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The number of shares of our common stock outstanding after the offering and the concurrent private placement to Merck is based on 54,224,993 shares of our common stock outstanding as of December 31, 2018 (including convertible preferred stock then outstanding on an as-converted basis), and excludes:

- 9,806,689 shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2018 at a weighted-average exercise price of \$5.86 per share;
- 1,550,250 shares of our common stock issuable upon the exercise of stock options granted after December 31, 2018 but before March 20, 2019 at an exercise price of \$12.06 per share;
- 17,874,624 shares of our common stock reserved for future issuance under the Restated 2018 Plan, which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance under this benefit plan;
- 1,000,000 shares of our common stock to be reserved for future issuance under the ESPP, which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance under this benefit plan; and
- 36,751 shares of our common stock reserved for future issuance under our NGM Biopharmaceuticals Matching Plan, or the 401(k) Matching Plan, as of December 31, 2018.

## DILUTION

If you invest in our common stock in this offering, your ownership interest will be immediately diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of December 31, 2018 was approximately (\$110.5) million, or (\$15.93) per share of our common stock. Our historical net tangible book deficit is the amount of our total tangible assets less our deferred IPO costs, liabilities and convertible preferred stock, which is not included within stockholders' deficit. Historical net tangible book deficit per share is our historical net tangible book deficit divided by the number of shares of common stock outstanding as of December 31, 2018.

Our pro forma net tangible book value as of December 31, 2018 was \$184.6 million, or \$3.40 per share of common stock. Pro forma net tangible book value gives effect to the conversion of all of our outstanding convertible preferred stock into an aggregate of 47,267,466 shares of our common stock and the reclassification to additional paid-in capital of our Series A convertible preferred stock warrant liability in connection with the conversion of our outstanding Series A convertible preferred stock warrant into shares of common stock, which are included in stockholders' equity, which will occur automatically in connection with the completion of this offering.

Pro forma as adjusted net tangible book value is our pro forma net tangible book value, plus the effect of the sale of 10,788,350 shares of our common stock in this offering and the concurrent private placement to Merck at the initial public offering price and private placement purchase price of \$16.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. This amount represents an immediate increase in pro forma as adjusted net tangible book value of \$1.96 per share to our existing stockholders, and an immediate dilution of \$10.64 per share to new investors participating in this offering.

The following table illustrates this dilution on a per share basis:

Initial public offering price per share	\$16.00
Pro forma net tangible book value per share as of December 31, 2018 before giving effect to this offering and the concurrent private placement	\$3.40
Increase in pro forma net tangible book value per share attributable to investors participating in this offering and the concurrent private placement	1.96
Pro forma as adjusted net tangible book value per share after this offering and the concurrent private placement	\$ 5.36
Pro forma as adjusted dilution per share to investors participating in this offering and the concurrent private placement	<u>\$10.64</u>

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If the underwriters exercise in full their option to purchase 1,000,000 additional shares of our common stock in this offering, the pro forma as adjusted net tangible book value would be \$5.51 per share, representing an immediate increase in pro forma as adjusted net tangible book value to existing stockholders of \$2.11 per share, and the dilution to new investors purchasing shares in this offering would be \$10.49 per share.

The following table summarizes, on a pro forma as adjusted basis as of December 31, 2018, the number of shares of our common stock, the total consideration and the average price per share (i) paid to us by our existing stockholders and (ii) to be paid by new investors participating in this offering and the concurrent private placement to Merck at the initial public offering price and private placement purchase price of \$16.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	Total Shares		Total Consideration		Average Price per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering	54,205,356	84%	\$317,324,191	65%	\$ 5.85
Merck participation in the concurrent private placement	4,121,683	6	65,946,928	13	16.00
Investors participating in this offering	6,666,667	10	106,666,672	22%	16.00
Total	64,993,706	<u>100%</u>	<u>\$489,937,791</u>	<u>100%</u>	<u>\$ 7.54</u>

If the underwriters exercise their option in full to purchase 1,000,000 additional shares of our common stock in this offering, the number of shares of common stock held by existing stockholders will be reduced to 82% of the total number of shares of common stock to be outstanding after this offering and the concurrent private placement to Merck, and the number of shares of common stock held by investors participating in this offering will be further increased to 11,788,350, or 18% of the total number of shares of common stock to be outstanding after this offering and the concurrent private placement to Merck.

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The foregoing discussion and tables are based on 54,224,993 shares of our common stock outstanding as of December 31, 2018 (including convertible preferred stock then outstanding on an as-converted basis), and excludes:

- 9,806,689 shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2018 at a weighted-average exercise price of \$5.86 per share;
- 1,550,250 shares of our common stock issuable upon the exercise of stock options granted after December 31, 2018 but before March 20, 2019 at an exercise price of \$12.06 per share;
- 17,874,624 shares of our common stock reserved for future issuance under the Restated 2018 Plan, which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance under this benefit plan;
- 1,000,000 shares of our common stock to be reserved for future issuance under the ESPP, which will become effective immediately prior to the completion of this offering, as well as any automatic increase in the number of shares of common stock reserved for future issuance under this benefit plan; and
- 36,751 shares of our common stock reserved for future issuance under our NGM Biopharmaceuticals Matching Plan, or the 401(k) Matching Plan, as of December 31, 2018.

We may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent we issue additional shares of common stock or other equity or convertible debt securities in the future, there will be further dilution to investors participating in this offering.

## SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read together with our consolidated financial statements and related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus. We derived the selected consolidated statements of operations data for the years ended December 31, 2017 and 2018 and the selected consolidated balance sheet data as of December 31, 2017 and 2018 from our audited consolidated financial statements and related notes appearing elsewhere in this prospectus. The selected consolidated financial data in this section are not intended to replace our consolidated financial statements and the related notes. Our historical results are not necessarily indicative of the results to be expected in the future.

	Year Ended December 31,	
	2017	2018
	(in thousands, except share and per share amounts)	
Related party revenue	\$ 77,141	\$ 108,665
Operating expenses:		
Research and development	79,736	95,714
General and administrative	14,830	17,265
Total operating expenses	94,566	112,979
Loss from operations	(17,425)	(4,314)
Interest income	2,358	3,622
Other income (expense), net	(152)	199
Net loss before taxes	(15,219)	(493)
Benefit from income taxes	(1,060)	—
Net loss	\$ (14,159)	\$ (493)
Net loss per common share, basic and diluted(1)	\$ (2.37)	\$ (0.08)
Weighted average shares used to compute net loss per common share, basic and diluted(1)	5,961,767	6,383,751
Pro forma net loss per common share, basic and diluted (unaudited)(1)		\$ (0.01)
Weighted average shares used to compute pro forma net loss per common share, basic and diluted (unaudited)(1)		53,651,217

- (1) See Note 2 to our consolidated financial statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the historical and pro forma basic and diluted net loss per share and the number of shares used in the computation of the per share amounts.

	As of December 31,	
	2017	2018
	(in thousands)	
<b>Consolidated balance sheet data:</b>		
Cash, cash equivalents, and short-term marketable securities	\$ 173,685	\$ 206,633
Working capital (excluding deferred revenue)	159,998	192,096
Total assets	248,941	246,085
Total liabilities	75,045	59,406
Convertible preferred stock warrant liability	121	198
Convertible preferred stock	294,874	294,874
Accumulated deficit	(146,700)	(147,193)
Total stockholders' deficit	(120,978)	(108,195)

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis should be read in conjunction with "Selected Consolidated Financial Data" and our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain 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 under "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Special Note Regarding Forward-Looking 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, five of which are in clinical testing. Our most advanced product candidate, NGM282, is wholly-owned and will enter Phase 2b development for the treatment of non-alcoholic steatohepatitis, or NASH, in mid-2019. In an ongoing Phase 2 clinical trial, NGM282 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 and subject to our Merck collaboration 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. For a detailed explanation see the section "Business—Our Collaboration with Merck." Through December 31, 2018, Merck has paid us \$336.4 million, of which \$94.0 million was an upfront payment, \$20.0 million was to license NGM313 and related compounds and \$222.4 million was reimbursement of research and development expenses. On March 15, 2019, Merck exercised its option to extend the collaboration through March 17, 2022, and has the right to extend it again through March 17, 2024.

We have incurred net losses in each year since our inception. Our consolidated net losses were \$14.2 million and \$0.5 million for the years ended December 31, 2017 and 2018, respectively. As of December 31, 2018, we had an accumulated deficit of \$147.2 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. Our net losses may fluctuate significantly from quarter to quarter and year to year, depending on the timing of our 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 \$294.9 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 \$239.2 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 in addition to the net proceeds from this offering, the concurrent private placement to Merck and amounts that may be available under our collaboration agreement with Merck. Until such time as we can generate meaningful revenue from product sales, if ever, we expect to finance our operating activities through public or private 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.

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 agreements, and we may also be entitled to receive additional milestone and other contingent payments pursuant to our research collaboration product development and license agreement with Merck upon the occurrence of specific events. Due to the nature of these collaboration agreements 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. In addition, we are required to adopt ASC 606 for the year ending December 31, 2019, which may have a material impact on the timing of our revenue recognition.

The following table summarizes the sources of our collaboration revenue for the years ended December 31, 2017 and 2018:

	Year Ended December 31,	
	2017	2018
	(in thousands)	
Related party revenue		
Recognition of upfront fee	\$18,800	\$ 18,800
License revenue	—	20,000
Collaboration service revenue	58,341	69,865
Total related party revenue	<u>\$77,141</u>	<u>\$108,665</u>

### 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.



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Our clinical development efforts are focused on multiple programs. Our lead product candidate, NGM282, 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 NGM282 for the foreseeable future, however, we may also devote financial resources to the development of our GDF15 receptor agonist program, or to our 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 NGM282 clinical trials we have initiated or plan to initiate include: (1) a 24-week expansion cohort of NGM282 (cohort 4) under our ongoing Phase 2 protocol as a double-blind, placebo-controlled study of once-daily 1 mg NGM282 for the treatment of patients with fibrosis stage F2 or F3 NASH, (2) a Phase 2b clinical trial of NGM282 in a double-blind, placebo-controlled format testing 0.3 mg, 1 mg and 3 mg daily doses of NGM282 for 24 weeks for the treatment of patients with fibrosis stage F2 or F3 NASH and (3) a Phase 2b clinical trial of NGM282 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 NGM282 for regulatory approval for the treatment of NASH, including preparation for Phase 3 testing of NGM282 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 are also conducting Phase 1 clinical trials for NGM120 and NGM217, each of which is subject to reimbursement under our Merck collaboration up to the funding caps provided in the agreement. NGM120 is currently in a Phase 1 clinical trial assessing safety, tolerability and pharmacokinetics. In 2019 we are planning to conduct a clinical study with NGM120 in cancer patients to explore proof of concept as an agent to treat CACS and, possibly, cancer. Merck has the 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 the option to license NGM217 following completion of a proof-of-concept study in humans.

NGM621 is currently in IND-enabling studies to enable initiation of a Phase 1 clinical trial 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 were both licensed to Merck at the inception of our collaboration with Merck, and substantially all of the related research and development expenses were borne directly by Merck under our collaboration agreement; however, on March 1, 2019, Merck notified us of its intent to terminate its license, effective May 31, 2019. Upon termination of the license, we will regain 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.

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Our research and development expenses related to the development of NGM282, 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 years ended December 31, 2017 and 2018:

	Year Ended	
	December 31,	
	2017	2018
	(in thousands)	
External research and development expenses:		
NGM282 (FGF19 analog)	\$15,126	\$15,359
NGM313 (FGFR1c/KLB agonist)	3,948	3,544
NGM386 and NGM395 (GDF15 analogs)	787	1,286
NGM120 (GFRAL antagonist)	3,621	3,442
NGM217 (undisclosed)	3,764	2,808
NGM621 (undisclosed)	186	6,791
Total external research and development expenses	27,432	33,230
Internal and unallocated research and development expenses(1)	52,304	62,484
Total research and development expenses	<u>\$79,736</u>	<u>\$95,714</u>

- (1) Internal and unallocated research and development expenses consist mainly 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 variables with respect to 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 Years Ended December 31, 2017 and 2018**

The following table summarizes our results of operations for the years ended December 31, 2017 and 2018:

	Year Ended December 31,		Change (\$)	Change (%)
	2017	2018		
	(in thousands)			
Related party revenue	\$ 77,141	\$108,665	\$ 31,524	41%
Operating expenses:				
Research and development	79,736	95,714	15,978	20%
General and administrative	14,830	17,265	2,435	16%
Total operating expenses	94,566	112,979	18,413	19%
Loss from operations	(17,425)	(4,314)	(13,111)	(75%)
Interest income	2,358	3,622	1,264	54%
Other income (expense), net	(152)	199	351	231%
Net loss before taxes	(15,219)	(493)	(14,726)	(97%)
Benefit from income taxes	(1,060)	—	(1,060)	(100%)
Net loss	\$ (14,159)	\$ (493)	\$ (13,666)	(97%)

**Total Related Party Revenue.** Total related party revenue was \$77.1 million and \$108.7 million for the years ended December 31, 2017 and 2018, respectively, of which \$18.8 million in both periods was related to the partial recognition of the upfront payment from Merck in 2015. The increase of \$31.5 million in total revenue was due to an additional \$20.0 million of revenue in 2018 recognized from the \$20.0 million received from Merck to license NGM313 and related compounds and an increase in both reimbursable personnel related expenses and higher overall external research and development expenses that we incurred in 2018.

**Research and Development Expenses.** Research and development expenses were \$79.7 million and \$95.7 million for the years ended December 31, 2017 and 2018, respectively. The increase in research and development expenses of \$16.0 million was primarily attributable to an increase of \$10.2 million in unallocated research and development expenses, primarily related to hiring- and personnel-related expenses and early research testing, and \$6.6 million in the NGM621 program external expenses primarily related to manufacturing costs of clinical materials. These increases were offset by a decrease of \$1.0 million in the NGM217 program external expenses for manufacturing costs of clinical materials that occurred in 2017.

**General and Administrative Expenses.** General and administrative expenses were \$14.8 million and \$17.3 million for the years ended December 31, 2017 and 2018, respectively. The increase in general and administrative expenses of \$2.4 million was primarily due to an increase of \$2.8 million in personnel-related expenses, \$0.7 million for increased rent expense and increases in professional fees and contract services expenses, including \$0.4 million for legal expenses and \$0.4 million in audit and tax expenses. These increases were offset by an increase of \$1.9 million in allocated overhead expenses from general and administrative expenses to research and development expenses.

**Interest Income.** Interest income was \$2.4 million and \$3.6 million for the years ended December 31, 2017 and 2018, respectively. The increase in interest income of \$1.2 million was

primarily attributable to higher yields on our available-for-sale marketable securities in 2018 compared to 2017.

**Benefit from Income Taxes.** Benefit from income taxes was \$1.1 million and \$0.0 million for the years ended December 31, 2017 and 2018, respectively. The benefit from income taxes in 2017 was due to a federal alternative minimum tax credit carryforward that became refundable as a result of the Tax Cuts and Jobs Act of 2017.

### Liquidity and Capital Resources

We have incurred losses and negative cash flows from operating activities since our inception. As of December 31, 2018, our operations have been financed primarily through the private placement of convertible preferred stock totaling \$294.9 million, upfront license fees paid by collaboration partners of \$123.0 million and research and development funding provided by collaboration partners of \$239.2 million. As of December 31, 2018, we had 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, compared to cash and cash equivalents of \$25.6 million, short-term marketable securities of \$148.1 million, working capital (excluding deferred revenue) of \$160.0 million and an accumulated deficit of \$146.7 million at December 31, 2017. The change from 2017 to 2018 is primarily attributed to the receipt of \$20.0 million from Merck in December 2018 for the license of NGM313.

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 NGM282, for any Merck licensed programs that we opt to co-develop and 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 given us notice of its intent to terminate the 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 years ended December 31, 2017 and 2018 (in thousands):

	Year Ended December 31,	
	2017	2018
Net cash provided by (used in):		
Operating activities	\$(17,413)	\$ (7,597)
Investing activities	(2,796)	38,729
Financing activities	339	198
Net increase (decrease) in cash and cash equivalents	<u>\$(19,870)</u>	<u>\$31,330</u>

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

During the year ended December 31, 2018, cash used in operating activities was \$7.6 million, which consisted of a net loss of \$0.5 million, adjusted for non-cash charges of \$16.5 million and cash used through changes in operating assets and liabilities of \$23.6 million. The non-cash charges consisted primarily of stock-based compensation expense of \$10.0 million and depreciation expense of \$7.2 million. The change in operating assets and liabilities was primarily due to an increase in receivable from related party collaboration of \$3.7 million under our agreement with Merck, an increase in prepaid expenses and other current assets of \$4.4 million, offset by increases in accounts payable and accrued expenses and other current liabilities of \$3.5 million and \$4.1 million, respectively, and decreases in deferred rent and deferred revenue of \$2.0 million and \$21.1 million, respectively. The decrease in deferred revenue is primarily due to the recognition of upfront fees from Merck and the timing of advance payments from Merck related to the reimbursement of costs associated with research and development activities.

During the year ended December 31, 2017, cash used in operating activities was \$17.4 million, which consisted of a net loss of \$14.2 million, adjusted for non-cash charges of \$14.5 million and cash used through changes in operating assets and liabilities of \$17.7 million. The non-cash charges consisted primarily of stock-based compensation expense of \$7.7 million and depreciation expense of \$6.4 million. The change in operating assets and liabilities was primarily due to an increase in prepaid expenses and other assets of \$1.1 million primarily resulting from a federal tax receivable generated as a result of the Tax Cuts and Jobs Act of 2017 that was signed into law in December 2017, a decrease in accounts payable of \$4.2 million and a decrease in deferred revenue of \$16.5 million due to the recognition of revenue related to upfront 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 a decrease in receivable from related party collaboration of \$2.8 million due to payments received from Merck under the collaboration agreement and an increase in accrued expenses and other liabilities of \$2.6 million resulting primarily from the timing of payments related to our clinical trial expenses and other research and development activities.

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

During the year ended December 31, 2018, cash provided by investing activities was \$38.7 million, which consisted of \$178.2 million in proceeds from the maturities of marketable securities, partially offset by purchases of marketable securities of \$133.6 million and purchases of property and equipment of \$5.8 million.

During the year ended December 31, 2017, cash used in investing activities was \$2.8 million, which consisted of \$217.3 million in purchases of marketable securities and purchases of property and

equipment of \$6.4 million, partially offset by proceeds from the maturities of marketable securities of \$220.9 million.

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

During the year ended December 31, 2018, cash provided by financing activities was \$0.2 million, which consisted proceeds from the issuance of common stock upon the exercise of previously granted stock options of \$2.6 million less deferred initial public offering costs of \$2.2 million and repurchases of common stock of \$0.2 million.

During the year ended December 31, 2017, cash provided by financing activities was \$0.3 million, which consisted of proceeds from the issuance of common stock upon the exercise of previously granted stock options.

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

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

### **Contractual Obligations**

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 December 31, 2018, our contractual obligations due by period (in thousands):

	Payments due by period				Total
	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years	
<b>Contractual obligations:</b>					
Operating lease obligations(1)	\$ 4,849	\$10,136	\$10,749	\$ —	\$25,734
<b>Total contractual obligations</b>	<b>\$ 4,849</b>	<b>\$10,136</b>	<b>\$10,749</b>	<b>\$ —</b>	<b>\$25,734</b>

(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 December 31, 2018 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 December 31, 2017 and 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 consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our 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 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 1 to our consolidated financial statements appearing elsewhere in this prospectus. 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***

All of our revenue to date has been generated from our collaboration agreements. Revenue from collaboration agreements 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 any commercialized products.

Revenues from research activities made under collaboration arrangements are recognized when there is persuasive evidence that an arrangement exists, services have been rendered, the price is fixed or determinable and collectability is reasonably assured. Revenue generated from our collaboration arrangements is not subject to repayment. Our obligations under collaboration agreements may include the transfer of intellectual property rights in the form of licenses, obligations to



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provide research and development services and obligations to participate on certain development committees with the collaboration party. We make judgments that affect the period over which we recognize revenue. On a quarterly basis, we review our estimated period of performance for our collaboration and license revenue based on the progress under the arrangement and account for the impact of any changes in estimated periods of performance on a prospective basis. We record amounts received prior to satisfying the above revenue recognition criteria as deferred revenue until all applicable revenue recognition criteria are met. Deferred revenue represents the portion of research or license payments received that have not been earned.

For revenue agreements with multiple-element arrangements, such as license and development agreements, we allocate revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence or third-party evidence. If neither exists, we use the best estimate of selling price for that deliverable. Revenue allocated is then recognized when the four basic revenue recognition criteria are met for each element.

Payments that are contingent upon the achievement of a substantive milestone are recognized entirely as revenue in the period in which the milestone is achieved. A milestone is defined as an event: (a) that can only be achieved based in whole or in part on either (1) the entity's performance or (2) on the occurrence of a specific outcome resulting from the entity's performance; (b) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved; and (c) that would result in additional payments being due to the entity. A milestone is considered substantive if the consideration earned from the achievement of the milestone meets all of the following criteria: (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone; (b) the consideration relates solely to past performance; and (c) the consideration is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. To the extent that non-substantive milestones are achieved and we have remaining performance obligations, payments in respect of such milestones are deferred and recognized as revenue over the estimated remaining period of performance. If there were no remaining performance obligations, we would recognize the revenue in the period it is earned.

Payments related to options to license our program candidates are considered substantive if, at the inception of the arrangement, we are at risk as to whether the collaboration partner will choose to exercise the option. Factors that we consider in evaluating whether an option is substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the arrangement without exercising the option, the cost to exercise the option and the likelihood that the option will be exercised. For arrangements under which an option is considered substantive, we do not consider the item underlying the option to be a deliverable at the inception of the arrangement and the associated option fees are not included in allocable arrangement consideration, assuming the option is not priced at a significant and incremental discount. Conversely, for arrangements under which an option is not considered substantive or if an option is priced at a significant and incremental discount, we would consider the item underlying the option to be a deliverable at the inception of the arrangement and a corresponding amount would be included in allocable arrangement consideration.

Revenues related to research collaboration services and grants are recognized as research costs are incurred, and/or the underlying services are performed over the term as specified in the related agreements.

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

We base our expense accruals related to clinical studies 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 studies 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 you 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 studies and other research activities.

### ***Stock-Based Compensation***

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

We account for stock options granted to non-employees using the fair value approach. These options are subject to periodic revaluation to reflect the current fair value at each reporting period until the non-employee completes the performance obligation or the date on which a performance commitment is reached.

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,

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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 of \$7.7 million and \$10.0 million for the years ended December 31, 2017 and 2018, respectively. As of December 31, 2018, we had unrecognized stock-based compensation cost related to options granted to employees and directors of \$16.7 million, net of forfeitures, which is expected to be recognized as expense over approximately 2.79 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, 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 the completion of this offering, the fair market value of each share of underlying common stock will be determined based on the closing price of our common stock as reported by the Nasdaq Global Select Market on the date of grant.

Based on the initial public offering price of \$16.00 per share, the intrinsic value of stock options outstanding at December 31, 2018 was \$99.4 million, of which \$75.1 million and \$24.4 million related to stock options that were vested and unvested, respectively, at that date.

### **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 are choosing to elect the extended transition period for complying with new or revised accounting standards 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) the last day of the fiscal year following the fifth anniversary of the completion of this offering, (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**

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes the revenue recognition requirements in Accounting Standards Codification (ASC) 605, Revenue Recognition. This ASU is based on the principle that revenue is recognized to depict 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 ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The ASU’s effective date will be for annual reporting periods beginning after December 15, 2018 and interim periods

beginning after December 15, 2019 using one of two retrospective application methods. The Company has engaged outside advisors to assist in analyzing its research collaboration, product development and license agreement with Merck to determine the differences in the accounting treatment under ASU 2014-09 compared to the current accounting treatment. The consideration the Company is eligible to receive under this agreement includes upfront payments, research and development funding, option payments, milestone payments, and royalties. The new revenue recognition standard differs from the current accounting standard in many respects, such as in the accounting for variable consideration and the measurement of progress toward completion of performance obligations. The Company currently anticipates adopting the new standard effective January 1, 2019 under the modified retrospective method.

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (ASU 2016-02). ASU 2016-02 is aimed at making leasing activities more transparent and comparable, and requires substantially all leases be recognized by lessees on their balance sheet as a right-of-use asset and corresponding lease liability, including leases currently accounted for as operating leases. ASU 2016-02 is effective for all annual reporting periods beginning after December 15, 2019. Early adoption is permitted. The Company is currently assessing the timing of adoption and the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718)—Improvements to Employee Share Based Payment Accounting as part of the FASB simplification initiative*. The new standard provides for changes to accounting for stock compensation including 1) excess tax benefits and tax deficiencies related to share based payment awards will be recognized as income tax expense in the reporting period in which they occur; 2) excess tax benefits will be classified as an operating activity in the statement of cash flows; 3) the option to elect to estimate forfeitures or account for them when they occur; and 4) increase tax withholding requirements threshold to qualify for equity classification. The Company adopted ASU 2016-09 as of January 1, 2018; however, there was no impact on the Company's consolidated financial statements as a result of adopting ASU 2016-09.

In November 2016, the FASB issued ASU No. 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 for the year ended December 31, 2018, noting no impact of this ASU on the presentation of its consolidated statement of cash flows due to no changes in restricted cash during the year.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope Modification Accounting*. ASU 2017-09 defines which changes to the terms or conditions of a share-based payment award require the Company to apply modification accounting. The Company adopted ASU 2017-09 on January 1, 2018; however, there was no impact on the Company's consolidated financial statements as a result of adopting ASU 2017-09.

In June 2018, the FASB issued ASU No. 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 to acquire goods and services

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from non-employees. This ASU will be effective for the Company for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020, with early adoption permitted. The Company is currently assessing the timing of adoption and the impact that the adoption of ASU 2018-07 will have on its consolidated financial statements and related disclosures.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when then collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. This ASU adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 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 Topic 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 Topic 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 consolidated financial statements.

## BUSINESS

### 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, five of which are in clinical testing. Our most advanced product candidate, NGM282, is wholly-owned and will enter Phase 2b development for the treatment of non-alcoholic steatohepatitis, or NASH, in mid-2019. In an ongoing Phase 2 clinical trial, NGM282 demonstrated the ability to rapidly improve NASH and reverse liver fibrosis at 12 weeks. We have created this portfolio using our research and drug discovery approach that employs unbiased, *in vivo*-based discovery to identify proprietary insights into critical biological processes. We combine this approach with our protein and antibody engineering expertise to find the appropriate modality to enhance each product candidate's therapeutic potential. Our executives, directors and advisors have extensive track records of successfully discovering, developing and delivering to patients first-in-class drugs, which positions us well to maximize the potential of our drug discovery approach.

In 2015, we entered into a five-year research collaboration, product development and license agreement with Merck Sharp & Dohme Corp., or Merck. On March 15, 2019, Merck exercised its option to extend the collaboration for two additional years. The collaboration includes an exclusive worldwide license to our growth differentiation factor 15, or GDF15, program. On March 1, 2019, Merck notified us of its intent to terminate its license to the program, effective May 31, 2019. Under the collaboration agreement, we also granted Merck options to take exclusive, worldwide licenses for the programs in our research and development pipeline on a program-by-program basis. Merck generally has a one-time right to exercise its option when a program completes a human proof-of-concept trial. In November 2018, Merck exercised its option to license NGM313, an agonistic antibody selectively activating fibroblast growth factor receptor 1c-beta-klotho, or FGFR1c/KLB, which is a potential treatment for NASH and type 2 diabetes. The collaboration enables us to develop more product candidates for major indications than we could likely advance on our own, with Merck bearing a majority of the associated cost and risk. We retain an option, when a candidate has advanced to Phase 3 clinical trials, to participate in up to 50% of the economic return from that candidate if it becomes an approved medicine. Overall, the Merck collaboration provides us with robust research and development support, while we retain our research independence and the option to split costs and profits on product candidates Merck elects to advance. We excluded our fibroblast growth factor 19, or FGF19, program, including NGM282, from the agreement and it remains wholly-owned by us.

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Our most advanced programs have focused on novel discoveries in hormone pathways that regulate cardio-metabolic processes and liver function, including those driving NASH, type 2 diabetes and obesity. We have identified multiple hormone pathways of interest, the most advanced of which are: FGF19 which plays a critical role in controlling bile acid, lipid and glucose metabolism; FGFR1c/KLB, which regulates insulin sensitivity, blood glucose and liver fat; and GDF15, which drives profound metabolic activity by regulating fuel flux and has been considered a challenging therapeutic target. We believe these hormone pathways work through distinct mechanisms and play an important role in metabolic regulation. Our seven proprietary product candidates are summarized below.

PRODUCT CANDIDATE	MECHANISM OF ACTION (Dosing Frequency)	POTENTIAL INDICATIONS	STAGE OF DEVELOPMENT				WORLDWIDE COMMERCIAL RIGHTS	EXPECTED UPCOMING MILESTONES
			Preclinical	Phase 1	Phase 2	Phase 3		
NGM282	FGF19 Analog (Once Daily)	NASH	Phase 2				NGM	Ph 2b (F2/F3) Initiation: Mid-2019 Ph 2b (F4) Initiation: 2H 2019 Interim Ph 2 Data: 2H 2019
NGM313	FGFR1c / KLB Agonistic Antibody (Once Monthly)	NASH, Type 2 Diabetes	Phase 1b				Merck License	Ph 2b Initiation: Late 2019 – Early 2020
NGM120	GFRAL Antagonistic Antibody (Long Acting)	Cancer Anorexia / Cachexia Syndrome (CACS)	Phase 1				Merck Option to License	Ph 1a/1b Initiation: 2H 2019
NGM217	Undisclosed (Long Acting)	Diabetes	Phase 1				Merck Option to License	Ph 1b/2a Initiation: 2020
NGM621	Undisclosed (Long Acting)	Dry Age-Related Macular Degeneration	Preclinical				Merck Option to License	Ph 1 Initiation: 2H 2019
NGM386	GDF15 Analog (Once Daily)	Obesity	Phase 1				NGM <sup>1</sup>	
NGM395	GDF15 Analog (Long Acting)	Obesity	Preclinical				NGM <sup>1</sup>	

<sup>1</sup> Effective May 31, 2019.

We are currently focused on the following programs:

- NGM282 is an engineered variant of the human hormone known as FGF19, which we are developing for the treatment of NASH. FGF19 is a highly specific and potent regulator of liver fat metabolism and bile acid synthesis that we believe is responsible for some of the beneficial effects of gastric bypass surgery on NASH. Preliminary results from Phase 2 clinical trials have provided clinical proof of concept for a once-daily injection of NGM282 by demonstrating statistically significant reductions in liver fat, liver transaminases and biomarkers of fibrosis, which has translated into improvements in liver histology and fibrosis at 12 weeks. We expect interim data in the second half of 2019 from our ongoing placebo-controlled Phase 2 clinical trial cohort assessing the histological effects of NGM282 after 24 weeks of treatment. We plan to commence testing of NGM282 in a Phase 2b dose range-finding clinical trial for the treatment of NASH patients with F2 and F3 liver fibrosis in mid-2019 and a Phase 2b clinical



trial in NASH patients with compensated cirrhosis in the second half of 2019. We expect to complete our Phase 2b clinical trial of NGM282 in NASH patients with F2 and F3 liver fibrosis in 2020. We excluded our FGF19 program, including NGM282, from our Merck collaboration, and it remains wholly-owned by us.

- NGM313 is an agonistic antibody binding KLB and has the potential as an insulin sensitizer and regulator of lipid homeostasis to be a once-monthly treatment for NASH and type 2 diabetes. NGM313 works by selectively activating the FGFR1c/KLB co-receptor complex, which regulates energy expenditure and glucose uptake in fat cells and other tissues. Preliminary data from a Phase 1b early proof-of-concept clinical trial in obese insulin resistant subjects with nonalcoholic fatty liver disease, or NAFLD, demonstrated that a single dose of NGM313 resulted in a statistically significant reduction in liver fat content and improvements in multiple metabolic parameters. Following review of the NGM313 data package, Merck exercised its option to license the program in November 2018. We expect Merck to initiate a Phase 2b study of NGM313 in NASH patients in the late 2019 or early 2020.
- NGM120 is an antagonistic antibody binding GFRAL that is designed to inhibit the effects of elevated GDF15 levels on cancer anorexia/cachexia syndrome, or CACS, and, possibly, cancer. NGM120 works by selectively inhibiting the interaction between GDF15 and its cognate receptor, GFRAL, through which the autonomic nervous system and, possibly, the neuroendocrine axis influence the body's fuel flux to propel the cachectic state, and, possibly, the cancer itself, in cancer patients that have high serum levels of GDF15. We are currently testing NGM120 in healthy volunteers in a Phase 1 clinical trial to assess its safety, tolerability and pharmacokinetic profile. We expect to initiate a Phase 1a/1b clinical trial of NGM120 in cancer patients in the second half of 2019. Merck has a one-time option to license NGM120 upon our completion of a proof-of-concept study in humans.
- NGM217 is an antibody binding an undisclosed target, designed to restore pancreatic islet function and increase insulin production in patients with diabetes. NGM217 is in a Phase 1 clinical trial in adults with diabetes, where we are assessing its ability to increase levels of C-peptide, a biomarker of insulin production. We expect to initiate a Phase 1b/2a proof-of-concept clinical trial in adults with diabetes in 2020. Merck has a one-time option to license NGM217 upon our completion of a proof-of-concept study in humans.
- NGM621 is an antibody binding an undisclosed target, designed to decrease levels of a protein implicated in the dry form of age-related macular degeneration, or dry AMD. NGM621 is in IND-enabling studies, and we expect to begin a Phase 1 safety, tolerability and pharmacokinetics clinical trial in patients with geographic atrophy, or GA, an advanced form of dry AMD, in the second half of 2019. Merck has a one-time option to license NGM621 upon our completion of a proof-of-concept study in humans.
- NGM386 and NGM395 are engineered variants of the human hormone known as GDF15, which were being developed by Merck under the collaboration for the treatment of obesity. We discovered that metabolic activity of GDF15 is mediated by glial cell-derived neurotrophic factor receptor alpha-like, or GFRAL, which is located in a region of the brain stem outside the blood-brain barrier. NGM386, a once-daily injection, and NGM395, a once-weekly or less frequent injection, are designed to stimulate a pathway that modulates the autonomic nervous system and, possibly, the neuroendocrine axis to modify body weight and fat levels in the body. Merck licensed this GDF15 receptor agonist program and completed the conduct of a Phase 1 clinical trial of NGM386 in overweight or obese but otherwise healthy adults. Preliminary data from the study indicated that NGM386 treatment for 28 days was generally well-tolerated but did not result in significant body weight loss in obese subjects. On March 1, 2019, Merck notified us of its intent to terminate its license to the GDF15 receptor agonist program, effective May 31, 2019. Upon effectiveness of this termination, we will regain full rights to the program, which

includes NGM386 and NGM395. We expect to decide whether to advance NGM386 and/or NGM395 following our analysis of the results of the NGM386 Phase 1 study.

Using our drug discovery approach, we have identified and are actively investigating over ten additional biological pathways with potential to intervene in disease. For these pathways, we are further identifying mechanistic insights and their relevance to human biology, and generating biologic drug candidates that appropriately modulate the signals we have identified. These programs are in various stages of development, ranging from functional validation to lead candidate generation. Discovery activity in selected therapeutic areas beyond cardio-metabolic, liver, oncologic and ophthalmic diseases is ongoing and in various stages of research.

Our management, scientists, board members and advisors have long track records of identifying multiple, class-defining drugs with meaningful clinical and commercial impact. Our scientific values and guiding principles have grown out of our team's experience and involvement at companies that have built prolific drug discovery and development platforms, particularly Amgen Inc., Genentech, Inc. and Tularik Inc. We believe that this collective experience uniquely positions our team to execute on our strategy.

## Our Strategy

Our strategy is to leverage our biology-centric drug discovery approach to uncover novel mechanisms of action and generate proprietary insights that will enable us to move rapidly into proof-of-concept studies and deliver to patients first-in-class medicines. Key elements of our strategy are:

- **Establish NGM282, Our Wholly-Owned Compound, as the Leading Treatment for NASH Patients with Moderate to Advanced Fibrosis:** In Phase 2 clinical trials in NASH, patients taking NGM282 have experienced rapid and robust reductions in liver fat, liver transaminases, hepatocellular ballooning and fibrosis. These results suggest that NGM282 has the potential to resolve disease and reverse fibrosis in NASH patients with moderate to advanced liver fibrosis. We plan to initiate a Phase 2b clinical trial of NGM282 in NASH patients with fibrosis stage F2 and F3 in mid-2019 and a Phase 2b clinical trial in NASH patients with compensated cirrhosis in the second half of 2019, which will inform dose selection for a Phase 3 clinical trial in these patient populations to support a filing for initial marketing approval. As part of our life cycle management strategy, we intend to also develop a version of NGM282 with an extended half-life, or exposure duration in the blood, which will enable less frequent dosing.
- **Leverage Our Collaboration with Merck to Advance Our Pipeline:** Our collaboration with Merck provides us with financial resources and access to industry-leading, late-stage clinical development and commercialization capabilities, which we believe affords us substantial freedom to pursue and achieve our vision. We intend to leverage Merck's financial support and translational expertise to accelerate and broaden our development efforts for our programs beyond NGM282, NGM386 and NGM395. Our option to elect a cost and profit share for collaboration products preserves our substantial economic participation in such programs.
- **Grow Our Pipeline and Extend Our Therapeutic Areas of Focus:** Our initial research focus is on the biology underlying cardio-metabolic, liver, oncologic and ophthalmic diseases. Our collaboration with Merck creates an incentive for us to develop multiple candidates through human proof-of-concept studies, but does not limit the therapeutic areas that we can explore. We are working to establish human proof of concept for NGM120 in cancer patients and NGM621 for dry AMD, and plan to continue growing our pipeline of product candidates at our historical rate, with the goal of identifying high-impact therapeutics that are first-in-class.
- **Build Capabilities to Deliver Medicines to Patients in Areas of High Unmet Medical Need:** We have worldwide rights to our lead product candidate, NGM282. If approved, we

intend to bring NGM282 to market by building our own specialty salesforce in the United States targeting hepatologists and may seek to expand our reach by leveraging partners' commercial capabilities. We believe a targeted salesforce would have the ability to deliver NGM282 to the majority of the initial target population of NASH patients with moderate to advanced fibrosis. For our other programs, our collaboration with Merck provides us the option to participate in co-detailing in the United States.

- **Strengthen Our Position as a Leading Drug Discovery and Development Company:** We aspire to operate one of the most productive research and development engines in the biopharmaceutical industry. In the last decade, our team of experienced scientists and drug developers has designated seven molecules for development, five of which are in clinical development. We intend to continue growing our pipeline of experimental medicines and build on our proficiency in discovery research by continuing to expand our capabilities in protein and antibody engineering, pharmacology, translational medicine and preclinical and clinical development.

### **Our Approach to Drug Discovery and Development**

We pursue drug discovery and development through a multi-step process geared towards translating powerful human biology into first-in-class medicines. Our founding team designed our approach based on many decades of experience in successful drug development at other companies, including Amgen, Genentech and Tularik. Our process pairs a research approach that generates novel insights into pathways demonstrating powerful biological effect with the expertise in protein and antibody engineering to transform those insights into product candidates. This process seeks to address the challenges in drug discovery in diseases that involve complex, integrated biological pathways.

#### **Identifying Pathways of Interest**

We identify target genes or pathways of interest by utilizing three approaches:

- an unbiased, *in vivo* functional evaluation system formed the foundation of our discovery efforts in metabolism and enabled us to identify and characterize novel human hormones that demonstrate profound biological effects, including FGF19 and GDF15, for which we have advanced development candidates;
- analysis of human genetics data to identify genetic markers, such as single nucleotide polymorphisms, or SNPs, that correlate with a particular phenotype associated with disease; and
- gene expression profiling to identify genes that are regulated by certain conditions or disease states and that may contribute to the associated pathology.

We then characterize and confirm the effects of modulating the biological activity of these potential targets using *in vivo* models designed to mimic the disease of interest. We interrogate the biological activity of candidate targets using *in vivo* models because *in vitro* experiments, which take place outside a living organism, are not capable of adequately reflecting complex biological processes and interactions that are regulated by multi-organ systems. Historically, *in vivo* screening at a scale and speed for drug discovery has not been practical as it has largely been dependent on generating purified protein for functional testing. We use recombinant adeno-associated virus, or rAAV, vectors, a proven research tool that can introduce the gene of interest directly into disease models to enable the biological function of the resultant protein to be assessed *in vivo*. With this rAAV technology, we initially developed an unbiased, *in vivo* functional evaluation system that formed the foundation of our

discovery efforts in cardio-metabolic disease and enabled us to identify novel pathways that demonstrate profound metabolic effects. In addition, we utilize *in vivo* models with loss of function mutations or knockouts to understand the function of certain human genes as they relate to the disease of interest. By employing these approaches in animal models of human diseases, we can elucidate the biology of potential human drug targets in a relevant *in vivo* setting and evaluate their impact on the manifestation and progression of disease.

### **Translation of Pathway Biology to Product Candidates**

Once a strong indication of biological activity is generated for a protein of interest, we employ a differentiated process aimed at quickly identifying a lead candidate to enable us to rapidly advance the program to evaluate the effect of these product candidates on biomarkers of disease or target activity in order to enable early demonstration of human proof of concept. We probe the mechanism of action, signaling pathways and the relationship between the protein structure and function to help inform how to translate the biological activity into a potential product candidate. Through these activities we have been able to identify novel interaction partners, their expression patterns and their signaling activities, which help elucidate biological mechanisms and inform selection of a lead candidate. We leverage our expertise in protein and antibody engineering to translate biological signals into differentiated product candidates. We have an unbiased antibody generation technology, along with an armamentarium of therapeutic protein and antibody engineering capabilities, including bispecific antibodies, bifunctional antibody fusions and methods for extending the half-lives of native proteins. This range of potential modalities not only allows us to generate a portfolio of product candidates from which to select a lead, but also provides important tools to define the biological activity of the candidates.

