UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 4, 2021

NGM Biopharmaceuticals, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38853**	**26-1679911**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

333 Oyster Point Boulevard **South San Francisco, California** **(Address of Principal Executive Offices)**	**94080** **(Zip Code)**

(650) 243-5555
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**NGM**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

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

Item 2.02. Results of Operations and Financial Condition.

On January 4, 2021, NGM Biopharmaceuticals, Inc. (the "***Company***") filed a preliminary prospectus supplement (the "***Preliminary Prospectus Supplement***") to its effective shelf registration statement on Form S-3 (File No. 333-238991) (the "***Registration Statement***") pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "***Securities Act***"), relating to an underwritten public offering of its common stock, par value $0.001 per share (the "***Common Stock***"). The Company included the following disclosure under the heading "Prospectus Supplement Summary—Financial Update" in the Preliminary Prospectus Supplement:

"Our consolidated financial statements for the year ended December 31, 2020 will not be available until after this offering is completed and consequently will not be available to you prior to investing in this offering. Based upon preliminary estimates and information available to us as of the date of this prospectus supplement, we expect to report that we had approximately $295 million of cash, cash equivalents and short-term marketable securities as of December 31, 2020. We have not yet completed our financial close process for the quarter and year ended December 31, 2020. This estimate of our cash, cash equivalents and short-term marketable securities as of December 31, 2020 is preliminary, has not been audited and is subject to change upon completion of our financial statement closing procedures and the audit of our consolidated financial statements. Additional information and disclosures would be required for a more complete understanding of our financial position and results of operations as of December 31, 2020."

The information set forth in Item 2.02 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), or incorporated by reference in any filing under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

Public Offering of Common Stock

On January 5, 2021, the Company entered into an underwriting agreement (the "***Underwriting Agreement***") with Goldman Sachs & Co. LLC, Citigroup Global Markets Inc. and Cowen and Company, LLC, as representatives of the several underwriters named therein (collectively, the "***Underwriters***"), relating to the public offering, issuance and sale of 4,629,630 shares of its common stock, par value $0.001 ("***Common Stock***"). The price to the public in the offering is $27.00 per share of Common Stock. Under the terms of the Underwriting Agreement, the Company also granted the Underwriters an option exercisable for 30 days to purchase up to an additional 694,444 shares of Common Stock at the public offering price, less underwriting discounts and commissions. The gross proceeds to the Company from the offering are expected to be approximately $125.0 million, before deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company, or approximately $143.7 million if the Underwriters exercise in full their option to purchase additional shares. The offering is expected to close on January 8, 2021, subject to customary closing conditions.

The Underwriting Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended, other obligations of the parties and termination provisions. The representations, warranties and covenants contained in the Underwriting Agreement were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to such agreement and may be subject to limitations agreed upon by the contracting parties.

The offering is being made pursuant to the Registration Statement and an accompanying prospectus previously filed with the SEC and a preliminary and final prospectus supplement thereunder. The Underwriting Agreement is filed as Exhibit 1.1 hereto, and the description of the material terms of the Underwriting Agreement is qualified in its entirety by reference to such exhibit. A copy of the opinion of Cooley LLP relating to the legality of the issuance and sale of the shares in the offering is attached as Exhibit 5.1 hereto.

Updated Company Disclosure

The Company is filing information for the purpose of updating the risk factor disclosure contained in its prior public filings, including those discussed under the heading "Item 1A. Risk Factors" in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, filed with the SEC on November 12, 2020. The Company is also supplementing and updating certain aspects of the description of its business from that described under the heading "Item 1. Business" in its Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 17, 2020. The updated Company disclosures are filed herewith as Exhibit 99.1 and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
1.1	Underwriting Agreement, dated as of January 5, 2021, by and among NGM Biopharmaceuticals, Inc., Goldman Sachs & Co. LLC, Citigroup Global Markets Inc. and Cowen and Company, LLC.
5.1	Opinion of Cooley LLP.
23.1	Consent of Cooley LLP (contained in Exhibit 5.1).
99.1	Updated Company Disclosure.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements, including, without limitation, statements relating to the Company's cash, cash equivalents and short-term marketable securities as of December 31, 2020, and the size, timing and completion of the public offering. These forward-looking statements are based upon the Company's current expectations. Actual results could differ materially from these forward-looking statements as a result of certain factors, including, without limitation, risks related to changes in the Company's reported cash, cash equivalents and short-term marketable securities as of December 31, 2020 due to the completion of financial closing procedures and the audit of the Company's financial statements, and risks related to market conditions and the satisfaction of customary closing conditions related to the public offering. There can be no assurance that the Company will be able to complete the public offering on the anticipated terms, or at all. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section titled "Risk Factors" in Exhibit 99.1 hereto. Except as required by law, the Company assumes no obligation to update these forward-looking statements, or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NGM Biopharmaceuticals, Inc.

Dated: January 6, 2021

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

Exhibit 1.1

NGM Biopharmaceuticals, Inc.

Common Stock, par value $0.001 per share

Underwriting Agreement

January 5, 2021

Goldman Sachs & Co. LLC
Citigroup Global Markets Inc.
Cowen and Company, LLC

As representatives (the "Representatives") of the several Underwriters named in Schedule I hereto

c/o Goldman Sachs & Co. LLC
200 West Street,
New York, New York 10282

c/o Citigroup Global Markets Inc.
388 Greenwich Street
New York, New York 10013

c/o Cowen and Company, LLC
599 Lexington Avenue
New York, New York 10022

Ladies and Gentlemen:

NGM Biopharmaceuticals, Inc., a Delaware corporation (the "Company"), proposes, subject to the terms and conditions stated in this agreement (this "Agreement"), to issue and sell to the Underwriters named in Schedule I hereto (the "Underwriters") an aggregate of 4,629,630 shares (the "Firm Shares") and, at the election of the Underwriters, up to 694,444 additional shares (the "Optional Shares") of common stock, par value $0.001 per share ("Stock") of the Company (the Firm Shares and the Optional Shares that the Underwriters elect to purchase pursuant to Section 2 hereof being collectively called the "Shares").

1. The Company represents and warrants to, and agrees with, each of the Underwriters that:

(a) A registration statement on Form S-3 (File No 333-238991 (the "Initial Registration Statement") in respect of the Shares has been filed with the Securities and Exchange Commission (the "Commission"); the Initial Registration Statement and any post-effective amendment thereto, each in the form heretofore delivered to you have been declared effective by the Commission in such form; other than a registration statement, if any, increasing the size of the offering (a "Rule 462(b) Registration Statement"), filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended (the "Act"), which became effective upon filing, no other

document with respect to the Initial Registration Statement or document incorporated by reference therein has been filed, or transmitted for filing, with the Commission (other than prospectuses filed pursuant to Rule 424(b) of the rules and regulations of the Commission under the Act, each in the form heretofore delivered to the Representatives); and no stop order suspending the effectiveness of the Initial Registration Statement, any post-effective amendment thereto or any part thereof or the Rule 462(b) Registration Statement, if any, has been issued and no proceeding for that purpose or pursuant to Section 8A of the Act has been initiated or, to the Company's knowledge, threatened by the Commission (the base prospectus filed as part of the Initial Registration Statement, in the form in which it has most recently been filed with the Commission on or prior to the date of this Agreement relating to the Shares, is hereinafter called the "Base Prospectus"; any preliminary prospectus (including any preliminary prospectus supplement) relating to the Shares filed with the Commission pursuant to Rule 424(b) under the Act is hereinafter called a "Preliminary Prospectus"; the various parts of the Initial Registration Statement and the Rule 462(b) Registration Statement, if any, including all exhibits thereto and including any prospectus supplement relating to the Shares that is filed with the Commission and deemed by virtue of Rule 430B under the Act to be part of the Initial Registration Statement, each as amended at the time such part of the Initial Registration Statement became effective or such part of the Rule 462(b) Registration Statement, if any, became or hereafter becomes effective, are hereinafter collectively called the "Registration Statement"; the Base Prospectus, as amended and supplemented immediately prior to the Applicable Time (as defined in Section 1(c) hereof), is hereinafter called the "Pricing Prospectus"; the form of the final prospectus relating to the Shares filed with the Commission pursuant to Rule 424(b) under the Act in accordance with Section 5(a) hereof is hereinafter called the "Prospectus"; any reference herein to the Base Prospectus, the Pricing Prospectus, any Preliminary Prospectus or the Prospectus shall be deemed to refer to and include the documents incorporated by reference therein pursuant to Item 12 of Form S-3, as of the date of such prospectus; any reference to any amendment or supplement to the Base Prospectus, any Preliminary Prospectus or the Prospectus shall be deemed to refer to and include any post-effective amendment to the Registration Statement, any prospectus supplement relating to the Shares filed with the Commission pursuant to Rule 424(b) under the Act and any documents filed under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and incorporated therein, in each case after the date of the Base Prospectus, such Preliminary Prospectus or the Prospectus, as the case may be; any reference to any amendment to the Registration Statement shall be deemed to refer to and include any annual report of the Company filed pursuant to Section 13(a) or 15(d) of the Exchange Act after the effective date of the Registration Statement that is incorporated by reference in the Registration Statement; any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Act or Rule 163B under the Act is hereinafter called a "Testing-the-Waters Communication"; and any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Act is hereinafter called a "Written Testing-the-Waters Communication"; and any "issuer free writing prospectus" as defined in Rule 433 under the Act relating to the Shares is hereinafter called an "Issuer Free Writing Prospectus");