After we have identified a lead candidate in a program, we design our early clinical trials to provide proof of biological activity, in addition to assessing safety and tolerability, to determine whether the activity we have observed in animal models can be translated into human subjects. We believe our deep understanding of the fundamental biological mechanisms observed for our chosen development candidates and the specific relationship between structure and pharmacological function distinguishes our drug discovery approach from many others applied in our industry today.

The cornerstone of our research and development approach is the experienced and talented team of scientists and drug developers who built and run it. A common theme in our team's expertise is the ability to translate biological signals in animal models into drugs with human activity. Members of our team played significant roles at prior companies in discovering and developing multiple approved drugs, including recombinant human insulin, human growth hormone, tissue plasminogen activator and interferon alpha and gamma, as well as metreleptin and evolocumab (Repatha®). Our team seamlessly integrates discovery biology, protein and antibody engineering, preclinical development, early clinical development and manufacturing for each program. Our scientific advisory board further strengthens our experience base and includes key contributors to the discovery of the statin class of drugs, as well as thought leaders in new areas complementary to our early-stage research efforts.

### **Our Initial Focus on Cardio-Metabolic and Liver Disease**

Cardio-metabolic and liver diseases, including NASH, diabetes and obesity, are among the largest unmet medical needs globally, and represent a leading cause of morbidity and mortality, a significant burden for healthcare systems and an area of relative underinvestment by the pharmaceutical industry. Metabolic syndrome is exhibited by 34% of adults in the United States and is believed to be at the center of this health epidemic. Metabolic syndrome comprises a constellation of co-morbid conditions, including type 2 diabetes, obesity, high blood pressure, poorly regulated lipids and NAFLD, a precursor condition to NASH. Despite a wave of public health campaigns to promote

better diet and exercise habits and a range of treatment options available for many of these cardio-metabolic diseases, morbidity and mortality rates remain high and more effective therapeutics are needed.

Cardio-metabolic and liver diseases represent areas of both rapidly growing unmet medical need and underinvestment, driven in part by the biological complexity of the diseases and the substantial costs necessary to develop new therapeutics. Leveraging our differentiated drug discovery approach, we have spent the last decade discovering and developing a portfolio of clinical-stage drug candidates that target various forms of cardio-metabolic disease including NASH, type 2 diabetes and obesity. Each of these drug candidates stem from novel insights we have made in understanding hormone pathways that regulate cardio-metabolic processes. NGM282 is our lead product candidate in development for treating NASH, a cardio-metabolic liver disease. As explained below, the clinically validated, dual mechanism of action of NGM282 supports its therapeutic potential in NASH, an indication with a high prevalence and for which there are no approved treatments. Our investment in cardio-metabolic diseases was further expanded in 2015 through our collaboration with Merck, which provided resources to advance multiple programs, in addition to our wholly-owned NGM282 program. Our six most advanced clinical candidates—NGM282, NGM313, NGM386, NGM120, NGM217 and NGM395—are notable because their preclinical profiles suggest the potential to broadly impact the drivers of various diseases with an underlying metabolic dysregulation. These programs are in human clinical trials or preparing to enter human clinical trials.

### **Other Focus Areas**

Beyond cardio-metabolic and liver diseases, we are also pursuing treatments for oncologic and ophthalmic diseases, which are also major disease categories that are growing in incidence and lack adequate treatments. NGM120 is our first product in oncology and NGM621 is our first product candidate in ophthalmic disease. All of our programs embody our focus on delivering transformative therapeutics to patients by applying our proprietary insights into powerful biology underlying major diseases.

### **Our Programs**

#### ***NGM282: A Rapid and Potent Approach to Treating NASH***

NGM282, an engineered version of human hormone FGF19 that is administered through a once daily subcutaneous injection, has demonstrated the ability to rapidly improve NASH and reverse liver fibrosis in clinical and preclinical studies. We believe the combination of breadth, magnitude and speed of effect demonstrated by NGM282 in these studies results in an agent that, if ultimately approved, could provide a needed medicine for physicians to treat NASH patients with moderate to advanced fibrosis. We have tested NGM282 in over 400 subjects, including more than 150 NASH patients, and we expect to initiate a Phase 2b clinical trial in NASH patients in mid-2019. NGM282 is wholly-owned, and it is not subject to our collaboration with Merck.

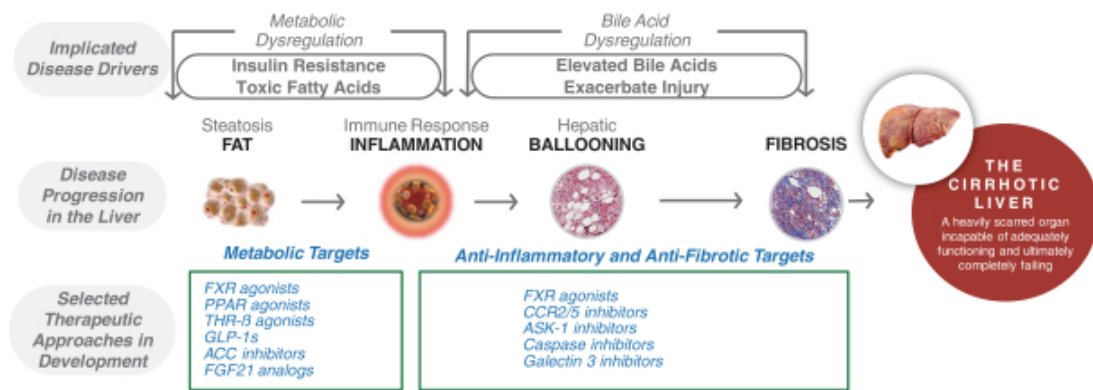
#### ***NASH: A Progressive Metabolic and Fibrotic Disease of the Liver that Affects Millions***

NASH is a life threatening form of liver disease. It results from the progression of NAFLD, which is a common co-morbidity of the metabolic syndrome and obesity. NAFLD is characterized by abnormal amounts of fat in the liver, a condition known as steatosis, and is often associated with insulin resistance. This abnormal fat in the liver contributes to the progression by certain NAFLD patients to NASH by developing a necroinflammatory state in the liver that ultimately drives scarring, also known as fibrosis, and, for many, progresses to liver failure, also known as cirrhosis.

The estimated global prevalence of NAFLD and NASH has risen rapidly in parallel with the dramatic rise in population levels of obesity and diabetes. NAFLD now represents the most common cause of liver disease in the Western world. In the United States alone, the prevalence of NASH was estimated to total 16.5 million cases and is projected to reach 27 million cases by 2030, with similar trends occurring globally. By 2020, NASH is expected to supplant hepatitis C as the leading cause for liver transplantation, and liver-related deaths in the NAFLD population are expected to increase by more than 150% in the next 15 years. The annual economic burden associated with NAFLD and NASH in the United States was estimated to have been over \$100 billion in 2016.

Although the mechanism underlying the development and progression from simple steatosis to NASH and cirrhosis is poorly understood, insulin resistance and inflammatory mediators, including lipotoxicity, cytokines and oxidative stress, are believed to promote the development of NASH and its extrahepatic complications. Excess lipotoxic, or fat, metabolites in the liver are believed to provide the primary insult in the pathogenesis of NASH, and several treatments are in development targeting mechanisms to reduce these disease drivers. Other treatments in development aim to reduce the inflammatory and fibrotic damage created by this metabolic dysregulation. Evidence also supports a role for bile acids in the pathogenesis of liver inflammation and fibrosis. Accumulation of bile acids, in particular, more toxic hydrophobic bile acids, within hepatocytes can cause mitochondrial dysfunction, endoplasmic reticulum stress and immune cell infiltration that can ultimately lead to inflammation, cell death and liver injury.

### Multiple Drivers Underlying the Pathogenesis of NASH



Most patients with NASH are diagnosed in their forties or fifties, however, NASH develops across all ages, including in children, which is thought to be linked to an increase in childhood obesity. Most NASH patients are asymptomatic, although some may present with fatigue, malaise and vague right-upper abdominal discomfort. Patients are more likely to be initially identified by elevated liver aminotransferases on routine lab tests or hepatic steatosis detected incidentally on abdominal imaging. While non-invasive diagnostic tools are under development, a definitive diagnosis of NASH is currently only achievable through liver biopsy to assess the components of the NAFLD activity score, or NAS.

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The histologic criteria for the diagnosis of adult NASH include steatosis, lobular inflammation and hepatocellular ballooning. Portal and periportal fibrosis followed by bridging fibrosis and cirrhosis are seen in patients as NASH progresses. Physicians assess the severity of NASH by liver biopsy using two different scoring systems, the NAS and the fibrosis stage (F0 to F4). The table below describes the scoring criteria of the two systems:

### **NAFLD Activity Score System**

Component	Score	Thresholds
Steatosis (% of microscopic field showing steatosis)	0	<5%
	1	5-33%
	2	>34%-66%
	3	>66%
Lobular Inflammation (Number of immune cell foci per 20x optical field in microscope)	0	None
	1	<2 foci
	2	2-4 foci
Hepatocellular Ballooning (amount of ballooning cells in microscopic field)	0	None
	1	Few cells
	2	Many cells
<b>Total NAS Score = steatosis score + lobular inflammation score + hepatocellular ballooning score</b>		

### **Fibrosis Score**

Fibrosis Stage	Description
F0	Absence of fibrosis
F1	Perisinusoidal or periportal
F2	Perisinusoidal and periportal
F3	Bridging fibrosis
F4	Cirrhosis

The NAS is a validated score of liver histology that is used to grade disease activity in patients with NAFLD and NASH. The NAS is the sum of the liver biopsy's individual scores for steatosis (0–3), lobular inflammation (0–3) and hepatocellular ballooning (0–2), with fibrosis (F0–F4) scored separately. Advanced liver fibrosis is generally considered fibrosis stage F3 and F4, which may ultimately lead to end-stage liver disease, liver cancer, liver transplant and/or death.

#### *FDA Draft Industry Guidance on NASH Drug Development and Endpoints*

There are no FDA-approved therapeutics for NASH. The FDA has provided draft industry guidance to the industry regarding acceptable development pathways for investigational NASH agents as follows:

- must be tested in NASH patients, typically characterized as having a NAS of four or greater and at least one point in each component, with F2 or F3 fibrosis;
- for an accelerated approval path (Subpart H (drugs)/Subpart E (biologics)), a surrogate endpoint that is “reasonably likely to predict clinical benefit” is acceptable. A subsequent post

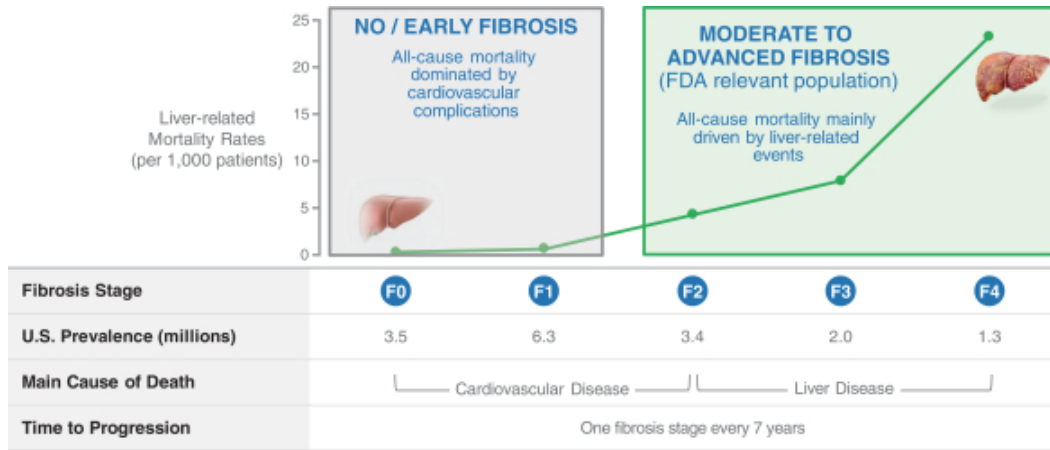
marketing confirmatory outcomes study is then required to be conducted to maintain licensure; and

- for a Subpart H/E approval, two biopsy-based surrogate endpoints are endorsed by the FDA, defined as the proportion of patients that achieve:
  - resolution of NASH, defined as a lobular inflammation score = 0 or 1 and a hepatocellular ballooning score = 0, with no worsening of fibrosis; or
  - ≥1 stage improvement in fibrosis with no worsening of NASH.

We believe many agents in development for NASH will opt for a Subpart H/E pathway and rely on the surrogate endpoints for initial approval. As detailed further below, fibrosis stage is currently the only measurement that is correlated to liver outcomes and therefore, the potential for many agents that will rely only on the resolution of NASH surrogate endpoint to demonstrate clinical benefit will remain uncertain until a confirmatory outcomes study is successfully completed.

*Stage of Fibrosis Predictive of Outcomes for NASH Patients*

The presence of fibrosis is the only factor that is highly predictive in identifying those patients who will progress to cirrhosis. The natural history of NASH is variable from patient to patient and, while the NAS is a valuable tool for diagnosing the disease, it does not appear to be predictive of disease progression. Of the estimated 64 million patients in the United States with NAFLD, approximately 10%–20% will progress to NASH over time. Of these NASH patients, approximately 10%–15% will progress to cirrhosis by advancing one fibrosis stage every seven years. The mortality rate of NASH patients with fibrosis has been estimated at 1.5%–3.5% per year, largely due to cardiovascular disease, followed by liver-related causes. However, patients with F2 or greater fibrosis stage have a greater chance of liver-related mortality than cardiovascular-related mortality, and each stage of worsening of fibrosis correlates to an exponential increase in liver-related mortality rates. Patients with F3 fibrosis and F4 fibrosis have an approximately 17 times greater risk and 42 times greater risk, respectively, of liver-related mortality than those NASH patients without fibrosis. Therefore, it is expected that treatments that can drive the regression of fibrosis are more likely to have a meaningful impact on clinical outcomes for NASH patients with F2 to F4 fibrosis.



*Current Treatments*

Currently, no agents have been approved for the treatment of NASH. Weight loss through diet and lifestyle management is currently considered the first-line treatment strategy for NASH and is



associated with improvement in liver histology and a reduction in cardiovascular and metabolic complications. However, fewer than 10% of patients are successful in achieving or maintaining at least a 10% total body weight loss that is sufficient to improve fibrosis and, therefore, require other interventions. In cases of morbid obesity, gastric bypass surgery has been successful in resolving NASH in a majority of patients, however, the effect on fibrosis improvement was less substantial and the risk of complications and expense of the surgery limit more widespread use.

In the absence of approved products, some physicians utilize agents approved for other indications, including Vitamin E and pioglitazone; however, the evidence of their effect on NASH is modest and/or they have safety issues that limit acceptance. Given the increasing disease burden and lack of approved treatment options, the development of novel pharmacologic therapies to treat NASH is critical.

#### *Treatments in Development*

While there are many agents in clinical development for NASH, the landscape can be subdivided into a few mechanistic classes based on the putative disease drivers they target. Most treatment approaches for NASH have focused on the prevention or reversal of liver injury either by predominantly treating the metabolic dysregulation of the disease or through directly targeting inflammatory or fibrogenic pathways. NASH is a chronic, slowly progressing disease and, currently, many believe that slowing the progression or reversing disease requires treatment periods of at least 12 months. To attempt to overcome modest individual agent activity, combination therapy is being pursued by some NASH drug developers, on the theory that the complex underlying pathophysiology of NASH will require targeting multiple mechanisms to achieve a sufficient disease-modifying effect to be clinically relevant.

#### *Drug Candidates Pursuing a Metabolic Approach to Treating NASH*

Certain NASH drug development candidates are focused on the metabolic components of the disease, such as insulin resistance and lipotoxicity, that are associated with the inception and early stages of the disease pathology. The rationale for these treatment candidates is based on an expectation that the improvement of the underlying liver insult of metabolic dysregulation will allow the liver to recover over the long-term, which would potentially allow the liver to repair itself and eventually improve fibrosis. Although clinical data for some compounds in this mechanistic class show a beneficial effect on steatosis and an improvement in the NAS, the effect on fibrosis is likely to be highly dependent on the compound being tested. Any of these metabolic-focused compounds that are ultimately approved may be appropriate to halt the progression of disease in earlier-stage NASH patients or used in combination with other agents. Considering the correlation of liver failure outcomes with fibrosis stage, we believe the NASH patients with moderate to advanced fibrosis (F2 to F4) will require a more potent and fast-acting agent to prevent the progression to end-stage liver disease.

#### *Drug Candidates Pursuing an Anti-Inflammatory and/or Anti-Fibrotic Approach to Treating NASH*

Candidates targeting various mechanisms with possible anti-inflammatory and anti-fibrotic effects are also in clinical testing for NASH. These classes of compounds have shown mixed results in meaningfully improving the fibrosis score of patients. Where fibrosis improvements have been shown, results have either been transient or not accompanied by significant improvements in other histological measures of the disease. These classes of compounds have also shown limited ability to improve NASH.

We believe the minimal efficacy on fibrosis improvement and lack of activity on resolving NASH that has been observed to date with anti-inflammatory and anti-fibrotic agents may reflect the difficulty in treating the disease without removing the underlying insult of lipotoxicity, or the challenge of

impinging on the complex process of hepatocellular death and fibrosis from collagen deposition by intervention through a single pathway.

#### *Drug Candidates with Multiple Mechanisms*

To date, drug candidates with multiple mechanisms of activity have shown the most promising effect on NASH. The FXR agonist, obeticholic acid, or OCA, demonstrated improvements in the NAS and fibrosis but not resolution of NASH as defined by the Phase 2 and Phase 3 study protocols. FXR agonists are known to regulate hundreds of genes, and one of the factors upregulated is FGF19. We believe FGF19 is the primary mediator of the activity of FXR agonists in NASH. FXR agonists are limited, however, in the magnitude of FGF19 levels they can achieve by the boundaries of normal physiology. We believe this limitation to sub-pharmacological levels of FGF19 will limit the ability of FXR agonists to produce a meaningful effect in NASH, in the same way that insulin secretagogues have mild activity compared to insulin itself in treating diabetes. Additionally, treatment with OCA has been associated with pruritus, or whole body itching. There are multiple FXR agonists in preclinical or clinical development seeking to improve on the properties of OCA; however, we believe their activity on NASH will be limited by their inability to sufficiently elevate FGF19 levels over a sustained period of time.

To our knowledge, we are the only program in clinical development for NASH directly activating the native FGF19 pathway to drive both a regression of fibrosis and resolution of NASH.

#### *NGM282: A rapid and potent approach to treating NASH*

NGM282, an engineered version of human hormone FGF19 that is administered through a once daily subcutaneous injection, has demonstrated the ability to rapidly improve NASH and reverse liver fibrosis in clinical and preclinical studies. We believe the combination of breadth, magnitude and speed of effect demonstrated by NGM282 in these studies results in an agent that, if ultimately approved, could provide a needed medicine for physicians to treat NASH patients with moderate to advanced fibrosis. We have tested NGM282 in over 400 subjects, including more than 150 NASH patients, and we expect to initiate a Phase 2b clinical trial in NASH patients with F2 and F3 liver fibrosis in mid-2019 and a Phase 2b clinical trial in NASH patients with F4 compensated cirrhosis in the second half of 2019. We obtained Fast Track designation for NGM282 for the treatment of NASH and PBC in adults. See “Government Regulation and Product Approval—Accelerated Approval Requirements.” NGM282 is wholly-owned, and it is not subject to our collaboration with Merck.

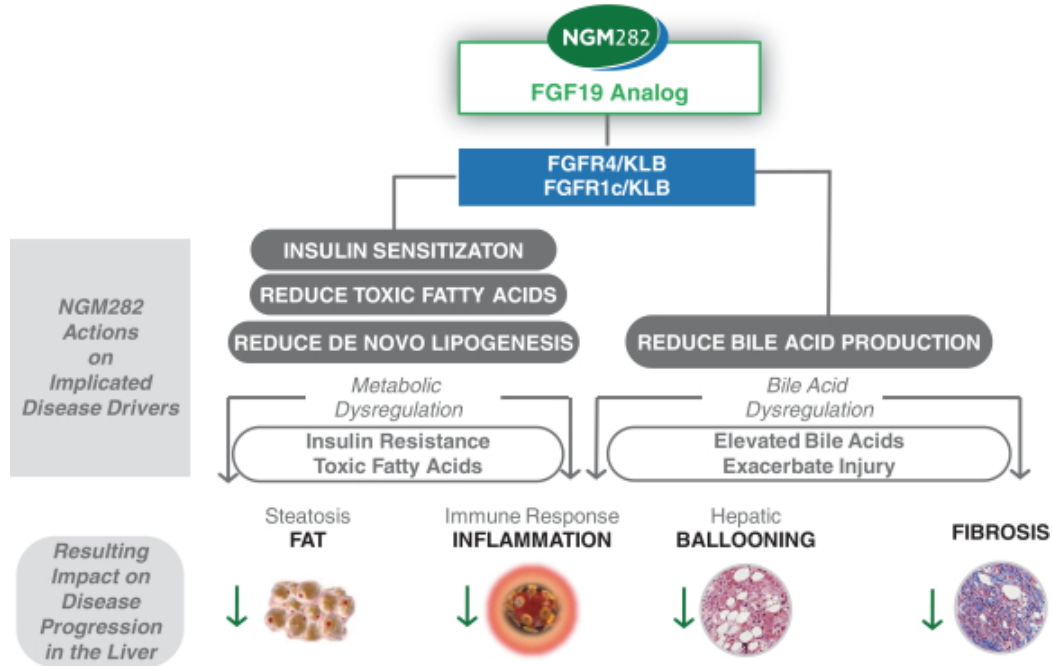
In a recent study, gastric bypass surgery has led to a resolution of NASH in approximately 80% of patients studied. We initially identified FGF19 using our rodent gastric bypass surgery model that was designed to discover hormones that may drive the beneficial metabolic effects observed following this type of surgery. We also demonstrated that serum levels of FGF19 are significantly increased in humans after gastric bypass surgery. FGF19 acts as an endocrine hormone to regulate systemic carbohydrate and energy homeostasis, similar to insulin, and also inhibit the production of bile acids in the liver. Systemic FGF19 levels are decreased in patients with NASH, type 2 diabetes or metabolic syndrome, and are normalized after gastric bypass surgery in diabetic human subjects.

The spectrum of activities ascribed to FGF19 appear to be mediated primarily through two different receptor complexes: FGFR4/KLB and FGFR1c/KLB. FGFR4/KLB receptor complexes are found primarily in the liver and FGFR1c/KLB receptor complexes are found primarily in adipose tissue and the central nervous system. When activated, FGFR4/KLB inhibits the expression of the cholesterol 7 $\alpha$ -hydroxylase 1, or CYP7A1, gene, which modulates bile acid production through the classical pathway in the liver. There is increasing evidence supporting the role of bile acids as a pathophysiological driver of NASH. Individuals with NASH are reported to have elevated hepatic and circulating concentrations of bile acids, as well as increased concentrations of fecal and urine bile

acids. As NASH patients progress to F2 and F3 fibrosis stages, serum levels of bile acids double as compared to healthy volunteers. Furthermore, serum levels of FGF19 are increasingly depressed as fibrosis levels increase in NASH patients as compared to healthy volunteers. A combination of activities from FGFR4/KLB and FGFR1c/KLB are believed to promote multiple beneficial metabolic effects in the liver and systemically, including improved insulin sensitization, a reduction in *de novo* lipogenesis and an increase in fatty acid oxidation.

We designed NGM282 as an analog of human FGF19 to improve the drug-like properties of the protein, remove a tumorigenic signal observed in rodents and retain the beneficial properties of triggering the FGFR4/KLB and FGFR1c/KLB pathways. We believe this tandem receptor-complex activation enables an improvement in the metabolic function of the liver and reduction in bile acid synthesis, which, in turn, enables NGM282 to have a more rapid and direct impact on fibrosis as compared to other agents that only address the metabolic dysfunction of NASH, as illustrated in the figure below.

### NGM282 Impacts Multiple Drivers of NASH Pathogenesis



#### Our Extensive Clinical Experience with NGM282

Our clinical development program for NGM282 was designed to first assess safety and tolerability of the agent and then test for activity in humans in a variety of disease settings we believed may benefit from the signaling activity of the FGF19 pathway. Each of these trials has provided insights into the agent's activity in humans and informed our development plans for NASH. A consistent profile of activity and tolerability has emerged for the compound across these studies.

After a Phase 1 clinical trial to assess safety and tolerability, we conducted a Phase 2 clinical trial in type 2 diabetes patients to assess the impact of NGM282 on insulin resistance and blood glucose levels. Although they were not histologically confirmed for NASH, the characteristics of many of the patients enrolled in this study are consistent with a population of presumptive NASH patients as they

demonstrated many of the hallmarks of NASH, including elevated levels of the liver transaminases known as alanine transaminase, or ALT, and aspartate transaminase, or AST. This trial validated the metabolic pathways of the drug by demonstrating improvements in many metabolic parameters across the patient population, but did not result in significant blood glucose lowering after 28 days of treatment. A consistent improvement in ALT and AST was observed for patients on treatment with NGM282, which suggested the agent was having a beneficial effect on liver health and, therefore, could have application in the treatment of NASH.

We have also explored the utility of NGM282-mediated bile acid synthesis inhibition in two cholestatic diseases, primary biliary cholangitis, or PBC, and primary sclerosing cholangitis, or PSC, but have decided not to pursue further development of NGM282 in these diseases at this time. Although we do not currently intend to pursue NGM282 for the treatment of PBC or PSC, we previously obtained orphan drug designations for NGM282 for the treatment of PBC in adults in the United States and PBC and PSC in adults in the European Union. See “Government Regulation and Product Approval—Orphan Drug Designation.” Both of these conditions are believed to have a strong bile acid component underlying the disease. NGM282 achieved a significant reduction in alkaline phosphatase, or ALP, an FDA-validated biomarker of disease in PBC, however, we determined the once-daily injectable nature of the product and competitive landscape compared to other development paths for the drug was not optimal. Similarly, in PSC, NGM282 treatment resulted in sustained reductions in a biomarker of fibrogenesis (PRO-C3), although there was no benefit in the primary endpoint of the trial, ALP. The FDA has not provided guidance on a development path for PSC that does not involve ALP and, therefore, we have determined not to move forward in this indication until a clear path is defined. Notably, PSC patients have a normal liver fat content level and the indication of fibrosis improvement in this population supports a role for the activity of a bile acid inhibitor, such as NGM282, as an anti-fibrotic in the liver.

A consistent tolerability observation across each trial has been dose-dependent gastrointestinal, or GI, adverse events that manifest in both the upper and lower GI tract. We conducted a Phase 1b trial in patients with chronic constipation and determined that NGM282 has a pro-kinetic effect on the GI tract, which means the increase in stool frequency is caused by greater GI motility and is not related to elevated fecal fat or elevated bile acid content. These results have helped inform mitigation protocols to help patients lessen these GI side effects.

#### *NGM282 Phase 2 Trial in NASH Patients*

Our Phase 2 clinical trial in patients with histologically-confirmed NASH was comprised of an initial double-blind placebo-controlled cohort (cohort 1), followed by a series of adaptive, open-label, single-blind cohorts (cohorts 2 and 3). We are also currently enrolling an additional expansion cohort (cohort 4) under this study to test NGM282 in a double blind, placebo-controlled setting with liver biopsies at baseline and following 24 weeks of treatment. Cohort 1 was designed to measure liver fat content by magnetic resonance imaging proton density fat fraction, or MRI-PDFF, and serum biomarker data at 12 weeks. This portion of the study generated distinct signals of therapeutic benefit and appropriate tolerability characteristics, which subsequently informed the adaptive cohorts 2 and 3. The open-label, single-blind cohorts (cohorts 2 and 3) were designed to explore additional dose levels of NGM282, as well as confirm the impact of NGM282 on liver histology, as defined by improvements in fibrosis and NAS. Additionally, the protocol was amended to study statin use for those patients that experienced a low density lipoprotein, or LDL, cholesterol increase during the first two weeks of NGM282 treatment, as further described below.

**Components of the NGM282 Phase 2 Clinical Trial in NASH**

Cohort	Doses (# of Patients)	Duration	Key Endpoints	Status
1	Placebo (27)	12W	<ul style="list-style-type: none"> <li>MRI-PDFF</li> <li>ALT/AST</li> <li>Exploratory fibrosis markers</li> </ul>	<i>Completed;</i> <i>The Lancet 2018</i> <i>Publication</i>
	NGM282 3 mg (27)			
	NGM282 6 mg (28)			
2	NGM282 0.3 mg (23)	12W	<ul style="list-style-type: none"> <li>Non-invasive measures</li> <li>Histology (3 mg)</li> <li>Lipid mitigation</li> </ul>	<i>Completed;</i> <i>EASL 2018</i> <i>Presentation</i>
	NGM282 1 mg (21)			
	NGM282 3 mg (22)			
3	NGM282 1 mg (28)	12W	<ul style="list-style-type: none"> <li>Non-invasive measures</li> <li>Histology</li> <li>Lipid mitigation</li> </ul>	<i>Completed;</i> <i>AASLD 2018</i> <i>Presentation</i>
4	Placebo (~25)	24W	<ul style="list-style-type: none"> <li>Non-invasive measures</li> <li>Histology</li> <li>Lipid mitigation</li> </ul>	<i>Ongoing</i>
	NGM282 1 mg (~50)			

NGM282 activity has been measured across a variety of imaging and serum biomarker measures, or non-invasive measures, as well as histological measures in order to provide a comprehensive assessment of the drug's activity on NASH disease pathology. For each of cohorts 1, 2 and 3, the primary endpoint was the absolute change from baseline to week 12 in liver fat content. Responders were defined as patients who achieved a 5% or larger reduction in absolute liver fat content, or LFC, as measured by MRI-PDFF. Key secondary endpoints included assessments of the safety and tolerability, percentage change from baseline (or relative change) in absolute LFC, normalization of LFC to less than 5% and changes from baseline and normalization in ALT and AST. Exploratory endpoints included the evaluation of biomarkers of NASH pathogenesis and fibrosis, as well as assessment of changes in liver histology in a sub-population of patients (3 mg dose group in cohort 2 and 1 mg dose group in cohort 3). The table below summarizes the preliminary data generated to date and demonstrates the consistent effect across each of the non-invasive measure of NASH in each of cohorts 1, 2 and 3 of our Phase 2 clinical trial, followed by a matrix explaining the significance of each of the metrics and biopsy measurements:

**NGM282 Significantly Impacts Key Parameters Consistent with Improvements in NASH**

Parameter Δ (W12-D1)	COHORT 1: DOUBLE BLIND			COHORT 2: OPEN LABEL <sup>1</sup>			COHORT 3: OPEN LABEL <sup>1</sup>
	Placebo (N=27)	3 mg (N=27)	6 mg (N=28)	0.3 mg (N=23)	1 mg (N=21)	3 mg bx (N=19)	1 mg bx (N=24)
<b>MRI-PDFF, Absolute %</b>	-0.9%	-9.7%	-11.9%	-5.3%	-11.0%	-11.2%	-10.9%
Absolute decrease ≥5% (% patients)	7%	74%	79%	57%	90%	100%	92%
<b>MRI-PDFF, Relative %</b>	-1%	-47%	-61%	-29%	-57%	-67%	-57%
Relative decrease ≥30% (% patients)	7%	85%	86%	48%	85%	100%	92%
<b>ALT, Absolute (IU)</b>	-2	-35	-32	-21	-43	-53	-64
<b>ALT, Relative %</b>	1%	-43%	-44%	-30%	-58%	-60%	-67%
<b>PRO-C3, Absolute ng/ml</b>	-1.2	-5.4	-3.6	-2.1	-4.7	-11.1	-4.5
<b>NAS Decrease ≥2 with at least 1 pt. in Inflammation or Ballooning</b> (% of patients)	NA	NA	NA	NA	NA	58%	50%
<b>Resolution of NASH</b> (% of patients)	NA	NA	NA	NA	NA	11%	13%
<b>Fibrosis improvement</b> (% of patients)	NA	NA	NA	NA	NA	42%	25%

<sup>1</sup> Cohorts 2-3 are preliminary data. Data for the 3 mg dose in Cohort 2 and 1 mg dose in Cohort 3 include only those patients who completed treatment with paired biopsies at baseline and week 12.

bx: biopsy

IU: international units

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A description of the key non-invasive and histological measurements collected in our NASH Phase 2 clinical trial is included in the table below:

Disease Marker	Type of Measurement	Correlation with Disease Severity or Drug Activity
LFC (MRI-PDFF)	Imaging biomarker	≥5% absolute LFC reductions correlated with a 2-point NAS score reduction; ≥30% relative reduction in LFC correlated with NAS score improvement and fibrosis improvement
Liver Transaminases (ALT/AST)	Serum biomarker	Increases associated with hepatic inflammation and injury due to lipotoxicity, bile acids or other pathways
PRO-C3	Serum biomarker	A protein fragment associated with collagen deposition in the fibrogenesis process. Higher PRO-C3 is correlated with more severe fibrosis
NAFLD Activity Score (NAS)	Histology	Used as a validated measure of NASH disease severity, usually requiring at least one point in each of steatosis, lobular inflammation and hepatocellular ballooning to define having NASH; not correlated with patient outcomes
Liver Fibrosis	Histology	Severity of fibrosis is directly correlated with patient outcomes (e.g., cirrhosis and hepatocellular carcinoma, or HCC)

Cohorts 2 and 3, summarized in more detail below, included patients who received liver biopsies after 12 weeks of treatment with either 1 mg or 3 mg of daily NGM282 to enable an assessment of any improvements in histological measures of NASH, such as fibrosis. Preliminary data from both the 3 mg dose group of cohort 2 and the 1 mg dose group of cohort 3 demonstrated that NGM282 has an impact on fibrosis regression in NASH subjects, with 42% and 25%, respectively, registering at least a one-stage improvement in fibrosis. We believe these histology results offer compelling support for NGM282's potential as a rapidly-acting agent for NASH patients with moderate to advanced fibrosis.

### *NGM282 Phase 2 Clinical Trial in NASH Patients: Cohort 1*

In the double-blind cohort of the Phase 2 clinical trial (cohort 1), 82 subjects with biopsy-confirmed NASH were randomized to NGM282 clinical doses of 3 mg or 6 mg (n = 55) or placebo (n = 27), administered as a daily subcutaneous injection for 12 weeks. Histologic inclusion criteria included biopsy-proven NASH with a NAS <sup>3</sup> 4 (at least 1 point in each component), F1 to F3 fibrosis and <sup>3</sup> 8% LFC.

As published in *The Lancet* in 2018, significant reductions in absolute and relative LFC were seen with both doses, with 79% of the 6 mg-treated subjects and 74% of the 3 mg-treated subjects meeting the primary endpoint of <sup>3</sup> 5% reduction in absolute LFC as measured by MRI-PDFF. There was no significant difference in absolute LFC reduction between the 3 mg and 6 mg doses. Normalization of absolute LFC (defined as ≤ 5% measured by MRI-PDFF) was observed in 26% and 39% of subjects treated with 3 mg and 6 mg, respectively, at week 12. Over 85% of NGM282 treated subjects achieved a decrease in relative LFC of ≥ 30%, which has been correlated to improvements in histology in several studies. These results were maintained across key baseline characteristics of gender (male vs. female), ethnicity (Hispanic vs. Non-Hispanic), diabetic status, ALT levels (< vs. ≥ 40 U/L), body mass index, or BMI, (< vs. ≥ 30), fibrosis stage (F1 vs. F2/F3) and statin use, with no significant difference in any sub-category.

Greater reductions from baseline in mean absolute ALT levels were observed for both NGM282 3 mg (-35 international units, or IU, p<0.0001) and 6 mg (-32 IU, p<0.0001) clinical doses at week 12 as compared with placebo. The p-value is a measure that states the probability that a comparable or better result would be produced purely by chance. A p-value of less than 0.05 means that if the drug was only as effective as the placebo, there would be less than a 5% chance that a comparable or better result would be produced purely by chance. Differences with a p-value of less than 0.05 are

generally considered statistically significant, indicating a high degree of confidence that the result is due to therapy with the drug and not due to chance. This decrease in ALT levels achieved statistical significance as early as week one, with a sustained reduction throughout the entire 12-week study treatment period. The mean relative percentage decreases in ALT levels from baseline to week 12 were also significant in both the doses, ranging from 43% to 44% ( $p < 0.001$ ). ALT levels achieved normalization (defined as  $< 19$  IU in females and  $< 30$  IU in males) in 24% of NGM282-treated patients by week 2 and 36% of treated subjects by week 12. Similarly, treatment with NGM282 resulted in significant mean absolute reductions in AST levels from baseline to week 12 as compared with placebo, with the majority of subjects decreasing below 40 IU as early as two weeks after starting treatment.

7 $\alpha$ -hydroxy-4-cholesten-3-one, or C4, is an intermediate in the classical bile acid synthesis pathway that is produced by the rate-limiting enzyme, CYP7A1. When activated, FGFR4 leads to a reduction in serum C4 levels. C4 levels were measured in patients to track target engagement by NGM282 and to determine how levels of C4 correspond to measures of therapeutic effect, such as reductions in liver transaminase levels. At both the 3 mg and 6 mg dose levels, serum concentrations of C4 were significantly reduced relative to placebo after one week of treatment, with more than 65% of patients at or below the limit of detection in the C4 assay. Levels of liver ALT and AST released from injured or dead hepatocytes are significantly elevated in NASH patients and can be measured as serum biomarkers of liver health. Reductions in serum levels of ALT and AST follow a similar time course as C4 reduction. We believe the potent and sustained inhibitory effect that NGM282 has on the classical bile acid synthesis pathway is important to achieving its therapeutic effect. FXR agonists can only elevate FGF19 to the upper end of normal physiological levels, which we believe is insufficient to achieve the complete and sustained inhibition of the classical bile acid pathway.

PRO-C3 levels, as well as levels of propeptide of type III procollagen, or PIIINP, and TIMP metalloproteinase inhibitor 1, or TIMP-1, which are components of the Enhanced Liver Fibrosis, or ELF, score, were reduced in the treated subjects, supporting a potential anti-fibrotic effect. Notably, more than 74% of NGM282-treated subjects achieved a reduction in PRO-C3 levels of  $\geq 15\%$  at 12 weeks, as compared to 24% of placebo-treated subjects. The overall ELF score for the 3 mg- and 6 mg-treated subjects was reduced by an average of 0.3 and 0.2, respectively, compared to no change for the placebo group.

Triglyceride level decreases were consistent with FGFR1c/KLB activity triggered by NGM282, while significant LDL cholesterol increases reflect potent FGFR4/KLB-mediated CYP7A1 inhibition. There were highly significant correlations between decreases in LFC and reductions in the serum levels of ALT, AST and C4.

#### *NGM282 Phase 2 Clinical Trial in NASH Patients: Cohort 2 and 3 Imaging and Biomarker Results*

Based on the profound impact seen with NGM282 in NASH patients across the measured non-invasive parameters assessed in cohort 1, an adaptive, open-label, single-blind cohort of three dosing groups known as cohort 2 was added to evaluate: 1) lower doses of NGM282 (0.3 and 1 mg); 2) histologic response at 12 weeks in a 3 mg dose group; and 3) the ability of concomitant statin use to mitigate drug-induced LDL cholesterol elevations. Additional MRI-PDFF images were collected at week 6 to further assess the potential for LFC responses at an earlier point in time and to evaluate the persistence of response at week 18 (six weeks after the end of treatment). The demographics and baseline patient characteristics of cohort 2 were similar to those in cohort 1. Preliminary data for the 3 mg dose in Cohort 2 and 1 mg dose in Cohort 3 include only those patients who completed treatment with paired biopsies at baseline and week 12. Preliminary data from cohort 2 demonstrates that a significant amount of the decrease in LFC occurs by week 6 and further consolidates towards normalization at week 12 in the 1 mg and 3 mg dosing groups. The 1 mg and 3 mg dose groups in

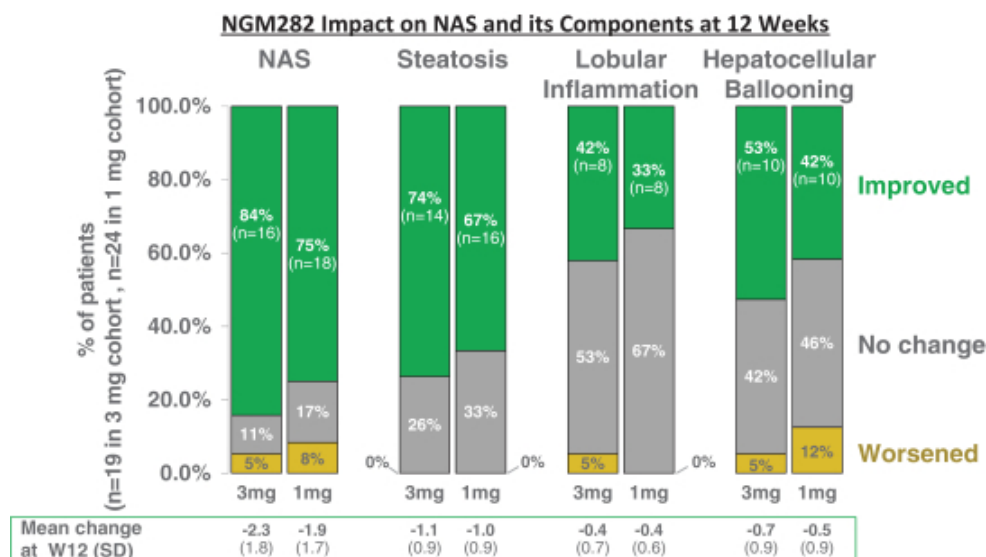


cohort 2 showed similar reductions of LFC and ALT levels, and were consistent with the week 12 changes observed with the 3 mg dose in cohort 1. Serum levels of C4 were significantly decreased at week 12, with the 3 mg dose group demonstrating reduction of 93% from baseline ( $p < 0.0001$ ). Preliminary data from cohort 2 indicates that the 1 mg and 3 mg dose groups also had statistically significant reductions from baseline in PRO-C3 levels (-4.7 and -11.1 ng/ml, respectively,  $p < 0.05$ ) and PIIINP (-2.0 and -3.3 ng/ml, respectively,  $p < 0.001$ ) and TIMP-1 (-33.1 and -42.7 ng/ml, respectively,  $p < 0.05$ ) components of the ELF score at week 12. The 0.3 mg dose group in cohort 2 demonstrated a reduced treatment response overall as compared to the 1 mg and 3 mg cohorts, based on the reductions in LFC, levels of ALT and the fibrosis markers. Preliminary data indicates that, six weeks after the end of NGM282 treatment, the relative levels of LFC and ALT levels remained suppressed, with reductions approximately 20% to 39% and 18% to 44% below baseline levels across doses evaluated in cohorts 2 and 3, respectively. Similarly, reductions in PRO-C3 levels and ELF score components in NGM282-treated patients were sustained six weeks after the end of NGM282 treatment.

*NGM282 Phase 2 Clinical Trial in NASH Patients: Cohort 2 (3 mg) and Cohort 3 Preliminary Histology Results*

Liver histology was evaluated at 12 weeks in the 3 mg dosing group of cohort 2 and in the 1 mg dosing group of cohort 3. Each of these cohorts enrolled primarily NASH patients with moderate to advanced fibrosis. Eighty-four percent of the 19 patients in the 3 mg dosing arm of cohort 2 had been diagnosed with F2 or worse fibrosis at baseline. Eighty-three percent of the 24 patients in cohort 3 had F2 or worse fibrosis at baseline. Liver biopsies at baseline and 12 weeks were blinded by both patient and treatment sequence. They were subsequently read by a central independent liver hepatopathologist using the NASH CRN criteria. Preliminary data from cohorts 2 and 3 showed improvements in fibrosis scores in both groups, with 42% of patients in the 3 mg dosing group of cohort 2 and 25% of the patients in cohort 3 improving by at least one stage, and a mean change of -0.5 and -0.1 fibrosis stage, respectively. All of the patients experiencing improvements in fibrosis scores were F2 or worse at baseline. Between the two cohorts, a total of four patients achieved a two stage improvement in fibrosis during the 12 weeks of treatment (three in the 3 mg dosing group of cohort 2 and one in cohort 3). There were two subjects in the 3 mg dosing group of cohort 2 who worsened by one stage in fibrosis (Stage 1b to 2 and Stage 3 to 4), with no substantive worsening of their NAS and reductions in LFC and ALT. Four patients in cohort 3 worsened by one stage in fibrosis. While each cohort involved a relatively small number of patients, these preliminary results demonstrated, for the first time, the possibility of improving fibrosis in F2 to F4 NASH subjects in as early as 12 weeks of treatment with a therapeutic agent. In addition, the patients with fibrosis improvements also had a mean reduction in NAS of 3.5 and 3.2 in the 3 mg dosing group of cohort 2 and cohort 3, respectively.

At 12 weeks, NGM282 treatment resulted in resolution of NASH, defined as having a lobular inflammation score of 0 or 1 and a hepatocellular ballooning score of 0, with no worsening of fibrosis in two patients in the 3 mg dosing arm of cohort 2 and three patients in cohort 3. Furthermore, 58% and 50% of patients achieved NAS improvements of two points or greater (with at least one-point reduction in lobular inflammation or hepatocellular ballooning) in the 3 mg dosing arm of cohort 2 and cohort 3, respectively. We anticipate that an increased proportion of patients could achieve resolution of NASH over a longer treatment duration beyond 12 weeks. In conjunction with the fibrosis improvement described above, these data support the notion that NGM282, as a single agent, has the potential to improve NASH and fibrosis to a larger degree and in a shorter period of time than other investigative agents have demonstrated to date.

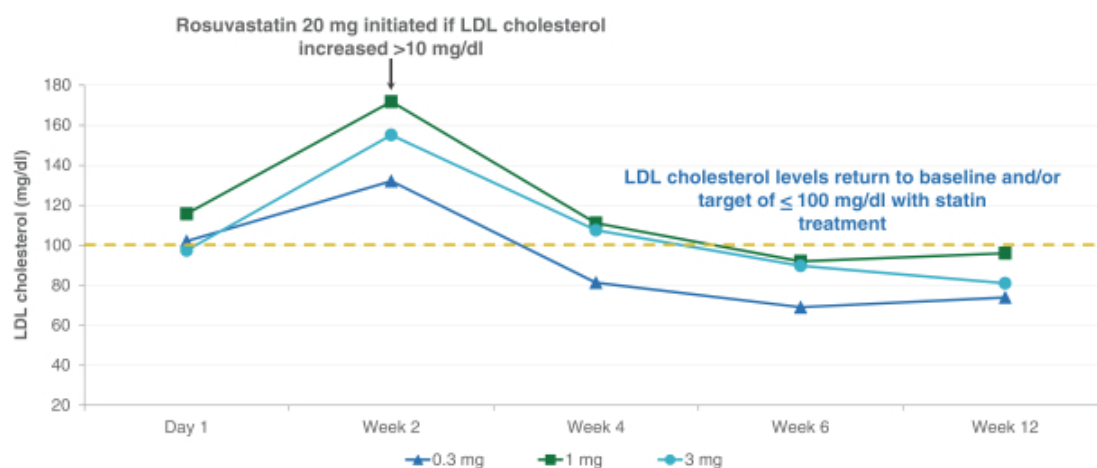


*NGM282 Increases in Serum Levels of LDL Cholesterol in NASH Patients*

A byproduct of NGM282’s potent inhibition of the classical bile acid synthesis pathway is the elevation of LDL cholesterol in the serum. Cholesterol serves as the precursor molecule in a multi-step enzymatic pathway that generates various forms of bile acids. CYP7A1 is the rate-limiting enzyme in this pathway and, therefore, serves as a regulatory control point for the primary pathway for bile acid synthesis, also known as the classical pathway. Notably, there is an alternative pathway for bile acid synthesis that is not regulated by CYP7A1 activity and produces a subset of the bile acid pool that is believed to produce less caustic varieties of bile. We believe a primary role of FGF19 and NGM282 is to inhibit bile acid synthesis through the classical pathway by activating a signaling cascade that shuts down CYP7A1 activity. As a direct effect of this on-target activity, cellular cholesterol is no longer metabolized to bile acids and is instead shunted into the blood stream, causing an elevation of serum LDL cholesterol. We have not observed the same magnitude of LDL cholesterol elevations with NGM282 in trials we have conducted in cholestatic disease patients, such as PBC and PSC.

We believe elevated serum LDL cholesterol is a confirmatory indication of NGM282 and FGF19 activity in NASH patients, which correlates with its beneficial effects on liver health. The impact of these drug-induced changes in cholesterol are unknown. Sustained LDL cholesterol elevations in untreated patients, however, are associated with cardiovascular disease through atherosclerotic plaque development. Through both preclinical studies in cynomolgous monkeys and in cohorts 2 and 3 of our Phase 2 clinical trial, we have demonstrated the ability of concomitant statin use to mitigate the

serum LDL cholesterol elevations driven by NGM282 activity. The figure below illustrates the mean LDL cholesterol levels over time for patients in cohort 2. Per protocol, the patients' LDL cholesterol levels were measured at baseline and then re-measured after two weeks of NGM282 treatment. If an elevation of LDL cholesterol of at least 10 mg/dl was recorded, patients were directed to take 20 mg of rosuvastatin daily for the remainder of the trial. Nearly all of the treated patients required statin use in cohorts 2 and 3. Where required, patients were elevated to 40 mg rosuvastatin to adequately control their LDL cholesterol while on treatment. Notably, approximately 80% of cohort 2 and 87% of cohort 3 at enrollment were not previously receiving statin treatment and, on average, the cohorts had baseline LDL cholesterol levels at or above recommended levels recommended by the American Association of Clinical Endocrinologists and the European Society of Cardiology/European Atherosclerotic Society, suggesting a statin would already be prescribed as standard of care. For each dose level in cohorts 2 and 3, concomitant statin use mitigated the drug-induced LDL cholesterol rise indicative of CYP7A1 suppression and, in many cases, brought patients below their baseline levels. Additionally, we have investigated the composition of the drug-induced LDL cholesterol particles. This analysis indicated that the NGM282-induced serum LDL cholesterol manifests as large and potentially less atherogenic lipoproteins, as opposed to the small dense lipoparticles that are thought to be more atherogenic. We believe concomitant statin use, along with NGM282's triglyceride lowering and high density lipoprotein, or HDL, cholesterol elevating properties, will provide an overall neutral to positive impact on patients' cardiovascular health.



*NGM282 Phase 2 Clinical Trial in NASH: Safety and Tolerability Profile*

The most common adverse events in cohorts 1, 2 and 3 included increased stool frequency, loose stools, nausea and injection site erythema, with the majority being Grade 1 (mild). A single serious adverse event of acute pancreatitis was reported in cohort 1 and assessed as possibly related to study drug. A total of seven serious adverse events (pleurisy, vertigo, headache, hypertension, cardiac arrest, chest pain and pneumonia), none of which were considered related to study drug, were reported in five subjects in cohort 2. One serious adverse event (kidney mass) was reported in cohort 3 and was not considered related to study drug. Preliminary data indicates that there were no tolerability signals identified in this population. The tolerability in cohorts 1, 2 and 3 was consistent with that observed in other study populations, including type 2 diabetes, PBC and PSC.

*NGM282 Future Clinical Development Plans*

In addition to our ongoing cohort 4, we are planning to begin, in mid-2019, a Phase 2b clinical trial that will test three dose levels of NGM282 in NASH patients with F2 and F3 fibrosis. The Phase 2b

clinical trial will be a multi-center, double-blind, placebo-controlled study administering 0.3 mg, 1 mg or 3 mg of NGM282 or placebo, once daily, subcutaneously for 24 weeks. We expect approximately 150 patients will be enrolled across 30 sites in the United States. Patients will receive liver biopsies to qualify for the trial and at end of treatment. The primary objective of this 24-week trial will be to measure the treatment effect of NGM282 dosing on liver histology according to preliminary FDA recommended Phase 3 endpoints of resolution of NASH with no worsening of fibrosis, and fibrosis improvement with no worsening of NASH, as defined above. Enrollment criteria, study design and study conduct will be consistent with the FDA draft industry guidance regarding the development of drugs for NASH that was distributed in December 2018.

Our development strategy is to generate interim results of our 24-week double-blind, placebo-controlled cohort 4 trial in 2019 and leverage these results to inform Phase 3 planning and design. We expect that Phase 2b clinical trial results in 2020 will provide further information to compile a detailed package for the regulatory agencies to support a pivotal, single dose level, Phase 3 program to enable a BLA filing.

We are also planning to initiate a clinical program testing NGM282 in a population of NASH patients with compensated cirrhosis in 2019. The objective of this trial is to evaluate whether the fibrosis regression and NAS improvements we have observed in patients with F2 and F3 fibrosis can also be achieved in early, or compensated, cirrhotic NASH patients, for which liver mortality rates are high and liver transplant is the only option. In 2030, the population of compensated cirrhotic NASH patients in the United States and EU is expected to reach 4.9 million.

We believe the totality of the data produced by these Phase 2 clinical trials will provide insights required to appropriately design Phase 3 clinical trials required for drug approval and optimally position the therapeutic in the market.

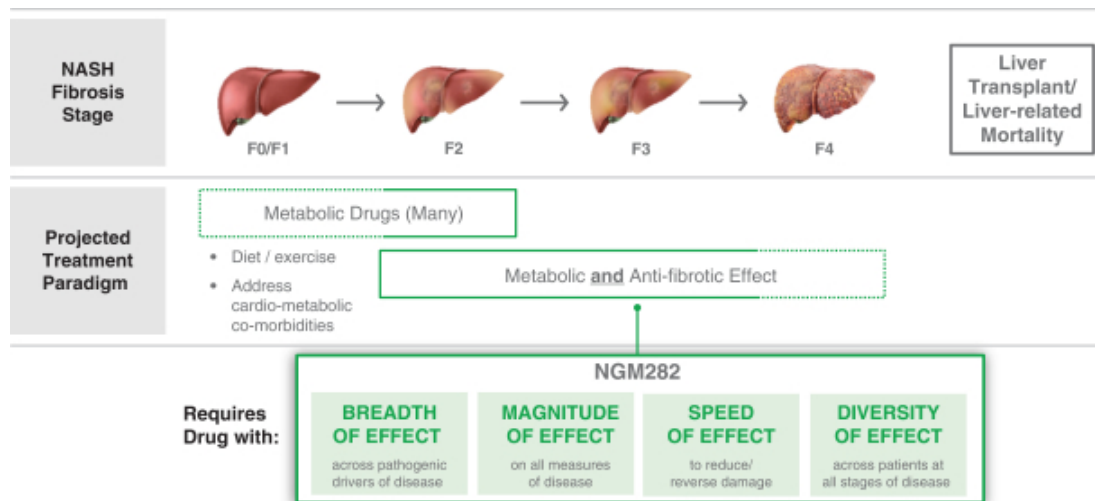
#### *Future Commercial Positioning of NGM282 as a Therapeutic in the NASH Market*

We believe the clinical data produced with NGM282 in NASH patients to date suggests a potential drug profile that is unique in the current landscape of NASH therapeutics in development. Our preliminary data suggests NGM282 is capable of improving fibrosis in patients after only 12 weeks of treatment, while also exerting a positive impact on the other parameters of NASH, including steatosis, lobular inflammation and hepatocellular ballooning. We believe that NGM282's initial signals of activity observed after 12 weeks of treatment with NGM282, while significant in effect, will lead to further improvement after 24 weeks of treatment. In particular, we believe NAS and fibrosis improvement are enabled by the liver's natural regenerative properties once the multiple insults of toxic fatty and bile acids are diminished. Our clinical results have shown that markers of liver steatosis and inflammation are reduced in a broad set of patients in the first few weeks of treatment. After only 12 weeks, this environment has allowed the liver to begin healing, but patient healing rates may vary and we believe the process has not reached its full potential. These properties are in contrast to other agents in development that, after 24 weeks or longer treatment, have either only shown impact on NAS components or a modest effect on fibrosis, and may have tolerability or safety issues.

If our initial signals of activity continue in later-stage clinical development, we believe that NGM282, as a once-daily injectable medication, will be well suited to treat NASH patients with F2, F3 and, potentially, early F4 fibrosis. Together, these target patient populations were believed to encompass approximately 6.7 million patients in the United States alone in 2015, and are expected to grow to 14.1 million by 2030. As diagrammed below, our goal is to position NGM282, if approved, to physicians as a potent, rapidly-acting medication that can repair NASH-damaged livers to avoid progression to end-stage liver disease and liver transplantation. This advanced disease population is typically under the care of hepatologists, as contrasted with the typically asymptomatic early-stage

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NASH population, the majority of whom have not yet been diagnosed. We expect other agents in development, many of which are delivered orally, will serve a complementary role in the treatment of earlier-stage disease or may ultimately require combination treatment with other mechanisms to have an improved effect over its single-agent activity.



### Commercial Product Development and Life-cycle Management

The drug product format of NGM282 for our clinical trials to date has been a pre-filled single-use glass syringe. Our manufacturing group is developing a formulation of the agent to enable testing a more commercially-attractive format in the form of a multi-use pen injector, similar to the devices currently delivering injectable type 2 diabetes treatments. We expect that the multi-dose pen format could be available for product launch, if the agent is approved. Our objective is to present a multi-dose pen with needle gauge 29 or smaller, which will be familiar to the large number of NASH patients with type 2 diabetes who also require injections of insulin or GLP-1 products.

Longer term, we are pursuing a life-cycle management strategy to develop a longer half-life version of NGM282 that will require less frequent dosing. At present, we have programs investigating delayed-release technologies and protein modification to support this strategy. These efforts are currently at the research stage.

### Early NGM282 Clinical Development and Preclinical Development

Our development program for NGM282 in NASH has been informed by several precursor and parallel clinical studies, as well as preclinical findings in a variety of NASH animal models. In all clinical trials, NGM282 had an acceptable tolerability profile. A summary of the studies conducted with NGM282 are listed below:

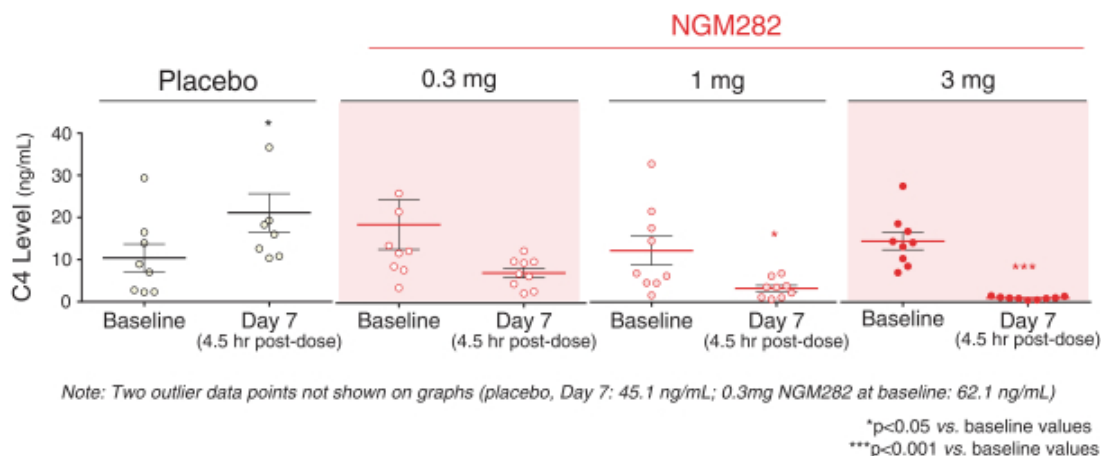
#### NGM282 Phase 1 Clinical Trial

We conducted a Phase 1 randomized, double-blind, placebo-controlled, single ascending dose, or SAD, and multiple ascending dose, or MAD, study to evaluate the safety, tolerability and pharmacokinetics of NGM282 in healthy adult participants.

Our Phase 1 clinical trial with NGM282, which is emblematic of our overall drug discovery approach in that we design early clinical trials to assess the translatability of preclinical studies to

humans, demonstrated a favorable tolerability profile, with signs of biological activity consistent with FGF19-like activity related to FGFR1c and FGFR4 signaling, suggesting potential utility as a treatment for NASH.

In this blinded, placebo-controlled, Phase 1 clinical trial, 119 overweight or obese but otherwise healthy adults were randomized to receive NGM282 or placebo as a daily subcutaneous injection in escalating doses. A rapid and dose-proportional reduction of serum C4 concentrations indicated that NGM282 has a statistically significant effect on bile acid synthesis at the 0.3 mg, 1 mg and 3 mg doses. A mean reduction of approximately 94% in serum C4 concentrations was noted at 3 mg when compared with pre-dose levels. This rapid reduction in C4 levels supports the potential biological activity of NGM282 as an inhibitor of CYP7A1-mediated bile acid synthesis.



Laboratory analysis of blood samples collected from subjects receiving NGM282 in the Phase 1 MAD trial showed that administration of the drug for seven days was associated with statistically significant reductions in triglyceride levels at doses of 1 mg and greater (-55, -50, -68 and -89 mg/d, respectively, for the 1, 3, 10 and 20 mg dose groups: p<0.05), and a statistically significant increase in total cholesterol concentrations (12, 40, 22 and 24 mg/d, respectively, for the 1, 3, 10 and 20 mg dose groups: p<0.05).

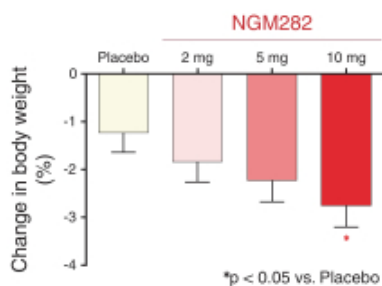
In both the SAD and MAD trials, NGM282 was well tolerated and exhibited approximately linear pharmacokinetics with no immunogenicity. There were no serious adverse events. The most frequently observed adverse events were diarrhea, vomiting, nausea and injection site reactions. Also, there were no laboratory changes in NGM282-treated subjects that would indicate an abnormality in any organ system, as determined by the Safety Data Monitoring Committee for the study, nor were anti-drug antibodies, or ADAs, observed.

#### NGM282 Phase 2a Clinical Trial (Type 2 Diabetes)

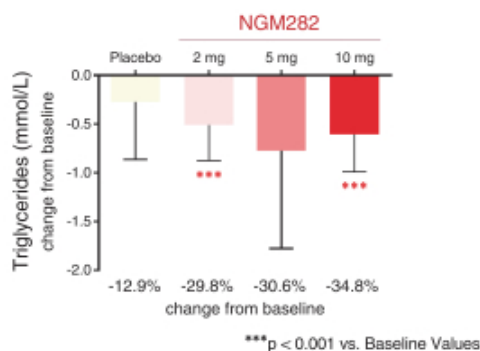
We conducted a 28-day, randomized, double-blind, multi-center trial to evaluate NGM282 in subjects with type 2 diabetes that were inadequately controlled by metformin. As a consequence of the contribution of obesity and insulin resistance to both conditions, there is a substantial overlap in the prevalence of type 2 diabetes and NASH patients. The type 2 diabetes trial was also designed to measure several of the metabolic parameters that are believed to play a role in the disease progression of NAFLD and NASH, including indicators of insulin sensitivity, triglyceride levels and liver transaminases, such as ALT and AST, enzyme levels. Three doses of NGM282 were tested to assess changes from baseline in biochemical markers associated with type 2 diabetes, such as fasting plasma glucose and stimulated glucose/insulin.

The primary endpoint measured by this trial was the change in fasting plasma glucose after 28 days of treatment. Although this endpoint was not different in the NGM282 subjects as compared to the control arm, there were trends towards improvement in insulin sensitivity, as measured by HOMA-IR, and a statistically significant weight loss observed in the 10 mg group, which lost an average of 2.6 kilograms over the 28 days of treatment ( $p < 0.05$ ). Moreover, there was a statistically significant reduction in triglyceride concentrations with the 2 mg ( $p < 0.001$ ) and 10 mg ( $p < 0.001$ ) doses, and dose-dependent reductions in ALT and AST levels, consistent with improvements in liver health. However, as this trial did not meet its primary endpoint, we decided not to pursue development of NGM282 in type 2 diabetes. The trial did establish that NGM282 demonstrated improvements in both metabolic and liver health in a patient population that closely resembles NASH patients.

**NGM282 promotes body weight loss in type 2 diabetes patients after 28 days of treatment**



**Significant reduction in serum triglycerides upon NGM282 administration in type 2 diabetes patients after 28 days**



Overall, NGM282 was well-tolerated at each dose. There were no serious adverse events reported, though nine subjects withdrew due to adverse events. The most frequently observed adverse events were GI side effects, which were primarily loose stools/diarrhea, nausea and injection site reactions. One subject developed antibodies against NGM282 that appear to cross-react with FGF19. This subject 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.

#### *NGM282 Phase 2 Clinical Trials in Cholestatic Diseases: PBC and PSC*

We conducted an exploratory Phase 2a clinical trial in PBC patients testing daily subcutaneous injections of NGM282 for 28 days, and followed it with a 52-week extension study to assess longer-term safety and tolerability of daily NGM282. While both doses tested in the 28-day study met the primary endpoint of a statistically significant reduction in ALP levels (a validated surrogate endpoint by the FDA), we determined that, with two oral alternatives on the market with similar efficacy, the indication was not well-suited for NGM282.

NGM282 was well tolerated at each dose and showed no evidence of drug-induced pruritus. The majority of adverse events were mild or moderate. In the 28-day study, one subject reported a serious adverse event (dizziness) deemed unrelated to drug. In the 52-week extension study, three subjects reported a total of five serious adverse events: community acquired pneumonia, iron deficiency anemia (2) and fractured finger, all deemed unrelated to study drug; and pneumonitis/alveolitis, which was considered unlikely related to study drug. A statistically significant elevation of LDL cholesterol concentration was not observed in this patient population.

We also conducted an exploratory Phase 2 clinical trial in PSC patients with NGM282. Unlike PBC, there are currently no approved medications for PSC and, similarly, there are no validated clinical

endpoints accepted by the FDA for approval. NGM282 did not achieve the primary endpoint in the study, which was a statistically significant reduction in ALP levels at the end of treatment. While ALP concentration has also been viewed as a possible surrogate endpoint in PSC, the correlation with disease progression is not as clear as in PBC, and the FDA is developing guidance to drug developers as to an acceptable path to approval. We do not intend to further develop NGM282 in PSC until a development path is more specifically defined in the indication. However, the results of the study also provide utility in understanding the mechanism of NGM282 across the diseases tested. Notably, PRO-C3 and ELF levels, which are markers of fibrosis, improved significantly in the treatment group, suggesting that NGM282 may also have a direct impact on fibrosis that is independent from its metabolic activity, as the PSC patient population does not have elevated liver fat content. Furthermore, a statistically significant elevation of LDL cholesterol concentration was not observed in this patient population.

The majority of adverse events were mild or moderate and resolved on treatment. Five total serious adverse events were reported in three subjects: increased bilirubin, cholangitis, PSC progression and intervertebral discitis, deemed unrelated to study drug; and bowel obstruction, deemed possibly related to NGM282 treatment.

#### *NGM282 Phase 1 Clinical Trial in GI Motility*

A consistent finding in our Phase 2 clinical trials has been an association of NGM282 to dose-related abdominal cramping and increased stool frequency. To further investigate and characterize these gastrointestinal effects, we conducted a randomized, placebo-controlled, 14-day study in patients with functional constipation that tested two doses of NGM282, 1 mg once daily and 6 mg once daily. The objective of the study was to evaluate the effects of NGM282 on colonic transit, stool frequency and consistency, hepatic bile acid synthesis, fecal fat and bile acid levels. Thirty-one patients with functional constipation were randomized on a 1:1:1 basis to placebo (n=10), 1 mg NGM282 (n=10) and 6 mg NGM282 (n=11) arm. Participants underwent tests measuring baseline colonic transit at 24 hours, baseline 48-hour stool fat and bile acid measurement after eating a high fat diet for four days. Patients then received once-daily treatment with NGM282 or placebo for 14 days with transit measurements and fecal fat and bile acid content collected during the last week of the study. Four patients discontinued the trial in the 6 mg cohort (three due to diarrhea and one due to injection site reactions) and no patients discontinued treatment in the placebo or 1 mg NGM282 cohorts. Overall, NGM282 altered bowel function in this group of chronic constipation subjects through increased frequency of bowel movements, looser stool form and increased ease of passage, and significantly accelerated gastric and colonic transit. There were no significant differences in fecal fat or weight between the placebo and treatment groups, suggesting that GI effects of NGM282 are not secondary to an increase in fecal fat. We believe the results of this study show that GI side effects are primarily due to increased colonic motility, rather than increased small bowel or colonic secretion, the latter of which is more characteristic of diarrhea than loose stools. We have applied this mechanistic understanding to our clinical trial by suggesting that subjects time their dosing around meals and moderate the size of a meal in proximity to dose. While the GI side effects of NGM282 are consistent through the clinical studies conducted to date, we have observed that those patients on 3 mg and lower doses that do experience GI side effects generally report mild to moderate effects that resolve on treatment and do not lead to discontinuation of the drug.

#### *NGM282 Engineered to Create a Non-tumorigenic Form of FGF19*

Human FGF19 is only about 50% identical to its mouse ortholog, known as FGF15. *In vivo* studies have shown that transgenic mice expressing the human FGF19 hormone at proportionally greater levels than levels expressed in healthy humans develop HCC. NGM282 is a variant of FGF19, engineered to remove the tumorigenic properties of human FGF19 in mice while retaining its beneficial



effects. Prior to designating NGM282 for development, we carried out an extensive *in vivo* analysis of the structure-function relationship to define the domains in FGF19 responsible for its various activities. Our goal was to identify a variant of human FGF19 that was non-tumorigenic in mice but that retained maximal activity against both the FGFR1c/KLB and FGFR4/KLB receptor complexes so that full metabolic and bile acid effects would be maintained. We designed and evaluated over 150 FGF19 variants to identify compounds with the desired profile. NGM282 is approximately 95% identical to the naturally-occurring human FGF19, with three amino acid substitutions and a five-amino acid deletion from the amino terminus.

NGM282 retains the metabolic activity of FGF19 through the FGFR1c/KLB receptor complex and the bile acid activity of FGF19 through the FGFR4/KLB receptor complex. Importantly, NGM282 is a biased ligand of FGFR4, meaning that it selectively activates signaling through the FGFR4/KLB receptor complex in a manner that retains beneficial activity on bile acid production but does not cause HCC in mice, as shown in three different models of oncogenic potential. Furthermore, co-administration of NGM282 and FGF19 via gene delivery in a *db/db* mouse model eliminated the expected FGF19-driven HCC, suggesting that NGM282 blocked the ability of FGF19 to occupy the relevant receptor and signal in such a way as to cause HCC. We have also explored the biological mechanism that drives the FGF19 oncogenic signal in mice and have determined that the interleukin-6, or IL-6/STAT3 axis is essential for the activity. The elements of the IL-6/STAT3 axis that drive the FGF19 oncogenic signal in mice are not activated with NGM282.

#### *NGM282's Therapeutic Potential Supported by Preclinical Animal Models of NASH*

We have assessed the therapeutic potential of NGM282 in multiple animal models of NASH and have observed a consistent pattern of disease prevention and improvement. The animal models in which we have tested NGM282 and the corresponding results are summarized in the table below.

Animal Model	Summary of NGM282 Activity
<b>STAM</b> Streptozotocin and high-fat diet-induced mouse model of NASH	<ul style="list-style-type: none"><li>• Significantly improves steatosis, lobular inflammation and hepatocellular ballooning</li><li>• Decreases serum level of liver enzymes and triglycerides</li></ul>
<b>High Fat, High Carbohydrate</b> Diet-induced mouse model of NASH	<ul style="list-style-type: none"><li>• Reduces liver fat</li><li>• Halts progression of liver fibrosis and inflammation</li></ul>
<b>HFFC: High Fat, Fructose and Cholesterol</b> Diet-induced mouse model of NASH	<ul style="list-style-type: none"><li>• Reduces liver fat</li><li>• Halts progression of liver fibrosis and inflammation</li></ul>
<b>Aged FXR Knockout</b> Genetically-modified mice that develop a NASH-like histopathology	<ul style="list-style-type: none"><li>• Normalizes liver enzymes</li><li>• Improves NAS</li><li>• Reduces liver fibrosis</li></ul>

In addition to testing NGM282 in these animal models of NASH, we tested a variant of FGF19 that only activates FGFR4 and does not activate FGFR1c. The purpose of creating this variant was to develop a tool by which we could understand the relative contribution of FGFR4 and FGFR1c signaling to the therapeutic effects of FGF19. In the diet-induced, high fat, high fructose, high cholesterol, or HFFC, mouse model of NASH, study animals were administered viral vectors expressing either: (1) an

analog of FGF19 that activates both FGFR4 and FGFR1c signaling; (2) an analog of FGF19 that activates only FGFR4 signaling; or (3) a control protein, green fluorescent protein, or GFP. After 24 weeks of treatment, the degree of liver fibrosis was compared across the study groups by means of Sirius red staining, which is a common method of identifying fibrosis. The results demonstrated that the mice that received the analog of FGF19 that activated only FGFR4 showed nearly as much fibrosis improvement compared to the compound that activated both FGFR4 and FGFR1c.

We believe these preclinical results show that inhibiting bile acid synthesis through the FGFR4 pathway enables NGM282 to have a more rapid and direct impact on fibrosis as compared to other agents that only address the metabolic dysfunction of NASH. These data, now further supported by our Phase 2 results in biopsy-confirmed NASH patients, show the spectrum of activity enabled by mimicking the native FGF19 hormone at pharmacological levels has a potent therapeutic benefit on multiple disease drivers of NASH.

### ***NGM313: An Insulin Sensitizer for the Treatment of Type 2 Diabetes and NASH***

NGM313, also known as MK-3655, is a proprietary, agonistic antibody selectively activating FGFR1c/KLB that we believe has the potential to be a once-monthly injectable insulin sensitizer for the treatment of NASH and type 2 diabetes. In November 2018, Merck exercised its option for a license to further research, develop and commercialize NGM313 and other FGFR1c/KLB agonists pursuant to our collaboration agreement. In Phase 1 clinical testing, NGM313 has demonstrated favorable tolerability and preliminary data has shown the agent is capable of reducing liver fat content and improving metabolic biomarkers in obese insulin resistant subjects with NAFLD after a single dose. We believe that NGM313 has the potential to be a treatment for those patients with NASH with early to moderate fibrosis with or without type 2 diabetes.

#### *Type 2 Diabetes*

Type 2 diabetes is a common co-morbidity of obesity and NAFLD, and a disease in which the concentration of blood sugar is elevated due to an imbalance of insulin production from insulin secreting beta cells in the pancreas and insulin action at the tissue level, known as insulin resistance, causing damage to small and large blood vessels and, potentially, leading to blindness, amputation and kidney disease along with an increased risk of heart attack, stroke and premature death. In type 2 diabetes, the body's tissues become resistant to the effects of insulin over time, requiring the pancreas to produce an unsustainably large amount of insulin to compensate. The growing epidemic of obesity is driving an increasing number of diabetes sufferers, as there is a close relationship between increasing BMI and the relative risk of developing type 2 diabetes.

According to the Centers for Disease Control and Prevention, or CDC, in 2015, an estimated 30 million people in the United States had diabetes, with 1.5 million new cases being added every year. Over 80 million people in the United States are pre-diabetic, the majority of whom are expected to become diabetic in the next ten years. The medical costs of treating the diabetic patient population in the United States alone are believed to be \$327 billion in 2017. Given the large patient population and high unmet need, pharmaceutical companies have developed multiple classes of therapies. The most recent classes include GLP-1 analogs, SGLT2 inhibitors and DPP-IV inhibitors, which, according to EvaluatePharma, collectively sold over \$21 billion worldwide in 2017 and are expected to sell as much as \$33 billion by 2022. According to EvaluatePharma, insulin, for which the recombinant human version was first introduced in 1982, and insulin analogues sold approximately \$21 billion in 2017 worldwide.

The currently available types of treatments include:

- various forms of insulin replacement therapies and agents to stimulate insulin secretion, whereby the insulin levels are boosted to help decrease blood glucose levels, including recombinant insulin, sulfonylureas and meglitinides;
- agents that inhibit the absorption of glucose in the gut, increase the excretion of glucose in the kidney and/or decrease the production of glucose in the liver, thereby reducing blood glucose levels, including alpha-glucosidase inhibitors, SGLT2 inhibitors and biguanides, like metformin;
- drugs that produce a combination of insulin boosting and glucose absorption-inhibiting activity, including incretins like GLP-1 analogs, and DPP-IV inhibitors; and
- drugs that increase the body's sensitivity to insulin, thereby making the insulin present in the blood have a more potent effect on lowering blood glucose, which currently consists of thiazolidinediones, or TZDs.

The majority of patients with type 2 diabetes are insulin resistant and have associated metabolic dysregulation caused by lipid abnormalities, fatty liver, hypertension and chronic vascular inflammation. Insulin resistance and beta cell dysfunction are interrelated pathogenic states that lead to persistent hyperglycemia and development of type 2 diabetes. Insulin resistance results from defective insulin signaling in glucose recipient tissues and the persistent elevation of glucose concentrations above the physiological range, leading to increased insulin demand. Beta cell dysfunction, resulting from inadequate glucose sensing to stimulate insulin secretion, is compounded by insulin resistance and also induces hyperglycemia in patients with type 2 diabetes. Preserving beta cell function and insulin signaling in type 2 diabetes patients remain an unmet medical need as persistent hyperglycemia leads to continued progression of diabetes. Even with the multiple classes of diabetes drugs available, only about one-half of patients with diabetes achieve their glycemic goal.

#### *Insulin Sensitizers for the Treatment of Type 2 Diabetes*

Insulin resistant patients that remain inadequately controlled often have NAFLD, low HDL cholesterol level and increased waist circumference, and are likely the best candidates for treatment with insulin sensitizers. TZDs, such as pioglitazone and rosiglitazone, are a notable class of drugs that function as insulin sensitizers to potentiate the effect of insulin, improving glycemic control and dyslipidemia and, therefore, providing a valuable addition to diabetes therapy. As a monotherapy, pioglitazone improves the sensitivity of hepatic and peripheral tissue to insulin, increases insulin-dependent glucose disposal, enhances cellular responsiveness to insulin and, thus, improves dysfunction in glucose homeostasis. This decreased insulin resistance results in a durable lowering of blood glucose, insulin and hemoglobin A1c, or HbA1c levels. However, the clinical use of TZDs has been limited by the risk of adverse events, including congestive heart failure, for which there is a FDA boxed warning, weight gain, peripheral edema/fluid retention, bone fractures and an association with bladder cancer for pioglitazone.

We believe the introduction of an insulin sensitizer without the adverse effects and safety profile of the TZDs would provide a meaningful addition as combination therapy with incretins, with the goal of normalizing glucose levels in patients with type 2 diabetes. While numerous new drug classes are available, none target insulin resistance nor have the potential to resolve persistent hyperglycemia when used in combination with other available diabetes treatments.

#### *Insulin Sensitizers for the Treatment of NASH*

Insulin resistance has been implicated as a key condition leading to hepatic steatosis and, subsequently, NASH. Activation of the immune system contributes to the development of insulin

resistant adipocytes that release excessive amounts of free fatty acids and cause insulin resistance and lipopoptosis in peripheral tissues, including the liver, muscle and pancreatic beta cells. Increased hepatic triglyceride synthesis and accumulation of triglyceride-derived toxic lipid metabolites activates intracellular inflammatory pathways within hepatocytes, Kupffer and other immune cells. The subsequent activation of hepatic stellate cells leads to collagen deposition, fibrosis development and, eventually, cirrhosis of the liver. Treatments that can rescue the liver from lipotoxicity, in particular the effects of free fatty acids, by restoring peripheral tissue insulin sensitivity and/or preventing activation of inflammatory pathways and oxidative stress, hold promise for the treatment of NASH.

An estimated 65% of type 2 diabetes patients have NASH. The presence of diabetes is associated with worse liver disease and, in patients with NAFLD and NASH, type 2 diabetes is associated with more severe hepatic and adipose tissue insulin resistance, and more advanced liver steatosis, inflammation and fibrosis by liver histology. In addition, administration of insulin may increase steatosis, making the treatment of patients with type 2 diabetes and NASH challenging.

The role of insulin resistance and hyperglycemia in the pathogenesis of NAFLD suggests that improving insulin sensitivity and normalizing glucose levels could prevent the development of NASH and progression of disease. It is inconclusive whether current drugs for the treatment of diabetes, such as metformin, DPP-IV inhibitors, SGLT2 inhibitors and GLP-1 agonists, are effective for the treatment of NASH and, for some, if histological benefit is observed, it is unclear whether the effect is related to the concomitant weight loss with treatment. Proof-of-concept studies with an insulin sensitizer, pioglitazone, whose main target at the molecular level is PPAR-gamma in adipose tissue, have shown that treatment after six months, as compared to placebo, resulted in statistically significant improvements in histological findings associated with NASH, with reductions in steatosis, hepatocellular ballooning and lobular inflammation. Fibrosis scores improved significantly relative to baseline in the pioglitazone group, however, the change from baseline did not differ significantly between the placebo and pioglitazone groups after six months of treatment. Pioglitazone treatment increased hepatic insulin sensitivity and glucose clearance, which led to significant reductions in plasma free fatty acids, glucose and insulin levels in NASH patients.

With approximately 17.5 million patients in the United States with type 2 diabetes and NASH, there exists a substantial unmet medical need for a single treatment that addresses pathophysiological states common to both diseases, including insulin resistance, lipid metabolism dysfunction and increased lipotoxicity at the level of the liver. To date, of the FDA approved anti-diabetes drugs on the market, only pioglitazone and liraglutide have demonstrated a benefit on components of the NAS in controlled studies on patients with NASH. We believe NGM313 has the potential as an insulin sensitizer for use as monotherapy or in combination with other drug classes, like GLP-1 analogs, to halt the progression of, and potentially reverse, diabetes and NASH.

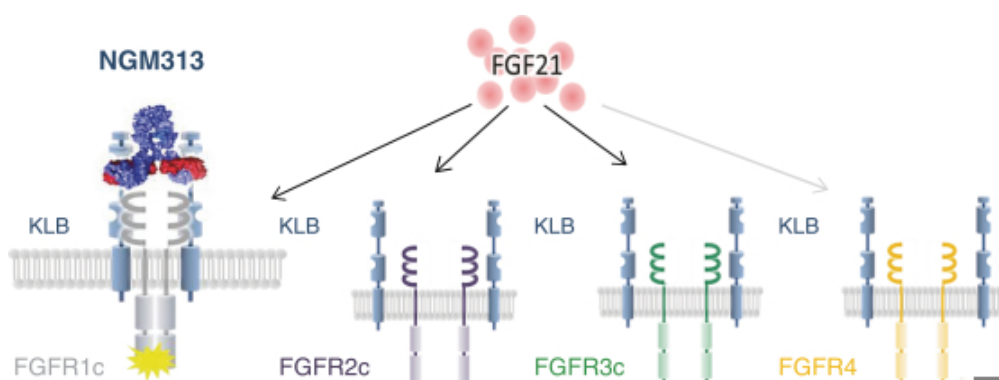
#### *NGM313 Mechanism of Action*

NGM313 is a humanized monoclonal agonistic antibody, with the potential for once-monthly dosing, that binds to a unique epitope of KLB, resulting in the selective activation of FGFR1c and signaling through the metabolic pathway utilized by FGF21-based ligand therapies. FGF21 is a protein hormone that is secreted by the liver, adipocytes, pancreas and skeletal muscle. In animal testing, FGF21 plays a role in fasting and starvation by acting on adipose, or fat, cells to increase energy expenditure by stimulating glucose uptake. Notably, the effect of FGF21 on glucose uptake is additive to, but not synergistic with, insulin. Unlike insulin, the response of fat cells to FGF21 requires prolonged exposure to this hormone. Moreover, FGF21 acts to lower plasma triglyceride levels over an extended period. FGF21 also protects animals from diet-induced obesity when overexpressed in transgenic mice and lowers blood glucose and triglyceride levels when administered to diabetic rodents.