(b) (A) No order preventing or suspending the use of any Preliminary Prospectus or any Issuer Free Writing Prospectus has been issued by the Commission, and (B) each Preliminary Prospectus, at the time of filing thereof, conformed in all material respects to the requirements of the Act and the rules and regulations of the Commission thereunder, and did not contain an untrue statement of a material fact or omit to state a material fact required to be

stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to any statements or omissions made in reliance upon and in conformity with the Underwriter Information (as defined in Section 9(b) of this Agreement);

(c) For the purposes of this Agreement, the "Applicable Time" is 8:00 pm (Eastern time) on the date of this Agreement. The Pricing Prospectus, as supplemented by the information listed on Schedule II(c) hereto, taken together (collectively, the "Pricing Disclosure Package"), as of the Applicable Time did not, and as of each Time of Delivery (as defined in Section 4(a) of this Agreement) will not, include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and each Issuer Free Writing Prospectus and each Written Testing-the-Waters Communication does not conflict with the information contained in the Registration Statement, the Pricing Prospectus or the Prospectus and each Issuer Free Writing Prospectus and each Written Testing-the-Waters Communication, as supplemented by and taken together with the Pricing Disclosure Package as of the Applicable Time, did not, and as of each Time of Delivery will not, include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to statements or omissions made in reliance upon and in conformity with the Underwriter Information;

(d) The documents incorporated by reference in the Pricing Prospectus and Prospectus, when they became effective or were filed with the Commission, as the case may be, conformed in all material respects to the requirements of the Act or the Exchange Act, as applicable, and the rules and regulations of the Commission thereunder, and none of such documents contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading; and any further documents so filed and incorporated by reference in the Pricing Prospectus and the Prospectus or any further amendment or supplement thereto, when such documents become effective or are filed with the Commission, as the case may be, will conform in all material respects to the requirements of the Act or the Exchange Act, as applicable, and the rules and regulations of the Commission thereunder and will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; and no such or any other documents were filed with the Commission since the Commission's close of business on the business day immediately prior to the date of this Agreement and prior to the execution of this Agreement, except as set forth on Schedule II(b) hereto;

(e) The Registration Statement conforms, and the Prospectus and any further amendments or supplements to the Registration Statement and the Prospectus will conform, in all material respects to the requirements of the Act and the rules and regulations of the Commission thereunder and do not and will not, as of the applicable effective date as to each part of the Registration Statement and any amendment thereto and as of the applicable filing date as to the Prospectus and any amendment or supplement thereto, contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; provided, however, that this representation and warranty shall not apply to any statements or omissions made in reliance upon and in conformity with the Underwriter Information;

(f) From the time of filing of the Initial Registration Statement through the date hereof, the Company has been and is an "emerging growth company" as defined in Section 2(a)(19) of the Act (an "Emerging Growth Company");

(g) Neither the Company nor any of its subsidiaries has, since the date of the latest audited financial statements included or incorporated by reference in the Pricing Prospectus, (i) sustained any material loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree or (ii) entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company and its subsidiaries taken as a whole or incurred any liability or obligation, direct or contingent, that is material to the Company and its subsidiaries taken as a whole, in each case otherwise than as set forth or contemplated in the Pricing Prospectus; and, since the respective dates as of which information is given in the Registration Statement and the Pricing Prospectus, there has not been (x) any change in the capital stock (other than as a result of (i) the exercise, if any, of stock options or the award, if any, of stock options or restricted stock in the ordinary course of business pursuant to the Company's equity plans that are described in the Pricing Prospectus and the Prospectus or filed as exhibits to the Registration Statement or (ii) the issuance, if any, of stock upon conversion of Company securities as described in the Pricing Prospectus and the Prospectus) or long term debt of the Company or any of its subsidiaries or (y) any Material Adverse Effect (as defined below); as used in this Agreement, "Material Adverse Effect" shall mean any material adverse change or effect, or any development involving a prospective material adverse change or effect, in or affecting (i) the business, properties, general affairs, management, financial position, stockholders' equity or results of operations of the Company and its subsidiaries, taken as a whole, except as set forth or contemplated in the Pricing Prospectus, or (ii) the ability of the Company to perform its obligations under this Agreement, including the issuance and sale of the Shares, or to consummate the transactions contemplated in the Pricing Prospectus and the Prospectus;

(h) The Company and its subsidiaries have good and marketable title in fee simple to all real property and good and marketable title to all personal property owned by them (other than with respect to Intellectual Property Rights (as defined below), which are addressed in Section 1(gg) below), in each case free and clear of all liens, encumbrances and defects except such as are described in the Pricing Prospectus or such as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and its subsidiaries; and any real property and buildings held under lease by the Company and its subsidiaries are held by them under, to the Company's knowledge, valid, subsisting and enforceable leases (subject to the effects of (A) bankruptcy, insolvency, fraudulent conveyance, fraudulent transfer, reorganization, moratorium or other similar laws relating to or affecting the rights or remedies of creditors generally; (B) the application of general principles of equity (including without limitation, concepts of materiality, reasonableness, good faith and fair dealing, regardless of whether enforcement is considered in proceedings at law or in equity); and (C) applicable law and public policy with respect to rights to indemnity and contribution) with such exceptions as are not material and do not materially interfere with the use made and proposed to be made of such property and buildings by the Company and its subsidiaries;

(i) Each of the Company and each of its subsidiaries has been (i) duly organized and is validly existing and in good standing under the laws of its jurisdiction of organization, with power and authority (corporate and other) to own its properties and conduct its business as described in the Pricing Prospectus, and (ii) duly qualified as a foreign corporation for the transaction of business and is in good standing under the laws of each other jurisdiction in which it owns or leases properties or conducts any business so as to require such qualification, except, in the case of this clause (ii), where the failure to be so qualified or in good standing would not, individually or in the aggregate, have a Material Adverse Effect, and each significant subsidiary, as such term is defined in Rule 1-02(w) of Regulation S-X, of the Company has been listed in the Registration Statement;

(j) The Company has an authorized capitalization as set forth in the Pricing Prospectus and all of the issued shares of capital stock of the Company have been duly and validly authorized and issued and are fully paid and non-assessable and conform to the description of the Stock contained in the Pricing Disclosure Package and the Prospectus; and all of the issued shares of capital stock of each subsidiary of the Company have been duly and validly authorized and issued, are fully paid and non-assessable and (except, in the case of any foreign subsidiary, for directors' qualifying shares) are owned directly or indirectly by the Company, free and clear of all liens, encumbrances, equities or claims;

(k) This Agreement has been duly authorized, executed and delivered by the Company;

(l) The Shares to be issued and sold by the Company to the Underwriters hereunder have been duly and validly authorized and, when issued and delivered against payment therefor as provided herein, will be duly and validly issued and fully paid and non-assessable and will conform to the description of the Stock contained in the Pricing Disclosure Package and the Prospectus; and the issuance of the Shares is not subject to any preemptive or similar rights;

(m) The issue and sale of the Shares and the compliance by the Company with this Agreement and the consummation of the transactions contemplated in this Agreement and the Pricing Prospectus will not conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, (A) any indenture, mortgage, deed of trust, loan agreement, lease or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any of the property or assets of the Company or any of its subsidiaries is subject, except, in the case of this clause (A) for such defaults, breaches, or violations that would not, individually or in the aggregate, have a Material Adverse Effect, (B) the certificate of incorporation or by-laws (or other applicable similar organizational document) of the Company or any of its subsidiaries, or (C) any statute or any judgment, order, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or any of its subsidiaries or any of their properties, except in the case of this clause (C) for such defaults, breaches, or violations that would not, individually or in the aggregate, have a Material Adverse Effect; and no consent, approval, authorization, order, registration or qualification of or with any such court or governmental agency or body is required for the issue and sale of the Shares or the consummation by the Company of the transactions contemplated by this Agreement, except such as have been obtained under the Act and for such consents, approvals, authorizations, orders, registrations or qualifications as may be required under state securities or Blue Sky laws in connection with the purchase and distribution of the Shares by the Underwriters;

(n) Neither the Company nor any of its subsidiaries is (i) in violation of its certificate of incorporation or by-laws (or other applicable similar organizational document), (ii) in violation of any statute or any judgment, order, rule or regulation of any court or governmental agency or body having jurisdiction over the Company or any of its subsidiaries or any of their properties, or (iii) in default in the performance or observance of any obligation, agreement, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement, lease or other agreement or instrument to which it is a party or by which it or any of its properties may be bound, except, in the case of the foregoing clauses (ii) and (iii), for such violations or defaults as would not, individually or in the aggregate, have a Material Adverse Effect;

(o) The statements set forth in the Pricing Prospectus and the Prospectus under the caption "Description of Capital Stock", insofar as they purport to constitute a summary of the terms of the Stock**,** and under the caption "Material U.S. Federal Income Tax Considerations for Non-U.S. Holders of Common Stock," insofar as they purport to describe the provisions of the laws and documents referred to therein, are accurate, complete and fair, in all material respects;

(p) There are no legal, governmental or regulatory investigations, actions, demands, claims, suits, arbitrations, inquiries or proceedings pending to which the Company or any of its subsidiaries or, to the Company's knowledge, any officer or director of the Company is a party or of which any property or assets of the Company or any of its subsidiaries or, to the Company's knowledge, any officer or director of the Company is the subject which, if determined adversely to the Company or any of its subsidiaries (or such officer or director), would individually or in the aggregate have a Material Adverse Effect; and, to the Company's knowledge, no such proceedings are threatened or contemplated by governmental authorities or threatened by others;

(q) The Company and each of its subsidiaries have filed all federal, state, local and foreign tax returns required to be filed through the date of this Agreement and have paid all taxes required to be paid thereon (except for cases in which the failure to file or pay would not have a Material Adverse Effect, or, except as currently being contested in good faith and for which reserves required by U.S. GAAP have been created in the financial statements of the Company), and no tax deficiency has been determined adversely to the Company or any of its subsidiaries which has had (nor does the Company nor any of its subsidiaries have any notice or knowledge of any tax deficiency which could reasonably be expected to be determined adversely to the Company or its subsidiaries and which could reasonably be expected to have) a Material Adverse Effect.