FGF21 exerts its effects on metabolic processes by signaling through the receptors known as FGFR1c, FGFR2c and FGFR3c, but not the receptor known as FGFR4. KLB functions as a co-receptor to enhance the binding of these receptors and is essential for mediating FGF21 activity. FGF receptors are expressed on cells in many tissue types, but KLB is mainly expressed in fat cells and other tissues, such as the pancreas and liver.

FGF21-based therapeutics have generated interest in the pharmaceutical research and development community because they represent a novel approach to treating multiple aspects of the metabolic syndrome; however, attempts by other companies to translate FGF21 into a product with clinical application have had limited success. While native FGF21 is thought to have limitations for drug development, including potential effects on cortisol, bone and blood pressure, various animal studies have demonstrated that modified FGF21 ligands simultaneously regulate insulin sensitivity and blood glucose and increase energy expenditure, fat utilization and lipid excretion. Multiple pharmaceutical companies have conducted human testing of therapeutics regulating the FGF21 pathway. Administration of modified FGF21 ligands to humans results in variable improvement in insulin sensitivity, reduction in liver fat content and improvement in lipid profile and body weight loss, suggesting potential utility in treating obesity, type 2 diabetes, dyslipidemia and NASH. However, the blood glucose reductions observed in humans following dosing with modified FGF21 ligands, to date, have not been meaningful. It is thought that these FGF21-based protein therapeutics have produced inadequate glucose reductions due to a shorter than optimal half-life or counter-regulatory mechanisms triggered from activity across multiple receptor types. It has been postulated that a therapeutic regulating the FGF21 pathway with an extended half-life might improve its efficacy profile for type 2 diabetes. Furthermore, while an FGF21-based agent has demonstrated significant reductions in liver steatosis and non-invasive markers of disease in NASH subjects, the effect of FGF21 on liver histology in NASH patients has not been assessed to date.

### **NGM313, an Agonistic Antibody of the FGFR1c/KLB Receptor Complex**



We believe that developing a specific, agonistic antibody that selectively activates the FGFR1c/KLB pathway would obviate the risks associated with therapeutics based on the native FGF21 ligand. The development candidate, NGM313, exhibits highly specific binding with KLB, resulting exclusively in the activation of FGFR1c-mediated signaling: it does not trigger signaling through other FGF receptors, such as FGFR2c, FGFR3c or FGFR4. Moreover, as NGM313 recognizes an epitope on KLB that is distinct from the FGF19 or FGF21 binding sites, it does not compete with these natural ligands for binding with the FGFR1c/KLB complex. We believe that this non-overlapping binding site reduces the potential for side effects resulting from NGM313 inhibition of endogenous FGF19 and FGF21 hormone activity.

*NGM313 Phase 1b Early Proof-of-Concept Clinical Trial*

We conducted a Phase 1b randomized, open-label, parallel group trial to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of a single NGM313 dose or daily oral pioglitazone in 25 obese insulin resistant subjects with NAFLD. The Phase 1b clinical trial evaluated the ability of NGM313 to decrease liver fat content (LFC) to support the clinical development of NGM313 in NASH, as well as its effect on glucose disposal to assess the potential of NGM313 in the treatment of patients with type 2 diabetes. A single subcutaneous dose of 240 mg NGM313 was selected based on the clinical pharmacokinetic and pharmacodynamic data, and the tolerability profile from the Phase 1 SAD/MAD trial described below. Pioglitazone was chosen as a positive control in this study as it is the only agent approved for clinical use as an insulin sensitizer for the treatment of type 2 diabetes and also has demonstrated beneficial activity in NASH patients. The highest approved daily oral dose of 45 mg pioglitazone was used in this study to provide the opportunity for maximal efficacy as a comparator in a trial with a short treatment duration of five weeks.

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The primary objectives of the study were to evaluate changes from baseline in LFC as measured by MRI-PDFF at day 36 and changes from baseline in whole body insulin sensitivity at day 29 in subjects treated with NGM313 as compared to pioglitazone. Preliminary results indicated that a single dose of NGM313 resulted in a statistically significant least squares mean change from baseline to day 36 of -6.3% and -37% in absolute and relative LFC, respectively ( $p < 0.0001$ ), while daily dosing of 45 mg pioglitazone resulted in a statistically significant least squares mean change from baseline to day 36 of -4.0% and -25%, respectively ( $p < 0.001$ ). The change from baseline with NGM313 treatment was not significantly different relative to that observed with pioglitazone ( $p = 0.08$ ), however, the study was not powered to demonstrate statistical significance between groups. Historically, a relative reduction of LFC of 29%, as measured by MRI-PDFF, was associated with a histological response of a NAS improvement of two stages or greater. In addition, preliminary results indicated that a single dose of NGM313 resulted in a statistically significant mean decrease from baseline of 0.24% in HbA1c at day 36 ( $p < 0.0001$ ), as compared to a decrease of 0.11% with a daily dose of 45 mg of pioglitazone, without hypoglycemia. A reduction in HbA1c of the magnitude observed in this study's insulin resistant, non-diabetic patient population in this time frame supports the promise of NGM313 to potentially improve glucose control in type 2 diabetes patients. This was accompanied by statistically significant reductions from baseline in HOMA-IR, serum concentrations of fasting glucose, ALT, AST, triglycerides and LDL cholesterol, and a statistically significant increase in HDL cholesterol levels at day 28 (all  $p < 0.05$ ), as summarized in the table below. PRO-C3 was also significantly reduced with NGM313 treatment but not with pioglitazone ( $p < 0.01$ ).

<b>Parameter (Change from Baseline at Day 28, unless otherwise noted below)</b>	<b>NGM313 240 mg (n=16)</b>
<b>Absolute LFC (Relative LFC, at Day 36)</b>	<b>-6.3% (-37%)</b>
<b>HbA1c (% , at Day 36)</b>	<b>-0.24</b>
<b>HOMA-IR</b>	<b>-2.9</b>
<b>Fasting Glucose (mg/dl)</b>	<b>-5.6</b>
<b>Triglycerides (mg/dl)</b>	<b>-72</b>
<b>HDL (mg/dl)</b>	<b>8</b>
<b>LDL (mg/dl)</b>	<b>-15</b>
<b>ALT (IU/L)</b>	<b>-4</b>
<b>AST (IU/L)</b>	<b>-3</b>

Preliminary data indicate that NGM313-treated patients had a least squares mean increase from baseline in body weight of 1.6 kg at day 36, as compared to 2.4 kg with pioglitazone. This study indicated that NGM313 was well-tolerated, with no serious adverse events and no adverse event leading to study discontinuation. All adverse events observed during the course of the study were deemed mild, with increased appetite (12%) being the only adverse event reported in at least 10% of NGM313-treated subjects.

Preliminary data from the Phase 1b clinical trial, in addition to the data described below from the Phase 1 SAD/MAD clinical trial, support the potential for NGM313 to be the first insulin sensitizer for the treatment of NASH and type 2 diabetes, without the safety concerns that plague currently available

agents targeting insulin resistance, such as edema, fluid retention, heart failure and bone fractures. Given that the metabolic changes of NGM313 were seen after only a single dose, it is likely that a more substantial improvement would be observed after longer duration of treatment. We expect Merck to initiate a Phase 2b histology study of NGM313 in NASH subjects in late 2019 or early 2020. If NGM313 is approved for the treatment of NASH, we expect that the drug would be used predominantly in NASH patients with early to moderate fibrosis. We anticipate that the NASH patients with more advanced fibrosis could be treated with NGM282 in order to more quickly reverse fibrosis and bring back the liver to a healthier state, whereas NGM313 could subsequently be used to halt the progression of disease by addressing the metabolic drivers of NASH.

#### *NGM313 Phase 1 SAD/MAD Clinical Trial*

Our first-in-human Phase 1 clinical trial was a blinded, placebo-controlled study in overweight or obese but otherwise healthy adults in which single and multiple once-monthly subcutaneous injections of NGM313 or placebo were tested to evaluate the safety, tolerability and pharmacokinetics of NGM313. NGM313 was well tolerated, with signs of biological activity indicative of insulin sensitization, after a single dose. In the SAD portion of the study, where single doses of 3 mg up to 360 mg of NGM313 were tested, higher doses resulted in small but statistically significant ( $p < 0.05$ ) mean reductions from baseline in HbA1c, fasting glucose levels, fasting insulin levels and HOMA-IR at day 29, as compared to placebo. The magnitude of change in glucose parameters is consistent with what would be expected with an insulin sensitizer in these subjects with normal glycemic control. In a dose dependent fashion, total adiponectin levels, a potential biomarker of insulin sensitivity, increased by approximately 140% at the 240 mg and 360 mg doses of NGM313. The statistically significant increases in adiponectin relative to placebo remained persistent through day 57 and day 85 after a single dose of 240 mg and 360 mg of NGM313 ( $p < 0.01$ ), respectively. Dose dependent changes in the lipid profile were also apparent at day 29, with observed increases in levels of HDL cholesterol, lower levels of LDL cholesterol and decreased levels of triglycerides that were statistically significant at the higher doses ( $p < 0.05$ ).

In the MAD portion of the study, three once-monthly doses of between 10 mg and 240 mg of NGM313 were administered and, after 12 weeks, mean decreases from baseline in HbA1c, fasting glucose, fasting insulin and HOMA-IR were observed at the higher doses relative to placebo. Similar to the SAD portion of the study, a favorable lipid profile was demonstrated at the end of treatment on day 85, as shown in the table below. An increase in placebo-subtracted body weight at end of treatment of 1.6 kg and 2.4 kg was noted in patients from the SAD and MAD cohorts that received the highest dose level of NGM313, respectively. This trend in body weight increase is consistent with the degree of insulin sensitization effects observed at these doses, and there was no evidence of edema, fluid retention or hemodilution associated with NGM313 treatment. Despite the change in weight, there was no statistically significant increase in the waist circumference in these cohorts of subjects receiving NGM313. The beneficial changes in glucose metabolism, lipid levels and biomarkers of insulin sensitization supported further evaluation of NGM313 in patients with fatty liver and insulin resistance.



**NGM313 Improves Key Glucoregulatory and Lipid Parameters**

Parameter	Phase 1 SAD (Change from Baseline at Day 29)		Phase 1 MAD (Change from Baseline at Day 85)	
	Placebo (n=19)	NGM313 240 mg (n=9)	Placebo (n=13)	NGM313 240 mg (n=14)
HbA1c (%)	-0.04	-0.18	0.03	-0.11
Fasting Glucose (mg/dl)	2.2	-3.8	-2.3	-4.7
Fasting Insulin (mU/l)	1.6	-4.0	-0.9	-3.9
HOMA-IR	0.5	-1.0	-0.1	-1.0
Triglycerides (mg/dl)	16	-46	10	-50
HDL (mg/dl)	-2	10	0	8
LDL (mg/dl)	-12	-25	-5	-15

In both the SAD and MAD cohorts, NGM313 was well tolerated. There were three serious adverse events reported (adjustment disorder in the placebo group; lower gastrointestinal hemorrhage and cholecystitis in the NGM313 groups), and they were considered to be unrelated to study drug. The majority of adverse events were mild to moderate in severity, and treatment-related events with the greatest proportion of subjects were gastrointestinal disorders, injection site reactions, upper respiratory tract infections, headache and increased appetite. In contrast to pioglitazone, where an increased risk of bone fractures in women has been described, there were no changes in bone mineral density and bone formation and resorption markers observed in the MAD trial among subjects treated with NGM313. No symptomatic hypoglycemia was observed with NGM313 treatment. The pharmacokinetic profile suggests that NGM313 displays nonlinear kinetics following a single dose, which is anticipated for an antibody that displays target-mediated clearance. There was some presence of anti-drug antibodies observed, but it did not appear to affect the pharmacokinetics or tolerability profile of NGM313.

**NGM386/NGM395: Engineered Variants of GDF15 for the Potential Treatment of Metabolic Disease**

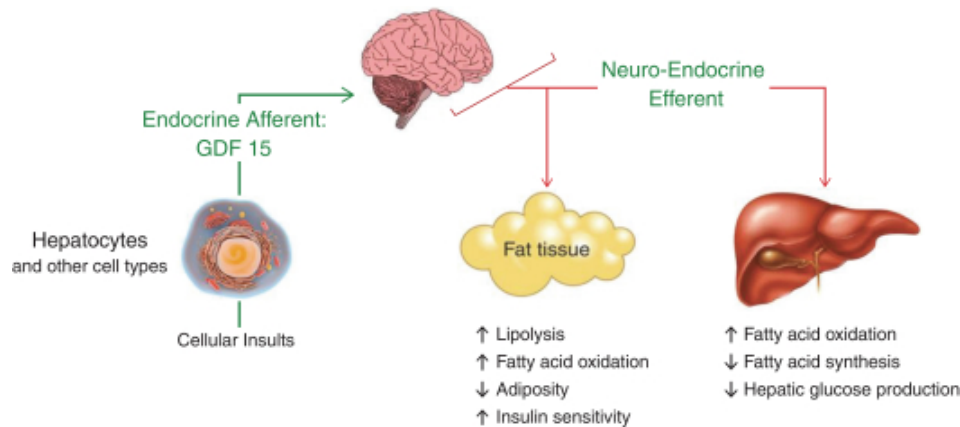
NGM386 and NGM395, also known as MK-4820 and MK-3606, respectively, are proprietary, engineered variants of the hormone GDF15 that were being developed by Merck under the collaboration as once-daily and once-weekly, or less frequent, subcutaneous injections for the treatment of obesity. In 2015, we granted Merck a worldwide license to further research, develop and commercialize NGM386, NGM395 and other GDF15 receptor agonists pursuant to our collaboration agreement. Merck completed the conduct of a Phase 1 MAD clinical trial with NGM386. On March 1, 2019, Merck notified us of its intent to terminate its license to the program, effective May 31, 2019. Upon effectiveness of this termination, we will regain full rights to the GDF15 receptor agonist program, which includes NGM386 and NGM395. We expect to decide whether to advance NGM386 and/or NGM395 following our analysis of the results of the NGM386 Phase 1 trial.

*Overview of GDF15 Pathway and Our Discovery of the GDF15 Receptor, GFRAL*

GDF15, also known as MIC-1 and NAG-1, is expressed in peripheral tissues relevant to metabolic function. We identified GDF15 in an unbiased screen of putative secretory factors using our

rAAV gene delivery approach in diet-induced obese, or DIO, mice. In this screen, GDF15 produced one of the most potent and efficacious metabolic responses we have observed, effectively normalizing blood glucose and significantly reducing body weight. The effects of GDF15 on food intake, energy expenditure and body weight were known. We discovered that GDF15 causes peripheral lipolysis, which is the burning of fats to create free fatty acids as a source of energy, through the sympathetic nervous system. However, the pharmaceutical industry's GDF15 drug discovery efforts had been significantly impeded by the lack of understanding regarding the identity of its cognate receptor and signaling pathways. We identified GFRAL as the exclusive, brainstem-restricted receptor for GDF15 in 2013 and, in 2017, published a landmark paper in the journal *Nature* describing its discovery and the elucidation of its crystal structure by our scientists.

Our research suggests that GDF15 is elevated in peripheral tissues following cellular insults, such as oxidative, metabolic or hypoxic stress, and may serve as a messenger hormone to communicate with the brain stem and orchestrate adaptive metabolic changes to cope with the energy demand of cells under various stress conditions. Among these adaptations are reduced food intake and a change in the fuel flux that favors the burning of free fatty acids through lipolysis, instead of burning carbohydrates. We discovered that GDF15 acts directly on GFRAL, a receptor located exclusively in the area postrema, or AP, and nucleus tractus solitarius, or NTS, of the brain stem. The AP is a circumventricular organ that is outside the blood-brain barrier, which means that it can readily sense any changes in the bloodstream. This discovery provided a mechanistic basis for the regulation by GDF15 of whole body metabolism through a distinct neural circuitry.



#### *Elucidating the Biology of GDF15 and GFRAL*

We have generated the following results supporting the biological role of GDF15 and its receptor, GFRAL:

- recombinant GDF15 protein was shown to confer potent metabolic benefits upon administration in mouse disease models, including decreased glucose levels without hypoglycemia, improved oral glucose tolerance, decreased insulin levels, increased lipolysis, reduced food intake and body weight loss;
- weight loss and metabolic effects from GDF15 expression in DIO mice were observed even at systemic levels as low as 0.6 ng/ml, a concentration comparable to the endogenous levels of this hormone found in humans;
- a mouse strain in which GFRAL was knocked out was overweight compared to normal mice when fed a high-fat diet. However, the GFRAL receptor knockout mice were non-responsive to

treatment with an engineered variant of GDF15 and, unlike their normal counterparts, the animals continued to show elevated body weight and increased food intake. This suggests that GFRAL is the only receptor through which GDF15 acts to achieve its metabolic effects; and

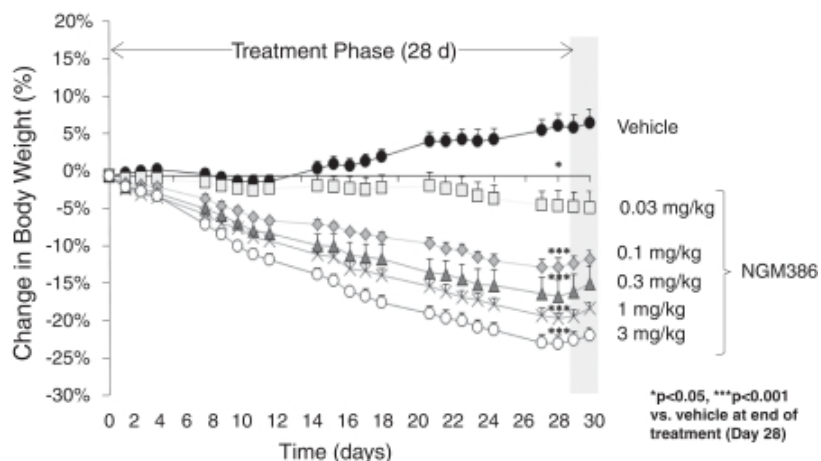
- a surgical procedure that cuts nerves in the sympathetic nervous system traveling through the vagus nerve, known as a vagotomy, reduces GDF15-induced body weight loss but does not affect GDF15-induced anorexia in mice. This suggests that GDF15 controls body weight through two pathways: a central pathway regulating food intake; and a peripheral, vagal-dependent pathway modulating fat utilization.

In addition to the evidence generated in our labs, independent research has reported that GDF15 gene knockout mice weigh more and have increased obesity due to increased spontaneous food intake. Infusion of human recombinant GDF15 that raised serum levels of GDF15 knockout mice to within the normal human range led to reduced body weight and food intake in a dose-dependent fashion.

#### NGM386 and NGM395, Engineered Protein Variants of GDF15

We discovered in 2013 that GFRAL was the cognate receptor for GDF15 several years before other pharmaceutical companies became aware of the receptor identity. During this multi-year period we developed novel insights into the mechanism of action of GDF15 and the structure and function of the GDF15/GFRAL interaction. Through high-resolution X-ray crystallography, we discovered that GDF15 crystal structure revealed a hydrophobic region on the protein surface that we believe impairs the solubility and, therefore, the manufacturability of the native hormone. Armed with this structural information and functional assays that we were able to develop through the elucidation of the GDF15 signaling pathway, we conducted a systematic "structure-activity relationship" analysis of GDF15 and GFRAL to identify the critical functional domains of both the hormone and its receptor. With this data, we generated NGM386 and NGM395 as optimized GDF15 variants that exhibit significantly improved pharmaceutical properties. Since 2015, Merck has been responsible for the development and manufacturing of NGM386 and NGM395. NGM386 is an engineered protein variant of GDF15 that has a pharmacokinetic profile suitable as a once-daily subcutaneous injection. Merck has completed long-term toxicology studies with NGM386 in two species with no treatment-related changes in organ weight, cell morphology or clinical pathology noted beyond body weight loss and injection site reactions.

#### **Efficacy on NGM386 in DIO Mice (n=6/group) Change in Body Weight after 28 Days *qd* Treatment**



NGM395, a long-acting fusion protein variant of GDF15, demonstrated results similar to NGM386, but with weekly dosing, in preclinical studies conducted in multiple species. NGM395 is currently in preclinical development, and has completed three-month studies in two species with no observation of treatment-related changes in organ weight, cell morphology, neurobehavior or clinical pathology that were not attributable to excessive body weight loss.

Merck initiated first-in-human studies of NGM386 in 2016, and completed the conduct of a Phase 1 MAD clinical trial in 2018. Preliminary data from the study indicated that NGM386 treatment for 28 days was generally well-tolerated but did not result in significant body weight loss in obese subjects. We expect to decide whether to advance NGM386 and/or NGM395 following our analysis of the results of the NGM386 Phase 1 trial.

***NGM120: An Antagonistic Antibody Binding GFRAL for the Potential Treatment of CACS***

NGM120 is a proprietary, antagonistic antibody binding GFRAL that is designed to inhibit the effects of elevated GDF15 levels in cancer patients. GDF15 is believed to contribute to uncontrolled weight loss in these patients, also known as cancer anorexia and cachexia syndrome, or CACS, and possibly to the cancer itself. NGM120 is currently in a Phase 1 trial to assess safety, tolerability and pharmacokinetics.

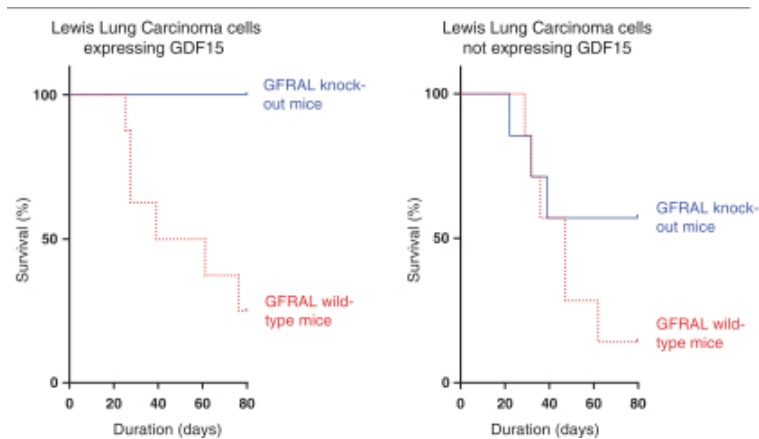
*CACS—Cancer Anorexia/Cachexia Syndrome*

CACS is a common co-morbidity of cancer and is associated with increased hospitalization and shortened survival compared to cancer patients that do not exhibit cachexia. While cachexia can occur in all types of cancer, particularly high incidence rates are observed in pancreatic, non-small cell lung and gastric cancers, at 54%, 36% and 67% of patients, respectively. Studies have shown that cancer patients that do not experience body weight loss have an improved prognosis. Current therapies targeting CACS are directed towards increasing appetite only, however, there is a lack of approved treatments that also address other aspects of the disease, including muscle mass loss and altered energy metabolism. A direct relationship has been established between GDF15 serum levels and cancer-associated weight loss in humans with certain cancers.

*Antagonists to the GDF15/GFRAL Pathway*

We believe that antagonistic antibodies blocking the interaction between GFRAL and GDF15 could provide a novel approach to developing treatments for anorexia, CACS and, potentially, cancer. Mice grafted with human tumors overexpressing GDF15 became cachectic, and this weight loss was found to be reversible by treatment with monoclonal antibodies to GDF15. In addition, in a study where Lewis Lung Carcinoma cells that were engineered to express human GDF15 were injected into wild-type and GFRAL knockout mice, tumor-derived GDF15 appears to impact survival in mice in which the GFRAL signaling pathway is intact, whereas mice lacking GFRAL are resistant to the effects of elevated GDF15 levels. This indicates the potential for anti-GFRAL antibodies to improve patient survival in certain tumor types that express high levels of GDF15, in addition to preserving body mass and preventing development of CACS.

**Impact of GDF15 on Survival in Mice Implanted with Lewis Lung Carcinoma Cells**

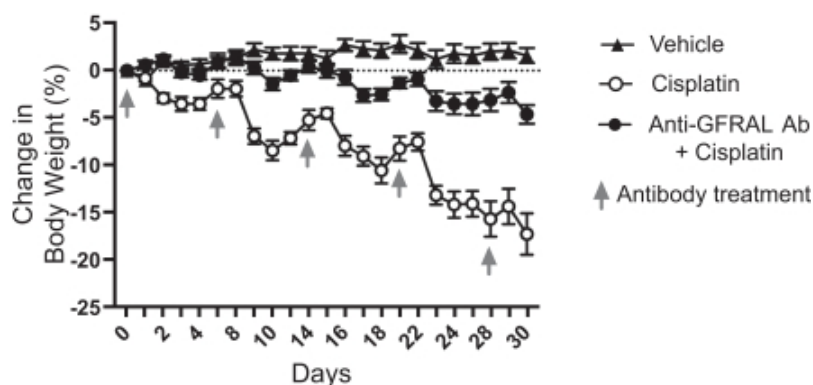


We believe that antibodies against GFRAL will be superior to antibodies against GDF15 because expression levels of GDF15 can rise dramatically in response to infection and other conditions involving cellular insult, meaning that large blood levels of antibodies antagonizing GDF15 will be required to achieve a therapeutic effect. By contrast, GFRAL is expressed at low levels in very specific regions of the brain stem, meaning that a relatively lower blood level of antibodies antagonizing GFRAL will be required to achieve a therapeutic effect.

We believe we have comprehensively characterized the receptor pathway and the structure-function relationship of GDF15 together with its cognate receptor, GFRAL. This understanding facilitated large-scale hybridoma campaigns that generated antibodies targeting key epitopes of the receptor complexes. We have generated and characterized multiple antagonistic antibodies against GFRAL, and from this portfolio, we chose to advance NGM120 as our development candidate.

### NGM120, Antagonistic Antibody Against GFRAL

We designed NGM120 as a potent, humanized monoclonal antibody inhibitor of GFRAL with the potential for once-monthly or less frequent dosing. In numerous preclinical pharmacology models, NGM120 reverses and inhibits GDF15-mediated body weight loss and increases in energy expenditure. For example, treatment of mice with cisplatin, a chemotherapy commonly used to treat various cancers, resulted in body weight loss of approximately 15% after 30 days. However, treatment with an anti-GFRAL antibody prevented substantial body weight loss in this model, as shown below:



NGM120 is in a Phase 1 clinical trial to assess safety, tolerability and pharmacokinetics. Both the SAD and MAD portions of the Phase 1 clinical trial are ongoing. In extensive preclinical testing, including three-month safety and toxicology studies in non-human primates and rats, NGM120 was well tolerated.

Our next study of NGM120 will be in cancer patients selected for high expression levels of GDF15. We intend to conduct a multicenter, Phase 1a/1b, open-label (Cohort 1) and blinded (Cohort 2) randomized study to evaluate the safety, tolerability and pharmacokinetics, and to obtain preliminary evidence of anti-tumor and anti-CACS activity, of NGM120 in patients with select advanced solid tumors. Antagonistic antibodies targeting the GDF15 receptor pathway are not included in the Merck license to GDF15 analogs and are subject to Merck's future option upon completion of a human proof-of-concept study.

### NGM217: A Potential Treatment for Diabetes

NGM217 is a humanized monoclonal antibody against an undisclosed target that has the potential to increase the production of insulin in the pancreas of diabetics by improving effective beta cell function. This improvement is likely to lead to a substantial reduction in glycemic variability, which manifests as hyperglycemia or hypoglycemia in diabetics. We have initiated a Phase 1 clinical trial evaluating the safety and tolerability of NGM217 in patients with diabetes.

Impaired beta cell function leads to the progressive failure of islet cells to secrete sufficient amounts of insulin to overcome peripheral insulin resistance, resulting in failure to maintain normal glucose homeostasis over time. The ability to increase effective beta cell function could be beneficial in three diabetes patient populations: patients with type 1 diabetes; patients with latent autoimmune diabetes in adults, or LADA; and patients with type 2 diabetes that are inadequately controlled with insulin treatment. In the United States, there are approximately 1.5 million adults with type 1 diabetes, and their beta cells produce little to no insulin. LADA is characterized by the slow, progressive autoimmune destruction of beta cells and approximately 10% of patients ages 40 to 75 in the United

States with type 2 diabetes have LADA. These patients often become unresponsive to oral type 2 diabetes and GLP-1 therapies, and usually require early use of insulin in order to preserve the remaining pancreatic beta cell function. For these patients, the ability to increase beta cell function closer to onset of disease would provide an additional treatment option beyond insulin. There also exists a population of late-stage type 2 diabetics who have inadequate glycemic control despite being on intensive daily insulin treatment. These patients will ultimately progress to a point where they become non-responsive to insulin. Given the significant unmet medical need among these diabetes patient populations, we believe that NGM217 has the potential to provide a desirable treatment alternative that increases the effective function of beta islet cells while slowing the rate of disease progression.

#### *Preclinical Studies and Ongoing Phase 1 Clinical Trial*

Preclinical studies assessing the safety of monthly injections of NGM217 demonstrated desirable pharmacokinetics. NGM217 was well tolerated at doses that substantially exceeded the doses to be tested in humans. We have commenced a Phase 1 clinical trial to obtain safety and tolerability data, including rate of hypoglycemia, as well as to select the proper dose for future clinical studies. Thereafter, we plan to commence a Phase 1b/2a proof-of-concept clinical trial in 2020 that investigates the ability of NGM217 to increase stimulated C-peptide, a marker of insulin production, as well as to reduce insulin requirements and improve glycemic control with no worsening of hypoglycemia.

#### **NGM621: A Potential Treatment for Dry AMD**

NGM621 is a humanized monoclonal antibody against an undisclosed target that has supportive human genetics data to suggest that inhibition of this pathway can effectively slow the progression of vision loss in dry AMD. AMD remains the leading cause of vision loss and blindness in people 65 years of age and over in the United States. Prevalence of AMD increases with age, and it is estimated that approximately 3 million people 40 years of age and older will be affected by AMD in the United States by 2020. AMD is a gradually progressive disease that involves the damage and degeneration of cells under the retina and, in the advanced stages, patients can develop either or both of the wet and dry form of AMD. Geographic atrophy, or GA, is an advanced form of dry AMD characterized by deposits under the retina and damage and dysfunction of retinal cells, resulting in single or multiple regions that become impaired in the central area of the retina called the macula. These patches of GA gradually enlarge to cause permanent loss of central vision. GA is prevalent in about 1 million people in the United States and over 5 million people worldwide in 2017 and occurs bilaterally, or in both eyes, in approximately 50% of patients within seven years of diagnosis.

While wet AMD is treated with anti-vascular endothelial growth factor, or anti-VEGF, therapeutics, there are currently no approved treatments for dry AMD and GA. Multiple modalities and classes of therapies are under investigation for GA, including APL-2, which is being developed by Apellis and recently entered Phase 3 clinical trials, and Zimura, which is in Phase 2b clinical trials and being developed by Ophthotech. In 2017, Roche announced that lampalizumab failed to meet the primary endpoint in two Phase 3 trials in GA and, to date, no investigative treatment for GA has shown efficacy in Phase 3. Both APL-2 and Zimura are being developed as intravitreal injections that are administered once monthly or once every two months by retinal specialists, consistent with the current practice for wet AMD treatment. Given the significant unmet medical need and the importance of dosing convenience for GA patients, we believe that NGM621 has the potential to provide a desirable treatment option with improved efficacy with respect to slowing the rate of disease progression and less frequent dosing.

### *Preclinical Studies and Planned Phase 1 Clinical Trial*

We expect to complete preclinical studies in cynomolgus monkeys to assess the safety of NGM621 intravitreal injections in the first half of 2019 to enable the planned Phase 1 and future clinical trials. Following submission of an IND to the FDA in the first half of 2019, we plan to initiate a Phase 1 SAD clinical trial in the second half of 2019 to evaluate the safety, tolerability and pharmacokinetic profile of single doses of intravitreal injections of NGM621 in GA patients.

## **Our Collaboration with Merck**

### **Overview and Benefits**

In 2015, we entered into a broad, strategic collaboration with Merck in order to advance novel biologic therapeutics for the treatment of highly prevalent diseases with significant unmet medical needs. The collaboration is complementary to our drug development model, and is designed to follow certain approaches used in historically successful collaboration agreements between large pharmaceutical companies and emerging biotechnology companies. The collaboration has provided us with the financial support to broaden and accelerate our existing research efforts, access to mid- and late-stage development expertise, in the future, the resources to enable large global trials and the global commercial and distribution capabilities that we believe our products will require. Importantly, this collaboration structure preserves our research independence and allows us to retain meaningful economic rights in our product candidates.

The collaboration includes an exclusive worldwide license to our GDF15 receptor agonist program. On March 1, 2019, Merck notified us of its intent to terminate its license to the program, effective May 31, 2019. Under the agreement, we also granted Merck options to take exclusive, worldwide licenses, on a program-by-program basis, for the programs in our research and development pipeline. Merck generally has a one-time right to exercise its option at the point at which a program completes a human proof-of-concept trial. In November 2018, Merck exercised its option to license our NGM313 program. On March 15, 2019, Merck exercised its option to extend our research collaboration, and thereby preserve its option to license programs in our research and development pipeline, through March 17, 2022. Merck has the right to extend the research collaboration again through March 17, 2024, and is required to inform us of its intent to extend one year prior to the expiration of the term. In addition, we excluded the NGM282 program from the agreement and it remains wholly owned and controlled by us.

The strategic value of our agreement with Merck can be summarized as follows:

- **Financial Support:** Under the terms of the agreement, Merck paid us an upfront cash licensing fee of \$94.0 million and purchased \$106.0 million of our Series E convertible preferred stock in 2015. In addition to the upfront cash component, Merck initially committed to provide us research and development reimbursement of up to \$50.0 million per year for at least five years. If our research and development expenses exceed \$50.0 million in a given year and we are conducting IND-enabling or later-staged activities, Merck is required to elect either to reimburse up to an additional \$25.0 million for use in funding IND-enabling or later-staged activities or to provide us with the equivalent value in in-kind services for preclinical and clinical development activities. The total Merck reimbursement for our research and development activities could therefore reach \$75.0 million per year through the first five years of the research phase. In connection with Merck's exercise of its option to extend our research collaboration in March 2019, 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. Merck paid us a fee of \$20.0 million in December 2018 in connection with the exercise of its license option for NGM313. From inception of the collaboration through December 31, 2018, Merck has paid us \$222.4 million of research and development reimbursement.

- **Economic Opportunity:** For programs that Merck licenses, we retain an option to participate in the development and commercialization of the drug up to a 50% cost and profit share, which includes an option to co-detail the product alongside Merck in the United States. If we elect to participate in the cost and profit share, subject to certain limitations and in addition to the committed annual funding, Merck has agreed to advance us a portion of our share of the overall development costs, which it will recoup from our share of any profit ultimately resulting from sales of the approved drug or, if unsuccessful, other compounds that reach commercialization and are subject to a cost and profit share. If we decide not to participate in the cost and profit share, Merck will owe us milestone payments and royalties as a percentage of global net sales in the low double digits to mid-teens upon commercialization. Our option to participate in the late-stage development and commercialization of licensed programs, such as NGM313, has not yet been triggered.
- **A Sharing of Expertise:** The collaboration provides Merck access to the deep expertise of our team via options on the programs emerging from our novel drug discovery approach, while it provides us with a partner experienced in running large, global, late-stage trials focused on population safety and cardiovascular outcome studies. Further, the agreement provides us with access to Merck's substantial commercial capabilities.
- **Independence and Control Provisions:** We maintain control over the direction and execution of our research and development program through human proof-of-concept testing, allowing our research team the freedom to seek the most promising candidates and flexibility to terminate or de-prioritize projects. In addition, we excluded NGM282 from the Merck collaboration to retain an independent clinical program and as a means to potentially enable full integration of our capabilities to position us for long-term success.

We believe our pipeline of therapies for the treatment of major diseases, like type 2 diabetes, obesity and NASH, is unusual amongst emerging biopharmaceutical companies, the uniqueness of which is further evidenced by the broad support provided by our collaboration with Merck. This collaboration provides us with a competitive advantage by enabling us to advance a portfolio of drug candidates in the cardio-metabolic area while still retaining significant economic ownership of the programs.

#### ***Detailed Description of the Merck Collaboration***

In 2015, we entered into a research collaboration, product development and license agreement with Merck, covering the discovery, development and commercialization of novel therapies across a range of therapeutic areas. In March 2019, Merck exercised its option to extend the collaboration for two additional years, from March 2020 to March 2022. The collaboration included an exclusive worldwide license to our GDF15 program, comprising NGM386 and NGM395 and other GDF15 analogs. On March 1, 2019, Merck notified us of its intent to terminate its license to the program, effective May 31, 2019. Upon termination of the license, we will regain full rights to the GDF15 receptor agonist program, which includes NGM386 and NGM395. These compounds are being evaluated for the treatment of obesity. The collaboration also includes a broad, multi-year drug discovery and early development program financially supported by Merck but scientifically directed by us with input from Merck. For those compounds resulting from this research and development program that progress through proof-of-concept studies, Merck has an exclusive option, at a cost of \$20.0 million for each compound, to obtain an exclusive, worldwide license. If Merck exercises its option with respect to such

a compound, we in turn have the right, at the start of the first Phase 3 clinical trial for that compound, to elect to participate in a worldwide cost and profit sharing arrangement with Merck, as well as the option to co-detail the compound in the United States, or we can elect instead to receive milestones and royalties from Merck based on its further development and commercialization of the compound. If we elect to participate in the cost and profit sharing arrangement, subject to certain limitations, Merck will provide us financial assistance in the form of advances of our share of the overall development costs, which it will recoup from our share of any profit ultimately resulting from sales of the compound or, if unsuccessful, other compounds that reach such stage. If the Company does not opt in to the cost and profit sharing option, then the Company is eligible to receive 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.

#### *Research and Early Development Program*

Under the agreement, we are conducting an extensive research and early development program, the goal of which is the identification, research and development, through human proof-of-concept studies, of multiple product candidates for various therapeutic areas. Included in this program are all NGM research and development programs that existed when we entered into the agreement with Merck, with the exception of the following: NGM282, any other compounds that target FGFR4 and inhibit CYP7A1 expression (including variants or derivatives of FGF19) and any compounds that are covered by or within the scope of third party license or option rights. We determine the scientific direction and areas of therapeutic interest, with input from Merck, and we are primarily responsible for the conduct of all research, preclinical and early clinical development activities, through human proof of concept. We make the final determinations as to which compounds to advance into and through initial clinical studies, which to progress into proof-of-concept studies, and the design of any proof-of-concept studies, with input from Merck through various governance committees.

The research and early development program has an initial term of five years, until March 17, 2020. On March 15, 2019, Merck exercised its option to extend the collaboration through March 17, 2022, and has the option to extend it again until March 17, 2024. We refer to this five, seven or nine-year period as the research phase of the collaboration.

Under the agreement, Merck reimburses the internal and external costs of our research and early development activities in an amount up to \$50.0 million per year during the initial five-year term, based on an estimated annual budget. If we exceed this budget in a particular year, and if the program is such that we are performing IND-enabling studies at that time, Merck is required to elect either to reimburse up to an additional \$25.0 million for use in funding IND-enabling or later-staged activities or to provide us with the equivalent value in in-kind services for preclinical and clinical development activities. The total Merck reimbursement for our research and development activities could therefore reach \$75 million per year through the first five years of the research phase. In connection with Merck's exercise of its option to extend our research collaboration in March 2019, 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. From inception of the collaboration through December 31, 2018, Merck has paid us \$222.4 million of research and development reimbursement. If Merck elects to extend the research phase for an additional two years, the level of funding that Merck will provide to us during such extension will be negotiated at the time of the extension, subject to certain minimum and maximum funding limits based on a percentage of the then-existing funding. With two exceptions, Merck may not terminate its annual funding of the research and early development program prior to the end of the research phase of the collaboration. Those two exceptions are: (i) if we

are acquired by a third party; or (ii) if we are in material uncured breach of our obligations under the research and early development program.

At the end of the research phase, Merck has the right to either require us 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 our 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.

#### *Merck Option to License NGM Programs*

During the research phase, or during the tail period, if there is one, following completion of a proof-of-concept study for a particular compound, regardless of the results of such study, Merck has the one-time option to obtain an exclusive, worldwide license, on specified terms, to that compound, as well as to all other molecules that are directed against the same target and that result in the same effect on such target, which we refer to as an Optioned Program. If Merck exercises its license option, Merck will be responsible, at its own cost, for the further development and any commercialization activities for compounds within that Optioned Program, subject to our options to cost and profit share worldwide, and to co-detail those compounds in the United States, as further described below.

If Merck does not exercise its license option with respect to a particular compound within a limited period of time, we will retain all rights to research, develop and commercialize that compound and its related molecules on a worldwide basis, either alone or in partnership with a third party, subject to the payment to Merck of certain royalties on any commercial sales of any resulting products. If, however, Merck does not exercise its license option because it determined further development of the compound was not warranted for technical, safety or efficacy reasons, and if later in the research phase we again complete a proof-of-concept study with the compound or a related compound, Merck's option rights would nonetheless apply to the compound for a limited period of time. Unless Merck has elected to conduct research and development activities itself, we also retain all rights to programs that have not completed proof-of-concept studies by the end of the research phase, or the tail period, if there is one.

#### *NGM Option to Elect Cost and Profit Share and Merck Financial Assistance*

If Merck exercises its license option, then at the point where it has advanced the licensed compound to its first Phase 3 clinical trial, we have the option for a limited period of time to participate in a cost and profit sharing arrangement with Merck on that compound. Where we exercise such an option, we call such compounds NGM Optioned Products. As part of our election to exercise our option to cost and profit share, we also select the percentage share—up to 50%—that we desire to fund of the total global costs of developing and, if approved, commercializing that NGM Optioned Product. The percentage of any profits we will receive from sales of the NGM Optioned Product will be the same as the percentage share we elect to contribute to funding costs. Our right to participate in cost and profit sharing under the agreement is subject to the following limitation: if at the point in time when we are exercising our option for a licensed compound the actual costs we have incurred across all NGM Optioned Products, plus the prospective costs allocated to us across all NGM Optioned Products, plus the costs we are electing to incur if we were to exercise our option for the compound, reaches \$1.0 billion (if the research phase ends in 2020), \$1.4 billion (if the research phase is extended to 2022) or \$1.8 billion (if the research phase is extended to 2024), then the Company will not be able to exercise its option on any further licensed compounds that Merck takes forward.

Our agreement also provides that, following our election to cost and profit share on an NGM Optioned Product, Merck will advance to us and/or assume a specified portion of the expected global costs for that NGM Optioned Product. These advances/assumed costs are subject to an aggregate cap across all NGM Optioned Products over the course of the collaboration. We refer to the amount Merck advances/assumes as the Advanced Amount. All Advanced Amounts are treated as an accumulated but deferred cost that we owe to Merck, accrue interest and are recouped by Merck in full out of our share of any profits resulting from sales of that NGM Optioned Product before we receive any of those profits. If an NGM Optioned Product fails to generate profit sufficient to repay the balance of the Advanced Amount, the balance will be carried forward and recouped out of profits resulting from sales of any subsequent NGM Optioned Product(s), even if we did not obtain any advances from Merck on our share of costs for such subsequent NGM Optioned Product. We are responsible for directly funding all global development and commercialization costs of an NGM Optioned Product that are over and above any Advanced Amount.

#### *Co-Detailing Rights in the United States*

For each NGM Optioned Product, we also have the option to participate in a portion of the commercial promotion, which we refer to as co-detailing, to provide up to 25% of the total requisite details in the United States of that NGM Optioned Product by fielding our own commercial sales force. We are required to make this election prior to receiving regulatory approval in the United States for the NGM Optioned Product. The specifics of our participation in co-detailing will be determined by the parties according to guidelines set out in the agreement. If we elect to co-detail with Merck, our costs are included in the overall shared commercialization costs, but we do not share in any greater portion of the profits than we otherwise would be entitled to for that NGM Optioned Product.

#### *Small Molecule Research and Development*

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

#### *Collaboration Governance*

Our collaboration with Merck is managed by a set of joint committees composed of equal numbers of representatives from each of us and Merck. A joint research committee, or JRC, has been established to review and discuss the preclinical work that we are conducting and to solicit Merck's input on our research activities. Once we nominate a clinical candidate, a joint early development committee oversees and facilitates the conduct of preclinical and early development activities. A separate joint committee exists to oversee the research and early development of compounds within

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the GDF15 program. For NGM313 and any other Optioned Program, a joint late development committee oversees and coordinates development. A joint commercialization committee will oversee the commercialization of any compound arising from an Optioned Program as to which we elect to cost and profit share. Decision making in these committees generally requires the agreement of both Merck's and our representatives, with unresolved issues escalating through to certain executive officers, and with us having the final say with respect to research and early development program matters and Merck having final say with respect to Optioned Program matters and late development and commercialization matters following the exercise of its option for a particular program.

### *Diligence*

We and Merck must each use commercially reasonable efforts to perform all of our respective activities under the collaboration.

### *Exclusivity*

During the initial research phase, plus an additional limited period of time, neither we nor Merck may directly or indirectly research, develop, manufacture or commercialize any large or small molecule product outside our collaboration with specified activity against the hormones or receptors that are the focus of the GDF15 program, for any indication. During the research phase, we may not directly or indirectly research, develop, manufacture or commercialize, outside of the collaboration, any product with specified activity against any target that we are researching or developing under the collaboration. After the research phase, if Merck exercises its license option for a program, we may not directly or indirectly research, develop, manufacture or commercialize any product with specified activity against the target that is the subject of that licensed program for so long as Merck's license to that program remains in effect.

### *Financial Terms*

In exchange for these various rights and access to our drug discovery approach, Merck paid us an upfront cash fee of \$94.0 million and purchased approximately \$106.0 million of our Series E convertible preferred stock. In connection with Merck's exercise of its option to extend our research collaboration in March 2019, 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. We are entitled to receive an extension payment of \$20.0 million from Merck if it chooses to further extend the extended research phase until March 17, 2024.

If Merck exercises its license option following completion of a human proof-of-concept study, Merck is required to pay us an option fee of \$20.0 million for each licensed program. In December 2018, we received a \$20.0 million payment from Merck in connection with the exercise of its license option for the NGM313 program. Merck does not owe us an option fee on the GDF15 receptor agonist program, as that was already licensed to Merck as of the effective date of our agreement.

If we do not elect to enter into a cost and profit sharing arrangement for a compound we have licensed to Merck including NGM313, we are 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.

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

	<u>First Indication</u>	<u>Second Indication</u>	<u>Third Indication</u>
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 break out 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):

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

We are also eligible to receive commercial milestone payments of up to \$125.0 million payable for such licensed product. We are also 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.

If Merck does not exercise its license option to a compound and we commercialize that compound or its related molecules, we will owe Merck royalties at low single digit rates. If Merck exercises its license option but then terminates its license to a program, such as the GDF15 receptor agonist program, and we take compounds in that program forward, we also owe Merck royalties on sales of those compounds, at low single digit rates.

### *Termination*

After the research phase, Merck may terminate the overall agreement for convenience upon written notice. Subject to certain limitations, Merck may partially terminate the agreement for convenience as it relates to any Optioned Program, such as NGM313, on written notice. It may also terminate the agreement as it relates to its rights to research and develop small molecule compounds.

Either we or Merck may terminate the agreement with respect to the GDF15 program or with respect to a specific Optioned Program if the other party is in material breach of its obligations regarding that specific program and fails to cure the breach within the specified cure period. 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 compounds arising from the GDF15 program or the relevant Optioned Program and if Merck terminates for our breach with respect to an Optioned Program and there are no other Optioned Programs at such time, then we would also be required to commence repaying any Advanced Amounts outstanding with respect to such Optioned Products. If we had exercised our option to participate in global cost and profit sharing of one or more

licensed compounds arising from the program as of the time of termination, the option would remain in effect.

If we terminate the GDF15 program or an Optioned Program for uncured breach by Merck, or if Merck terminates a program for convenience, all licenses granted to Merck with respect to such program will terminate and Merck will grant to us an exclusive license under Merck's intellectual property related to the terminated program, for use in the further development and commercialization of products arising under the terminated program, subject to the payment of a modest royalty back to Merck, assign to us all related regulatory filings and approvals, and provide certain other transition assistance to us. On March 1, 2019, Merck notified us of its intent to terminate its license to the GDF15 program, effective May 31, 2019.

Merck also has the right to terminate the agreement for convenience, and for uncured material breach by us, on written notice as it relates to its license to any particular licensed small molecule compound. We in turn have the right to terminate if Merck has failed to cure any material breach as it relates to any licensed small molecule compound. If Merck terminates for convenience, or we terminate for such breach by Merck, all licenses to Merck with respect to the relevant small molecule compound terminate, but Merck retains all interest in and to the actual small molecule compound it had developed. If Merck terminates for our uncured material breach, we would continue to receive the full amount of milestones and royalties we were otherwise eligible for with respect to the relevant compounds, but we would lose our rights to participate in the various governance committees as they relate to those small molecule program compounds.

#### *Effect of our Change in Control and Certain Competitive Acquisitions*

If we undergo any change in control, which includes the acquisition of us by any third party, or the sale of all or substantially all of our assets relating to the Merck agreement to a third party, or the sale of more than 50% of our voting stock to a third party, Merck has the right to terminate our research and early development program, in its entirety, or only with respect to certain of the programs then being pursued. If it does so, all funding for the terminated programs would cease, and we would transition, at Merck's expense, to Merck any clinical studies then being conducted by us if directed by Merck. If Merck takes over the studies, it would continue to have the option to license a particular program upon completion of the first proof-of-concept study, but if Merck ceases development of the compounds prior to such proof-of-concept study, the program would revert back to us and Merck would have no further rights.

If our change in control involves another pharmaceutical company with significant annual sales of pharmaceutical products, which we refer to as a Pharma Acquisition, Merck would have certain additional rights which could only be exercised within the first year following the Pharma Acquisition. These include: limiting our right to cost and profit share; Merck ceasing to provide any additional Advanced Amounts with respect to one or more Optioned Programs; and requiring us to repay any or all then-outstanding Advanced Amounts, plus interest, in installments; and termination of our co-detailing rights. Merck would also have the right following any Pharma Acquisition to terminate or restrict our participation on our various governance committees, and to limit the information it provides to us to higher level summaries.

If our acquirer in the event of a change in control is at that time pursuing research, development, commercialization, manufacturing or otherwise has any rights to any compounds that modulate a target that is the subject of an Optioned Program, which we refer to as a Competing Mature Program, Merck also has certain rights, unless our acquirer elects to cease those research, development and commercialization activities. These rights include: Merck ceasing to provide any additional Advanced Amounts with respect to any compounds arising from the Optioned Program that have the same target

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as the Competing Mature Program, and requiring us to repay any or all then-outstanding Advanced Amounts, plus interest, in installments, with respect to any compounds arising from that Optioned Program, and termination of our co-detailing rights with respect to the relevant compounds, termination of our participation in governance committees with respect to those compounds, and restrictions on the information we receive from Merck with respect to the compounds. However, our rights to share in costs/profits with respect to any such compounds, if exercised, would remain in effect, as would any milestone or royalty payment obligations of Merck with respect to the compounds.

In addition, if our acquirer in the event of a change in control is at that time researching, developing, manufacturing or otherwise has rights to any compounds that modulate a target that is also being actively pursued under our research and early development program, and which has not reached the proof-of-concept study stage but is ready for preclinical development, which we refer to as a Competing Early Program, Merck has the right to require us to select either to provide information demonstrating that the Competing Early Program does not actually modulate the relevant target in the same manner as our candidate, or to contribute the Competing Early Program to our collaboration with Merck as though it had originated under our research and early development program, or to divest the Competing Early Program. If we contribute the Competing Early Program to our collaboration with Merck, all the same financial obligations of Merck would apply, and we would retain all of our option rights with respect to the relevant compounds if Merck exercises its license option when the first compound arising under the program completes the first proof-of-concept study.

### *Equity Investments by Merck*

Concurrently with the execution of our collaboration with Merck, we entered into a stock purchase agreement with Merck for the purchase of 8,833,333 shares of our Series E convertible preferred stock, for an aggregate purchase price of approximately \$106.0 million. Under a letter agreement entered in connection with this investment, Merck has the irrevocable option to purchase and, if it does not, we have the irrevocable option to require Merck to purchase, an additional amount of our shares of our common stock pursuant to a private placement conducted in parallel with this offering, up to a limit of the number of shares that will result in Merck owning approximately 19.9% of our outstanding shares, at the same price per share as offered to the public. If Merck elects to further extend the research phase of our collaboration until March 17, 2024, it has the option to purchase an additional \$5.0 million of our common stock at a price per share equal to the last closing price of our shares on the date it notifies us of its desire to exercise such option, with such option subject to an overall cap on Merck's ownership interest of 19.9%.

### *Standstill, Lock-Up and Voting Agreements*

The letter agreement also includes standstill provisions that provide that for the period that ends on the earlier of the end of our initial five-year research phase, the announcement of our intent to consummate a change in control transaction (subject to certain exceptions) or the termination of our collaboration agreement, neither Merck nor its representatives will, directly or indirectly, among other things, (i) acquire any of our securities to the extent it would result in Merck owning more than 19.9% of our shares, (ii) solicit proxies for our securities, (iii) participate in a business combination involving us, or take any action that might result in us having to make a public announcement about (i) or (ii), seek to influence our management or policies, except that Merck is not precluded from making confidential, non-public proposals to us or third parties with our express consent. In addition, during the period that ends on the earlier of the end of our initial five-year research phase, the termination of the collaboration agreement or the date on which Merck's ownership of our securities drops below 5%, 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. Merck has also agreed, subject to specified exceptions, and during the period of our five-year initial research phase, not to sell any of its shares of our capital stock (subject to certain limited exceptions).



## Government Regulation and Product Approval

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics, such as those we are developing. We, along with third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practice regulation;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a biologic license application, or BLA, after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practices, or cGMP, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with current Good Clinical Practices, or cGCP; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

### ***Preclinical and Clinical Development***

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the

proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- **Phase 1**—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- **Phase 2**—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- **Phase 3**—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so called Phase 4 studies may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and

tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

### ***BLA Submission and Review***

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk

minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 postmarket studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

### ***Accelerated Approval Program***

Any marketing application for a biologic submitted to the FDA for approval may be eligible for FDA programs intended to expedite the FDA review and approval process, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide a significant improvement in the treatment, diagnosis or prevention of a serious disease or condition compared to marketed products. For products containing new molecular entities, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

Additionally, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval (Subpart H and E regulations) upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

### ***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusive approval (or exclusivity), which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

### **Post-Approval Requirements**

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of a product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of existing product approvals;
- product seizure or detention, or refusal of the FDA to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may

believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

### ***Biosimilars and Reference Product Exclusivity***

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-approved reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical study or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, recent government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

### ***Other U.S. Healthcare Laws and Compliance Requirements***

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, or HHS (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and

abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA (discussed below).

The federal false claims and civil monetary penalty laws, including the FCA, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

We may develop products that, once approved, may be administered by a physician. Under currently applicable U.S. law, certain products not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Medicare Part B is part of original Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary's health condition. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of HHS as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these 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. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties.



In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

### ***Coverage, Pricing and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we may obtain regulatory approval. In the United States and in foreign markets, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

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 third-party payors, such as private health insurers and health maintenance organizations, decide which therapeutics they will pay for and establish reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor’s determination that use of a therapeutic is:

- a covered benefit under its health plan;

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- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

Third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded drugs and drugs administered under the supervision of a physician. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Different pricing and reimbursement schemes exist in other countries. In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care, the increasing influence of health maintenance organizations, and additional legislative changes in the United States has increased, and we expect will continue to increase, the pressure on healthcare pricing. The downward pressure on the rise in healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is

attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

### **Healthcare Reform**

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts, which through subsequent legislative amendments, will be increased to 70%, starting in 2019, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in 2014 and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Discount Program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expansion of healthcare fraud and abuse laws, including the FCA and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- requirements to report certain financial arrangements with physicians and teaching hospitals;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians;

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- establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and
- a licensure framework for follow on biologic products.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance as part of a tax reform bill. Further, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Moreover, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". More recently, in July 2018, CMS announced that it is suspending further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program pending the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Congress is continuing to consider legislation that would alter other aspects of the Affordable Care Act. The ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is unclear.

On December 14, 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. Multiple parties have announced an intention to appeal this decision to the United States Court of Appeals for the Fifth Circuit. 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.

We anticipate that the Affordable Care Act, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and 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. 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.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, 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 of at least \$1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year,

which went into effect beginning on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, 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 federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint", or plan, 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. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

### ***The Foreign Corrupt Practices Act***

The Foreign Corrupt Practices Act, or FCPA, prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

### ***Additional Regulation***

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

### **Other Regulations**

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

### **Competition**

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Although we believe that we hold a leading position in research into cardio-metabolic disease and NASH, our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. Smaller or earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety and tolerability profile, reliability, convenience of dosing, price, the level of generic competition and reimbursement.

There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the research and development of products that may be similar to our products. A number of pharmaceutical companies, including Abbvie, Allergan, AstraZeneca/MedImmune, 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, Conatus, CymaBay, Enanta, Galectin, Galmed, Genfit, Gilead, Intarcia, 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 we are targeting. It is probable that the number of companies seeking to develop products and therapies for the treatment of metabolic disorders, liver, oncologic and ophthalmic diseases will increase. For example, we are aware of other companies, including Enanta, Gilead, Intercept, Metacrine, Novartis and Terns that are seeking to develop FXR agonist drug candidates that modulate FGF19. Many of these and other existing or potential competitors have substantially greater financial, technical, human and other resources than we have and may be better equipped to develop, manufacture and market products. These companies may develop and introduce products and processes competitive with or superior to ours. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended purposes of our products, which might render our technology and products noncompetitive or obsolete.

If NGM282 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; GS-0976, an ACC inhibitor, GS-9674, an FXR agonist, and selonsertib, an ASK1 inhibitor, from Gilead; OCA from Intercept; MGL-3196, a beta-thyroid hormone receptor agonist from Madrigal; pegbelfermin, a PEGylated FGF21, from Bristol-Myers Squibb; 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; 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 NGM282 and NGM313 and any variants of NGM282 and NGM313 we may commercialize, including the second-generation, half-life extended version of FGF19 we are currently developing.

If NGM386 or NGM395 were approved for the treatment of obesity, these products would face competition from currently approved and marketed products, including *Saxenda* (liraglutide), *Contrave*

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(bupropion and naltrexone), *Qsymia* (phentermine and topiramate extended-release), *Belviq* (lorcaserin HCL) and *Xenical* (orlistat). Further competition could arise from products currently in development, including Lilly's LY3298176 (dual GLP-1/GIP receptor agonist). To the extent any of our product candidates are approved for cardio-metabolic indications, particularly obesity, the commercial success of our products will also depend on our ability to demonstrate benefits over the then-prevailing standard of care, including diet and exercise. Finally, morbidly obese patients sometimes undergo the gastric bypass procedure, with salutary effects on the many co-morbid conditions of obesity. Some of these programs have been advanced further in clinical development than our clinical programs or have already received regulatory approval.

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.

### **Manufacturing**

We currently use third-party manufacturers to manufacture clinical quantities of NGM282, NGM313, NGM386, NGM395, NGM217, NGM120 and NGM621. As we advance our product candidates through clinical development and greater quantities of our biological molecules are required, we plan to continue to use third parties to manufacture our product candidates.

We also plan to rely on third parties to manufacture commercial quantities of any products we successfully develop. Among the conditions for FDA approval of a pharmaceutical product is the requirement that the manufacturer's quality control and manufacturing procedures conform to cGMP, which must be followed at all times. The FDA typically inspects manufacturing facilities every two years. In complying with cGMP regulations, pharmaceutical manufacturers must expend resources and time to ensure compliance with product specifications as well as production, record keeping, quality control, reporting, and other requirements.

### **Sales and Marketing**

We currently have no marketing, sales or distribution capabilities. In order to commercialize any products outside of our existing collaborations that are approved for commercial sale, we must either develop a sales and marketing infrastructure or collaborate with third parties that have sales and marketing experience.

We may elect to establish our own sales force to market and sell a product for which we obtain regulatory approval if we elect to exercise our co-detail option on a product candidate from our collaboration with Merck or if we expect that the geographic market for a product we develop on our own is limited or that the prescriptions for the product will be written principally by a relatively small number of physicians. If we decide to market and sell any products ourselves, we do not expect to establish direct sales capability until shortly before the products are approved for commercial sale.

We plan to seek third-party support from established pharmaceutical and biotechnology companies, such as Merck, for those products that would benefit from the promotional support of a

large sales and marketing force. In these cases, we might seek to promote our products in collaboration with marketing partners or rely on relationships with one or more companies with large established sales forces and distribution systems.

## **Intellectual Property**

Our success depends, in part, on our ability to obtain and maintain intellectual property protection for our product candidates, technology and know-how, to defend and enforce our intellectual property rights, in particular, our patent rights, to preserve the confidentiality of our trade secrets, and to operate without infringing the proprietary rights of others. We seek to protect our biological molecules and technologies by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business, where patent protection is available. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing of third-party intellectual property to develop and maintain our proprietary position. We, or our collaborator, file patent applications directed to our key product candidates in an effort to establish intellectual property positions regarding new biological molecules relating to our product candidates as well as uses of our product candidates and/or new biological molecules for the treatment of diseases.

### ***Licensing Arrangements***

In October 2014, we entered into a Multi-Product Licence Agreement, or the Lonza License, with Lonza Sales AG, or Lonza, under which we obtained from Lonza a worldwide, non-exclusive license to use Lonza's glutamine synthetase gene expression system, known as GS Xceed™, to manufacture and commercialize our proprietary products, including our product candidates that are currently subject to our collaboration with Merck.

Pursuant to the Lonza License, we paid Lonza an upfront fee of £250,000. Upon the initiation of the first phase 2 clinical trial, the first phase 3 clinical trial and the first commercial sale of any product manufactured using GS Xceed™, we are required to pay Lonza one-time milestone payments of £100,000, £100,000 and £150,000, respectively.

We are also required to pay low single-digit royalties to Lonza based on net sales of the product manufactured using GS Xceed™. Our royalty obligation to Lonza continues on a product-by-product basis until the later of the expiration of the last-to-expire licensed patent or ten years after the first commercial sale of the product. We are also required to pay an annual license fee to Lonza of up to £300,000 per product if a party other than Lonza, we, our affiliates or our strategic partners (including Merck) manufactures the product for commercial activities. We are currently required to pay this fee for NGM313, NGM386, NGM395, NGM217, NGM120 and NGM621.

The Lonza License continues until the expiration of the royalty term. We have the right to terminate the Lonza License upon written notice to Lonza. Each party may terminate the Lonza License for the other party's uncured material breach or bankruptcy. In addition, Lonza may terminate the Lonza License if we participate in the opposition or challenge of any Lonza patent or patent application licensed to us under the Lonza License.

### ***Patents and Other Proprietary Rights***

As of January 31, 2019, we owned 27 issued U.S. patents and 32 pending U.S. patent applications (six of which are provisional applications) along with 29 issued patents and approximately 241 corresponding patent applications in foreign jurisdictions (five of which are Patent Cooperation



Treaty, or PCT, applications), associated with, for example, the treatment of, cardio-metabolic, liver, ophthalmic and bile acid related diseases. The issued patents and pending patent applications contain claims directed to various aspects of our work, including compositions of matter, methods of treatment, use of our product candidates in combination with certain other therapeutics and formulations.

#### *NGM282 Patent Portfolio*

Our NGM282 product candidate, and related compositions-of-matter and methods of use, are covered by fifteen U.S. patents, as well as issued patents in the following foreign countries: Australia, Japan, Malaysia, Mexico, New Zealand, Peru, and South Africa; and are disclosed and claimed in other applications that are pending in the United States and the following foreign countries and regions: Australia, Brazil, Canada, Chile, China, Egypt, the European Patent Office, or EPO, Hong Kong, India, Indonesia, Israel, Japan, Republic of Korea, Mexico, New Zealand, Philippines, Russian Federation, Singapore, South Africa, Ukraine, United Arab Emirates and Vietnam. The earliest expected expiration date for these patents and any patents issuing from these patent applications is June 2032, exclusive of possible patent term extensions or adjustments. Any changes we make to the NGM282 molecule to cause it 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 applications and/or seek other forms of protection for any such altered molecule. The patent landscape surrounding FGF19, the naturally occurring hormone upon which NGM282 is based, 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 NGM282 molecule, including the half-life extended variant of FGF19 that we are developing.

#### *NGM313 Patent Portfolio*

Our NGM313 product candidate, and related compositions-of-matter and methods of use, are covered by two issued U.S. patents and one issued Colombia patent; and are disclosed and claimed in other applications that are pending in the United States and the following foreign countries: Australia, Brazil, Canada, Chile, China, the EPO, Hong Kong, India, Indonesia, Israel, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Peru, Philippines, Russian Federation, Singapore, South Africa, Ukraine and Vietnam. The earliest expected expiration date for these patents and any patents issuing from these patent applications is January 2035, exclusive of possible patent term extensions or adjustments. Any changes we make to the NGM313 molecule to cause it 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 applications and/or seek other forms of protection for any such altered molecule. The patent landscape surrounding antibodies to FGFR1c/KLB 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 NGM313 molecule.

#### *NGM386 Patent Portfolio*

Our NGM386 product candidate, and related compositions-of-matter and methods of use, are covered by one issued U.S. patent, one issued Lebanese patent and one issued Algerian patent; and are disclosed and claimed in other applications that are pending in the United States and the following foreign countries and regions: the African Regional Intellectual Property Organization, Argentina, Australia, Barbados, Belize, Brunei Darussalam, Brazil, Canada, Chile, China, Colombia, Costa Rica, Dominican Republic, El Salvador, Ecuador, Egypt, the Eurasian Patent Office, the EPO, Georgia, Guatemala, Gulf Cooperation Council, Honduras, Hong Kong, India, Indonesia, Iran, Israel, Jamaica, Japan, Jordan, Republic of Korea, Malaysia, Mexico, Republic of Moldova, Mongolia, New Zealand, Nicaragua, Nigeria, Pakistan, Panama, Peru, Philippines, Singapore, Sri Lanka, South Africa, Taiwan R.O.C., Thailand, Trinidad and Tobago, Tunisia, Ukraine, Venezuela and Vietnam. The earliest

expected expiration date for these patents and any patents issuing from these patent applications is July 2035, exclusive of possible patent term extensions or adjustments. Any changes we make to the NGM386 molecule to cause it 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 applications and/or seek other forms of protection for any such altered molecule. The patent landscape surrounding GDF15, the naturally-occurring hormone upon which NGM386 is based, 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 NGM386 molecule.

#### *NGM395 Patent Portfolio*

Our NGM395 product candidate, and related compositions-of-matter and methods of use, are covered by one issued U.S. patent and one issued Lebanese patent; and are disclosed and claimed in other applications that are pending in the United States and the following foreign countries and regions: the African Regional Intellectual Property Organization, Algeria, Argentina, Australia, Barbados, Brazil, Brunei Darussalam, Canada, Chile, China, Colombia, Costa Rica, Dominican Republic, El Salvador, Ecuador, Egypt, the Eurasian Patent Office, the EPO, Georgia, Guatemala, Gulf Cooperation Council, Honduras, Hong Kong, India, Indonesia, Iran, Israel, Jamaica, Japan, Jordan, Republic of Korea, Malaysia, Republic of Moldova, Mongolia, Mexico, New Zealand, Nicaragua, Nigeria, Pakistan, Panama, Peru, Philippines, Singapore, Sri Lanka, South Africa, Taiwan R.O.C., Thailand, Trinidad and Tobago, Tunisia, Ukraine, Venezuela and Vietnam. The earliest expected expiration date for these patents and any patents issuing from these patent applications is October 2035, exclusive of possible patent term extensions or adjustments. Any changes we make to the NGM395 molecule to cause it 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 applications and/or seek other forms of protection for any such altered molecule. The patent landscape surrounding GDF15, the naturally occurring hormone upon which NGM395 is based, 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 NGM395 molecule.

#### *NGM120 Patent Portfolio*

Our NGM120 product candidate, and related compositions-of-matter and methods of use, are disclosed and claimed in one issued U.S. patent and in applications pending in the following foreign countries and regions: Australia, Brazil, Canada, Chile, China, Colombia, Egypt, the EPO, India, Indonesia, Israel, Japan, Republic of Korea, Malaysia, Mexico, New Zealand, Peru, Philippines, Russian Federation, Singapore, South Africa, Taiwan R.O.C., Ukraine and Vietnam. The earliest expected expiration date for this patent and any patents issuing from these patent applications is October 2037, exclusive of possible patent term extensions or adjustments. Any changes we make to the NGM120 molecule to cause it to have what we view as more advantageous properties may not be covered by our existing patent and patent applications, and we may be required to file new applications and/or seek other forms of protection for any such altered molecule. The patent landscape surrounding antibodies to GFRAL 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 NGM120 molecule, nor can there be any assurance that we will obtain sufficiently broad claims to be able to prevent others from selling competing products.

#### *NGM217 Patent Portfolio*

We do not currently own or have a license to any issued patent that covers our NGM217 product candidate. However, our NGM217 product candidate, and related compositions-of matter and methods of use, are disclosed and claimed in pending United States and PCT applications. The earliest

expected expiration date for any patents issuing from these patent applications is January 2038, exclusive of possible patent term extensions or adjustments. Any changes we make to the NGM217 molecule to cause it to have what we view as more advantageous properties may not be covered by our existing patent applications, and we may be required to file new applications and/or seek other forms of protection for any such altered molecule. There can be no assurance that we would be able to secure patent protection that would adequately cover an alternative to our NGM217 molecule, nor can there be any assurance that we will obtain sufficiently broad claims to be able to prevent others from selling competing products.

#### *NGM621 Patent Portfolio*

We do not currently own or have a license to any issued patent that covers our NGM621 product candidate. However, our NGM621 product candidate, and related compositions-of-matter and methods of use, are disclosed and claimed in a pending United States provisional application filed in April 2018 that we expect to use as the basis for U.S. non-provisional and PCT applications. Any changes we make to the NGM621 molecule to cause it to have what we view as more advantageous properties may not be covered by our existing patent applications, and we may be required to file new applications and/or seek other forms of protection for any such altered molecule. There can be no assurance that we would be able to secure patent protection that would adequately cover an alternative to our NGM621 molecule, nor can there be any assurance that we will obtain sufficiently broad claims to be able to prevent others from selling competing products.

The actual term of any patent that may issue from the above-described patent applications claiming one of our product candidates could be longer than described above due to patent term adjustment or patent term extension, if available, or shorter if we are required to file terminal disclaimers. The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country.

The U.S. patent system permits the filing of provisional and non-provisional patent applications. A provisional patent application is not examined for patentability by the USPTO, and automatically expires 12 months after its filing date. As a result, a provisional patent application cannot mature into an issued patent. Provisional applications are often used, among other things, to establish an early effective filing date for a later-filed non-provisional patent application. A non-provisional patent application is examined by the USPTO and can mature into a patent once the USPTO determines that the claimed invention meets the standards for patentability. If we do not timely file any non-provisional patent applications with respect to any of our provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed therein. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

Our ability to maintain and solidify our proprietary position for our product candidates and technology will depend on our success in obtaining effective patent claims and enforcing those claims once granted. We do not know whether any of our patent applications will result in the issuance of any patents, or what the scope of the claims in any future issued patents may be. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated, narrowed, rendered unenforceable or circumvented, which could limit our ability to stop competitors from marketing identical or substantially similar products or could reduce the length of term of patent protection that we may have for our products. In addition, the claims granted in any of our issued patents may not provide us with advantages against competitors with similar biological molecules or technology. Furthermore, our competitors may independently develop technologies that are similar or

identical to technology developed by us but that do not infringe our patents or other intellectual property. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, by the time that any of our drug candidates or those developed by our collaborator can be commercialized, the key patent may have expired or may only continue to remain in force for a short period of time following commercialization, thereby reducing the usefulness of the patent.

We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use technology or know-how owned by others in their work for us, disputes may arise as to the rights in related inventions. For this and more comprehensive risks related to our intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property.”

### **Employees**

As of December 31, 2018, we had 164 employees. Approximately 135 employees are engaged in research and development, and the others are engaged in business development, finance and other administrative functions.

### **Facilities**

We lease and occupy approximately 122,000 square feet of laboratory and office space in South San Francisco, California. The lease is scheduled to expire in December 2023. We believe that our current spaces are adequate for our needs. We also believe we will be able to obtain additional space, as needed, on commercially reasonable terms.

### **Legal Proceedings**

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

## MANAGEMENT

### Directors and Executive Officers

The following table sets forth the name, age and position of each of our directors and executive officers as of December 31, 2018.

<u>NAME</u>	<u>AGE</u>	<u>POSITION</u>
<i>Executive Officers</i>		
William J. Rieflin	58	Executive Chairman of the Board of Directors
David J. Woodhouse, Ph.D.	48	Chief Executive Officer, Acting Chief Financial Officer and Director
Jin-Long Chen, Ph.D.	56	Founder, Chief Scientific Officer and Director
Aetna Wun Trombley, Ph.D.	39	President and Chief Operating Officer
<i>Non-Employee Directors</i>		
David V. Goeddel, Ph.D.(1)	67	Lead Independent Director
Suzanne Sawochka Hooper(1)(2)	53	Director
Mark Leschly(2)	50	Director
David Schnell, M.D.(3)	58	Director
Peter Svennilson	57	Director
McHenry T. Tichenor, Jr.(2)(3)	63	Director

(1) Member of the Nominating and Corporate Governance Committee.

(2) Member of the Audit Committee.

(3) Member of the Compensation Committee.

#### **Executive Officers**

*William J. Rieflin* became executive chairman of our board of directors in September 2018, after having served as our Chief Executive Officer and a member of our board of directors since September 2010. From 2004 until 2010, he served as President of XenoPort, Inc., a biotechnology company focused on the discovery and development of transported prodrugs. From 1996 to 2004, he held various positions with Tularik, a biotechnology company focused on the discovery and development of product candidates based on the regulation of gene expression that was acquired by Amgen in 2004, most recently serving as Executive Vice President, Administration, Chief Financial Officer, General Counsel and Secretary. Mr. Rieflin has served as a director at FLX Bio, Inc. since 2015 and Kallyope Inc. since 2016. Mr. Rieflin also served as a director of Flexus Biosciences, until its acquisition in 2015, a director of XenoPort, until its acquisition in 2016 and as a director of Anacor Pharmaceuticals, until its acquisition in 2016. Mr. Rieflin received a B.S. from Cornell University, an M.B.A. from the University of Chicago Graduate School of Business and a J.D. from Stanford Law School. We believe that Mr. Rieflin's extensive experience with us, which is a consequence of his tenure as Chief Executive Officer, brings necessary historic knowledge and continuity to our board of directors. In addition, we believe his experiences prior to joining us provided him with operational and industry expertise that are important to our board of directors.

*David J. Woodhouse, Ph.D.* became our Chief Executive Officer, Acting Chief Financial Officer and a member of our board of directors in September 2018, after having served as our Chief Financial Officer from March 2015 until September 2018. From 2002 to 2015, he was an investment banker at Goldman Sachs & Co. LLC, most recently as a Managing Director in the healthcare investment banking group and co-head of biotechnology investment banking. Earlier in his career, Dr. Woodhouse worked at Dynavax Technologies and also as a research assistant at Amgen, Inc. Dr. Woodhouse received a B.A. in pharmacology from the University of California, Santa Barbara, an M.B.A. from the

Tuck School of Business at Dartmouth and a Ph.D. in molecular pharmacology from Stanford University School of Medicine. We believe Dr. Woodhouse's experience with us, as well as his financial and executive experience, make him qualified to serve on our board of directors. In addition, Dr. Woodhouse's experience in healthcare investment banking prior to joining us provided him with industry expertise that is important to our board of directors.

*Jin-Long Chen, Ph.D.*, our founder, has served as a member of our board of directors and as our Chief Scientific Officer since January 2008. From 2004 to 2008, Dr. Chen held various positions at Amgen, most recently as its Vice President, Metabolic Research. Prior to joining Amgen, Dr. Chen was Vice President, Biology at Tularik. He has served as a director of Tenaya Therapeutics, Inc. since 2016. Dr. Chen received a B.S. from Fu-Jen Catholic University, an M.S. from National Taiwan University and a Ph.D. from the University of California, Berkeley. We believe that Dr. Chen's extensive experience with us, which is a consequence of his long tenure as Chief Scientific Officer, brings necessary historic knowledge and continuity to our board of directors. In addition, we believe that his experiences prior to joining us provided him with operational and industry expertise that are important to our board of directors.

*Aetna Wun Trombley, Ph.D.*, became our President in September 2018 and has served as our Chief Operating Officer since June 2015. Prior to that, Dr. Trombley was our Vice President and Executive Director, Business Development between September 2011 and June 2015. She was most recently at Novartis in Basel, Switzerland, where she was Chief of Staff for the Chief Executive Officer and worked on key corporate initiatives and strategic projects across the company's healthcare businesses. Earlier in her career, Dr. Trombley worked at Xenoport, Inc., and at McKinsey & Company, where she advised pharmaceutical and medical device clients on strategic, commercial and operational issues. Dr. Trombley has served as a director of Carmot Therapeutics, Inc. since 2016. She received a B.S. in Chemistry from the University of California, San Diego and a Ph.D. in Chemistry from MIT.

### **Directors**

*David V. Goeddel, Ph.D.* became lead independent director of our board of directors in September 2018, after having served as chairman since January 2008 and served as our Chief Executive Officer from 2008 to 2010. Dr. Goeddel has been a Managing Partner of The Column Group, or TCG, a venture capital partnership, since 2007. Dr. Goeddel co-founded Tularik in November 1991, was Vice President of Research until 1996 and Chief Executive Officer from 1996 through 2004. He served as Amgen's first Senior Scientific Vice President until May 2006. Prior to Tularik, he was the first scientist hired by Genentech, and from 1978 to 1993 served in various positions, including Fellow, Staff Scientist and Director of Molecular Biology. He is a member of the National Academy of Sciences and the American Academy of Arts and Sciences. Dr. Goeddel received a B.S. in Chemistry from the University of California, San Diego and a Ph.D. from the University of Colorado. We believe that Dr. Goeddel's scientific background, experience in the venture capital industry, experience serving as a director of other publicly traded and privately held life science companies and experience in founding and serving as President and Chief Executive Officer of a public biopharmaceutical company give him the qualifications, skills and financial expertise to serve on our board of directors.

*Suzanne Sawochka Hooper* has served as a member of our board of directors since August 2018. From March 2012 to March 2019, Ms. Hooper served as the Executive Vice President and General Counsel of Jazz Pharmaceuticals plc. From 1999 until February 2012, she was a partner in the law firm Cooley LLP. Ms. Hooper previously served as a director of Gentium S.p.A. Ms. Hooper received a J.D. from the University of California, Berkeley, Boalt Hall School of Law and a B.A. in Political Science from the University of California, Santa Barbara. Ms. Hooper is a member of the State Bar of California. We believe Ms. Hooper's legal and operational background and executive experience

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make her qualified to serve on our board of directors. In addition, Ms. Hooper's experience as the executive vice president of a publicly traded pharmaceutical company provided her with operational expertise that is important to our board of directors.

*Mark Leschly* has served as a member of our board of directors since January 2008. Since July 1999, he has been a managing partner at Rho Capital Partners, Inc., an investment and venture capital management company. Since 2017, Mr. Leschly has been the Chairman and CEO of Universal Tennis, LLC, which is the developer of a software platform for tennis analytics and tournament management. Since 2014, Mr. Leschly has also been the owner and managing member of Iconica LLC, which primarily focuses on investments at the intersection of sports, media and technology. From 2002 to 2016, he was a member of the Board of Directors of Anacor Pharmaceuticals, Inc. Mr. Leschly also serves on the board of a number of private companies. Mr. Leschly received an A.B. from Harvard University and an M.B.A. from the Stanford Graduate School of Business. We believe that Mr. Leschly's experience in venture capital and in investing in life sciences companies is valuable to our board of directors. In addition, we believe that Mr. Leschly's prior service on several public company boards has given him experience in corporate governance matters, which is valuable in his position as a director.

*David Schnell, M.D.* has served as a member of our board of directors since January 2008. Dr. Schnell co-founded and has been a Managing Director at Prospect Venture Partners since 1997. Prior to that, Dr. Schnell served as a Partner at Kleiner Perkins Caufield & Byers, a venture capital firm. Dr. Schnell has led private investments for and served on the board of directors of numerous public and private companies. Dr. Schnell previously served on the board of directors of Amira Pharmaceuticals, Inc. (acquired by Bristol-Myers Squibb), Gloucester Pharmaceuticals (acquired by Celgene Corporation), Kythera Biopharmaceuticals, Inc. (acquired by Allergan plc) and Rinat Neuroscience Corporation (acquired by Pfizer), among others. Dr. Schnell received a B.S. in Biological Sciences from Stanford University, an M.A. in Health Services Research from Stanford University School of Medicine, and an M.D. from Harvard Medical School. We believe Dr. Schnell's medical background, venture and executive experience and numerous directorships make him qualified to serve on our board of directors. In addition, Dr. Schnell brings insight on compensation-related matters to the compensation committee based on his breadth of exposure to emerging and public companies.

*Peter Svenilson* has served as a member of our board of directors since January 2008. He founded and has been a Managing Partner of TCG since 2007. He also currently serves on the boards of Constellation Pharmaceuticals, Inc., Gritstone Oncology, Inc., ORIC Pharmaceuticals, Inc. and Ribon Therapeutics, Inc. He was the Chairman of Aragon Pharmaceuticals before it was sold to Johnson & Johnson in 2013 and was the Chairman of Seragon Pharmaceuticals, Inc. until it was sold to Genentech, Inc./F. Hoffman-La Roche AG in 2014. Mr. Svenilson was also a former director of PTC Therapeutics, Inc. Prior to TCG, he founded Three Crowns Capital and was a Managing Partner from 1996 to 2007. Prior to Three Crowns Capital, he was an Associate Managing Director at Nomura Securities from 1987 to 1993. Mr. Svenilson is currently a trustee for The Institute for Advanced Study in Princeton, New Jersey. Mr. Svenilson received an M.B.A. from the Stockholm School of Economics and Finance. We believe that Mr. Svenilson's experience in venture capital and in fund raising for life sciences companies makes him qualified to serve on our board of directors.

*McHenry T. Tichenor, Jr.* has served as a member of our board of directors since March 2010. He has also served as the President of Tichenor Ventures, LLC since January 2010 and held a board observer role at Peloton Therapeutics, Inc. since October 2012. He served as a director of Belo Corp. from 2009 to 2013. Mr. Tichenor served as President, Chief Executive Officer and Director of Tichenor Media System, Inc. from 1981 to 1997, which he subsequently merged with the Hispanic Broadcasting Corporation and, ultimately, with Univision Communications. Mr. Tichenor currently serves as the Executive Director of WWWW Foundation, Inc., a non-profit organization devoted, in part, to cancer research. From 2010 to 2018, Mr. Tichenor served as Board Chairman of the Sarcoma Alliance for Research through Collaboration, a non-profit sponsor of clinical trials for the prevention, treatment and

cure of sarcomas. Mr. Tichenor earned a B.A. with Honors in Plan II and an M.B.A. from The University of Texas at Austin, and an M.S. in biotechnology from The University of Texas at Dallas. We believe Mr. Tichenor's financial and scientific background, venture and executive experience, and multiple directorships make him qualified to serve on our board of directors. In addition, Mr. Tichenor's experience as the chief executive officer of a publicly traded company provided him with operational expertise that is important to our board of directors.

### **Composition of the Board of Directors**

Our amended and restated bylaws provide that the size of our board of directors will be determined from time to time by resolution of our board of directors. Our board of directors currently consists of nine directors, six of whom qualify as independent directors under the rules and regulations of the Securities and Exchange Commission, or SEC, and Nasdaq Stock Market, LLC, or Nasdaq.