(r) The Company is not and, after giving effect to the offering and sale of the Shares and the application of the proceeds thereof, as described in the Pricing Prospectus, will not be an "investment company", as such term is defined in the Investment Company Act of 1940, as amended (the "Investment Company Act");

(s) At the time of filing the Initial Registration Statement and any post-effective amendment thereto, at the earliest time thereafter that the Company or any offering participant made a bona fide offer (within the meaning of Rule 164(h)(2) under the Act) of the Shares, and at the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405 under the Act;

(t) Ernst & Young LLP, who have certified certain financial statements of the Company and its subsidiaries, are independent public accountants as required by the Act and the rules and regulations of the Commission thereunder;

(u) The financial statements included in the Registration Statement, the Pricing Prospectus and the Prospectus, together with the related schedules and notes, present fairly in all material respects the financial position of the Company and its subsidiaries at the dates indicated and the statement of operations, stockholders' equity and cash flows of the Company and its subsidiaries for the periods specified; said financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") applied on a consistent basis throughout the periods involved. The supporting schedules, if any, present fairly in all material respects and in accordance with GAAP the information required to be stated therein. The selected consolidated financial data and the summary consolidated financial data included in the Registration Statement, the Pricing Prospectus and the Prospectus present fairly the information shown therein and have been compiled on a basis consistent with that of the audited financial statements included therein. Except as included therein, no historical or pro forma financial statements or supporting schedules are required to be included in the Registration Statement, the Pricing Prospectus or the Prospectus under the Act or the rules and regulations promulgated thereunder;

(v) The Company maintains a system of internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act that (i) complies with the requirements of the Exchange Act applicable to the Company, (ii) has been designed by the Company's principal executive officer and principal financial officer, or under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and (iii) is sufficient to provide reasonable assurance that (A) transactions are executed in accordance with management's general or specific authorization, (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain accountability for assets, (C) access to assets is permitted only in accordance with management's general or specific authorization and (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and the Company's internal control over financial reporting is effective and the Company is not aware of any material weaknesses in its internal control over financial reporting (it being understood that this subsection shall not require the Company to comply with Section 404 of the Sarbanes-Oxley Act of 2002, as amended, and the rules and regulations promulgated in connection therewith (the "Sarbanes-Oxley Act") as of an earlier date than it would otherwise be required to do so under applicable law);

(w) Since the date of the latest audited financial statements included or incorporated by reference in the Prospectus, there has been no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially and adversely affect, the Company's internal control over financial reporting;

(x) The Company maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) under the Exchange Act) that comply with the requirements of the Exchange Act applicable to the Company; such disclosure controls and procedures have been designed to ensure that material information relating to the Company and its subsidiaries is made known to the Company's principal executive officer and principal financial officer by others within those entities; and such disclosure controls and procedures are effective;

(y) Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person associated with or acting on behalf of the Company or any of its subsidiaries has, in the course of its actions for, or on behalf of, the Company or any of its subsidiaries (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expenses relating to political activity; (ii) made or taken any act in furtherance of an offer, promise, or authorization of any direct or indirect unlawful payment or benefit to any foreign or domestic government official or employee, including of any government-owned or controlled entity or public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party, party official, or candidate for political office; (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended (the "FCPA"), and the rules and regulations thereunder, including, without limitation, by making use of the mails or any means or instrumentality of U.S. interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any "foreign official" (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office in contravention of the FCPA; (iv) violated or is in violation of any provision of the U.K. Bribery Act 2010; (v) violated or is in violation of any provision of any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or any other applicable anti-bribery or anti-corruption law; or (vi) made, offered, authorized, requested, or taken an act in furtherance of any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment or benefit. The Company and its subsidiaries and, to the knowledge of the Company, the Company's affiliates have conducted their respective businesses in compliance with the FCPA and the Company has instituted and maintains policies and procedures under its code of conduct designed to ensure, and which are reasonably expected to continue to ensure, continued compliance with the FCPA. No part of the proceeds of the offering will be used, directly or indirectly, in violation of the FCPA or the U.K. Bribery Act 2010, each as may be amended, or similar law of any other relevant jurisdiction, or the rules or regulations thereunder;

(z) The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with the requirements of applicable anti-money laundering laws, including, but not limited to, the Bank Secrecy Act of 1970, as amended by the USA PATRIOT ACT of 2001, and the rules and regulations promulgated thereunder, and the anti-money laundering laws of the various jurisdictions in which the Company and its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines issued, administered or enforced by any governmental agency having jurisdiction over the Company or any of its subsidiaries (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened;

(aa) Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or any of its subsidiaries (i) is, or is controlled or 50% or more owned in the aggregate by, or is acting on behalf of, one or more individuals or entities that are currently the subject or the target of any sanctions administered or enforced by the U.S. Government, including, without limitation, the Office of Foreign Assets Control of the U.S. Department of the Treasury ("OFAC"), or the U.S. Department of State and including, without limitation, the designation as a "specially designated national" or "blocked person," the European Union, Her Majesty's Treasury, the

United Nations Security Council, or other relevant sanctions authority (collectively, "Sanctions" and such persons "Sanctioned Persons"), or (ii) is located, organized or resident in a country or territory that is, or whose government is, the subject or the target of Sanctions that broadly prohibit dealings with that country or territory (collectively, "Sanctioned Countries" and each, a "Sanctioned Country"), and the Company will not directly or indirectly use the proceeds of the offering of the Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity (i) to fund or facilitate any activities of or business with any person, or in any Sanctioned Country or (ii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions. Neither the Company nor any of its subsidiaries has knowingly engaged in any dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country, in the preceding three years, nor does the Company or any of its subsidiaries have any plans to engage in dealings or transactions with or for the benefit of a Sanctioned Person, or with or in a Sanctioned Country;

(bb) (i) The Company and each of its subsidiaries (x) is in material compliance with all, and has not violated any, applicable material federal, state or local laws, rules, regulations, requirements, decisions, judgments, decrees and orders relating to pollution, hazardous or toxic substances, wastes, pollutants, contaminants or the protection of human health or safety, the environment or natural resources (collectively, "Environmental Laws"); (y) has received and is in material compliance with all, and has not violated any, material permits, licenses, certificates or other authorizations or approvals required of it under any Environmental Laws to conduct its business; and (z) has not received notice of any actual or potential liability of the Company, or obligation of the Company under or relating to, or any actual or potential violation of, any Environmental Laws by the Company, including for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, and have no knowledge of any event or condition that would reasonably be expected to result in any such notice, and (ii) there are no costs or liabilities associated with Environmental Laws of or relating to the Company, except in the case of each of (i) and (ii) above, for any such matter as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and (iii) except as described in each of the Pricing Disclosure Package and the Prospectus, (x) there is no proceeding that is pending, or that is known by the Company to be contemplated, against the Company under any Environmental Laws in which a governmental entity is also a party, other than such proceeding regarding which the Company reasonably believes no monetary sanctions of $100,000 or more will be imposed, and (y) the Company is not aware of any facts regarding compliance with Environmental Laws, or liabilities or other obligations under Environmental Laws or concerning hazardous or toxic substances or wastes, pollutants or contaminants, that individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect;

(cc) The Company possesses all material licenses, sub-licenses, certificates, authorizations and permits issued by the appropriate federal, state or foreign regulatory authorities necessary to conduct its business, as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, including, without limitation, from the U.S. Food and Drug Administration ("FDA") and equivalent foreign regulatory authorities; and the Company has not received any notice of proceedings relating to the revocation or modification of any such material license, sub-license, certificate, authorization or permit, except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus;

(dd) The Company has operated and currently is in material compliance with all applicable rules, regulations and policies of the FDA;

(ee) Any studies, tests and preclinical and clinical trials conducted by the Company and, to the knowledge of the Company, any studies, tests and preclinical and clinical trials conducted on behalf of the Company or in which the Company has participated, were, and if still pending are, being conducted in accordance with experimental protocols, procedures and controls pursuant to accepted professional scientific standards and all applicable rules and regulations, including those of the FDA and comparable regulatory agencies outside of the United States, to which the Company is subject and, for studies submitted to regulatory authorities as a basis for regulatory approval and preclinical and clinical trials, current Good Clinical Practices and Good Laboratory Practices except where the failure to be so conducted would not reasonably be expected to have a Material Adverse Effect; the descriptions of the results of such studies, tests and trials contained in the Registration Statement, the Pricing Prospectus and the Prospectus are, to the Company's knowledge, accurate and complete in all material respects and fairly present the data derived from such studies, tests and trials; the Company is not aware of any studies, tests or trials, the results of which the Company believes reasonably call into question the study, test, or trial results described or referred to in the Registration Statement, the Pricing Prospectus and the Prospectus when viewed in the context in which such results are described and the clinical state of development; and, except to the extent disclosed in the Registration Statement, the Pricing Prospectus or the Prospectus, the Company has not received any notices or correspondence from the FDA or any other comparable federal, state, local or foreign governmental or regulatory authority requiring the termination or suspension of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company;

(ff) To the Company's knowledge, the manufacturing facilities and operations of its suppliers and manufacturers are operated in compliance in all respects with all applicable statutes, rules, regulations and policies of the FDA and comparable regulatory agencies outside of the United States to which the Company is subject;

(gg) Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company and its subsidiaries own, possess or license adequate rights to use all trademarks, service marks, trade names, domain names and other source identifiers, all goodwill associated with the foregoing, inventions, technology, patents, copyrights, know-how, trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures, and other intellectual property rights (including all registrations and applications for registration of the foregoing, as applicable) (collectively, "Intellectual Property Rights") used or held for use in the conduct of their respective businesses as currently conducted and as proposed in the Registration Statement, the Pricing Disclosure Package and the Prospectus to be conducted, except where the failure to own, possess or license such Intellectual Property Rights would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has materially infringed, misappropriated or otherwise violated the Intellectual Property Rights of any third party, and neither the manufacture of, nor the use or

sale of, any of the product candidates described in the Registration Statement, the Pricing Disclosure Package and the Prospectus will materially infringe, misappropriate or otherwise violate the Intellectual Property Rights of any third party. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there are no rights of third parties (including any liens or encumbrances) to any of the Intellectual Property Rights owned or purported to be owned by, or exclusively licensed to, the Company or any of its subsidiaries. Except as would not, individually or in aggregate, if determined adversely to the Company or any of its subsidiaries, reasonably be expected to have a Material Adverse Effect, there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by any third party (i) challenging the Company's or any subsidiary of the Company's rights in or to, or alleging a violation of any of the terms of, any of their owned or licensed Intellectual Property Rights; (ii) alleging that the Company or any of its subsidiaries has infringed, misappropriated or otherwise violated any Intellectual Property Rights of any third party; or (iii) challenging the validity, scope or enforceability of any Intellectual Property Rights owned by or exclusively licensed to the Company or any of its subsidiaries, and in the case of each of (i), (ii) and (iii), the Company is unaware of any facts that would form a reasonable basis for any such action, suit, proceeding or claim. To the Company's knowledge, there is no infringement, misappropriation, breach or default, or other violation by others of any Intellectual Property Rights owned by or exclusively licensed to the Company or any of its subsidiaries, and all Intellectual Property Rights owned by or licensed to the Company or any of its subsidiaries are valid and enforceable, except in each case as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company and its subsidiaries have at all times taken reasonable steps in accordance with normal industry practice to maintain the confidentiality of all Intellectual Property Rights owned by the Company, the value of which to the Company or any Company subsidiary is contingent upon maintaining the confidentiality thereof. All founders, current and former employees, consultants and other parties involved in the development of Intellectual Property Rights for the Company or any of its subsidiaries have signed confidentiality and invention assignment agreements with the Company or any of its subsidiaries pursuant to which the Company or any of its subsidiaries either (x) has obtained ownership of and is the exclusive owner of such Intellectual Property Rights, or (y) has obtained a valid and unrestricted right to exploit such Intellectual Property Rights, sufficient for the conduct of the business as currently conducted and as proposed in the Registration Statement, the Pricing Disclosure Package and the Prospectus to be conducted;

(hh) (i) Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (x) to the Company's knowledge, there has been no security breach or other compromise of or relating to any of the Company's or its subsidiaries' information technology and computer systems, networks, hardware, software, data (including the data of their respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of them), equipment or technology (collectively, "IT Systems and Data") and (y) the Company and its subsidiaries have not been notified of, and have no knowledge of any event or condition that would reasonably be expected to result in, any security breach or other compromise to their IT Systems and Data; (ii) the Company and its subsidiaries are presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Systems and Data and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification, except as would not, in the case of clauses (i) and (ii), individually or in the aggregate, have a Material Adverse Effect; and (iii) the Company and its subsidiaries have implemented backup and disaster recovery technology consistent with industry standards and practices;

(ii) No forward-looking statement (within the meaning of Section 27A of the Act and Section 21E of the Exchange Act) included or incorporated by reference in any of the Registration Statement, the Pricing Prospectus or the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith;

(jj) Nothing has come to the attention of the Company that has caused the Company to believe that the statistical and market-related data included in each of the Registration Statement, the Pricing Prospectus and the Prospectus is not based on or derived from sources that are reliable and accurate in all material respects;

(kk) There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply in all material respects with any provision of the Sarbanes-Oxley Act, including Section 402 related to loans and Sections 302 and 906 related to certifications;

(ll) Neither the Company nor any of its affiliates has taken or will take, directly or indirectly, any action designed to or that could reasonably be expected to cause or result in the stabilization or manipulation of the price of any security of the Company or any of its subsidiaries in connection with the offering of the Shares; and

(mm) The Company and its subsidiaries, taken as a whole, are insured against such losses and risks and in such amounts as are prudent and customary in the businesses in which they are engaged and as required by law.

2. Subject to the terms and conditions herein set forth, (a) the Company agrees to issue and sell to each of the Underwriters, and each of the Underwriters agrees, severally and not jointly, to purchase from the Company, at a purchase price per share of $25.38, the number of Firm Shares set forth opposite the name of such Underwriter in Schedule I hereto and (b) in the event and to the extent that the Underwriters shall exercise the election to purchase Optional Shares as provided below, the Company agrees to issue and sell to each of the Underwriters, and each of the Underwriters agrees, severally and not jointly, to purchase from the Company, at the purchase price per share set forth in clause (a) of this Section 2 (provided that the purchase price per Optional Share shall be reduced by an amount per share equal to any dividends or distributions declared by the Company and payable on the Firm Shares but not payable on the Optional Shares), that portion of the number of Optional Shares as to which such election shall have been exercised (to be adjusted by you so as to eliminate fractional shares) determined by multiplying such number of Optional Shares by a fraction, the numerator of which is the maximum number of Optional Shares which such Underwriter is entitled to purchase as set forth opposite the name of such Underwriter in Schedule I hereto and the denominator of which is the maximum number of Optional Shares that all of the Underwriters are entitled to purchase hereunder.

The Company hereby grants to the Underwriters the right to purchase at their election up to 694,444 Optional Shares, at the purchase price per share set forth in the paragraph above, provided that the purchase price per Optional Share shall be reduced by an amount per share equal to any dividends or distributions declared by the Company and payable on the Firm Shares but not payable

on the Optional Shares. Any such election to purchase Optional Shares may be exercised only by written notice from you to the Company, given within a period of 30 calendar days after the date of this Agreement and setting forth the aggregate number of Optional Shares to be purchased and the date on which such Optional Shares are to be delivered, as determined by you but in no event earlier than the First Time of Delivery (as defined in Section 4 hereof) or, unless you and the Company otherwise agree in writing, earlier than two or later than ten business days after the date of such notice.

3. Upon the authorization by you of the release of the Shares, the several Underwriters propose to offer the Shares for sale upon the terms and conditions set forth in the Pricing Disclosure Package and the Prospectus.

4. (a) The Shares to be purchased by each Underwriter hereunder, in definitive or book-entry form, and in such authorized denominations and registered in such names as the Representatives may request upon at least forty-eight hours' prior notice to the Company shall be delivered by or on behalf of the Company to the Representatives, through the facilities of the Depository Trust Company ("DTC"), for the account of such Underwriter, against payment by or on behalf of such Underwriter of the purchase price therefor by wire transfer of Federal (same-day) funds to the account specified by the Company to the Representatives at least forty-eight hours in advance. The Company will cause the certificates, if any, representing the Shares to be made available for checking and packaging at least twenty-four hours prior to the Time of Delivery (as defined below) with respect thereto at the office of DTC or its designated custodian (the "Designated Office"). The time and date of such delivery and payment shall be, with respect to the Firm Shares, 9:30 a.m., New York City time, on January 8, 2021 or such other time and date as the Representatives and the Company may agree upon in writing, and, with respect to the Optional Shares, 9:30 a.m., New York City time, on the date specified by the Representatives in the written notice given by the Representatives of the Underwriters' election to purchase such Optional Shares, or such other time and date as the Representatives and the Company may agree upon in writing. Such time and date for delivery of the Firm Shares is herein called the "First Time of Delivery", such time and date for delivery of the Optional Shares, if not the First Time of Delivery, is herein called the "Second Time of Delivery", and each such time and date for delivery is herein called a "Time of Delivery".