### **Election of Directors**

Upon the completion of this offering, our amended and restated certificate of incorporation will provide for a classified board of directors consisting of three classes of directors. We will have three directors in each of Class I and Class II and two directors in Class III, each serving a staggered three-year term. At each annual meeting of stockholders, our stockholders will elect successors to directors whose terms then expire to serve from the time of election and qualification until the third annual meeting following election. After the completion of this offering, our directors will be divided among the three classes as follows:

- Class I directors will be Mark Leschly, William J. Rieflin and Peter Svenilsson, and their terms will expire at the annual meeting of stockholders to be held in 2019;
- Class II directors will be Jin-Long Chen, David Schnell, M.D. and McHenry T. Tichenor, Jr., and their terms will expire at the annual meeting of stockholders to be held in 2020; and
- Class III directors will be David V. Goeddel, Ph.D., Suzanne Sawochka Hooper and David J. Woodhouse, Ph.D., and their terms will expire at the annual meeting of stockholders to be held in 2021.

The classification of our board of directors may have the effect of delaying or preventing changes in control of our company. We expect that additional directorships resulting from an increase in the number of directors, if any, will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

### **Independence of the Board of Directors and Board Committees**

Upon the completion of this offering, we anticipate that our common stock will be listed on the Nasdaq Global Select Market. Rule 5605 of the Nasdaq Marketplace Rules, or the Nasdaq Listing Rules, requires that independent directors compose a majority of a listed company's board of directors within one year of listing. In addition, the Nasdaq Listing Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. Under Nasdaq Listing Rule 5605(a)(2), a director will only qualify as an "independent director" if, in the opinion of our board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3 under the Exchange Act, a member of an audit committee of a listed company may not,



other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries. In addition to satisfying general independence requirements under the Nasdaq Listing Rules, members of the compensation committee must also satisfy additional independence requirements set forth in Nasdaq Listing Rule 5605(d)(2). In order to be considered independent for purposes of Nasdaq Listing Rule 5605(d)(2), a member of a compensation committee of a listed company may not, other than in his or her capacity as a member of the compensation committee, the board of directors or any other board committee, accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries. Additionally, the board of directors of the listed company must consider whether the compensation committee member is an affiliated person of the listed company or any of its subsidiaries and, if so, must determine whether such affiliation would impair the director's judgment as a member of the compensation committee.

Our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family and other relationships, including those relationships described under "Certain Relationships and Related Person Transactions," our board of directors determined that none of Drs. Goeddel and Schnell, Messrs. Leschly, Svenilson and Tichenor and Ms. Hooper, representing six of our nine directors, has a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under Rule 5605(a)(2) of the Nasdaq Listing Rules. Dr. Woodhouse is not considered independent because he currently serves as our Chief Executive Officer. Mr. Rieflin is not considered independent because he served as our Chief Executive Officer within the past three years. Dr. Chen is not considered independent because he currently serves as our Chief Scientific Officer. Our board of directors also determined that each member of the audit, compensation and nominating and corporate governance committees satisfies the independence standards for such committees established by the SEC and the Nasdaq Listing Rules, as applicable. In making these determinations on the independence of our directors, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining independence, including the beneficial ownership of our capital stock by each non-employee director.

## **Board Leadership Structure and the Role of the Board in Risk Oversight**

### ***Board Leadership Structure***

The positions of our executive chairman of the board and chief executive officer are currently separated. Separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing the chairman of the board to lead our board of directors in its fundamental role of providing advice to and oversight of management. Our board of directors recognizes the time, effort and energy that the chief executive officer must devote to his position in the current business environment, as well as the commitment required to serve as our chairman, particularly as our board of directors' oversight responsibilities continue to grow.

Although our amended and restated bylaws that will be in effect upon the completion of this offering will not require that we separate the chairman of the board and chief executive officer positions, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time. Our board of directors recognizes that, depending on the circumstances, other leadership models, such as combining the role of executive chairman of the board with the role of

chief executive officer, might be appropriate. Accordingly, our board of directors may periodically review its leadership structure. Our board of directors believes its administration of its risk oversight function has not affected its leadership structure.

Our corporate governance guidelines to be in effect following this offering will provide that in the event that the chairman of the board of directors is not an independent director, our board may designate one of the independent directors to serve as lead independent director. Our board of directors has appointed Dr. Goeddel to serve as our lead independent director. As lead independent director, Dr. Goeddel, with the executive chairman, establishes the agenda for regular board meetings, presides over periodic meetings of our independent directors, serves as a liaison among our chief executive officer, our executive chairman and the independent directors and performs such additional duties as our board of directors or executive chairman may otherwise determine or delegate.

We anticipate that our independent directors will meet alone in executive session at no less than four regular meetings of our board of directors each year. The purpose of these executive sessions is to promote open and candid discussion among non-employee directors.

### ***Role of the Board in Risk Oversight***

We face a number of risks, including those described under the section titled "Risk Factors" included elsewhere in this prospectus. Our board of directors believes that risk management is an important part of establishing, updating and executing on the company's business strategy. Our board of directors, as a whole and at the committee level, has oversight responsibility relating to risks that could affect the corporate strategy, business objectives, compliance, operations and the financial condition and performance of the company. Our board of directors focuses its oversight on the most significant risks facing the company and on its processes to identify, prioritize, assess, manage and mitigate those risks. Our board of directors and its committees receive regular reports from members of the company's senior management on areas of material risk to the company, including strategic, operational, financial, legal and regulatory risks. While our board of directors has an oversight role, management is principally tasked with direct responsibility for management and assessment of risks and the implementation of processes and controls to mitigate their effects on the company.

The audit committee, as part of its responsibilities, oversees the management of financial risks, including accounting matters, liquidity and credit risks, corporate tax positions, insurance coverage and cash investment strategy and results. The audit committee is also responsible for overseeing the management of risks relating to the performance of our internal audit function, if required, and our independent registered public accounting firm, as well as our system of internal control and disclosure controls and procedures. The compensation committee is responsible for overseeing the management of risks relating to our executive compensation and overall compensation and benefit strategies, plans, arrangements, practices and policies. The nominating and corporate governance committee oversees the management of risks associated with our overall compliance and corporate governance practices and the independence and composition of our board of directors. These committees provide regular reports, on at least a quarterly basis, to the full board of directors.

### **Committees of the Board**

Our board of directors has a standing audit committee, compensation committee and nominating and corporate governance committee. The composition and responsibilities of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors.

### ***Audit Committee***

The audit committee is responsible for assisting our board of directors in its oversight of the integrity of our financial statements, the qualifications and independence of our independent registered public accounting firm and our internal financial and accounting controls. The audit committee has direct responsibility for the appointment, compensation, retention (including termination) and oversight of our independent registered public accounting firm, and our independent registered public accounting firm reports directly to the audit committee. The audit committee also prepares the audit committee report that the SEC requires to be included in our annual proxy statement.

The members of the audit committee are Messrs. Leschly and Tichenor and Ms. Hooper, and Mr. Tichenor serves as chair of the audit committee. All members of the audit committee qualify as an independent director under the corporate governance standards of the Nasdaq Listing Rules and the independence requirements of Rule 10A-3 of the Exchange Act. Our board of directors has determined that Mr. Tichenor qualifies as an “audit committee financial expert” as such term is currently defined in Item 407(d)(5) of Regulation S-K. The audit committee has adopted a written charter that satisfies the applicable standards of the SEC and the Nasdaq Listing Rules, which we will post on our website upon completion of this offering.

### ***Compensation Committee***

The compensation committee approves the compensation objectives for the company, approves the compensation of the chief executive officer and approves or recommends to our board of directors for approval the compensation for other executives. The compensation committee reviews all compensation components, including base salary, bonus, benefits and other perquisites.

The members of the compensation committee are Dr. Schnell and Mr. Tichenor, and Dr. Schnell serves as chair of the compensation committee. Each member of the compensation committee is a non-employee director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and each is an independent director as defined by the Nasdaq Listing Rules, including Nasdaq Listing Rule 5605(d)(2). The compensation committee has adopted a written charter that satisfies the applicable standards of the SEC and the Nasdaq Listing Rules, which we will post on our website upon completion of this offering.

### ***Nominating and Corporate Governance Committee***

The nominating and corporate governance committee is responsible for making recommendations to our board of directors regarding candidates for directorships and the structure and composition of our board and the board committees. In addition, the nominating and corporate governance committee is responsible for developing and recommending to our board corporate governance guidelines applicable to the company and advising our board on corporate governance matters.

The members of the nominating and corporate governance committee are Dr. Goeddel and Ms. Hooper, and Dr. Goeddel serves as chair of the nominating and corporate governance committee. Each member of the nominating and corporate governance committee is a non-employee director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and an independent director as defined by the Nasdaq Listing Rules. The nominating and corporate governance committee has adopted a written charter that satisfies the applicable standards of the Nasdaq Listing Rules, which we will post on our website upon completion of this offering.

### **Code of Business Conduct and Ethics**

We adopted a code of business conduct and ethics that applies to all of our employees, officers and directors including those officers responsible for financial reporting. Upon completion of this offering, we will post the code of business conduct and ethics on our website. We intend to disclose future amendments to the code or any waivers of its requirements on our website to the extent permitted by the applicable rules and exchange requirements.

### **Compensation Committee Interlocks and Insider Participation**

None of the members of our compensation committee have ever been officers or employees of the company. None of our executive officers serves, or has served during the last three years, as a member of the board of directors, compensation committee or other board committee performing equivalent functions of any entity that has one or more executive officers serving as one of our directors or on our compensation committee.

## EXECUTIVE AND DIRECTOR COMPENSATION

### Executive Compensation

The following table provides information regarding the compensation of our current and former principal executive officer and each of our two other most highly compensated executive officers during the fiscal year ended December 31, 2018. Throughout this prospectus we refer to these executive officers as our named executive officers.

#### Summary Compensation Table

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Option Awards \$(1)</u>	<u>Non-Equity Incentive Plan Compensation \$(2)</u>	<u>All Other Compensation \$(3)</u>	<u>Total (\$)</u>
David J. Woodhouse, Ph.D. <i>Chief Executive Officer and Acting Chief Financial Officer</i>	2018	412,500	3,670,498	57,000	750	4,140,748
William J. Rieflin <i>Executive Chairman and Former Chief Executive Officer</i>	2018	553,125	1,198,957	61,050	—	1,813,132
Aetna Wun Trombley, Ph.D. <i>President and Chief Operating Officer</i>	2017	545,000	1,199,498	65,400	—	1,809,898
Jin-Long Chen, Ph.D. <i>Founder and Chief Scientific Officer</i>	2018	382,500	2,669,262	51,000	—	3,102,762
	2017	485,000	1,065,739	58,200	750	1,609,689
	2017	460,000	1,136,366	55,200	750	1,652,316

- (1) Amounts reflect the grant date fair value of option awards granted in the applicable year measured pursuant to Financial Accounting Standard Board Accounting Standard Codification, Topic 718. For information regarding assumptions underlying the value of equity awards, see Note 2 to our consolidated financial statements and the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates—Stock-Based Compensation," included elsewhere in this prospectus. These amounts do not reflect actual value that the named executive officers may realize.
- (2) Amounts represent the annual performance-based cash bonuses earned by our named executive officers based on the achievement of certain corporate performance objectives and individual performance during 2017 and 2018. These amounts were paid to the named executive officers in early 2018 and 2019, respectively. Please see the descriptions of the annual performance bonuses paid to our named executive officers under "Performance Bonuses" below.
- (3) Amounts shown in this column represent defined contribution retirement matching contributions provided to the named executive officers on the same terms as provided to all of our regular full-time employees in the United States. For more information regarding these benefits, see below under "—401(k) Plan and Matching Plan."

#### Narrative to Summary Compensation Table

##### Performance Bonuses

We maintain an annual performance-based cash bonus program in which each of our named executive officers participated in 2017 and 2018. Each of our named executive officers' target bonus is expressed as a percentage of base salary that can be achieved by meeting corporate goals at target level. The annual bonuses for each of our named executive officers were targeted at 12% of their

respective base salaries. Pursuant to the bonus program, we expect the same target bonuses for each of these officers in 2019 as in 2018.

For 2017 and 2018, our named executive officers were eligible to earn annual cash bonuses based on the achievement of certain corporate performance objectives approved by the compensation committee and our board of directors, as well as individual performance. For 2018, our board of directors set corporate performance goals in the three broad strategic areas of advancing therapeutic programs through development, discovering new molecules through an active research program and building capability. Each area included specific performance objectives.

In early 2019, the compensation committee reviewed and approved the achievement of our 2018 corporate goals and determined that the corporate goals were met. Based on this level of corporate achievement, the bonus pool for the company was fully funded.

### ***Equity Compensation***

Each of our named executive officers currently hold options or restricted stock. In 2018, Drs. Woodhouse, Trombley, and Chen and Mr. Rieflin were granted options to purchase our common stock, in each case, pursuant to our 2018 Equity Incentive Plan.

In January 2018, our board of directors granted to Drs. Woodhouse, Trombley and Chen and Mr. Rieflin options to purchase 62,500, 62,500, 200,000 and 225,000 shares of our common stock, respectively, which vest as to 1/48<sup>th</sup> of the shares subject to the option each month from January 1, 2018, subject to each executive officer's continued service to us on each applicable vesting date. In addition, the options granted to Drs. Woodhouse and Trombley and Mr. Rieflin are subject to the accelerated vesting provisions set forth in their respective employment agreement, as described below under "Other Elements of Compensation—Potential Payments Upon Termination or Change of Control."

In July 2018, our board of directors granted to Drs. Woodhouse and Trombley options to purchase 500,000 and 350,000 shares of our common stock, respectively, which vest as to 1/48<sup>th</sup> of the shares subject to the option each month from July 13, 2018, subject to the executive officer's continued service to us on each applicable vesting date.

In March 2019, our board of directors and our stockholders approved the amendment and restatement of our 2018 Equity Incentive Plan, or the Restated 2018 Plan, to facilitate the grant of cash and equity incentives to directors, employees (including our named executive officers) and consultants and to enable us to obtain and retain services of these individuals, which is essential to our long-term success. The Restated 2018 Plan will become effective upon the completion of this offering. For additional information about the Restated 2018 Plan, please see the section titled "Equity Incentive Plans" below.

**Outstanding Equity Awards at Fiscal Year-End**

The following table provides information regarding equity awards held by the named executive officers that were outstanding as of December 31, 2018.

Name	Grant Date	Option Awards(1)				Stock Awards	
		Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock (#) That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested (\$) (2)
David J. Woodhouse, Ph.D.	4/22/2015	270,000	—	7.54	4/21/2025	—	—
	1/20/2017	100,000	—	7.70	1/19/2027	—	—
	1/31/2018	62,500	—	8.14	1/30/2028	—	—
	7/25/2018	500,000	—	11.00	7/24/2028	—	—
Aetna Wun Trombley, Ph.D.	9/14/2011	125,000	—	1.02	9/13/2021	—	—
	1/24/2013	62,500	—	1.44	1/23/2023	—	—
	1/24/2014	62,500	—	2.16	1/23/2024	—	—
	1/31/2015	75,000	—	4.00	1/30/2025	—	—
	6/16/2015	50,000	—	7.64	6/15/2025	—	—
	1/27/2016	50,000	—	7.64	1/26/2026	—	—
	1/20/2017	70,000	—	7.70	1/19/2027	—	—
	1/31/2018	62,500	—	8.14	1/30/2028	—	—
	7/25/2018	350,000	—	11.00	7/24/2028	—	—
William J. Rieflin	1/31/2015(3)	—	—	—	—	4,428	53,396
	1/27/2016(4)	—	—	—	—	64,323	775,735
	1/20/2017(5)	—	—	—	—	123,698	1,491,798
	1/31/2018	225,000	—	8.14	1/30/2028	—	—
Jin-Long Chen, Ph.D.	2/25/2010	150,000	—	0.52	2/24/2020	—	—
	2/11/2011	150,000	—	0.60	2/10/2021	—	—
	3/2/2012	162,500	—	1.44	3/1/2022	—	—
	1/24/2013	175,000	—	1.44	1/23/2023	—	—
	1/24/2014	175,000	—	2.16	1/23/2024	—	—
	1/31/2015	200,000	—	4.00	1/30/2025	—	—
	1/27/2016	225,000	—	7.64	1/26/2026	—	—
	1/20/2017	225,000	—	7.70	1/19/2027	—	—
1/31/2018	200,000	—	8.14	1/30/2028	—	—	

- (1) Unless otherwise noted, shares subject to the options vest on a monthly basis upon the vesting commencement date over 48 months, subject to the continued service with us through each vesting date. The options are subject to an early exercise right and may be exercised in full prior to the vesting of the shares underlying the stock option.
- (2) Because our common stock was not traded on a public market on December 31, 2018, the market value has been calculated based on an assumed fair market value of our common stock of \$12.06 per share as of December 31, 2018. See the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates—Stock-Based Compensation."
- (3) Reflects the unvested portion of an early exercise for 212,500 shares of common stock granted on January 31, 2015. Our right to repurchase the unvested shares lapse in equal increments on a monthly basis through December 31, 2018.
- (4) Reflects the unvested portion of an early exercise for 237,500 shares of common stock granted on January 27, 2016. Our right to repurchase the unvested shares lapse in equal increments on a monthly basis through December 31, 2018.
- (5) Reflects the unvested portion of an early exercise for 237,500 shares of common stock granted on January 20, 2017. Our right to repurchase the unvested shares lapse in equal increments on a monthly basis through December 31, 2018.

## Other Elements of Compensation

### ***Health, Welfare and Retirement Benefits***

Our named executive officers are eligible to participate in all of our employee benefit plans, such as medical, dental, vision, group life, short and long-term disability plans, in each case on the same basis as other employees, subject to applicable laws. We provide a 401(k) plan and a matching plan to our employees, including our named executive officers, as discussed in the section below titled “—401(k) Plan and Matching Plan.” We also provide vacation and other paid holidays to all employees, including our named executive officers. We do not provide a pension plan for our employees, and none of our named executive officers participated in a nonqualified deferred compensation plan in 2018.

### ***401(k) Plan and Matching Plan***

We maintain a defined contribution employee retirement plan for our employees. Our 401(k) plan is intended to qualify as a tax-qualified plan under Section 401 of the Code so that contributions to our 401(k) plan and income earned on such contributions are not taxable to participants until withdrawn or distributed from the 401(k) plan. Our 401(k) plan provides that each participant may contribute up to 100% of his or her pre-tax compensation, up to a statutory limit of \$19,000 for 2019. Participants who are at least 50 years old can also make “catch-up” contributions, which in 2019 may be up to an additional \$6,000 above the statutory limit. Under our 401(k) plan, each employee is fully vested in his or her deferred salary contributions. Employee contributions are held and invested by the plan’s trustee. Our 401(k) plan also permits us to make discretionary and matching contributions, subject to established limits and a vesting schedule.

Our NGM Biopharmaceuticals Matching Plan, or our 401(k) Matching Plan, effective January 1, 2011, is intended to be a tax-qualified defined contribution plan under Subsections 401(a) and 401(m) of the Code. All employees are eligible to participate and may enter the 401(k) Matching Plan as of the date they become eligible to participate in the 401(k) plan. Each participant who makes pre-tax contributions to the 401(k) plan is eligible to have a matching contribution in our common stock made by us to his or her 401(k) Matching Plan account, which is generally equal to 50% of the participant’s plan contribution, up to a maximum employer contribution of \$1,500 per year. We may make additional discretionary contributions for all participants to the 401(k) plan. Each participant’s contributions, and the corresponding investment earnings, are generally not taxable to the participants until withdrawn. Participant contributions are held in trust as required by law. Individual participants may direct the trustee to invest their accounts in authorized investment alternatives.

### ***Perquisites and Other Personal Benefits***

We do not provide perquisites or other personal benefits to our named executive officers.

### ***No Tax Gross-Ups***

In 2017 and 2018, we did not make gross-up payments to cover our named executive officers’ personal income taxes that pertained to any of the compensation or perquisites paid or provided by our company.

### ***Agreements with our Named Executive Officers***

*Offer Letters or Employment Agreements.* We have entered into offer letters or employment agreements with all of our named executive officers. We designed these agreements to be part of a competitive compensation package and to keep our named executive officers focused on our business



goals and objectives. These agreements provide for base salaries and incentive compensation, and each component reflects the scope of each named executive officer's anticipated responsibilities and the individual experience they bring to the company. Each named executive officer is also eligible to participate in our employee benefit plans on the same terms as other regular, full-time employees. The employment of each of our named executive officers is "at will" and may be terminated at any time. In addition, each of our named executive officers has executed a form of our standard proprietary information and inventions agreement. The key terms of the offer letters or employment agreements are described below.

We entered into an employment agreement with Dr. Woodhouse effective as of January 28, 2015. Pursuant to Dr. Woodhouse's employment agreement, we agreed to an initial annual base salary of \$300,000. We also agreed to grant Dr. Woodhouse options to purchase shares of our common stock, subject to approval by our board of directors. Dr. Woodhouse's annual base salary was increased from \$330,000 to \$350,000 effective January 1, 2018.

On July 25, 2018, we entered into a new employment agreement with Dr. Woodhouse upon his promotion to Chief Executive Officer. Pursuant to Dr. Woodhouse's new employment agreement, we agreed to increase his annual base salary from \$350,000 to \$475,000, effective July 1, 2018. We also agreed to grant Dr. Woodhouse options to purchase shares of our common stock, subject to approval by our board of directors.

We entered into an employment agreement with Dr. Trombley effective as of April 28, 2011. Pursuant to Dr. Trombley's employment agreement, we agreed to an initial annual base salary of \$225,000. We also agreed to grant Dr. Trombley options to purchase share of our common stock, subject to approval by our board of directors. Dr. Trombley's annual base salary was increased from \$317,000 to \$340,000 effective January 1, 2018.

On July 25, 2018, we entered into a new employment agreement with Dr. Trombley upon her promotion to President and Chief Operating Officer. Pursuant to Dr. Trombley's new employment agreement, we agreed to increase her annual base salary from \$340,000 to \$425,000, effective July 1, 2018. We also agreed to grant Dr. Trombley options to purchase shares of our common stock, subject to approval by our board of directors.

We entered into an employment agreement with Mr. Rieflin effective as of September 30, 2010. Pursuant to Mr. Rieflin's employment agreement, we agreed to an initial annual base salary of \$400,000 and a hiring bonus of \$100,000. We also agreed to grant to Mr. Rieflin options to purchase shares of our common stock, subject to approval by our board of directors. Mr. Rieflin's annual base salary was increased from \$545,000 to \$575,000 effective January 1, 2018.

We entered into an employment offer letter with Dr. Chen on January 7, 2008. Dr. Chen resigned from his position as President on October 31, 2014, but remained as Chief Scientific Officer. Pursuant to Dr. Chen's employment offer letter, we agreed to an initial annual base salary of \$300,000 and a hiring bonus of \$50,000. We also agreed to grant to Dr. Chen founder's shares of our common stock, subject to approval by our board of directors. Dr. Chen's annual base salary was increased from \$460,000 to \$485,000 effective January 1, 2018.

#### ***Potential Payments Upon Termination or Change of Control***

The employment agreements with Drs. Woodhouse and Trombley and Mr. Rieflin described above under "—Agreements with our Named Executive Officers" contain severance benefits. These severance benefits provide that, in the event we terminate the executive's employment without "cause,"

or he or she resigns for “good reason,” each as defined in the employment agreement, on or within 18 months following a change in control of the company, the named executive officer will be entitled to receive the severance benefits described below. These severance benefits are subject to the named executive officer executing a general release of claims in favor of us, and complying with his obligations under the proprietary information and inventions agreement entered into with us.

**David J. Woodhouse, Ph.D.** In the event of a qualifying termination following a change in control, Dr. Woodhouse will be entitled to: (i) payments equal to 12 months of his base salary, as in effect on the date of his termination payable in substantially equal installments in accordance with our normal payroll policies then in effect, less applicable withholdings, with such installments to commence on the first payroll period following the later of the date of his termination and the effective date of his general release of claims; (ii) acceleration of any unvested shares subject to outstanding equity awards held by Dr. Woodhouse on the date of his termination; and (iii) if elected by Dr. Woodhouse, payment or reimbursement of COBRA premiums through the earlier of 12 months from his termination date or the date he and his covered dependents, if any, cease to be eligible for such continued coverage.

**Aetna Wun Trombley, Ph.D.** In the event of a qualifying termination following a change in control, Dr. Trombley will be entitled to: (i) payments equal to 9 months of her base salary, as in effect on the date of her termination payable in substantially equal installments in accordance with our normal payroll policies then in effect, less applicable withholdings, with such installments to commence on the first payroll period following the later of the date of her termination and the effective date of her general release of claims; (ii) acceleration of any unvested shares subject to outstanding equity awards held by Dr. Trombley on the date of her termination; and (iii) if elected by Dr. Trombley payment or reimbursement of COBRA premiums through the earlier of 9 months from her termination date or the date she and her covered dependents, if any, cease to be eligible for such continued coverage.

**William J. Rieflin.** In the event of a qualifying termination following a change in control, Mr. Rieflin will be entitled to: (i) payments equal to 12 months of his base salary, as in effect on the date of his termination payable in substantially equal installments in accordance with our normal payroll policies then in effect, less applicable withholdings, with such installments to commence on the first payroll period following the later of the date of his termination and the effective date of his general release of claims; (ii) acceleration of any unvested shares subject to outstanding equity awards held by Mr. Rieflin on the date of his termination; and (iii) if elected by Mr. Rieflin, payment or reimbursement of COBRA premiums through the earlier of 12 months from his termination date or the date he and his covered dependents, if any, cease to be eligible for such continued coverage.

In addition, Mr. Rieflin's employment agreement provides that in the event that the severance and other benefits provided for or otherwise payable to him constitute “parachute payments” within the meaning of Section 280G of the Code and are subject to the excise tax imposed by Section 4999 of the Code, and either the holders of at least 75% of the voting power of our capital stock as of September 30, 2010 do not still hold at least 75% of such voting power at the time of any proposed stockholder vote to approve parachute payments, or our board of directors does not recommend approval of such parachute payments, then Mr. Rieflin may be entitled to receive an additional tax gross-up payment with respect to such federal excise tax obligations. Our obligation to provide such tax gross-up payment will be terminated once we are a reporting company under the Exchange Act.

### Equity Incentive Plans

The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus is a part.

### ***Amended and Restated 2018 Equity Incentive Plan***

In January 2018 our board of directors adopted, and in May 2018, our stockholders approved, our 2018 Plan. In March 2019, our board of directors and our stockholders approved the amendment and restatement of our 2018 Plan, or the Restated 2018 Plan, in anticipation of becoming a publicly traded company and which will become effective upon the completion of this offering.

#### *Types of Awards; Eligibility*

The Restated 2018 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, and other forms of equity-based awards, all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. Incentive stock options may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

#### *Share Reserve*

Initially, we have reserved 17,874,624 shares of our common stock for issuance pursuant to the Restated 2018 Plan, subject to certain adjustments set forth in the plan, including any shares of common stock subject to awards outstanding under the 2008 Plan that terminate by expiration, forfeiture, cancellation or otherwise without the issuance of such shares, up to a maximum of 8,441,785 shares, are added to 2018 Plan share reserve.

The number of shares available for issuance under the Restated 2018 Plan will automatically increase on January 1st of each calendar year for ten years, starting on January 1, 2019 (assuming the Restated 2018 Plan becomes effective in calendar year 2019) and ending on and including January 1, 2028, in an amount equal to 4.0% of the total number of issued and outstanding shares of our common stock as of December 31 of the immediately preceding year, or a lesser number of shares determined by our board of directors. The maximum number of shares of our common stock that may be issued upon the exercise of incentive stock options under our Restated 2018 Plan is 36,000,000 shares.

Shares subject to awards granted under our Restated 2018 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, do not reduce the number of shares available for issuance under our Restated 2018 Plan. Additionally, shares become available for future grant under our Restated 2018 Plan if they were issued under our Restated 2018 Plan and we repurchase them or they are forfeited because they fail to vest. Shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to an award are also returned to the Restated 2018 Plan and become available for future grant. Shares issued under the Restated 2018 Plan may be previously unissued shares or reacquired shares bought by us on the open market.

As of December 31, 2018, options to purchase a total of 2,591,630 shares of common stock at a weighted average exercise price of \$9.42 were issued and outstanding under the 2018 Plan and 6,287 shares of common stock had been issued upon the exercise of options granted under the 2018 Plan.

#### *Administration*

Our board of directors, or a duly authorized committee thereof, has the authority to administer the Restated 2018 Plan. Our board has delegated concurrent authority to administer our Restated 2018 Plan to the compensation committee under the terms of the compensation committee's charter. Our board of directors may also delegate to one or more of our officers the authority to designate employees (other than other officers) to be recipients of certain awards, and determine the number of shares of common stock to be subject to such awards.

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Subject to the terms of the Restated 2018 Plan, the plan administrator has the authority in its discretion to, among other things, select recipients of awards, determine the number of shares, terms and conditions and forms of agreement related to awards, construe and interpret terms of the plan and awards, and prescribe, amend and rescind rules related to the plan. All actions of the plan administrator will be final and binding on all persons.

The plan administrator also has the authority to modify outstanding awards under our Restated 2018 Plan, and to reduce the exercise, purchase or strike price of any outstanding award, cancel any outstanding award in exchange for a new award, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, with the consent of any adversely affected participant.

### *Options*

The Restated 2018 Plan authorizes the plan administrator to grant incentive stock options (under Section 421 of the Code) and options that do not qualify as incentive stock options, or nonstatutory stock options. The plan administrator will determine the exercise price of each option, provided that the price generally will be equal to at least 100% of the fair market value of the shares of common stock on the date on which the option is granted. Options granted under the Restated 2018 Plan vest at the rate specified by the plan administrator. Options may have a maximum term of up to 10 years from the date of grant, subject to earlier expiration following the cessation of a participant's continuous service with us, as provided in the 2018 Plan and the specific award agreement.

### *Tax Limitations On Incentive Stock Options*

The aggregate fair market value, determined at the time of grant, of our common stock with respect to incentive stock options that are exercisable for the first time by a participant during any calendar year under all of our stock plans may not exceed \$100,000. We will generally treat options or portions thereof that exceed such limit as nonstatutory stock options. No incentive stock option may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (1) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (2) the term of the incentive stock option does not exceed five years from the date of grant.

### *Restricted Stock Awards*

A restricted stock award is an award of shares of common stock that may, but need not, be subject to restrictions on transferability and other restrictions as the plan administrator determines in its sole discretion on the date of grant. The restrictions, if any, may lapse over a specified period of time or through the satisfaction of conditions, in installments or otherwise, as the plan administrator may determine. A participant who receives a restricted stock award will have all of the rights of a stockholder as to those shares, including the right to vote and the right to receive dividends or distributions on the shares, except that the board of directors may require any dividends to be reinvested in shares. During the period, if any, when stock awards are non-transferable or forfeitable, a participant is prohibited from selling, transferring, assigning, pledging or otherwise encumbering or disposing of his or her award shares. Except as otherwise provided in the applicable award agreement, restricted stock awards that have not vested may be forfeited or repurchased by us upon the participant's cessation of continuous service for any reason.

### *Restricted Stock Units*

Restricted stock units represent the participant's right to receive a compensation amount, based on the value of our common stock, if the vesting criteria established by the plan administrator are met.

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We may issue restricted stock unit awards that settle on vesting in cash, delivery of shares of common stock, a combination of cash and stock, as deemed appropriate by the plan administrator and provided in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant's cessation of continuous service for any reason.

### *Stock Appreciation Rights*

Stock appreciation rights provide the participant with the right to receive, upon exercise of the stock appreciation right, cash, shares of common stock or a combination of cash and stock. The plan administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (1) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (2) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the Restated 2018 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator. Stock appreciation rights may have a maximum term of up to 10 years, subject to earlier expiration following the cessation of a participant's continuous service with us, as provided in the Restated 2018 Plan and the specific award agreement.

### *Performance Awards*

The Restated 2018 Plan permits the grant of awards that vest (or are eligible to vest) in whole or in part upon the achievement of certain pre-established performance goals during a designated performance period.

### *Other Equity-Based Awards*

The plan administrator may grant other types of equity-based awards under the Restated 2018 Plan. Other equity-based awards are payable in cash, shares of common stock or other equity, or a combination thereof, and may be restricted or unrestricted, as determined by the plan administrator. The terms and conditions that apply to other equity-based awards are determined by the plan administrator.

### *Transferability*

A participant generally may not transfer awards granted under our Restated 2018 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our Restated 2018 Plan.

### *Changes to Capital Structure*

In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (1) the class and maximum number of shares reserved for issuance under the Restated 2018 Plan, (2) the class and maximum number of shares by which the share reserve may increase automatically each year, (3) the class and maximum number of shares that may be issued upon the exercise of incentive stock options, and (4) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

### *Corporate Transaction*

Our 2018 Plan provides that in the event of a corporate transaction, the successor corporation may assume each outstanding award or may substitute similar awards for each outstanding award. If outstanding awards are not assumed or substituted, the vesting of such awards held by current service providers will accelerate in full prior to the consummation of the transaction, and any awards not exercised will terminate upon closing of the corporate transaction. In addition, the plan administrator may provide for unexercised awards that will otherwise terminate upon closing of the corporate transaction to be cancelled at closing in exchange for a payment equal in value to the amount such award holder would have received in such transaction upon exercise of the award, minus the exercise price.

Under the Restated 2018 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our consolidated assets, (2) a sale or other disposition of at least 50% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

### *Amendment; Termination*

Our board of directors may amend or terminate the Restated 2018 Plan at any time; provided that no amendment may adversely impair the benefits of participants with outstanding awards without such participant's consent. Our stockholders must approve any amendment if such approval is required under applicable law or listing requirements. No incentive stock options may be granted after the tenth anniversary of the date our board of directors adopted our Restated 2018 Plan.

## **2008 Equity Incentive Plan**

### *General*

In January 2008, our board of directors adopted and our stockholders approved our 2008 Plan. Our 2008 Plan provided for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards and restricted stock unit awards to our employees, directors and consultants and those of our affiliates.

Our 2008 Plan expired pursuant to its terms in January 2018, and therefore no new awards may be issued from this plan. However, outstanding options granted under the 2008 Plan will remain outstanding, subject to the terms of the 2008 Plan and the relevant award agreement, until such options are exercised or they terminate or expire by their terms.

### *Authorized Shares*

As of December 31, 2018, options to purchase a total of 7,215,059 shares of common stock at a weighted average exercise price of \$4.58 were issued and outstanding under the 2008 Plan and a total of 5,256,824 shares of common stock (net of early exercised options repurchased) had been issued upon the exercise of options granted under the 2008 Plan.

### *Administration*

Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2008 Plan. Our board has delegated concurrent authority to administer our 2008 Plan to the

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compensation committee under the terms of the compensation committee's charter. Among other powers, the plan administrator has the authority to modify outstanding awards under our 2008 Plan, and to reduce the exercise price of any outstanding award, cancel any outstanding award in exchange for a new award, cash or other consideration, or take any other action that is treated as a repricing under generally accepted accounting principles, in each case with the consent of any adversely affected participant.

### *Corporate Transaction*

Our 2008 Plan provides that in the event of a corporate transaction, the successor corporation may assume each outstanding award or may substitute similar awards for each outstanding award. If outstanding awards are not assumed or substituted, the vesting of such awards held by current service providers will accelerate in full prior to the consummation of the transaction, and any awards not exercised will terminate upon closing of the corporate transaction. In addition, the plan administrator may provide for unexercised awards that will otherwise terminate upon closing of the corporate transaction to be cancelled at closing in exchange for a payment equal in value to the amount such award holder would have received in such transaction upon exercise of the award, minus the exercise price.

Under the 2008 Plan, a corporate transaction is generally the consummation of (1) a sale or other disposition of all or substantially all of our consolidated assets, (2) a sale or other disposition of at least 90% of our outstanding securities, (3) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (4) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

### **2019 Employee Stock Purchase Plan**

In March 2019, our board of directors adopted, and our stockholders approved, the 2019 Employee Stock Purchase Plan, or ESPP, which will become effective upon the completion of this offering. The purpose of the ESPP is to enable our eligible employees, through payroll deductions or cash contributions, to purchase shares of our common stock, to increase our employees' interest in our growth and success and encourage employees to remain in our employment.

### *Share Reserve*

Following this offering, the ESPP authorizes the issuance of 1,000,000 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2020 (assuming the ESPP becomes effective before such date) through January 1, 2029 by the least of (1) 1.0% of the total number of shares of our 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). The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. As of the date hereof, no shares of our common stock have been purchased under the ESPP.

### *Administration*

Our board of directors, or a duly authorized committee thereof, has the authority to administer the ESPP. Our board of directors has delegated concurrent authority to administer the ESPP to our compensation committee. The ESPP is implemented through a series of offerings of purchase rights to eligible employees. Under the ESPP, we may specify offerings with durations of not more than

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27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances.

The ESPP is intended to qualify as an “employee stock purchase plan” within the meaning of Section 423 of the Code for our U.S. employees. In addition, the ESPP authorizes grants of purchase rights that do not comply with Section 423 of the Code under a separate non-423 component. In particular, where such purchase rights are granted to employees who are employed or located outside the United States, our board of directors may adopt rules that are beyond the scope of Section 423 of the Code.

### *Payroll Deductions*

Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the ESPP and may contribute, normally through payroll deductions, up to 15.0% of their earnings for the purchase of our common stock under the ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of employees participating in the ESPP at a price per share equal to the lower of (1) 85% of the fair market value of a share of our common stock on the first date of an offering or (2) 85% of the fair market value of a share of our common stock on the date of purchase.

### *Limitations*

Employees may have to satisfy one or more of the following service requirements before participating in the ESPP, as determined by our board of directors: (1) customarily employed for more than 20 hours per week, (2) customarily employed for more than five months per calendar year or (3) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the ESPP at a rate in excess of \$25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value pursuant to Section 424(d) of the Code.

### *Changes to Capital Structure*

In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (1) the number of shares reserved under the ESPP, (2) the maximum number of shares by which the share reserve may increase automatically each year and (3) the number of shares and purchase price of all outstanding purchase rights.

### *Corporate Transactions*

In the event of certain significant corporate transactions, including the consummation of: (1) a sale of all our assets, (2) the sale or disposition of 90% of our outstanding securities, (3) a merger or consolidation where we do not survive the transaction and (4) a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the ESPP may be assumed, continued or substituted



for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days prior to such corporate transaction, and such purchase rights will terminate immediately.

#### *Plan Amendments, Termination*

Our board of directors has the authority to amend or terminate our ESPP, provided that except in certain circumstances any such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

### **Non-Employee Director Compensation**

#### ***Future Director Compensation***

In March 2019, our board of directors approved a non-employee director compensation policy, which will be effective for all non-employee directors upon the completion of this offering. Each non-employee director will receive an annual base retainer of \$40,000. In addition, our non-employee directors will receive the following cash compensation for board services, as applicable:

- the lead independent director will receive an additional annual retainer of \$25,000;
- each member of our audit, compensation and nominating and corporate governance committees, other than the chairperson, will receive an additional annual retainer of \$10,000, \$6,000 and \$5,000, respectively; and
- each chairperson of our audit, compensation and nominating and corporate governance committees will receive an additional annual retainer of \$30,000, \$15,000 and \$5,000, respectively.

We will pay all amounts in quarterly installments. We will also reimburse each of our directors for their travel expenses incurred in connection with their attendance at board of directors and committee meetings. In addition, newly appointed non-employee directors will receive a one-time initial award of options with a grant date fair value of \$500,000, which will vest one-third after the first year, with the remaining shares vesting quarterly in years two and three following the grant date, such that the shares will be fully vested on the third anniversary of the date of grant, subject to the director's continued service on the board of directors. Thereafter, each non-employee director will receive an annual award of options with a grant date fair value of \$200,000, which will vest quarterly over one year from the grant date, such that the shares will be fully vested on the first anniversary of the date of grant, subject to the director's continued service on the board of directors. In addition, in the event of a change in control of the company, the shares underlying such grants will vest and become exercisable immediately prior to the effectiveness of such change in control.

#### ***Director Compensation***

Other than Ms. Hooper, who received an annual retainer of \$40,000 and an initial option grant of 25,000 shares, our non-employee directors did not receive any cash or equity compensation for their services as directors during 2018.

### **Limitation of Liability and Indemnification Agreements**

Our amended and restated certificate of incorporation and amended and restated bylaws, each to become effective upon the completion of this offering, provide that we will limit the liability of our

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directors, and may indemnify our directors and officers, to the maximum extent permitted by the Delaware General Corporation Law, or DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of their duty of loyalty to the corporation or its stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- transaction from which the directors derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies, such as injunctive relief or rescission.

We have entered into separate indemnification agreements with our directors and officers in addition to the indemnification provided for in our amended and restated bylaws. These indemnification agreements provide, among other things, that we will indemnify our directors and officers for certain expenses, including damages, judgments, fines, penalties, settlements and costs and attorneys' fees and disbursements, incurred by a director or officer in any claim, action or proceeding arising in his or her capacity as a director or officer of our company or in connection with service at our request for another corporation or entity. The indemnification agreements also provide for procedures that will apply in the event that a director or officer makes a claim for indemnification.

We also maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers. We believe that these indemnification provisions and insurance are useful to attract and retain qualified directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder's investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

## CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Other than compensation arrangements, we describe below transactions and series of similar transactions, since January 1, 2016, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed \$120,000; and
- any of our directors, executive officers, or holders of more than 5% of our common stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

We have entered into various employment-related agreements and compensatory arrangements with our directors and executive officers that, among other things, provide for compensatory and certain severance and change in control benefits. For a description of these agreements and arrangements, see the sections titled “Executive and Director Compensation—Agreements with our Named Executive Officers” and “Executive and Director Compensation—Potential Payments upon Termination or Change of Control.”

### Merck Collaboration

In 2015, we entered into a research collaboration, product development and license agreement with Merck, pursuant to which we subsequently licensed our NGM313 program to Merck. In March 2019, Merck exercised its option to extend this collaboration from March 2020 through March 2022. For a detailed description of this agreement, see the section titled “Business—Our Collaboration with Merck.”

### Concurrent Private Placement

Merck, a strategic collaborator and existing stockholder, has agreed to purchase 4,121,683 shares of our common stock in a separate private placement concurrent with the completion of this offering at a price of \$16.00 per share. This will result in Merck owning approximately 19.9% of our outstanding shares of common stock following the completion of this offering. The sale of such shares will not be registered under the Securities Act of 1933, as amended. The completion of this offering is not contingent upon the completion of such concurrent private placement.