(b) The documents to be delivered at each Time of Delivery by or on behalf of the parties hereto pursuant to Section 8 hereof, including the cross receipt for the Shares and any additional documents requested by the Underwriters pursuant to Section 8(l) hereof, will be delivered at the offices of Davis Polk & Wardwell LLP, counsel for the Underwriters, at 1600 El Camino Real, Menlo Park, California 94025 (the "Closing Location"), and the Shares will be delivered at the Designated Office, all at such Time of Delivery. A meeting will be held at the Closing Location at 5:00 p.m., New York City time, on the New York Business Day next preceding such Time of Delivery, at which meeting the final drafts of the documents to be delivered pursuant to the preceding sentence will be available for review by the parties hereto. For the purposes of this Section 4, "New York Business Day" shall mean each Monday, Tuesday, Wednesday, Thursday and Friday which is not a day on which banking institutions in New York City are generally authorized or obligated by law or executive order to close.

5. The Company agrees with each of the Underwriters:

(a) To prepare the Prospectus in a form approved by you and to file such Prospectus pursuant to Rule 424(b) under the Act not later than the Commission's close of business on the second business day following the execution and delivery of this Agreement or, if applicable, such earlier time as may be required under the Act; to make no further amendment or any supplement to the Registration Statement, the Base Prospectus or the Prospectus prior to the last Time of Delivery which shall be disapproved by you promptly after reasonable notice

thereof; to advise you, promptly after it receives notice thereof, of the time when any amendment to the Registration Statement has been filed or becomes effective or any amendment or supplement to the Prospectus has been filed and to furnish you with copies thereof; to file promptly all material required to be filed by the Company with the Commission pursuant to Rule 433(d) under the Act; within the time required by such Rule; to file promptly all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of the Prospectus and for so long as the delivery of a prospectus (or in lieu thereof, the notice referred to in Rule 173(a) under the Act) is required in connection with the offering or sale of the Shares; to advise you, promptly after it receives notice thereof, of the issuance by the Commission of any stop order or of any order preventing or suspending the use of any Preliminary Prospectus or other prospectus in respect of the Shares, of the suspension of the qualification of the Shares for offering or sale in any jurisdiction, of the initiation or threatening of any proceeding for any such purpose, or of any request by the Commission for the amending or supplementing of the Registration Statement or the Prospectus or for additional information; and, in the event of the issuance of any stop order or of any order preventing or suspending the use of any Preliminary Prospectus or other prospectus relating to the Shares or suspending any such qualification, to promptly use its best efforts to obtain the withdrawal of such order;

(b) Promptly from time to time to take such action as you may reasonably request to qualify the Shares for offering and sale under the securities laws of such jurisdictions as you may request and to comply with such laws so as to permit the continuance of sales and dealings therein in such jurisdictions for as long as may be necessary to complete the distribution of the Shares, provided that in connection therewith the Company shall not be required to qualify as a foreign corporation or to file a general consent to service of process in any jurisdiction or subject itself to taxation for doing business in any jurisdiction in which it is not otherwise subject to taxation;

(c) If by the third anniversary (the “Renewal Deadline”) of the initial effective date of the Registration Statement, any of the Shares remain unsold by the Underwriters, the Company will file, if it has not already done so and is eligible to do so, a new shelf registration statement relating to the Shares, in a form satisfactory to you and will use its best efforts to cause such registration statement to be declared effective within 180 days after the Renewal Deadline. The Company will take all other action necessary or appropriate to permit the public offering and sale of the Shares to continue as contemplated in the expired registration statement relating to the Shares. References herein to the Registration Statement shall include such new automatic shelf registration statement or such new shelf registration statement, as the case may be;

(d) Prior to 10:00 a.m., New York City time, on the New York Business Day next succeeding the date of this Agreement and from time to time, to furnish the Underwriters with written and electronic copies of the Prospectus in New York City in such quantities as you may reasonably request, and, if the delivery of a prospectus (or in lieu thereof, the notice referred to in Rule 173(a) under the Act) is required at any time prior to the expiration of nine months after the time of issue of the Prospectus in connection with the offering or sale of the Shares and if at such time any event shall have occurred as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made when such Prospectus (or in lieu thereof, the notice referred to in Rule 173(a) under the Act) is delivered, not misleading, or, if for any other reason it shall be

necessary during such same period to amend or supplement the Prospectus or to file under the Exchange Act any document incorporated by reference in the Prospectus in order to comply with the Act or the Exchange Act, to notify you and upon your request to file such document and to prepare and furnish without charge to each Underwriter and to any dealer (whose name and address the Underwriters shall furnish to the Company in connection with such request) in securities as many written and electronic copies as you may from time to time reasonably request of an amended Prospectus or a supplement to the Prospectus which will correct such statement or omission or effect such compliance; and in case any Underwriter is required to deliver a prospectus (or in lieu thereof, the notice referred to in Rule 173(a) under the Act) in connection with sales of any of the Shares at any time nine months or more after the time of issue of the Prospectus, upon your request but at the expense of such Underwriter, to prepare and deliver to such Underwriter as many written and electronic copies as you may request of an amended or supplemented Prospectus complying with Section 10(a)(3) of the Act;

(e) To make generally available to its securityholders as soon as practicable, but in any event not later than sixteen months after the effective date of the Registration Statement (as defined in Rule 158(c) under the Act), an earnings statement of the Company and its subsidiaries (which need not be audited) complying with Section 11(a) of the Act and the rules and regulations of the Commission thereunder (including, at the option of the Company, Rule 158);

(f) During the period beginning from the date hereof and continuing to and including the date 90 days after the date of the Prospectus (the "Clear Market Period"), not to (i) offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, or file with or confidentially submit to the Commission a registration statement under the Act relating to, any securities of the Company that are substantially similar to the Shares, including but not limited to any options or warrants to purchase shares of Stock or any securities that are convertible into or exchangeable for, or that represent the right to receive, Stock or any such substantially similar securities, or publicly disclose the intention to make any offer, sale, pledge, disposition or filing or (ii) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Stock or any such other securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Stock or such other securities, in cash or otherwise (other than the Shares to be sold hereunder or pursuant to employee stock option plans existing on, or upon the conversion or exchange of convertible or exchangeable securities outstanding as of, the date of this Agreement), without the prior written consent of the Representatives; provided, however, that the foregoing restrictions shall not apply to (A) the Shares sold hereunder, (B) the issuance by the Company of shares of Stock upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof, (C) the issuance by the Company of Stock or other securities convertible or exercisable into Stock, in each case pursuant to the Company's and its subsidiaries stock plans that are described in the Pricing Prospectus, (D) the filing of any registration statement (including amendments or prospectuses thereto) (1) on Form S-8 or any successor form thereto with respect to the registration of securities to be offered under any employee benefit or equity incentive plans of the Company or its subsidiaries or (2) that the Company may be required to file pursuant to that certain Amended and Restated Investor Rights Agreement, dated as of March 20, 2015, by and between the Company and the investor parties thereto, (E) the issuance of shares of Stock to Merck Sharp & Dohme Corp. ("Merck") and/or its designate affiliate(s) and the entry into by the Company of a purchase agreement related thereto, in each case pursuant to the exercise by

Merck of its option to acquire shares of Stock from the Company pursuant to that certain Letter Agreement, dated as of March 20, 2015, by and between the Company and Merck, or (F) the issuance of shares of Stock or any security convertible into or exercisable for shares of Stock in connection with transactions that include a commercial relationship (including without limitation, joint ventures, marketing or distribution arrangements, collaboration agreements or intellectual property license agreements) or any acquisition by the Company or any of its subsidiaries of the securities, business, property or other assets of another person or entity or pursuant to any employee benefit plan assumed by the Company in connection with such acquisition, and the issuance of any such securities pursuant to any such agreement; provided further, that, in the case of clause (F), the aggregate number of shares of Stock that the Company may sell or issue or agree to sell or issue pursuant to clause (F) shall not exceed 5% of the total number of shares of Stock issued and outstanding immediately following the completion of the transactions contemplated by this Agreement, and provided further that the Company shall cause each recipient of such securities pursuant to clause (F) to execute and deliver to you, on or prior to the issuance of such securities, a lock-up letter as described in Section 8(j) hereof (and with a date of expiration 30 days earlier than the date of expiration for the lock-up applicable to the Company), and enter stop transfer instructions with the Company's transfer agent and registrar of such securities, which the Company agrees it will not waive or amend without the prior written consent of the representatives. Notwithstanding anything to the contrary contained in this Section 5(f), the Company shall be permitted to keep in effect the Open Market Sale Agreement[SM], dated as of June 5, 2020, as amended, by and between the Company and Jefferies LLC (the "Jefferies Agreement"), and the prospectus supplement related thereto provided that pursuant to the terms of this Section 5(g), no sales under the Jefferies Agreement may be made during the Clear Market Period.

(g) If the Company elects to rely upon Rule 462(b), the Company shall file a Rule 462(b) Registration Statement with the Commission in compliance with Rule 462(b) by 10:00 p.m., Washington, D.C. time, on the date of this Agreement, and the Company shall at the time of filing either pay to the Commission the filing fee for the Rule 462(b) Registration Statement or give irrevocable instructions for the payment of such fee pursuant to Rule 111(b) under the Act;

(h) To promptly notify you if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Shares within the meaning of the Act and (ii) the last Time of Delivery;

(i) Upon request of any Underwriter, to furnish, or cause to be furnished, to such Underwriter an electronic version of the Company's trademarks, servicemarks and corporate logo for use on the website, if any, operated by such Underwriter for the purpose of facilitating the on-line offering of the Shares (the "License"); provided, however, that the License shall be used solely for the purpose described above, is granted without any fee and may not be assigned or transferred;

(j) To use the net proceeds received by it from the sale of the Shares in the manner specified in the Pricing Prospectus under the caption "Use of Proceeds"; and

(k) To use its reasonable best efforts to list for quotation the Shares on The Nasdaq Global Select Market.

6. (a) The Company represents and agrees that, without the prior consent of the Representatives, it has not made and will not make any offer relating to the Shares that would constitute a "free writing prospectus" as defined in Rule 405 under the Act; each Underwriter represents and agrees that, without the prior consent of the Company and the Representatives, it has not made and will not make any offer relating to the Shares that would constitute a free writing prospectus required to be filed with the Commission; any such free writing prospectus the use of which has been consented to by the Company and the Representatives is listed on Schedule II(a) or Schedule II(c) hereto;

(b) The Company represents and agrees that (i) it has not engaged in, or authorized any other person to engage in, any Testing-the-Waters Communications, other than Testing-the-Waters Communications with the prior consent of the Representatives with entities that the Company reasonably believes are qualified institutional buyers as defined in Rule 144A under the Act or institutions that are accredited investors as defined Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Act; and (ii) it has not distributed, or authorized any other person to distribute, any Written Testing-the-Waters Communications, other than those distributed with the prior consent of the Representatives that are listed on Schedule II(d) hereto; and the Company reconfirms that the Underwriters have been authorized to act on its behalf in engaging in Testing-the-Waters Communications;

(c) The Company has complied and will comply with the requirements of Rule 433 under the Act applicable to any Issuer Free Writing Prospectus, including timely filing with the Commission or retention where required and legending;

(d) The Company agrees that if at any time following issuance of an Issuer Free Writing Prospectus or Written Testing-the-Waters Communication any event occurred or occurs as a result of which such Issuer Free Writing Prospectus or Written Testing-the-Waters Communication would conflict with the information in the Registration Statement, the Pricing Prospectus or the Prospectus or would include an untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances then prevailing, not misleading, the Company will give prompt notice thereof to the Representatives and, if requested by the Representatives, will prepare and furnish without charge to each Underwriter an Issuer Free Writing Prospectus, Written Testing-the-Waters Communication or other document which will correct such conflict, statement or omission; provided, however, that this representation and warranty shall not apply to any statements or omissions in an Issuer Free Writing Prospectus or Written Testing-the-Waters Communication made in reliance upon and in conformity with the Underwriter Information; and

(e) Each Underwriter represents and agrees that any Written Testing-the-Waters Communications undertaken by it were with entities that are qualified institutional buyers as defined in Rule 144A under the Act or institutions that are accredited investors as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Act.

7. The Company covenants and agrees with the several Underwriters that the Company will pay or cause to be paid the following: (i) the fees, disbursements and expenses of the Company's counsel and accountants in connection with the registration of the Shares under the Act and all other expenses in connection with the preparation, printing, reproduction and filing of the Registration Statement, the Base Prospectus, any Preliminary Prospectus, any Written Testing-the-Waters Communication, any Issuer Free Writing Prospectus and the Prospectus and amendments and supplements thereto and the mailing and delivering of copies thereof to the Underwriters and dealers; (ii) the cost of printing or producing any Agreement among Underwriters, this Agreement, any Blue Sky Memorandum, closing documents (including any compilations thereof) and any other documents in

connection with the offering, purchase, sale and delivery of the Shares; (iii) all expenses in connection with the qualification of the Shares for offering and sale under state securities laws as provided in Section 5(b) hereof, including the fees and disbursements of counsel for the Underwriters in connection with such qualification and in connection with the Blue Sky survey(s), up to a maximum of $2,500; (iv) any filing fees incident to, and the fees and disbursements of counsel for the Underwriters in connection with, any required reviews by FINRA of the terms of the sale of the Shares (provided that the maximum aggregate amount payable by the Company pursuant to clause (iii) and this clause (iv) for fees and disbursements of counsel to the Underwriters shall not together exceed $15,000); (v) the cost of preparing certificates for the Shares, if applicable; (vi) the cost and charges of any transfer agent or registrar or dividend disbursing agent; (vii) all fees and expenses in connection with listing the Shares on the Exchange; and (viii) all other costs and expenses incident to the performance of its obligations hereunder which are not otherwise specifically provided for in this Section, provided, however, that with respect to costs associated with the "road show" undertaken in connection with the marketing of the Shares, (A) the Company shall pay the costs relating to investor presentations, including, without limitation, expenses associated with the production of road show slides and graphics and fees and expenses of any consultants engaged in connection with the road show presentations, (B) the Company and the Underwriters shall each pay their respective lodging expenses in connection with attending such presentations or meetings and (C) the Company and the Underwriters shall each pay their respective travel expenses in connection with attending such presentations, except that ground transportation costs and the cost of any aircraft chartered in connection with the road show shall each be paid 50% by the Company and 50% by the Underwriters. It is understood, however, that, except as provided in this Section, and Sections 9 and 12 hereof, the Underwriters will pay all of their own costs and expenses, including the fees of their counsel, transfer taxes on resale of any of the Shares by them, and any advertising expenses connected with any offers they may make.

8. The obligations of the Underwriters hereunder, as to the Shares to be delivered at each Time of Delivery, shall be subject, in their discretion, to the condition that all representations and warranties and other statements of the Company herein are, at and as of the Applicable Time and such Time of Delivery, true and correct, the condition that the Company shall have performed all of its obligations hereunder theretofore to be performed, and the following additional conditions:

(a) The Prospectus shall have been filed with the Commission pursuant to Rule 424(b) under the Act within the applicable time period prescribed for such filing by the rules and regulations under the Act and in accordance with Section 5(a) hereof; all material required to be filed by the Company pursuant to Rule 433(d) under the Act shall have been filed with the Commission within the applicable time period prescribed for such filings by Rule 433; if the Company has elected to rely upon Rule 462(b) under the Act, the Rule 462(b) Registration Statement shall have become effective by 10:00 p.m., Washington, D.C. time, on the date of this Agreement; no stop order suspending the effectiveness of the Registration Statement or any part thereof shall have been issued and no proceeding for that purpose or pursuant to Section 8A of the Act shall have been initiated or threatened by the Commission; no stop order suspending or preventing the use of the Pricing Prospectus, Prospectus or any Issuer Free Writing Prospectus shall have been initiated or threatened by the Commission; and all requests for additional information on the part of the Commission shall have been complied with to your reasonable satisfaction;

(b) Davis Polk & Wardwell LLP, counsel for the Underwriters, shall have furnished to you such written opinion or opinions, dated such Time of Delivery in form and substance satisfactory to you, with respect to such matters as you may reasonably request, and such counsel shall have received such papers and information as they may reasonably request to enable them to pass upon such matters;

(c) Cooley LLP, counsel for the Company, shall have furnished to you their written opinion and negative assurance letter, dated such Time of Delivery, in form and substance reasonably satisfactory to you;

(d) Each of Jones Day and Fish & Richardson P.C., intellectual property counsel for the Company, shall have furnished to you their written opinion with respect to certain intellectual property matters, dated such Time of Delivery, in form and substance reasonably satisfactory to you;

(e) On the date of the Prospectus at a time prior to the execution of this Agreement, at 9:30 a.m., New York City time, on the effective date of any post-effective amendment to the Registration Statement filed subsequent to the date of this Agreement and also at each Time of Delivery, Ernst & Young LLP shall have furnished to you a letter or letters, dated the respective dates of delivery thereof, in form and substance satisfactory to you;

(f) (i) Neither the Company nor any of its subsidiaries shall have sustained since the date of the latest audited financial statements included or incorporated by reference in the Pricing Prospectus any loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor dispute or court or governmental action, order or decree, otherwise than as set forth or contemplated in the Pricing Prospectus, and (ii) since the respective dates as of which information is given in the Pricing Prospectus there shall not have been any change in the capital stock (other than as a result of (A) the exercise or settlement (including any "net" or "cashless" exercise or settlements) of outstanding stock options or warrants, (B) the award of stock options in the ordinary course of business pursuant to the Company's equity incentive plans that are described in the Pricing Prospectus or (C) the repurchase of stock from employees or consultants terminating their service to the Company) or long-term debt of the Company or any of its subsidiaries or any change or effect, or any development involving a prospective change or effect, in or affecting (x) the business, properties, general affairs, management, financial position, stockholders' equity or results of operations of the Company and its subsidiaries, taken as a whole, except as set forth or contemplated in the Pricing Prospectus, or (y) the ability of the Company to perform its obligations under this Agreement, including the issuance and sale of the Shares, or to consummate the transactions contemplated in the Pricing Prospectus and the Prospectus, the effect of which, in any such case described in clause (i) or (ii), is in your judgment so material and adverse as to make it impracticable or inadvisable to proceed with the public offering or the delivery of the Shares being delivered at such Time of Delivery on the terms and in the manner contemplated in the Pricing Prospectus and the Prospectus;

(g) On or after the Applicable Time (i) no downgrading shall have occurred in the rating accorded the Company's debt securities or preferred stock by any "nationally recognized statistical rating organization", as that term is defined by the Commission for purposes of Rule 436(g)(2) under the Act, and (ii) no such organization shall have publicly announced that it has under surveillance or review, with possible negative implications, its rating of any of the Company's debt securities or preferred stock;