### Amended and Restated Investor Rights Agreement

We have entered into an amended and restated investor rights agreement with certain holders of our convertible preferred stock, including entities with which certain of our directors are affiliated. This agreement provides that the holders of common stock issuable upon conversion of our convertible preferred stock have the right to demand that we file a registration statement or request that their shares of common stock be covered by a registration statement that we are otherwise filing. With respect to this offering, the registration rights have been validly waived. In addition to registration rights, the amended and restated investor rights agreement provides for certain information rights and a right of first offer. The provisions of the amended and restated investors' rights agreement, other than those related to registration rights, will terminate upon the completion of this offering. For a detailed description of registration rights under this agreement, see “Description of Capital Stock—Registration Rights.”

### **Voting Agreement**

We have entered into an amended and restated voting agreement under which certain holders of our capital stock, including certain holders of 5% of our capital stock and entities affiliated with certain of our directors, have agreed to vote in a certain way on certain matters, including with respect to the election of directors. All of our current directors were elected pursuant to the terms of this agreement. The amended and restated voting agreement will terminate upon the completion of this offering.

### **Right of First Refusal and Co-Sale Agreement**

We have entered into an amended and restated right of first refusal and co-sale agreement with our founder, our chief executive officer and the holders of our convertible preferred stock, including certain holders of 5% of our capital stock and entities affiliated with certain of our directors, pursuant to which the holders of convertible preferred stock have a right of first refusal and co-sale in respect of certain sales of securities by our founder and our chief executive officer. Upon the completion of this offering, the right of first refusal and co-sale agreement will terminate.

### **Other Transactions**

In May 2016, entities affiliated with The Column Group and Tichenor Ventures, LLC purchased a total of 314,940 shares of our common stock at a price of \$7.64 per share from a total of six employees, including 205,317 shares purchased from Dr. Chen.

In November 2016, entities affiliated with The Column Group purchased a total of 200,000 shares of our Series D convertible preferred stock at a price of \$12.00 per share from one stockholder.

In December 2016, entities affiliated with The Column Group purchased a total of 110,000 shares of our Series B and Series C convertible preferred stock at a price of \$12.00 per share from a total of eight stockholders.

### **Indemnification Agreements**

We have entered into indemnification agreements with each of our current directors and officers. For more information regarding these agreements, see "Executive and Director Compensation—Limitation of Liability and Indemnification Agreements."

### **Policies and Procedures Regarding Transactions with Related Persons**

We intend to adopt a related person transaction policy that will be in effect upon completion of this offering. Pursuant to the related person transaction policy, all proposed related person transactions must be approved by either (i) our audit committee (or any other committee of our board of directors consisting of independent directors), or (ii) our full board of directors. This review will cover any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, the amount involved exceeds \$120,000, and a related person had or will have a direct or indirect material interest, including purchases of goods or services by or from a related person or entities in which the related person has a material interest, and indebtedness, guarantees of indebtedness and employment by us of a related person. A "related person" is any person who is or was one of our executive officers, directors or director nominees or is a holder of more than 5% of our common stock, or their immediate family members or any entity owned or controlled by any of the foregoing persons.

All of the transactions described above were entered into prior to the adoption of this policy and were approved by our board of directors.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our capital stock as of March 20, 2019 by:

- each of our named executive officers;
- each of our directors;
- all of our current executive officers and directors as a group; and
- each person, or group of affiliated persons, known by us to beneficially own more than 5% of any class of our voting securities.

We have based our calculation of beneficial ownership prior to this offering and concurrent private placement to Merck on 54,310,541 shares of common stock outstanding as of March 20, 2019, which includes 47,283,839 shares of our common stock resulting from the conversion of all outstanding shares of our convertible preferred stock into our common stock immediately prior to the completion of this offering and concurrent private placement to Merck, as if this conversion had occurred as of March 20, 2019. We have based our calculation of beneficial ownership after this offering and concurrent private placement to Merck on 65,098,891 shares of our common stock outstanding immediately following the completion of this offering and the concurrent private placement to Merck. Ownership information assumes no exercise of the underwriters' option to purchase additional shares.

Entities affiliated with The Column Group, an existing stockholder, have agreed to purchase 1,875,000 shares of our common stock in this offering at the initial public offering price. The information set forth in the table below reflects the purchase of all of these shares in this offering by such entities, with such entities purchasing number of shares indicated in the footnotes to the table. The underwriters will receive the same underwriting discount on any shares purchased by these entities as they will on any other shares sold to the public in this offering.

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Beneficial ownership is determined according to the rules of the SEC and generally means that a person has beneficial ownership of a security if he or she possesses sole or shared voting or investment power of that security, and includes options and warrants that are currently exercisable within 60 days of March 20, 2019. Options to purchase shares of our common stock that are exercisable within 60 days of March 20, 2019 are deemed to be beneficially owned by the persons holding these options for the purpose of computing percentage ownership of that person, but are not treated as outstanding for the purpose of computing any other person's ownership percentage. Except as indicated in the footnotes below, each of the beneficial owners named in the table below has, and upon completion of this offering will have, to our knowledge, sole voting and investment power with respect to all shares of common stock listed as beneficially owned by him or her, subject to community property laws where applicable. Unless otherwise indicated, the address for each of the stockholders in the table below is c/o NGM Biopharmaceuticals, Inc., 333 Oyster Point Blvd., South San Francisco, California 94080.

Name of beneficial owner	Number of shares beneficially owned	Percentage of Shares Beneficially Owned	
		Before offering and private placement	After offering and private placement
<b>5% and Greater Stockholders:</b>			
Entities affiliated with The Column Group(1)	13,569,091	25.0%	23.7%
Merck Sharp & Dohme Corp.(2)	8,833,333	16.3%	19.9%
Prospect Ventures Partners III, L.P.(3)	4,925,000	9.1%	7.6%
Topspin Fund L.P.(4)	4,833,334	8.9%	7.4%
Entities affiliated with Rho Ventures(5)	3,766,667	6.9%	5.8%
<b>Executive Officers and Directors:</b>			
William J. Rieflin(6)	3,044,168	5.6%	4.7%
Jin-Long Chen, Ph.D.(7)	2,968,943	5.5%	4.6%
Aetna Wun Trombley Ph.D.(8)	1,007,500	1.9%	1.5%
David J. Woodhouse, Ph.D.(9)	1,212,500	2.2%	1.9%
David V. Goeddel, Ph.D.(10)	13,759,091	25.3%	24.0%
Suzanne Sawochka Hooper(11)	25,000	—	—
Mark Leschly(12)	3,766,667	6.9%	5.8%
David Schnell, M.D.(13)	4,925,000	9.1%	7.6%
Peter Svenilson(14)	13,569,091	25.0%	23.7%
McHenry T. Tichenor, Jr.(15)	1,872,315	3.4%	2.9%
All executive officers and directors as a group (10 persons)(16)	32,581,184	55.3%	49.7%

- (1) Consists of (i) 11,103,333 shares held of record by The Column Group, LP, (ii) 2,265,758 shares held of record by The Column Group II, LP, (iii) 100,000 shares held of record by The Column Group GP, LP and (iv) 100,000 shares held of record by The Column Group Management, LP. Mr. Svenilson and Dr. Goeddel are managing partners of The Column Group GP, LP, The Column Group II GP, LP and Pono Capital, GP, LP, which are the general partners of The Column Group, LP and The Column Group II, LP, respectively, and share voting and investment power with respect to such shares. Mr. Svenilson and Dr. Goeddel disclaim beneficial ownership over such shares except to the extent of any pecuniary interest therein. The principal address of The Column Group, LP is 1700 Owens Street, Suite 500, San Francisco, California 94158. In addition, the percentage of shares beneficially owned after the offering reflects that entities affiliated with The Column Group have purchased 1,875,000 shares of our common stock in this offering at the initial public offering price.
- (2) Merck has agreed to vote its shares in favor of our nominees to the board of directors, increases in the authorized capital stock of the company and amendments to our equity plans approved by

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our board of directors, in each case as recommended by the chairman our board of directors. Merck has also agreed, subject to specified exceptions, and during the period of our five-year initial research phase, not to sell any of its shares of our capital stock. The principal address of Merck is One Merck Drive, Whitehouse Station, New Jersey 08889. In addition, the percentage of shares beneficially owned after this offering includes 4,121,683 shares of our common stock that Merck will purchase, in a separate private placement concurrent with the completion of this offering.

- (3) The voting and investment power with respect to such shares is shared by the following managing members of its general partner, Prospect Management Co. III, L.L.C.: Dr. Schnell and Dr. Russell Hirsch. Drs. Schnell and Hirsch disclaim beneficial ownership over such shares except to the extent of any pecuniary interest therein. The principal address of Prospect Venture Partners III L.P. is 525 University Avenue, Suite 1350, Palo Alto, California 94301.
- (4) The voting and investment power with respect to such shares is shared by the following managing partners of Topspin Fund L.P.: Leo Guthart and Steven Winick. Messrs. Gyenes, Guthart, Simons and Winick disclaim beneficial ownership over such shares except to the extent of any pecuniary interest therein. The principal address of Topspin Fund L.P. is Three Expressway Plaza, #200, Roslyn Heights, New York, New York 11577.
- (5) Consists of (a) 3,462,649 shares held of record by Rho Ventures V, L.P. and (b) 304,019 shares held of record by Rho Ventures V Affiliates L.L.C. The voting and investment power with respect to the shares held by Rho Ventures V, L.P. and Rho Ventures V Affiliates L.L.C. is shared by the following members of Rho Capital Partners LLC, which is the managing member of RMV V, L.L.C., which is the general partner of Rho Ventures V, L.P. and the managing member of Rho Ventures V Affiliates L.L.C.: Habib Kairouz, Mark Leschly and Joshua Ruch. Messrs. Kairouz, Leschly and Ruch disclaim beneficial ownership over such shares except to the extent of any pecuniary interest therein. The address for the funds affiliated with Rho Ventures is Carnegie Hall Tower, 152 West 57th Street, 23rd Floor, New York, New York 10019.
- (6) Consists of (i) 2,769,168 shares held in trust for which Mr. Rieflin serves as trustee and shares voting and investment control and (ii) 275,000 shares pursuant to options exercisable within 60 days of March 20, 2019, of which 67,708 shares have vested as of March 20, 2019.
- (7) Consists of (i) 906,443 shares, (ii) 225,000 shares held in trusts for which Dr. Chen shares voting and investment control and (iii) 1,837,500 shares pursuant to options exercisable within 60 days of March 20, 2019, of which 1,378,125 shares have vested as of March 20, 2019.
- (8) Consists of 1,007,500 shares pursuant to options exercisable within 60 days of March 20, 2019, of which 530,103 shares have vested as of March 20, 2019.
- (9) Consists of (i) 80,000 shares held in trust for which Dr. Woodhouse serves as trustee and shares voting and investment control and (ii) 1,132,500 shares pursuant to options exercisable within 60 days of March 20, 2019, of which 434,062 shares have vested as of March 20, 2019.
- (10) Consists of (i) 190,000 shares held in trust for which David V. Goeddel and Alena Z. Goeddel serve as co-trustees, and (ii) the shares described in footnote (1) above.
- (11) Consists of 25,000 shares pursuant to options exercisable within 60 days of March 20, 2019, of which no shares have vested as of March 20, 2019.
- (12) Consists of the shares described in footnote (5) above.
- (13) Consists of the shares described in footnote (3) above.
- (14) Consists of the shares described in footnote (1) above.
- (15) Consists of 1,872,315 shares held of record by Tichenor Ventures, LLC. Mr. Tichenor is the president and managing partner of Tichenor Ventures, LLC and has sole voting and investment power with respect to such shares. The principal address of Tichenor Ventures, LLC is 100 Crescent Court, Suite 700, Dallas, Texas 75201.
- (16) Consists of (i) 28,303,684 shares held of record by our executive officers and directors, of which 158,334 shares are subject to repurchase by us at the original purchase price as of March 20, 2019 and (ii) 3,727,500 shares pursuant to options exercisable within 60 days of March 20, 2019, of which 2,228,018 shares have vested as of March 20, 2019.

## DESCRIPTION OF CAPITAL STOCK

### General

The following description of our capital stock summarizes the most important terms of our capital stock as they are expected to be in effect upon the completion of this offering. The descriptions of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws that will be in effect upon the completion of this offering. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part.

Our amended and restated certificate of incorporation provides for common stock and undesignated convertible preferred stock, the rights, preferences and privileges of which may be designated from time to time by our board of directors.

Upon the completion of this offering, our amended and restated certificate of incorporation will authorize us to issue up to 400,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share. As of December 31, 2018, assuming the conversion of all outstanding shares of our convertible preferred stock into an aggregate of 47,267,466 shares of our common stock, there were outstanding:

- 54,205,356 shares of our common stock held by approximately 178 stockholders of record;
- 9,806,689 shares of our common stock issuable upon exercise of outstanding stock options; and
- 19,637 shares of our common stock (on an as-converted basis) issuable upon exercise of an outstanding Series A convertible preferred stock warrant, at an exercise price of \$2.00 per share which automatically net exercised into shares of our Series A convertible preferred stock that are convertible into 16,380 shares of our common stock on February 3, 2019.

### Common Stock

#### *Voting Rights*

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. In addition to any vote of holders of a specific class or series, or required by law or the amended and restated certificate of incorporation, the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

#### *Dividends*

Subject to preferences that may apply to any outstanding convertible preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose.

#### *Liquidation*

In the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preference of any outstanding convertible preferred stock.



### ***Rights and Preferences***

Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our convertible preferred stock that we may designate in the future.

### ***Fully Paid and Nonassessable***

All outstanding shares of our common stock are fully paid and nonassessable, and the shares of common stock to be issued upon completion of this offering will be fully paid and nonassessable.

### **Preferred Stock**

In connection with this offering, all outstanding shares of our convertible preferred stock will convert into shares of common stock.

Upon completion of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the number, rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and sinking fund terms, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control or other corporate action. We have no current plan to issue any shares of convertible preferred stock.

### **Registration Rights**

We are party to an amended and restated investor rights agreement that provides that holders of our convertible preferred stock and certain holders of our common stock, including certain holders of 5% of our capital stock and entities affiliated with certain of our directors, have certain registration rights, as set forth below. The registration of shares of our common stock pursuant to the exercise of registration rights described below would enable the holders to sell these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than the underwriting discounts and commissions, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares such holders may include. The demand, piggyback and Form S-3 registration rights described below will expire (i) five years after the effective date of the registration statement, of which this prospectus forms a part, (ii) with respect to any particular holder, at such time that such holder can sell its shares under Rule 144 of the Securities Act during any three-month period or (iii) upon termination of the investors' rights agreement.

### ***Demand Registration Rights***

The holders of an aggregate of 54,205,356 shares of common stock outstanding as of December 31, 2018, including shares issuable upon conversion of outstanding convertible preferred

stock, giving effect to the company conversion as if it occurred on such date, will be entitled to certain demand registration rights. At any time following 180 days after the completion of this offering, the holders of 40% of the shares having demand registration rights may request that we register at least a majority of their shares of common stock for sale under the Securities Act. We will affect the registration as requested, unless, in the good faith judgment of our board of directors, such registration would be materially detrimental to the company and its stockholders and should be delayed. In addition, when we are eligible for the use of Form S-3, or any successor form, holders of the shares having demand registration rights may make unlimited requests that we register all or a portion of their common stock for sale under the Securities Act on Form S-3, or any successor form, so long as the aggregate price to the public in connection with any such offering is at least \$2.0 million.

#### ***Piggyback Registration Rights***

In connection with this offering, the holders of an aggregate of 54,205,356 shares of common stock outstanding at December 31, 2018, including shares issuable upon conversion of outstanding convertible preferred stock, giving effect to the company conversion as if it occurred on such date, were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering. In the event that we propose to register any of our securities under the Securities Act in another offering, either for our own account or for the account of other security holders, the holders of these shares will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, including a registration statement on Form S-3 as discussed below, other than with respect to a demand registration or a registration statement on Forms S-4 or S-8 or related to stock issued upon conversion of debt securities, the holders of these shares are entitled to notice of the registration and have the right, subject to limitations that the underwriters may impose on the number of shares included in the registration, to include their shares in the registration.

#### ***Form S-3 Registration Rights***

The holders of an aggregate of 54,205,356 shares of common stock outstanding at December 31, 2018, including shares issuable upon conversion of outstanding convertible preferred stock, giving effect to the company conversion as if it occurred on such date, will be entitled to certain Form S-3 registration rights. Any holder or holders of these shares can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to certain specified exceptions. Such request for registration on Form S-3 must cover securities the aggregate offering price of which, before payment of the underwriting discount, equals or exceeds \$2.0 million. We will not be required to effect more than two registrations on Form S-3 within any 12-month period.

### **Anti-Takeover Provisions**

#### ***Certificate of Incorporation and Bylaws to Be in Effect Upon the Completion of this Offering***

Our amended and restated certificate of incorporation and amended and restated bylaws, each to become effective upon the completion of this offering, will include a number of provisions that may deter or impede hostile takeovers or changes of control or management. These provisions include:

- ***Issuance of Undesignated Preferred Stock:*** After the filing of our amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of undesignated preferred stock with rights and preferences, including voting rights, designated from time to time by our board of directors. The existence of authorized but unissued shares of preferred stock enables our board of directors to make it more difficult to attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise.

- **Classified Board:** Our amended and restated certificate of incorporation provides for a classified board of directors consisting of three classes of directors, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. This provision may have the effect of delaying a change in control of our board.
- **Board of Directors Vacancies:** Our amended and restated certificate of incorporation and amended and restated bylaws authorize only our board of directors to fill vacant directorships. In addition, the number of directors constituting our board of directors may be set only by resolution adopted by a majority vote of our entire board of directors. These provisions prevent a stockholder from increasing the size of our board of directors and gaining control of our board of directors by filling the resulting vacancies with its own nominees.
- **Stockholder Action; Special Meetings of Stockholders:** Our amended and restated certificate of incorporation provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. Stockholders will not be permitted to cumulate their votes for the election of directors. Our amended and restated bylaws provide that only the chairman of our board of directors, our chief executive officer, or a majority of our board of directors may call special meetings of our stockholders.
- **Advance Notice Requirements for Stockholder Proposals and Director Nominations:** Our amended and restated bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders, or to nominate candidates for election as directors at our annual meeting of stockholders. Our amended and restated bylaws also specify certain requirements as to the form and content of a stockholder's notice. These provisions may make it more difficult for our stockholders to bring matters before our annual meeting of stockholders or to nominate directors at annual meetings of stockholders.

We designed these provisions to enhance the likelihood of continued stability in the composition of our board of directors and its policies, to discourage certain types of transactions that may involve an actual or threatened acquisition of us and to reduce our vulnerability to an unsolicited acquisition proposal. We also designed these provisions to discourage certain tactics that may be used in proxy fights. However, these provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they may also reduce fluctuations in the market price of our shares that could result from actual or rumored takeover attempts.

Certain provisions in our collaboration agreement with Merck may also deter a change of control. See "Risk Factors—Some provisions of our charter documents, Delaware law and our collaboration 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."

#### **Section 203 of the Delaware General Corporation Law**

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in a business combination with any interested stockholder for a period of three years following the date the person became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested holder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the

corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (a) by persons who are directors and also officers and (b) pursuant to employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 of the DGCL defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 of the DGCL defines an "interested stockholder" as an entity or person who, together with the entity's or person's affiliates and associates, beneficially owns, or is an affiliate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

A Delaware corporation may opt out of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may as a result, discourage or prevent mergers or other takeover or change in control attempts of us.

#### **Choice of Forum**

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty owed by any director, officer or other employee to us or our stockholders; (iii) any action asserting a claim against us or any director or officer or other employee arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or amended and restated bylaws; or (iv) any action asserting a claim against us or any director or officer or other employee that is governed by the internal affairs doctrine. This provision would not apply to 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 further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

**Transfer Agent and Registrar**

Our transfer agent and registrar for our common stock upon the completion of this offering will be American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219.

**The Nasdaq Global Select Market**

Our common stock has been approved for listing on the Nasdaq Global Select Market under the trading symbol "NGM."

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market for our common stock existed, and a liquid trading market for our common stock may not develop or be sustained after this offering. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the anticipation of such sales, could adversely affect prevailing market prices of our common stock from time to time and could impair our ability to raise equity capital in the future. Furthermore, because only a limited number of shares of our common stock will be available for sale shortly after this offering due to certain contractual and legal restrictions on resale described below, sales of substantial amounts of our common stock in the public market after such restrictions lapse, or the anticipation of such sales, could adversely affect the prevailing market price of our common stock and our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of December 31, 2018, upon completion of this offering and the concurrent private placement with Merck, 64,993,706 shares of our common stock will be outstanding.

All of the shares sold in this offering will be freely tradable unless purchased by our affiliates. The remaining 60,872,023 shares of common stock outstanding after this offering will be restricted as a result of securities laws or lock-up agreements as described below. Following the expiration of the lock-up period, all shares will be eligible for resale, subject to compliance with Rule 144 or Rule 701 of the Securities Act, to the extent these shares have been released from any repurchase option that we may hold.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 of the Securities Act.

### Rule 144

In general, under Rule 144 of the Securities Act as in effect on the date of this prospectus, beginning 90 days after the date of this prospectus, any person who is not our affiliate at any time during the preceding three months, and who has beneficially owned their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares of our common stock provided current public information about us is available and, after owning such shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares of our common stock without restriction.

Beginning 90 days after the date of this prospectus, a person who is our affiliate or who was our affiliate at any time during the preceding three months, and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 649,937 shares, or 659,937 shares if the underwriters exercise their option to

purchase additional shares in full, immediately following this offering, based on the number of shares of our common stock outstanding upon completion of this offering; or

- the average weekly trading volume of our common stock on Nasdaq during the four calendar weeks preceding the filing of a Notice of Proposed Sale of Securities pursuant to Rule 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Upon expiration of the 180-day lock-up period described below, 58,432,247 shares of our common stock will be eligible for sale under Rule 144. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

### **Rule 701**

In general, under Rule 701 of the Securities Act, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act, is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

### **Lock-up Agreements**

We, along with our directors and executive officers and the holders of substantially all of our common stock (including shares issuable upon exercise or conversion of existing securities and shares issuable to Merck in the concurrent private placement), have agreed with the underwriters that, for a period of 180 days following the date of this prospectus, we or they will not offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of any shares of our common stock (including, for our directors and officers, any shares issued in this offering or other issuer-directed shares), or any options or warrants to purchase any shares of our common stock, or any securities convertible into, exchangeable for or that represent the right to receive shares of our common stock, whether now owned or later acquired, owned directly or with respect to which we or they have beneficial ownership within the rules and regulations of the SEC, subject to specified exceptions. The underwriters may, in their sole discretion, at any time without prior notice, release all or any portion of the shares from the restrictions in any such agreement.

Merck has also agreed, subject to specified exceptions, during the period of the initial five-year research phase under our collaboration agreement, not to sell any of its shares of our capital stock. See "Our Collaboration with Merck—Detailed Description of the Merck Collaboration—Standstill, Lock-Up and Voting Agreements."

### **Equity Incentive Plans**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issuable under our equity incentive plans. We expect to file the registration statement covering such shares

shortly after the date of this prospectus, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144. For more information on our equity incentive plans, see “Executive and Director Compensation—Equity Incentive Plans.”

### **Registration Rights**

Holders of 54,205,356 shares of our convertible preferred stock and common stock have the right to demand that we file a registration statement or request that we cover their shares by a registration statement that we otherwise file. For more information, see “Description of Capital Stock—Registration Rights.” Except for shares purchased by affiliates, registration of their shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration statement, subject to the expiration of the lock-up period and to the extent these shares have been released from any repurchase option that we may hold.



## **MATERIAL UNITED STATES FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK**

The following is a summary of the material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the acquisition, ownership and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local or foreign tax laws, or any other U.S. federal tax laws. This discussion is based on the Internal Revenue Code of 1986, as amended, or the Code, and applicable Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the Internal Revenue Service, or IRS, all as in effect as of the date hereof. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a particular holder in light of such holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other pass-through entities (and investors therein);
- "controlled foreign corporations";
- "passive foreign investment companies";
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons subject to the alternative minimum tax;
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;
- accrual-method taxpayers subject to special tax accounting rules under Section 451(b) of the Code;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner and the activities of the partnership. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

**THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS. IN ADDITION, SIGNIFICANT CHANGES IN U.S. FEDERAL INCOME TAX LAWS WERE RECENTLY ENACTED. YOU SHOULD ALSO CONSULT WITH YOUR TAX ADVISOR WITH RESPECT TO SUCH CHANGES IN U.S. TAX LAW AS WELL AS POTENTIAL CONFORMING CHANGES IN STATE TAX LAWS.**

#### **Definition of Non-U.S. Holder**

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a “U.S. person” or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

#### **Distributions on Our Common Stock**

As described under the section titled “Dividend Policy,” we have not paid and do not anticipate paying dividends. However, if we make cash or other property distributions on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder’s tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under the section titled “—Gain on Disposition of Our Common Stock” below.

Subject to the discussions below regarding effectively connected income, backup withholding and Sections 1471 through 1474 of the Code (commonly referred to as FATCA), dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our paying agent with a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or applicable successor form) including a U.S. taxpayer identification number and certifying such holder’s qualification for the reduced rate. This certification must be provided to us or our paying agent before the payment of dividends and must be updated periodically. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder’s behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our paying agent, either directly or through other intermediaries.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder's U.S. trade or business (and are attributable to such holder's permanent establishment in the United States if required by an applicable tax treaty), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

Any dividends paid on our common stock that are effectively connected with a non-U.S. holder's U.S. trade or business (and if required by an applicable income tax treaty, are attributable to a permanent establishment maintained by the non-U.S. holder in the United States) generally will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

### **Gain on Disposition of Our Common Stock**

Subject to the discussions below regarding backup withholding and FATCA, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States, and if required by an applicable income tax treaty, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation, or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not regularly traded on an established securities market during the calendar year in which the sale or other disposition occurs.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We believe that we are not currently and do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular graduated U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Gain described in the second bullet point above will be subject to U.S.

federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

### **Information Reporting and Backup Withholding**

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of dividends on our common stock paid to such holder and the amount of any tax withheld with respect to those dividends. These information reporting requirements apply even if no withholding was required because the dividends were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or certain other requirements are met. Backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

### **FATCA Withholding Taxes**

FATCA imposes a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock. While FATCA would also apply to gross proceeds from the sale or other dispositions of our common stock, recently proposed regulations promulgated by the Treasury Department, which state that taxpayers may rely on the proposed regulations until final regulations are issued, eliminate this requirement.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

## UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, Citigroup Global Markets Inc. and Cowen and Company, LLC are the representatives of the underwriters.

<u>Underwriters</u>	<u>Number of Shares</u>
Goldman Sachs & Co. LLC	2,866,667
Citigroup Global Markets Inc.	2,266,667
Cowen and Company, LLC	1,533,333
Total	<u>6,666,667</u>

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 1,000,000 shares of common stock from us. Any shares sold to underwriters pursuant to the option will be sold at the initial public offering price, less underwriting discounts and commissions. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase 1,000,000 additional shares of common stock from us.

<u>Paid by Us</u>	<u>No Exercise</u>	<u>Full Exercise</u>
Per Share	\$ 1.12	\$ 1.12
Total	\$ 7,466,667	\$ 8,586,667

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$0.672 per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

At our request, the underwriters have reserved up to 333,333 shares being offered by this prospectus for sale at the initial public offering price to our directors, officers, employees, business associates and related persons through a directed share program. The number of shares available for sale to the general public will be reduced by the number of directed shares purchased by participants in the program. Any directed shares not purchased will be offered by the underwriters to the general public on the same basis as all other shares offered. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with the sales of the directed shares.

In connection with this offering, we have agreed with the underwriters, subject to certain exceptions, including for the issuance of up to 5% of our outstanding shares of common stock immediately following the closing of this offering and the concurrent private placement to Merck in

connection with acquisitions or strategic transactions provided that any recipient of such shares enter into a lock-up agreement substantially similar to what is described below, not to dispose of or hedge any of our common stock or securities convertible into or exchangeable for shares of common stock for 180 days following the date of this prospectus, except with the prior written consent of the representatives. This agreement also does not apply to any existing employee benefit plans.

In addition, our executive officers and directors and holders of substantially all of our common stock (including shares issuable upon exercise or conversion of existing securities and shares issuable to Merck in the concurrent private placement) have agreed with the underwriters, subject to certain exceptions, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of any shares of our common stock, or any options or warrants to purchase any shares of our common stock, or any securities convertible into, exchangeable for or that represent the right to receive shares of our common stock (including any preferred shares), whether now owned or acquired after entry in the lock-up agreement, owned directly by the party to the lock-up agreement (including holding as a custodian) or with respect to which the party to the lock-up agreement has beneficial ownership within the rules and regulations of the Securities and Exchange Commission (collectively, "lock-up securities"), or to engage in any hedging or other transaction which is designed to or which reasonably could be expected to lead to or result in a sale or disposition of the lock-up securities, for 180 days following the date of this prospectus, except with the prior written consent of the representatives.

The restrictions in the immediately preceding paragraph do not apply to our directors, officers or holders of our outstanding common stock or other securities in certain circumstances, including (i) the transfers not for value of our common stock as bona fide gifts, by will, to an immediate family member or to certain trusts; (ii) to the extent the party to the lock-up agreement is an entity, the transfer of our common stock to affiliates, limited partners, general partners, limited liability company members or stockholders; (iii) transfers of our common stock pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction made to all of our stockholders and involving a change of control of us; (iv) transfer of our common stock to us for the net exercise of options granted pursuant to our equity incentive plans described elsewhere in this prospectus or to cover tax withholding for grants pursuant to our equity incentive plans; (v) shares of our common stock acquired after the date of this offering and, unless the party to the lock-up agreement is one of our directors or officers, sale of shares of our common stock acquired in this offering; (vi) the establishment of a 10b5-1 trading plan under the Exchange Act; and (vii) the conversion of shares of our outstanding convertible preferred stock into shares of our common stock. The exceptions described in (i) through (iii) above are subject to a requirement that the transferee enter into a lockup agreement with the underwriters containing similar restrictions and the exceptions described in (i), (ii) and (iv) through (vi) above are subject to a requirement that no public announcement or filing under Section 16 of the Exchange Act shall be required or voluntarily made during the restricted period.

The representatives, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

Prior to the offering, there has been no public market for the shares. The initial public offering price was negotiated among us and the representatives. Among the factors considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, were our historical performance, estimates of the business potential and our earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

Our common stock has been approved for listing on the Nasdaq Global Select Market under the symbol "NGM".

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In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional shares for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of our common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of our common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Select Market, in the over-the-counter market or otherwise.

The underwriters do not expect sales to discretionary accounts to exceed 5% of the total number of shares offered.

We estimate that our total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$3.5 million. We have agreed to reimburse the underwriters for expenses of up to \$40,000 related to the clearance of this offering with the Financial Industry Regulatory Authority, Inc. and compliance with state securities or "blue sky" laws.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to our assets, securities and/or instruments (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

### **European Economic Area**

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relative Member State") an offer to the public of our common shares may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of our common shares may be made at any time under the following exemptions under the Prospectus Directive:

- To any legal entity which is a qualified investor as defined in the Prospectus Directive;
- To fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), subject to obtaining the prior consent of the Representatives for any such offer; or
- In any other circumstances falling within Article 3(2) of the Prospectus Directive;

provided that no such offer or shares of our common stock shall result in a requirement for the publication by us or any Brazilian placement agent of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer to public" in relation to our common shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and our common shares to be offered so as to enable an investor to decide to purchase our common shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression "Prospectus Directive" means Directive 2003/71/EC (as amended), including by Directive 2010/73/EU and includes any relevant implementing measure in the Relevant Member State.

This European Economic Area selling restriction is in addition to any other selling restrictions set out below.

### **United Kingdom**

In the United Kingdom, this prospectus is only addressed to and directed as qualified investors who are (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the Order); or (ii) high net worth entities and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "relevant persons"). Any investment or investment activity to which this prospectus relates is available only to relevant persons and will only be engaged with relevant persons. Any person who is not a relevant person should not act or rely on this prospectus or any of its contents.



## Canada

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this offering memorandum (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

## Hong Kong

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) ("Companies (Winding Up and Miscellaneous Provisions) Ordinance") or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) ("Securities and Futures Ordinance"), (ii) to "professional investors" as defined in the Securities and Futures Ordinance and any rules made thereunder or (iii) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

## Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA")) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore ("Regulation 32").

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA or (6) as specified in Regulation 32.

### **Japan**

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended), or the FIEA. The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

## LEGAL MATTERS

Cooley LLP is serving as our counsel in this offering. Davis Polk & Wardwell LLP of Menlo Park, California is representing the underwriters in this offering. As of the date of this prospectus, entities comprised of partners and associates of Cooley LLP beneficially own 10,000 shares of our preferred stock, which will be converted into 10,000 shares of common stock in connection with of this offering.

## EXPERTS

The consolidated financial statements of NGM Biopharmaceuticals, Inc. at December 31, 2017 and 2018, and for each of the two years in the period ended December 31, 2018, appearing in this prospectus and registration statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered by this prospectus. This prospectus, which constitutes part of that registration statement, does not contain all of the information set forth in the registration statement or the accompanying exhibits and schedules. Some items included in the registration statement are omitted from this prospectus in accordance with the rules and regulations of the SEC. For further information with respect to us and the common stock offered in this prospectus, we refer you to the registration statement and the accompanying exhibits and schedules. Statements contained in this prospectus regarding the contents of any contract, agreement or any other document are summaries of the material terms of these contracts, agreements or other documents. With respect to each of these contracts, agreements or other documents filed as an exhibit to the registration statement, reference is made to such exhibit for a more complete description of the matter involved.

A copy of the registration statement and the accompanying exhibits and schedules and any other document we file may be inspected without charge and copied at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the SEC's website is <http://www.sec.gov>.

Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act, and we will file periodic reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We maintain a website at <http://www.ngmbio.com>. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports, proxy statements and other information filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Stockholders and the Board of Directors of  
NGM Biopharmaceuticals, Inc.

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of NGM Biopharmaceuticals, Inc. (the Company) as of December 31, 2017 and 2018, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' deficit and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2018, and the results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

***Basis for Opinion***

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2008.

San Francisco, California  
March 25, 2019

**NGM BIOPHARMACEUTICALS, INC.  
CONSOLIDATED BALANCE SHEETS**

(In Thousands, Except Share and Per Share Amounts)

	December 31, 2017	December 31, 2018	Pro Forma Stockholders' Equity (Deficit) as of December 31, 2018 (unaudited) (Note 2)
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 25,593	\$ 56,923	
Short-term marketable securities	148,092	149,710	
Related party receivable from collaboration	—	3,669	
Prepaid expenses and other current assets	1,848	4,255	
Total current assets	175,533	214,557	
Long-term marketable securities	45,150	—	
Property and equipment, net	24,873	23,893	
Restricted cash	2,249	2,249	
Deferred IPO costs	—	2,292	
Other non-current assets	1,136	3,094	
Total assets	<u>\$ 248,941</u>	<u>\$ 246,085</u>	
<b>Liabilities, convertible preferred stock and stockholders' equity (deficit)</b>			
Current liabilities:			
Accounts payable	\$ 1,892	\$ 5,775	
Accrued liabilities	11,686	14,003	
Deferred rent, current	1,957	2,683	
Deferred revenue, current	21,358	19,025	
Total current liabilities	36,893	41,486	
Deferred rent, non-current	14,904	12,221	
Deferred revenue, non-current	22,742	3,942	
Early exercise stock option liability	385	1,559	
Convertible preferred stock warrant liability	121	198	—
Total liabilities	75,045	59,406	
Commitments and Contingencies (Note 7)			
Convertible preferred stock, \$0.001 par value;			
96,268,206 shares authorized at December 31, 2017 and 2018; 47,267,466 shares issued and outstanding at December 31, 2017 and 2018; aggregate liquidation preference of \$277,774 at December 31, 2017 and 2018; no shares issued and outstanding at December 31, 2018, pro forma (unaudited)			
	294,874	294,874	—
Stockholders' deficit:			
Common stock, \$0.001 par value;			
129,000,000 shares authorized at December 31, 2017 and 2018; 6,218,806 and 6,937,890 shares issued and outstanding at December 31, 2017 and 2018, respectively; 54,224,993 shares issued and outstanding at December 31, 2018, pro forma (unaudited)			
	6	7	54
Additional paid-in capital	26,147	39,258	334,283
Accumulated other comprehensive loss	(431)	(267)	(267)
Accumulated deficit	(146,700)	(147,193)	(147,193)
Total equity (deficit)	(120,978)	(108,195)	186,877
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 248,941</u>	<u>\$ 246,085</u>	<u>\$ 186,877</u>

See accompanying notes to the consolidated financial statements.

**NGM BIOPHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

(In Thousands, Except Share and Per Share Amounts)

	Year Ended December 31,	
	2017	2018
Related party revenue	\$ 77,141	\$ 108,665
Operating expenses:		
Research and development	79,736	95,714
General and administrative	14,830	17,265
Total operating expenses	<u>94,566</u>	<u>112,979</u>
Loss from operations	(17,425)	(4,314)
Interest income	2,358	3,622
Other income (expense), net	(152)	199
Net loss before taxes	(15,219)	(493)
Benefit from income taxes	(1,060)	—
Net loss	<u>\$ (14,159)</u>	<u>\$ (493)</u>
Net loss per common share, basic and diluted	<u>\$ (2.37)</u>	<u>\$ (0.08)</u>
Weighted average shares used to compute net loss per common share, basic and diluted	<u>5,961,767</u>	<u>6,383,751</u>
Pro forma net loss per common share, basic and diluted (unaudited)		<u>\$ (0.01)</u>
Weighted average shares used to compute pro forma net loss per common share, basic and diluted (unaudited)		<u>53,651,217</u>

See accompanying notes to the consolidated financial statements.

**NGM BIOPHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

(In Thousands)

	Year Ended December 31,	
	2017	2018
Net loss	\$(14,159)	\$(493)
Other comprehensive gain (loss), net of tax:		
Net unrealized gain (loss) on available-for-sale marketable securities	(329)	164
Total comprehensive loss	<u>\$(14,488)</u>	<u>\$(329)</u>

*See accompanying notes to the consolidated financial statements.*



**NGM BIOPHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT**

(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, 2016	47,267	\$294,874	5,802	\$ 6	\$ 17,575	\$ (102)	\$ (132,541)	\$ (115,062)
Issuance of common stock to participants in 401(k) Matching Plan	—	—	10	—	82	—	—	82
Vesting of common stock from early exercises	—	—	184	—	527	—	—	527
Exercise of stock options	—	—	109	—	339	—	—	339
Stock-based compensation expense	—	—	—	—	7,624	—	—	7,624
Changes in unrealized gain on available-for-sale securities	—	—	—	—	—	(329)	—	(329)
Net loss	—	—	—	—	—	—	(14,159)	(14,159)
Balance at December 31, 2017	47,267	294,874	6,105	6	26,147	(431)	(146,700)	(120,978)
Issuance of common stock to participants in 401(k) Matching Plan	—	—	11	—	91	—	—	91
Vesting of common stock from early exercises	—	—	161	—	764	—	—	764
Exercise of stock options	—	—	479	1	2,582	—	—	2,583
Repurchase of common stock	—	—	(23)	—	(185)	—	—	(185)
Stock-based compensation expense	—	—	—	—	9,859	—	—	9,859
Changes in unrealized gain on available-for-sale securities	—	—	—	—	—	164	—	164
Net loss	—	—	—	—	—	—	(493)	(493)
Balance at December 31, 2018	47,267	\$294,874	6,733	\$ 7	\$ 39,258	\$ (267)	\$ (147,193)	\$ (108,195)

See accompanying notes to the consolidated financial statements.

**NGM BIOPHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In Thousands)

	Year Ended December 31,	
	2017	2018
<b>Cash flows from operating activities</b>		
Net loss	\$ (14,159)	\$ (493)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	6,441	7,223
Amortization of premium (discount) on marketable securities	241	(876)
Stock-based compensation expenses	7,717	9,962
Change in fair value of convertible preferred stock warrant liability	3	77
Other non-cash expenses	82	91
Changes in operating assets and liabilities		
Receivable from related party collaboration	2,769	(3,669)
Prepaid expenses and other assets	(1,103)	(4,365)
Accounts payable	(4,230)	3,484
Accrued expenses and other liabilities	2,603	4,059
Deferred rent	(1,256)	(1,957)
Deferred revenue	(16,521)	(21,133)
Net cash (used in) operating activities	<u>(17,413)</u>	<u>(7,597)</u>
<b>Cash flows from investing activities</b>		
Purchase of marketable securities	(217,291)	(133,609)
Proceeds from maturities of marketable securities	220,917	178,182
Purchase of property and equipment	(6,422)	(5,844)
Net cash (used in) provided by investing activities	<u>(2,796)</u>	<u>38,729</u>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock upon exercise of stock options	339	2,583
Payments of deferred financing costs	—	(2,200)
Repurchase of common stock	—	(185)
Net cash provided by financing activities	<u>339</u>	<u>198</u>
Net (decrease) increase in cash, cash equivalents, and restricted cash	(19,870)	31,330
Cash, cash equivalents, and restricted cash at beginning of period	47,712	27,842
Cash, cash equivalents, and restricted cash <sup>(1)</sup> at end of period	<u>\$ 27,842</u>	<u>\$ 59,172</u>
<b>Supplemental disclosures of cash flow information:</b>		
Income taxes paid	\$ 536	\$ 1
<b>Non-cash investing and financing activities:</b>		
Vesting of common stock from early exercises	\$ 527	\$ 764
Cost of property and equipment in accounts payable and accrued liabilities	208	607
Deferred IPO costs in accounts payable and accrued liabilities	—	92

(1) Includes restricted cash of \$2,249 included in the consolidated balance sheets at December 31, 2017 and 2018

See accompanying notes to the consolidated financial statements.