(h) On or after the Applicable Time there shall not have occurred any of the following: (i) a suspension or material limitation in trading in securities generally on the New York Stock Exchange or on The Nasdaq Global Select Market; (ii) a suspension or material limitation in trading in the Company's securities on The Nasdaq Global Select Market; (iii) a general moratorium on commercial banking activities declared by either Federal or New York State authorities or a material disruption in commercial banking or securities settlement or clearance services in the United States; (iv) the outbreak or escalation of hostilities involving the United States or the declaration by the United States of a national emergency or war or (v) the occurrence of any other calamity or crisis or any change in financial, political or economic conditions in the United States or elsewhere;, if the effect of any such event specified in clause (iv) or (v) in your sole judgment makes it impracticable or inadvisable to proceed with the public offering or the delivery of the Shares being delivered at such Time of Delivery on the terms and in the manner contemplated in the Pricing Prospectus and the Prospectus;

(i) The Shares to be sold at each Time of Delivery shall have been duly listed for quotation on The Nasdaq Global Select Market, subject only to official notice of issuance;

(j) The Company shall have obtained and delivered to the Underwriters executed copies of an agreement from each of the Company's directors and executive officers listed on Schedule III hereto, substantially to the effect set forth in Annex I hereto in form and substance satisfactory to you;

(k) The Company shall have complied with the provisions of Section 5(c) hereof with respect to the furnishing of prospectuses on the New York Business Day next succeeding the date of this Agreement; and

(l) The Company shall have furnished or caused to be furnished to you at such Time of Delivery certificates of officers of the Company satisfactory to you as to the accuracy of the representations and warranties of the Company herein at and as of such Time of Delivery, as to the performance by the Company of all of its obligations hereunder to be performed at or prior to such Time of Delivery, as to the matters set forth in subsections (a) and (e) of this Section and as to such other matters as you may reasonably request.

9. (a) The Company will indemnify and hold harmless each Underwriter against any losses, claims, damages or liabilities, joint or several, to which such Underwriter may become subject, under the Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, the Base Prospectus, any Preliminary Prospectus, the Pricing Prospectus or the Prospectus, or any amendment or supplement thereto, any Issuer Free Writing Prospectus, any "roadshow" as defined in Rule 433(h) under the Act (a "roadshow"), any "issuer information" filed or required to be filed pursuant to Rule 433(d) under the Act or any Testing-the-Waters Communication, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, and will reimburse each Underwriter for any legal or other expenses reasonably incurred by such Underwriter in connection with investigating or defending any such action or claim as such expenses are incurred; provided, however, that the Company shall not be liable in any such case to the extent that any such loss, claim, damage or liability arises out of or is based upon an untrue statement or alleged untrue statement or omission or alleged omission made in the Registration Statement, the Base Prospectus, any Preliminary Prospectus, the Pricing Prospectus or the Prospectus, or any amendment or supplement thereto, or any Issuer Free Writing Prospectus or any Testing-the-Waters Communication, in reliance upon and in conformity with the Underwriter Information.

(b) Each Underwriter will indemnify and hold harmless the Company against any losses, claims, damages or liabilities to which the Company may become subject, under the Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, the Base Prospectus, any Preliminary Prospectus, the Pricing Prospectus or the Prospectus, or any amendment or supplement thereto, or any Issuer Free Writing Prospectus, or any roadshow or any Testing-the-Waters Communication, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, the Base Prospectus, any Preliminary Prospectus, the Pricing Prospectus or the Prospectus, or any amendment or supplement thereto, or any Issuer Free Writing Prospectus, or any roadshow or any Testing-the-Waters Communication, in reliance upon and in conformity with the Underwriter Information; and will reimburse the Company for any legal or other expenses reasonably incurred by the Company in connection with investigating or defending any such action or claim as such expenses are incurred. As used in this Agreement with respect to an Underwriter and an applicable document, "Underwriter Information" shall mean the written information furnished to the Company by such Underwriter through the Representatives expressly for use therein; it being understood and agreed upon that the only such information furnished by any Underwriter consists of the following information in the Prospectus furnished on behalf of each Underwriter: the concession and reallowance figures appearing in the fifth paragraph under the caption "Underwriting", and the information contained in the tenth, eleventh and twelfth paragraphs under the caption "Underwriting" beginning with the words "In connection with the offering . . . ."

(c) Promptly after receipt by an indemnified party under subsection (a) or (b) of this Section 9 of notice of the commencement of any action, such indemnified party shall, if a claim in respect thereof is to be made against the indemnifying party under such subsection, notify the indemnifying party in writing of the commencement thereof; provided that the failure to notify the indemnifying party shall not relieve it from any liability that it may have under the preceding paragraphs of this Section 9 except to the extent that it has been materially prejudiced (through the forfeiture of substantive rights or defenses) by such failure; and provided further that the failure to notify the indemnifying party shall not relieve it from any liability that it may have to an indemnified party otherwise than under the preceding paragraphs of this Section 9. In case any such action shall be brought against any indemnified party and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate therein and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party (who shall not, except with the consent of the indemnified party, be counsel to the indemnifying party), and, after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party shall not be liable to such indemnified party under such subsection for any legal expenses of other counsel or any other expenses, in each case subsequently incurred by such indemnified party, in connection with the defense thereof other than reasonable costs of investigation. No indemnifying party shall, without the written consent of the indemnified party, effect the settlement or compromise of, or consent to the entry of any judgment with respect to, any pending or threatened action or claim in respect of which indemnification or contribution may be sought hereunder (whether or not the indemnified party is an actual or potential party to such action or claim) unless such settlement, compromise or judgment (i) includes an unconditional release of the indemnified party from all liability arising out of such action or claim and (ii) does not include any statement as to or an admission of fault, culpability or a failure to act, by or on behalf of any indemnified party.

(d) If the indemnification provided for in this Section 9 is unavailable to or insufficient to hold harmless an indemnified party under subsection (a) or (b) above in respect of any losses, claims, damages or liabilities (or actions in respect thereof) referred to therein, then each indemnifying party shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities (or actions in respect thereof) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other from the offering of the Shares. If, however, the allocation provided by the immediately preceding sentence is not permitted by applicable law, then each indemnifying party shall contribute to such amount paid or payable by such indemnified party in such proportion as is appropriate to reflect not only such relative benefits but also the relative fault of the Company on the one hand and the Underwriters on the other in connection with the statements or omissions which resulted in such losses, claims, damages or liabilities (or actions in respect thereof), as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover page of the Prospectus. The relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company on the one hand or the Underwriters on the other and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this subsection (d) were determined by *pro rata* allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above in this subsection (d). The amount paid or payable by an indemnified party as a result of the losses, claims, damages or liabilities (or actions in respect thereof) referred to above in this subsection (d) shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this subsection (d), no Underwriter shall be required to contribute any amount in excess of the amount by which the total price at which the Shares underwritten by it and distributed to the public were offered to the public exceeds the amount of any damages which such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations in this subsection (d) to contribute are several in proportion to their respective underwriting obligations and not joint.

(e) The obligations of the Company under this Section 9 shall be in addition to any liability which the Company may otherwise have and shall extend, upon the same terms and conditions, to each employee, officer and director of each Underwriter, each person, if any, who controls any Underwriter within the meaning of the Act and each broker-dealer or other affiliate of any Underwriter; and the obligations of the Underwriters under this Section 9 shall be in addition to any liability which the respective Underwriters may otherwise have and shall extend, upon the same terms and conditions, to each officer and director of the Company and to each person, if any, who controls the Company within the meaning of the Act.

10. (a) If any Underwriter shall default in its obligation to purchase the Shares which it has agreed to purchase hereunder, you may in your discretion arrange for you or another party or other parties to purchase such Shares on the terms contained herein. If within thirty-six hours after such default by any Underwriter you do not arrange for the purchase of such Shares, then the Company shall be entitled to a further period of thirty-six hours within which to procure another party or other parties satisfactory to you to purchase such Shares on such terms. In the event that, within the respective prescribed periods, you notify the Company that you have so arranged for the purchase of such Shares, or the Company notifies you that it has so arranged for the purchase of such Shares, you or the Company shall have the right to postpone such Time of Delivery for a period of not more than seven days, in order to effect whatever changes may thereby be made necessary in the Registration Statement or the Prospectus, or in any other documents or arrangements, and the Company agrees to file promptly any amendments or supplements to the Registration Statement or the Prospectus which in your opinion may thereby be made necessary. The term "Underwriter" as used in this Agreement shall include any person substituted under this Section with like effect as if such person had originally been a party to this Agreement with respect to such Shares.

(b) If, after giving effect to any arrangements for the purchase of the Shares of a defaulting Underwriter or Underwriters by you and the Company as provided in subsection (a) above, the aggregate number of such Shares which remains unpurchased does not exceed one-eleventh of the aggregate number of all of the Shares to be purchased at such Time of Delivery, then the Company shall have the right to require each non-defaulting Underwriter to purchase the number of Shares which such Underwriter agreed to purchase hereunder at such Time of Delivery and, in addition, to require each non-defaulting Underwriter to purchase its pro rata share (based on the number of Shares which such Underwriter agreed to purchase hereunder) of the Shares of such defaulting Underwriter or Underwriters for which such arrangements have not been made; but nothing herein shall relieve a defaulting Underwriter from liability for its default.