**NGM BIOPHARMACEUTICALS, INC.  
NOTES TO 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, NGM313, NGM386, NGM395, NGM217, NGM120 and NGM621) focused on non-alcoholic steatohepatitis, or NASH, type 2 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.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation and Principles of Consolidation***

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and include the consolidated accounts of the Company and its subsidiary. During 2012, the Company established a wholly owned foreign subsidiary in Australia. All intercompany balances and transactions have been eliminated in consolidation.

***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 one-for-two 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 consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

***Unaudited Pro Forma Stockholders' Equity and Net Loss per Common Share***

The December 31, 2018 unaudited pro forma stockholders' equity has been prepared assuming upon the closing of the Company's initial public offering (IPO): (1) the automatic conversion of all outstanding shares of convertible preferred stock into shares of common stock and (2) the conversion of the warrant exercisable for convertible preferred stock outstanding as of December 31, 2018 into a warrant exercisable for shares of common stock, resulting in the reclassification of the related convertible preferred stock warrant liability to additional paid-in capital. All warrants for preferred stock will automatically net exercise into 16,380 shares of Series A Preferred stock on February 3, 2019. The

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

unaudited pro forma stockholders' equity does not include the shares expected to be sold and related proceeds to be received from the IPO or from the concurrent private placement of shares to Merck Sharp & Dohme Corp. (Merck). For purposes of the pro forma basic and diluted net loss per common share, all shares of convertible preferred stock have been treated as though they had been converted to common stock in all periods in which such shares were outstanding.

	Year ended December 31, 2018 (unaudited)
Net loss	\$ (493)
Shares used in computing net loss per share—basic and diluted	6,383,751
Pro forma adjustment to reflect assumed conversion of convertible preferred stock	47,267,466
Shares used to compute pro forma net loss per share—basic and diluted	53,651,217
Pro forma net loss per share—basic and diluted	\$ (0.01)

**Use of Estimates**

The preparation of 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 and clinical trial accruals. 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 years ended December 31, 2017 and 2018, the Company incurred a net loss of \$14.2 million and \$0.5 million, respectively. At December 31, 2018, the Company had an accumulated deficit of \$147.2 million and does not expect to experience positive cash flows from operations in the near future. The Company had \$206.6 million of cash, cash equivalents and marketable securities at December 31, 2018. Based on the Company's business plan, management believes this is sufficient to meet its obligations for at least the next twelve months from the issuance date of these consolidated financial statements.

**Deferred Initial Public Offering Costs**

Costs incurred in connection with the initial public offering primarily consist of direct incremental legal, printing and accounting fees. Initial public offering costs are capitalized as incurred and will be offset against proceeds upon consummation of this offering. In the event the offering is terminated or abandoned, deferred initial public offering costs will be expensed in the period such determination has been made. As of December 31, 2018 there was \$2.3 million of deferred initial public offering costs included in other long-term assets on the accompanying consolidated balance sheets. The Company did not incur any initial public offering costs in 2017.

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

***Fair Value of Financial Instruments***

The carrying amounts of cash and cash equivalents, receivables from collaborations, the related party receivable 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 consolidated financial statements.

***Cash and Cash Equivalents***

Cash and cash equivalents are stated at fair value. Cash equivalents relate 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 December 31, 2017 and 2018, cash and cash equivalents consisted of bank deposits and investments in money market funds.

***Marketable Securities***

The Company determines the appropriate classification of its marketable securities at the time of purchase and re-evaluates such designation 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' 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 regularly reviews all of its investments 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***

As of December 31, 2017 and 2018, the Company had \$2.3 million of restricted cash classified as a non-current asset. The restricted cash serves as collateral for a facility lease entered into in 2015 (Note 7). Restricted cash is classified as current if the collateral will be returned in less than 12 months.

***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 invests in money market funds and marketable securities through custodial relationships with

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

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. The Company is not exposed to any significant concentrations of credit risk from these financial instruments.

Receivables and related party receivables from collaborations (Note 6) are typically unsecured. Accordingly, the Company may be exposed to credit risk generally associated with its current collaboration agreement with Merck and any future collaboration agreements with other collaboration partners. To date, the Company has not experienced any losses related to these receivables.

Merck accounted for 100% of the Company's revenue for the years ended December 31, 2017 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 December 31, 2017 and 2018 and during the twelve months then ended, 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

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

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 are classified as a liability on the consolidated balance sheets. The convertible preferred stock warrants are recorded as a liability because the underlying shares of convertible preferred stock are contingently redeemable, which, therefore, may obligate the Company to transfer assets at some point in the future to settle these warrants. As a result, the warrants are subject to remeasurement at each balance sheet date, with changes in estimated fair value recognized as a component of total other income (expense), net in the Company's consolidated statements of operations. The Company will continue to adjust the liability for changes in estimated fair value until the earlier of exercise or automatic exercise of the warrant upon the completion of a liquidation event or end of the warrant term.

***Revenue Recognition***

All of the Company's revenue to date has been generated from its collaboration agreements. Revenue from collaboration agreements 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. Revenue from research activities earned under collaboration arrangements are recognized when there is persuasive evidence that an arrangement exists, services have been rendered, the price is fixed or determinable and collectability is reasonably assured. Revenue generated from the Company's collaboration arrangements is not subject to repayment. The Company's obligations under collaboration agreements may include the transfer of intellectual property rights in the form of licenses, obligations to provide research and development services and obligations to participate on certain development committees with the collaboration party. The Company makes judgments that affect the period over which the Company recognizes revenue. At each reporting period, the Company reviews its estimated period of performance for its collaboration and license revenue based on the progress under the arrangement and accounts for the impact of any changes in estimated periods of performance on a prospective basis. The Company records amounts received prior to satisfying the above revenue recognition criteria as deferred revenue until all applicable revenue recognition criteria are met. Deferred revenue represents the portion of research or license payments received that have not been earned.

For revenue agreements with multiple-element arrangements, such as license and development agreements, the Company allocates revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, the Company determines the selling price for each deliverable using vendor-specific objective evidence or third-party evidence. If neither exists, the Company uses the best estimate of selling price for that deliverable. Revenue allocated is then recognized when all of the following criteria are met: persuasive evidence of an arrangement exists; transfer of technology has been completed or services have been rendered; the price to the customer is fixed or determinable and collectability is reasonably assured.

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

Payments that are contingent upon the achievement of a substantive milestone are recognized entirely as revenue in the period in which the milestone is achieved. A milestone is defined as an event: (a) that can only be achieved based in whole or in part on either (1) the Company's performance or (2) on the occurrence of a specific outcome resulting from the Company's performance; (b) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved; and (c) that would result in additional payments being due to the entity. A milestone is considered substantive if the consideration earned from the achievement of the milestone meets all of the following criteria: (a) the consideration is commensurate with either (1) the Company's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone; (b) the consideration relates solely to past performance; and (c) the consideration is reasonable relative to all of the deliverables and payment terms (including other potential milestone consideration) within the arrangement. To the extent that non-substantive milestones are achieved and the Company has remaining performance obligations, payments in respect of such milestones are deferred and recognized as revenue over the estimated remaining period of performance. If there were no remaining performance obligations, the Company would recognize the revenue in the period it is earned.

Payments related to options to license the Company's program candidates are considered substantive if, at the inception of the arrangement, the Company is at risk as to whether the collaboration partner will choose to exercise the option. Factors that the Company considers in evaluating whether an option is substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the arrangement without exercising the option, the cost to exercise the option and the likelihood that the option will be exercised. For arrangements under which an option is considered substantive, the Company does not consider the item underlying the option to be a deliverable at the inception of the arrangement and the associated option fees are not included in allocable arrangement consideration, assuming the option is not priced at a significant and incremental discount. Conversely, for arrangements under which an option is not considered substantive or if an option is priced at a significant and incremental discount, the Company would consider the item underlying the option to be a deliverable at the inception of the arrangement and a corresponding amount would be included in allocable arrangement consideration.

Revenue related to research collaboration services and grants are recognized as research costs are incurred and/or the underlying services are performed over the term as specified in the related agreements.

***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



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Company uses information it receives from internal personnel and outside service providers to estimate the clinical trial costs incurred.

***Stock-Based Compensation***

The Company values stock-based payments to employees on the grant date of each award and recognizes the estimated fair value of such awards 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. Stock-based payments to consultants are subject to periodic remeasurement over their vesting terms. Stock-based payments are valued using the Black-Scholes option-pricing model. Because 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). During the years ended December 31, 2017 and 2018, the Company recorded a foreign exchange remeasurement loss of \$0.1 million and gain of \$0.2 million, respectively.

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 to other income (expense), net on the consolidated statements of operations. During the years ended December 31, 2017 and 2018, the Company recorded a foreign exchange transaction gain of \$37,000 and loss of \$31,000, respectively.

***Comprehensive Loss***

Comprehensive loss is comprised of net loss and certain changes in equity that are excluded from net loss. For the years ended December 31, 2017 and 2018, the difference between comprehensive loss and net loss consisted of changes in net unrealized loss on marketable securities of \$0.3 million, and changes in net unrealized gain on marketable securities of \$0.2 million, 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 years ended December 31, 2017 and 2018, all potential common shares were determined to be anti-dilutive.

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

	Year Ended December 31,	
	2017	2018
Numerator:		
Net loss	\$ (14,159)	\$ (493)
Denominator:		
Weighted-average number of common shares used in calculating net income per share— basic and diluted	5,961,767	6,383,751
Net loss per share—basic and diluted	\$ (2.37)	\$ (0.08)

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

	Year Ended December 31,	
	2017	2018
Convertible preferred stock	47,267,466	47,267,466
Options to purchase common stock	8,468,702	9,806,689
Warrants to purchase convertible preferred stock	19,637	19,637
Total	55,755,805	57,093,792

### **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 years ended December 31, 2017 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 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 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 November 2015, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2015-17, *Income Taxes (Topic 740)—Balance Sheet Classification of Deferred Taxes* (ASU 2015-17). This ASU simplifies the presentation of deferred income taxes by requiring non-current classification in a classified statement of financial position. ASU 2015-17 is

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effective for financial statements issued for fiscal years beginning after December 15, 2017. ASU 2015-17 may be either applied prospectively to all deferred tax assets and liabilities or retrospectively to all periods presented. The Company adopted ASU 2015-17 as of December 31, 2017; however, there was no impact on the Company's consolidated financial statements as a result of adopting ASU 2015-17.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation—Stock Compensation (Topic 718)—Improvements to Employee Share Based Payment Accounting* as part of the FASB simplification initiative. The new standard provides for changes to accounting for stock compensation including 1) excess tax benefits and tax deficiencies related to share based payment awards will be recognized as income tax expense in the reporting period in which they occur; 2) excess tax benefits will be classified as an operating activity in the statement of cash flows; 3) the option to elect to estimate forfeitures or account for them when they occur; and 4) increase tax withholding requirements threshold to qualify for equity classification. The Company adopted ASU 2016-09 as of January 1, 2018 and recorded a \$5.2 million increase to net operating loss deferred tax asset and a corresponding \$5.2 million increase in valuation allowance.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope Modification Accounting*. ASU 2017-09 defines which changes to the terms or conditions of a share-based payment award require the Company to apply modification accounting. The Company adopted ASU 2017-09 on January 1, 2018; however, there was no impact on the Company's consolidated financial statements as a result of adopting ASU 2017-09.

In November 2016, the FASB issued ASU No. 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 consolidated statements of cash flows due to there being no changes in the Company's restricted cash balances for any of the years presented.

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

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which supersedes the revenue recognition requirements in Accounting Standards Codification (ASC) 605, Revenue Recognition. This ASU is based on the principle that revenue is recognized to depict 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 ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The ASU's effective date will be for annual reporting periods beginning after December 15, 2018 and interim periods beginning after December 15, 2019 using one of two retrospective application methods. The Company has engaged outside advisors to assist in analyzing its research collaboration, product development and license agreement with Merck to determine the differences in the accounting treatment under ASU 2014-09 compared to the current accounting treatment. The consideration the Company is

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eligible to receive under this agreement includes upfront payments, research and development funding, option payments, milestone payments, and royalties. The new revenue recognition standard differs from the current accounting standard in many respects, such as in the accounting for variable consideration and the measurement of progress toward completion of performance obligations. The company currently anticipates adopting the new standard effective January 1, 2019 under the modified retrospective method.

In February 2016, the FASB issued ASU No. 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 consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU No. 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 to acquire goods and services from non-employees. This ASU will be effective for the Company for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020, with early adoption permitted. The Company is currently assessing the timing of adoption and the impact that the adoption of ASU 2018-07 will have on its consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU No. 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 consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606

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when then collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in Topic 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. This ASU adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 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 Topic 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 Topic 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 consolidated financial statements.

In June 2016, the FASB issued ASU No. 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 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 consolidated financial statements.

The FASB 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.

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To date, the Company has not recorded any impairment charges on marketable securities related to 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 equivalents and marketable securities, all of which are classified as available-for-sale securities consisted of the following (in thousands):

	At December 31, 2017			Fair Value
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	
Money market funds	\$ 18,263	\$ —	\$ —	\$ 18,263
Corporate and agency bonds	93,025	—	(301)	92,724
Commercial paper	34,393	—	—	34,393
U.S. government agencies securities	66,256	—	(131)	66,125
Total	<u>\$ 211,937</u>	<u>\$ —</u>	<u>\$ (432)</u>	<u>\$ 211,505</u>
Classified as:				
Cash and cash equivalents				\$ 18,263
Short-term marketable securities				148,092
Long-term marketable securities				45,150
Total cash equivalents and marketable securities				<u>\$ 211,505</u>

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	At December 31, 2018			Fair Value
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	
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	<u>\$184,961</u>	<u>\$ —</u>	<u>\$ (267)</u>	<u>\$184,694</u>
Classified as:				
Cash and cash equivalents				\$ 34,984
Short-term marketable securities				149,710
Long-term marketable securities				—
Total cash equivalents and marketable securities				<u>\$184,694</u>

Cash and cash equivalents in the table above excludes cash on deposit with banks of \$7.3 million as of December 31, 2017 and \$21.9 million as of December 31, 2018.

As of December 31, 2017 and 2018, the Company's marketable securities had the following remaining contractual maturities (in thousands):

	At December 31, 2017	
	Amortized Cost	Fair Value
Less than one year	\$ 148,280	\$148,092
Greater than one year but less than five years	45,394	45,150
Total	<u>\$ 193,674</u>	<u>\$193,242</u>

	At December 31, 2018	
	Amortized Cost	Fair Value
Less than one year	\$ 149,976	\$149,710
Greater than one year but less than five years	—	—
Total	<u>\$ 149,976</u>	<u>\$149,710</u>

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**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 December 31, 2017 and 2018 (in thousands):

	Fair Value Measurements at December 31, 2017			
	Total	Level 1	Level 2	Level 3
<b>Assets</b>				
Money market funds	\$ 18,263	\$18,263	\$ —	\$ —
Corporate and agency bonds	92,724	—	92,724	—
Commercial paper	34,393	—	34,393	—
U.S. government agencies securities	66,125	—	66,125	—
	<u>\$211,505</u>	<u>\$18,263</u>	<u>\$193,242</u>	<u>\$ —</u>
<b>Liabilities</b>				
Convertible preferred stock warrant liability	\$ 121	\$ —	\$ —	\$ 121
	<u>\$ 121</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 121</u>

	Fair Value Measurements at December 31, 2018			
	Total	Level 1	Level 2	Level 3
<b>Assets</b>				
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	—
	<u>\$184,694</u>	<u>\$34,983</u>	<u>\$149,711</u>	<u>\$ —</u>
<b>Liabilities</b>				
Convertible preferred stock warrant liability	\$ 198	\$ —	\$ —	\$ 198
	<u>\$ 198</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 198</u>

There were no transfers of assets or liabilities between the fair value measurement levels during the years ended December 31, 2017 and 2018.

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

<b>Fair Value Using Level 3 Inputs</b>	<b>Amounts</b>
Balance at December 31, 2016	\$ 118
Change in fair value of warrant liability included in other income (expense), net	3
Balance at December 31, 2017	121
Change in fair value of warrant liability included in other income (expense), net	77
Balance at December 31, 2018	<u>\$ 198</u>

The original estimated fair value of the convertible preferred stock warrants of approximately \$28,000, issued in February 2009 in conjunction with entering into a loan and security agreement with



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a lender, was measured upon issuance using the Black-Scholes option-pricing model. The Company recorded other expense of \$3,000 and \$77,000 for the change in estimated fair value of the warrant liabilities for the years ended December 31, 2017 and 2018, respectively. The inputs used in the determination of the fair value of the warrants as of December 31, 2018 used an estimated fair value per share of the Company's common stock fair value per share, one month for the expected term of the warrant, 64.99% for the stock value volatility using publicly traded peer company volatility as a basis, and 2.44% for the risk-free interest rate on U.S. Treasury securities at 1-month constant maturity.

#### 4. Balance Sheet Components

##### *Property and Equipment*

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

	<u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
Computer equipment	\$ 911	\$ 1,123
Laboratory equipment and office furniture	16,715	18,977
Leasehold improvements	22,300	25,314
Construction in process	127	679
	<u>40,053</u>	<u>46,093</u>
Less accumulated depreciation and amortization	(15,180)	(22,200)
Total property and equipment, net	<u>\$ 24,873</u>	<u>\$ 23,893</u>

Depreciation expense was approximately \$6.4 million and \$7.2 million for the years ended December 31, 2017 and 2018, respectively.

##### *Accrued Liabilities*

Accrued liabilities consist of the following (in thousands):

	<u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
Accrued expenses	\$ 3,569	\$ 2,595
Clinical trials and research and development costs	3,239	4,844
Personnel-related costs	3,784	4,148
Manufacturing costs	1,094	2,416
Total accrued liabilities	<u>\$11,686</u>	<u>\$14,003</u>

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## 5. Research Collaboration and License Agreements

### Summary of Collaboration Revenue

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

	Year Ended December 31,	
	2017	2018
Related party revenue		
Recognition of upfront fee	\$18,800	\$ 18,800
License revenue	—	20,000
Collaboration service revenue	58,341	69,865
Total related party revenue	<u>\$77,141</u>	<u>\$108,665</u>

### JDRF

In September 2011, the Company entered into a Research, Development and Commercialization Agreement with JDRF International, or JDRF, to conduct a research program to discover potential therapeutics for the treatment of diabetes. Under the terms of the agreement, the Company was eligible to receive research funding of up to \$1.8 million. This research funding has been recognized in the service period in which it was earned. During the years ended December 31, 2017 and 2018 the Company did not recognize any revenue from this agreement.

### Merck

In February 2015, the Company entered into a research collaboration, product development and license agreement with Merck, covering the discovery, development and commercialization of novel therapies across a range of therapeutic areas (Merck Collaboration Agreement). The collaboration includes an exclusive worldwide license to the GDF15 program, comprising NGM386 and NGM395 and other GDF15 analogs. These compounds are being evaluated for the treatment of obesity. The collaboration also includes a broad, multi-year drug discovery and early development program financially supported by Merck but scientifically directed by the Company with input from Merck. For those compounds resulting from the research and development program that progress through human proof-of-concept studies, Merck has an exclusive option, at a cost of \$20.0 million for each compound, to obtain an exclusive, worldwide license. If Merck exercises its option with respect to such a compound, 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 its 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 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 or, if unsuccessful, 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 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.

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**Research and Early Development Program.** Pursuant to the collaboration agreement, 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 studies, 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. Under the agreement, Merck reimburses the internal and external costs of the Company's research and early development activities (research phase) in an amount up to \$50.0 million per year, based on an estimated annual budget. If the Company exceeds this budget in a particular year, and if the program is such that the Company is performing IND-enabling studies at that time, Merck is required to elect either to reimburse up to an additional \$25.0 million for use in funding IND-enabling or later-staged activities or will provide the Company with the equivalent value in in-kind services for preclinical and clinical development activities.

Merck has the option to extend the initial five-year research phase for two additional two-year consecutive periods by paying a fee for each extension. Exercising the option for the first of the two-year periods is required to be communicated by Merck to the Company by March 17, 2019. The level of research funding during the research phase extensions will be negotiated at the time of the extension, subject to certain minimum and maximum funding limits based on a percentage of the then-existing funding. At the end of any 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 (tail period), by agreeing to pay all of the Company's internal and external costs, or to take over such selected programs and conduct such research and development activities itself, at its own cost.

**Merck Option to License the Company's Programs.** 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 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 license option, Merck will be responsible, at its own cost, for any further development and commercialization activities for compounds within that Optioned Program, subject to the Company's options to cost and profit share worldwide and to co-detail those compounds in the United States, as further described below. If Merck does not exercise its license option with respect to a particular compound within a limited period of time, the Company will retain all rights to research, develop and commercialize that compound and its related molecules on a worldwide basis at the Company's expense, either alone or in partnership with a third party, subject to the payment to Merck of low single digit percentage royalties on any commercial sales of any resulting products.

**Company Option to Elect Cost and Profit Share and Merck Financial Assistance.** If Merck exercises its license option, then, at the point where it has advanced the licensed compound to its first Phase 3 clinical study, the Company has the option for a limited period of time to share up to 50% of the costs and profits with Merck on that compound (NGM Optioned Products). As part of the Company's election to exercise the option to cost and profit share, the Company will also select the percentage share, up to 50%, that it desires to fund of the total global costs of developing and, if approved, commercializing that NGM Optioned Product. The percentage of any profits the Company will receive from sales of the NGM Optioned Product will be the same as the percentage share the Company elects to contribute to the total global costs of developing the product. The Company's right

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to participate in cost and profit sharing for each of the compounds that Merck licenses is subject to the following limitation: if, at the point in time when the Company is able to exercise its option for a licensed compound, the actual costs the Company has incurred across all NGM Optioned Products, plus the prospective costs allocated to the Company across all NGM Optioned Products, plus the costs the Company is electing to incur if it exercises its option for the compound, reaches \$1.0 billion (if the research phase ends in 2020), \$1.4 billion (if the research phase is extended to 2022), or \$1.8 billion (if the research phase is extended to 2024), then the Company will not be able to exercise its options on any further licensed compounds that Merck takes forward.

Pursuant to the collaboration agreement, at the Company's election to cost and profit share on a NGM Optioned Product, Merck will advance to the Company a specified portion of the expected global costs for that NGM Optioned Product. These advances are subject to an aggregate cap across all NGM Optioned Products over the term of the collaboration.

**Co-Detailing Rights in the United States.** For each NGM Optioned Product, the Company also has the option to participate in a portion of the commercial promotion (co-detailing) to provide up to 25% of the total requisite details in the United States of the NGM Optioned Product by fielding its own commercial sales force. The Company will be required to make this election prior to receiving regulatory approval in the U.S. for the NGM Optioned Product. The specifics of the participation in co-detailing will be determined by the parties according to guidelines set out in the collaboration agreement. If the Company elects to co-detail with Merck, the Company's costs are included in the overall shared commercialization costs, but it will not share in any greater portion of the profits than it otherwise would be entitled to for that NGM Optioned Product.

**Small Molecule Research and Development.** 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.

**Upfront payment; Series E Convertible Preferred Stock Purchase Agreement, Extension of Research Phases(s) and Private Placement.** Under the terms of the collaboration agreement, the Company received an upfront payment of \$94.0 million. In addition, Merck entered into a stock purchase agreement 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 \$105.9 million. In April 2015, the Company received the \$94.0 million upfront payment.

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In connection with the Series E convertible preferred stock purchase agreement, the Company entered into a Side Letter Agreement whereby Merck has the irrevocable option to purchase or, if it does not, the Company has the irrevocable option to require Merck to purchase an additional amount of the Company's common stock pursuant to a private placement conducted in parallel with its IPO, up to a limit of the number of shares that will result in Merck owning approximately 19.9% of the Company's outstanding shares, at the same price per share as offered to the public. If Merck elects to extend the research phase of the collaboration until March 17, 2022, it has the option to purchase an additional \$5.0 million of the Company's common stock at a price per share equal to the last closing price of the Company's shares on the date it notifies the Company of its desire to exercise such option and, if Merck elects again to extend the research phase to March 17, 2024, it has an option to purchase another \$5.0 million of the Company's common stock on the same terms; with both options subject to an overall cap on Merck's ownership interest of 19.9%. Merck did not exercise a similar option in connection with its extension of the collaboration through 2022 in March 2019.

**Standstill, Lock-Up and Voting Agreements.** The Side Letter Agreement also includes standstill provisions providing that for the period ending on the earlier of the end of the initial five-year research term, the announcement of the Company's intent to consummate a change in control transaction (subject to certain exceptions) or the termination of the collaboration agreement, neither Merck nor its representatives will, directly or indirectly, among other things: (i) acquire any of the Company's securities to the extent it would result in Merck owning more than 19.9% of the Company's shares, (ii) solicit proxies for the Company's securities or (iii) participate in a business combination involving the Company, take any action that might result in the Company having to make a public announcement about (i) or (ii) or seek to influence the Company's management or policies, except that Merck is not precluded from making confidential, non-public proposals to the Company or third parties with the Company's express consent. In addition, during the period that ends on the earlier of the end of the initial five-year research term, the announcement of the Company's intent to consummate a change in control transaction 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 the Company's board of directors. Merck has also agreed, subject to specified exceptions and 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 identified several significant deliverables under the agreement, including the license and know-how to the GDF15 program, the license to a Small Molecule Program and research and development services to be performed by the Company on behalf of Merck, including research and early development activities up through human proof of concept. The Company concluded that the license to the GDF15 program and the license for the Small Molecule Program do not have stand-alone value to Merck apart from the related research and development services deliverables as there are no other vendors selling similar, competing products on a stand-alone basis and Merck is unable to use the license for its intended purpose without the Company's performance of research and development services. Accordingly, the Company has accounted for the deliverables as one unit of accounting. As such, a total of \$94.0 million of revenue is being recognized on a straight-line basis over the period over which the Company expects to fulfill its performance obligations (the performance period), which was determined to be five years. The Company evaluates the performance period at each reporting period.

The Company is also eligible to receive additional payments specific to Merck opting into an Optioned Program. Except for the GDF15 program, each Optioned Program is eligible to receive a

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one-time payment of \$20.0 million upon Merck's exercise of its one-time option to obtain an exclusive, worldwide license for a licensed compound following the completion of a human proof-of-concept study. In addition, if the Company does not opt in to 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):

	<u>First Indication</u>	<u>Second Indication</u>	<u>Third Indication</u>
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):

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

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.

The Company has concluded that certain research, clinical development and regulatory milestones that may be received under the Merck Collaboration Agreement, if the Company is involved in future product research, development and commercialization, are substantive. Factors considered in the evaluation of the milestones included the degree of risk associated with performance of the milestone, the level of effort and investment required, whether the milestone consideration was reasonable relative to the deliverables, whether there are substantive uncertainties at the date the arrangement was entered into that the milestone will be achieved, whether the products and services are priced at a significant and incremental discount, whether the consideration relates solely to past performance and whether the milestone was earned at least in part based on the Company's performance. Revenues from substantive milestones, if they are non-refundable, are recognized as revenue upon successful accomplishment of the milestones. Research, clinical and regulatory milestones are deemed non-substantive if they are based solely on the collaborator's performance. Non-substantive milestones will be recognized when achieved to the extent the Company has no remaining performance obligations under the arrangement. Milestone payments earned upon achievement of commercial milestone events will be recognized when earned. In November 2018, Merck exercised its option to license NGM313 and, in December 2018, paid the Company \$20.0 million.

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**6. Related Party Transactions**

Revenues from related parties refer to the collaboration agreement with Merck. The Company recognized related party revenue of \$77.1 million and \$108.7 million for the years ended December 31, 2017 and 2018, respectively. As of December 31, 2017, the Company had deferred revenue from related party collaboration agreements of \$44.1 million, comprised of \$41.5 million of amortized upfront payments and \$2.6 million relating to advance payments for research and development activities. As of December 31, 2018, the Company had deferred revenue from related party collaboration agreements of \$23.0 million, comprised of \$22.7 million of unamortized upfront payments and \$0.3 million relating to advance payments for research and development activities.

**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 June 2015, the Company entered into an operating lease for additional office space for its corporate office at 600 Gateway Blvd, in South San Francisco, California (600 Gateway) for approximately 7,900 square feet that expired in November 2016.

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 lease agreement requires a letter of credit in the amount of \$2.3 million as a security deposit to the lease, which the Company has recorded as long-term restricted cash. The Company has the right to reduce the letter of credit amount by \$0.4 million on each the 3rd anniversary and 4th anniversary of rent commencement date, respectively.

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 December 31, 2018 because of 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 December 31, 2017 and 2018, the remaining lease payment obligations that are due for 630 Gateway were approximately \$5.7 million and \$3.9 million, respectively, of which are to be paid directly from Merck to the lessor in their entirety.

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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 \$2.2 million for the years ended December 31, 2017 and 2018, respectively.

Future minimum payments under the unassigned lease obligations described above are as follows as of December 31, 2018 (in thousands):

Year Ended December 31:	
2019	4,849
2020	4,995
2021	5,141
2022 and thereafter	10,749
Total	<u>\$25,734</u>

### ***Indemnification***

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

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

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

## **8. Convertible Preferred Stock**

### ***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 for its shares within the 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.



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Convertible preferred stock at December 31, 2017 and 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
	<u>48,134</u>	<u>47,267</u>		<u>\$ 277,774</u>	<u>\$ 294,874</u>

**Amended and Restated Certificate of Incorporation**

In March 2015, the Company amended and restated its certificate of incorporation in conjunction with the Series E convertible preferred stock offering. The significant rights and obligations of the Company's convertible preferred stock as of December 31, 2017 are 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 is convertible at the option of the holder into the number of fully paid and non-assessable shares of common stock that result from dividing the original issue price by the conversion price of the convertible preferred stock. The conversion ratio for each series of convertible preferred stock is 1:1.

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Conversion of each series of convertible preferred stock into common stock is automatic upon the earlier of: (a) the closing of an initial public offering of the Company's common stock, registered under the Securities Act of 1933, which results in aggregate proceeds equal to or exceeding \$30.0 million to the Company; or (b) at any time upon the affirmative election of the holders.

### 9. Convertible Preferred Stock Warrant

During 2009, the Company entered into a \$1.7 million loan and security agreement with one lender. On June 29, 2010, the Company paid off the loan. In conjunction with the debt facility, the Company issued to the lender a warrant to acquire a total of 19,637 shares of Series A convertible preferred stock exercisable at \$2.00 per share and that automatically net exercises to Series A preferred stock on February 3, 2019. The warrant was valued at approximately \$1.44 per share, as calculated using the Black-Scholes option-pricing model using a Series A preferred stock estimated fair value of \$2.00 per share, a volatility of 60%, a risk-free interest rate of 3.59%, an expected life of ten years and no dividends. The estimated warrant fair value was initially calculated as approximately \$28,000 and was recorded as a discount to the debt. At each subsequent reporting date, the estimated fair value of the warrant is remeasured (Note 3) to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants, or the completion of a deemed liquidation event. At that time, the convertible preferred stock warrant liability will be reclassified to convertible preferred stock or additional paid-in-capital, as applicable.

### 10. Stockholders' Deficit

#### Common Stock

As of December 31, 2017 and 2018, the Company had 6,218,806 and 6,937,890 shares of common stock outstanding, respectively, which includes shares subject to repurchase of 113,827 and 205,108, respectively, as a result of early exercise of stock options not yet vested. As of December 31, 2017 and 2018, the Company reserved shares of common stock, on an as-if-converted basis, for issuance as follows:

	December 31,	
	2017	2018
Conversion of convertible preferred stock	47,267,466	47,267,466
Common stock options outstanding	8,354,874	9,806,689
Common stock options available for grant	612,604	2,125,875
Warrant to purchase convertible preferred stock	19,637	19,637
401(k) Matching Plan	47,975	36,751
Total	<u>56,302,556</u>	<u>59,256,418</u>

#### 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

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December 31, 2018, 12,681,305 shares of common stock have 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 determined the fair value of common stock using valuations prepared by an unrelated third-party valuation firm. 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:

	Options Available for Grant	Outstanding Options		Weighted Average Remaining Contractual Life (in Years)	Aggregate Intrinsic Value (in thousands)
		Number of Options	Weighted Average Exercise Price		
Balances at December 31, 2016	2,209,595	6,873,061	\$ 4.08	7.16	\$ 75,895
Options granted	(1,888,625)	1,888,625	7.70		
Options exercised	—	(117,398)	3.62		
Options cancelled	289,414	(289,414)	6.84		
Options repurchased	2,220	—	3.72		
Balances at December 31, 2017	612,604	8,354,874	\$ 4.82	6.79	\$ 89,094
Additional shares reserved	3,695,698	—			
Options granted	(2,781,900)	2,781,900	9.34		
Options exercised	—	(730,956)	6.18		
Options cancelled	599,129	(599,129)	7.00		
Options repurchased	344	—	6.02		
Balances at December 31, 2018	<u>2,125,875</u>	<u>9,806,689</u>	<u>\$ 5.86</u>	<u>6.62</u>	<u>\$ 105,226</u>
Vested and expected to vest at December 31, 2018		<u>9,454,737</u>	<u>\$ 5.76</u>	<u>6.54</u>	<u>\$ 101,547</u>
Outstanding and exercisable as of December 31, 2018		<u>9,806,689</u>	<u>\$ 5.86</u>	<u>6.62</u>	<u>\$ 105,226</u>

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 years ended December 31, 2017 and 2018 was \$7.70 and \$9.34 per share, respectively. The intrinsic value of stock

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options exercised was \$0.5 million and \$1.9 million for the years ended December 31, 2017 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 years ended December 31, 2017 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.

At December 31, 2017 there were 113,827 shares of common stock outstanding, subject to the Company's right of repurchase at prices ranging from \$2.16 to \$7.64 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. At December 31, 2017 and 2018, the Company recorded \$0.4 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 years ended December 31, 2017 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 years ended December 31, 2017 and 2018, which was allocated as follows (in thousands):

	Year Ended December 31,	
	2017	2018
Research and development	\$4,473	\$5,232
General and administrative	2,994	4,524
	<u>\$7,467</u>	<u>\$9,756</u>

#### *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.

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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:

	Year Ended December 31,	
	2017	2018
Risk-free interest rate	1.73%	2.59%
Expected term of options (in years)	6.25	5.98
Expected stock price volatility	75.48%	64.60%
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.

As of December 31, 2018, there was approximately \$16.7 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 2.79 years.

#### **Stock Options Granted to Non-employees**

The Company grants stock options to non-employees in exchange for services performed for the Company. During the years ended December 31, 2017 and 2018, the Company did not grant any options to purchase shares of common stock to non-employees. The following table summarizes stock-based compensation expense related to stock-based payment awards to non-employees for the years ended December 31, 2017 and 2018, which was allocated as follows (in thousands):

	Year Ended December 31,	
	2017	2018
Research and development	\$250	\$103
General and administrative	—	—
	<u>\$250</u>	<u>\$103</u>

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

	Year Ended December 31,	
	2017	2018
Risk-free interest rate	2.48%	—
Term of options (in years)	6.95	—
Expected stock price volatility	64.93%	—
Expected Dividends	—	—

In general, the options vest over the contractual periods of the respective non-employee arrangement. The Company revalues the options each reporting period and, accordingly, adjusts the compensation expense related to these options over the remaining vesting periods. As of December 31, 2017 and 2018, non-employee stock options to purchase 31,876 and 16,042 shares, respectively, remain unvested. There were no options granted to non-employees during the year ended December 31, 2018.

## **11. Income Taxes**

### ***Tax Cuts and Jobs Act of 2017***

In December 2017, the 2017 Tax Cuts and Jobs Act (the "2017 Tax Act") was enacted and includes a broad range of provisions, many of which differ significantly from those contained in previous U.S. tax law. The Company accounts for changes in tax law in accordance with ASC 740 which requires companies to recognize the effect of such changes in the period of enactment. However, the SEC staff issued Staff Accounting Bulletin 118 which will allow companies to record provisional amounts during a measurement period that is similar to the measurement period used when accounting for business combinations. Accordingly, the Company adjusted its deferred taxes and related valuation allowances on a provisional basis to reflect the reduction in U.S. federal corporate tax rate from 35% to 21%, based on current understanding of the new law. As of December 31, 2018, the Company has completed its analysis of the income effects of the 2017 Tax Act. There was no material impact on the Company's consolidated financial statements as a result of the analysis.

### ***Income Taxes***

The benefit from income taxes was \$1.0 million for the year ended December 31, 2017, related to the receivable for refund of Company's AMT carryovers. There was no provision or benefit for the year ended December 31, 2018.

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The components of the Company's losses before income taxes were as follows (in thousands):

	Year Ended December 31,	
	2017	2018
Domestic	\$ (8,974)	\$ 5,502
Foreign	(6,245)	(5,995)
<b>Total</b>	<b><u>\$(15,219)</u></b>	<b><u>\$ (493)</u></b>

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

	Year Ended December 31,	
	2017	2018
U.S. federal tax at statutory rate	34.0%	21.0%
Foreign rate differential	(1.6)	109.5
State tax, net of federal benefit	1.3	(4.5)
Stock-based compensation	(14.5)	(93.1)
Change in Valuation Allowance	68.7	401.6
Remeasurement of deferred taxes	(85.0)	—
Other permanent differences	4.0	(434.7)
<b>Total</b>	<b><u>6.9%</u></b>	<b><u>(0.2)%</u></b>

The components of the net deferred tax assets are as follows (in thousands):

	December 31,	
	2017	2018
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 22,964	\$ 26,545
Research and development credit	4,957	2,918
Deferred revenue	8,819	4,838
Other temporary differences	3,234	3,350
<b>Total gross deferred tax assets</b>	<b><u>39,974</u></b>	<b><u>37,651</u></b>
<b>Deferred tax liabilities:</b>		
Depreciation and amortization	(1,218)	(1,368)
Non-qualified stock options with 83(b) election	(345)	(54)
<b>Total gross deferred tax liabilities</b>	<b><u>(1,563)</u></b>	<b><u>(1,422)</u></b>
<b>Net deferred tax assets before valuation allowance</b>	<b><u>38,411</u></b>	<b><u>36,229</u></b>
Deferred tax asset valuation allowance	(38,411)	(36,229)
<b>Net deferred tax assets</b>	<b><u>\$ —</u></b>	<b><u>\$ —</u></b>

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising

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

from the above-mentioned future tax benefits is currently not likely to be realized and, accordingly, has provided a valuation allowance.

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by approximately \$2.2 million and \$1.3 million during the years ended December 31, 2017 and 2018, respectively.

As of December 31, 2017 and 2018, the Company had approximately \$60.2 million and \$69.8 million, respectively, in federal net operating loss carryforwards and had approximately \$71.8 million and \$71.9 million, respectively, in state net operating loss carryforwards to reduce future taxable income. The federal and state net operating loss carryforwards will begin to expire in the years 2028 through 2037, if not utilized. Federal NOL carryforwards generated after December 31, 2017 do not expire as per the Tax Cuts and Jobs Act (the Act), and can be carried forward indefinitely. California does not conform to these provisions.

As of December 31, 2017 and 2018, the Company had approximately \$3.1 million and \$3.1 million, respectively, in federal, and \$4.0 million and \$4.0 million, respectively, in state research and development tax credits. The federal research credits will begin to expire in the years 2028 through 2037, if not utilized, and the state research and development credits have no expiration date.

As of December 31, 2017 and 2018, the Company had foreign net operating loss carryforwards of approximately \$17.3 million and \$22.9 million, which have no expiration date.

Utilization of the Company's net operating losses and credits may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

A reconciliation of the Company's unrecognized tax benefits for the years ended December 31, 2017 and 2018 is as follows (in thousands):

	<u>December 31,</u>	
	<u>2017</u>	<u>2018</u>
Balance at beginning of year	\$1,528	\$1,528
Additions (deletions) based on tax positions related to prior year	—	2,291
Balance at end of year	<u>\$1,528</u>	<u>\$3,819</u>

There is approximately \$3.8 million of unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate before consideration of valuation allowance. The Company does not believe that its unrecognized tax benefits will significantly change within the next 12 months.

It is the Company's practice to recognize interest and penalties related to income tax matters in income tax expense. As of December 31, 2017 and 2018, the Company had no accrued interest and penalties related to uncertain tax positions.

The Company files federal, state, and foreign income tax returns with varying statutes of limitations. The tax years from inception in 2008 forward remain open to examination due to the carryover of unused net operating losses and tax credits.



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**12. Employee Benefit Plan**

The Company sponsors a 401(k) defined contribution plan for its employees. Employee contributions are voluntary. In December 2011, the Company adopted the 401(k) Matching Plan, whereby the Company will make matching contributions in the form of common stock at a rate of \$1.00 for each \$2.00 of employee contributions up to a maximum \$1,500 of common stock per year. As of December 31, 2017 and 2018, the Company had reserved 47,975 and 36,751 shares of common stock for issuance pursuant to the 401(k) Matching Plan, respectively. Matching contributions of 10,660 and 11,223 shares, or \$93,000 and \$103,000 were issued for the years ended December 31, 2017 and 2018, respectively.

**13. Subsequent Events**

For the consolidated financial statements as of the years ended December 31, 2017 and 2018, the Company has reviewed and evaluated material subsequent events through the consolidated financial statements' issuance date of March 25, 2019.

On February 3, 2019, all warrants for preferred stock automatically net exercised into 16,380 shares of Series A convertible preferred stock.

On March 1, 2019, Merck notified the Company of its intent to terminate its license to the GDF15 receptor agonist program, effective May 31, 2019. Upon termination of the license, the Company will regain full rights to the program, which includes NGM386 and NGM395. The Company expects to decide whether to advance NGM386 and/or NGM395 following an analysis of the results of the NGM386 Phase 1 study.

On March 15, 2019, Merck exercised its option to extend the collaboration through March 17, 2022. In lieu of a \$20.0 million extension fee payable to NGM, during such two year extension period Merck will make additional payments totaling up to \$20.0 million in support of NGM's research and development activities across 2021 and the first quarter of 2022.

On March 22, 2019, the Company effected a one-for-two reverse stock split of its outstanding capital stock, as described in Note 2, "Summary of Significant Accounting Policies."

6,666,667 Shares

Common Stock



**Goldman Sachs & Co. LLC**

**Citigroup**

**Cowen**

Through and including April 28, 2019 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

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