(c) If, after giving effect to any arrangements for the purchase of the Shares of a defaulting Underwriter or Underwriters by you and the Company as provided in subsection (a) above, the aggregate number of such Shares which remains unpurchased exceeds one-eleventh of the aggregate number of all of the Shares to be purchased at such Time of Delivery, or if the Company shall not exercise the right described in subsection (b) above to require non-defaulting Underwriters to purchase Shares of a defaulting Underwriter or Underwriters, then this Agreement (or, with respect to the Second Time of Delivery, the obligations of the Underwriters to purchase and of the Company to sell the Optional Shares) shall thereupon terminate, without liability on the part of any non-defaulting Underwriter or the Company, except for the expenses to be borne by the Company and the Underwriters as provided in Section 7 hereof and the indemnity and contribution agreements in Section 9 hereof; but nothing herein shall relieve a defaulting Underwriter from liability for its default.

11. The respective indemnities, rights of contribution, agreements, representations, warranties and other statements of the Company and the several Underwriters, as set forth in this Agreement or made by or on behalf of them, respectively, pursuant to this Agreement, shall remain in full force and effect, regardless of any investigation (or any statement as to the results thereof) made by or on behalf of any Underwriter or any director, officer, employee, affiliate or controlling person of any Underwriter, or the Company, or any officer or director or controlling person of the Company, and shall survive delivery of and payment for the Shares.

12. If this Agreement shall be terminated pursuant to Section 10 hereof, the Company shall not then be under any liability to any Underwriter except as provided in Sections 7 and 9 hereof; but, if for any other reason, any Shares are not delivered by or on behalf of the Company as provided herein, the Company will reimburse the Underwriters through you for all reasonable and documented out-of-pocket expenses approved in writing by you, including fees and disbursements of counsel, reasonably incurred by the Underwriters in making preparations for the purchase, sale and delivery of the Shares not so delivered, but the Company shall then be under no further liability to any Underwriter except as provided in Sections 7 and 9 hereof.

13. In all dealings hereunder, you shall act on behalf of each of the Underwriters, and the parties hereto shall be entitled to act and rely upon any statement, request, notice or agreement on behalf of any Underwriter made or given by you jointly.

All statements, requests, notices and agreements hereunder shall be in writing, and if to the Underwriters shall be delivered or sent by mail, telex or facsimile transmission to the Representatives at Goldman Sachs & Co. LLC, 200 West Street, New York, New York 10282-2198, Attention: Registration Department, Fax: 646-291-1469; at Citigroup Global Markets Inc., 388 Greenwich Street, New York, New York 10013, Attention: General Counsel; and at Cowen and Company, LLC, Attention: Head of Equity Capital Markets, Fax: 646-562-1249, with a copy to the General Counsel, Fax: 646-562-1124; and if to the Company shall be delivered or sent by mail, telex or facsimile transmission to the address of the Company set forth on the cover of the Registration Statement, Attention: Secretary; and if to any stockholder that has delivered a lock-up letter described in Section 8(j) hereof shall be delivered or sent by mail to his, her or its respective address as such stockholder provides in writing to the Company; provided, however, that any notice to an Underwriter pursuant to Section 9(c) hereof shall be provided, however, that any notice to an Underwriter pursuant to Section 9(c) hereof shall be delivered or sent by mail, telex or facsimile transmission to such Underwriter at its address set forth in its Underwriters' Questionnaire, or telex constituting such Questionnaire, which address will be supplied to the Company by you upon request. Any such statements, requests, notices or agreements shall take effect upon receipt thereof.

In accordance with the requirements of the USA Patriot Act (Title III of Pub. L. 107-56 (signed into law October 26, 2001)), the Underwriters are required to obtain, verify and record information that identifies their respective clients, including the Company, which information may include the name and address of their respective clients, as well as other information that will allow the Underwriters to properly identify their respective clients.

14. This Agreement shall be binding upon, and inure solely to the benefit of, the Underwriters, the Company and, to the extent provided in Sections 9 and 11 hereof, the officers and directors of the Company and each person who controls the Company or any Underwriter, or any director, officer, employee, or affiliate of any Underwriter, and their respective heirs, executors, administrators, successors and assigns, and no other person shall acquire or have any right under or by virtue of this Agreement. No purchaser of any of the Shares from any Underwriter shall be deemed a successor or assign by reason merely of such purchase.

15. Time shall be of the essence of this Agreement. As used herein, the term "business day" shall mean any day when the Commission's office in Washington, D.C. is open for business.

16. The Company acknowledges and agrees that (i) the purchase and sale of the Shares pursuant to this Agreement is an arm's-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other, (ii) in connection therewith and with the process leading to such transaction each Underwriter is acting solely as a principal and not the agent or fiduciary of the Company, (iii) no Underwriter has assumed an advisory or fiduciary responsibility in favor of the Company with respect to the offering contemplated hereby or the process leading thereto (irrespective

of whether such Underwriter has advised or is currently advising the Company on other matters) or any other obligation to the Company except the obligations expressly set forth in this Agreement, (iv) the Company has consulted its own legal and financial advisors to the extent it deemed appropriate, and (v) none of the activities of the Underwriters in connection with the transactions contemplated herein constitutes a recommendation, investment advice, or solicitation of any action by the Underwriters with respect to any entity or natural person. The Company agrees that it will not claim that the Underwriters, or any of them, has rendered advisory services of any nature or respect, or owes a fiduciary or similar duty to the Company, in connection with such transaction or the process leading thereto.

17. This Agreement supersedes all prior agreements and understandings (whether written or oral) between the Company and the Underwriters, or any of them, with respect to the subject matter hereof.

18. This Agreement and any transaction contemplated by this Agreement shall be governed by and construed in accordance with the laws of the State of New York without regard to principles of conflict of laws that would results in the application of any other law than the laws of the State of New York. The Company agrees that any suit or proceeding arising in respect of this Agreement or any transaction contemplated by this Agreement will be tried exclusively in the U.S. District Court for the Southern District of New York or, if that court does not have subject matter jurisdiction, in any state court located in The City and County of New York and the Company agrees to submit to the jurisdiction of, and to venue in, such courts.

19. The Company and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

20. Notwithstanding anything herein to the contrary, the Company is authorized to disclose to any persons U.S. federal and state tax treatment and tax structure of the potential transaction and all materials of any kind (including tax opinions and other tax analyses) provided to the Company relating to that treatment and structure, without the Underwriters imposing any limitation of any kind. However, any information relating to the tax treatment and tax structure shall remain confidential (and the foregoing sentence shall not apply) to the extent necessary to enable any person to comply with securities laws. For this purpose, “tax structure” is limited to any facts that may be relevant to that treatment.

21. This Agreement may be executed by any one or more of the parties hereto in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

22. Recognition of the U.S. Special Resolution Regimes.

(a) In the event that any Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from such Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.

(b) In the event that any Underwriter that is a Covered Entity or a BHC Act Affiliate of such Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against such Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

(c) As used in this section:

"BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k).

"Covered Entity" means any of the following:

(i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b);

(ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 47.3(b); or

(iii) a "covered FSI" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b).

"Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. §§ 252.81, 47.2 or 382.1, as applicable.

"U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

If the foregoing is in accordance with your understanding, please sign and return to us six counterparts hereof, and upon the acceptance hereof by you, on behalf of each of the Underwriters, this letter and such acceptance hereof shall constitute a binding agreement between each of the Underwriters and the Company. It is understood that your acceptance of this letter on behalf of each of the Underwriters is pursuant to the authority set forth in a form of Agreement among Underwriters, the form of which shall be submitted to the Company for examination upon request, but without warranty on your part as to the authority of the signers thereof.

Very truly yours,

NGM Biopharmaceuticals, Inc.

By: /s/ Siobhan Nolan Mangini
Name: Siobhan Nolan Mangini
Title: Chief Financial officer

Accepted as of the date hereof:

Goldman Sachs & Co. LLC
Citigroup Global Markets Inc.
Cowen and Company, LLC

Goldman Sachs & Co. LLC

By: /s/ Elizabeth Wood
Name: Elizabeth Wood
Title: Managing Director

Citigroup Global Markets Inc.

By: /s/ Bradley Wolff
Name: Bradley Wolff
Title: Managing Director

Cowen and Company, LLC

By: /s/ Bill Follis
Name: Bill Follis
Title: Managing Director

SCHEDULE I

Underwriter	Number of Firm Shares to be Purchased	Maximum Number of Optional Shares Which May be Purchased
Goldman Sachs & Co. LLC	1,990,741	298,611
Citigroup Global Markets Inc.	1,203,704	180,556
Cowen and Company, LLC	925,926	138,889
Raymond James & Associates, Inc.	277,778	41,667
B. Riley Securities, Inc.	231,481	34,721
Total	4,629,630	694,444

SCHEDULE II

(a) Issuer Free Writing Prospectuses not included in the Pricing Disclosure Package:

Electronic roadshow dated January 5, 2021

(b) Additional Documents Incorporated by Reference:

None

(c) Information other than the Pricing Prospectus that comprise the Pricing Disclosure Package:

The initial public offering price per share for the Shares is $27.00

The number of Shares purchased by the Underwriters is 4,629,630.

(d) Written Testing-the-Waters Communications:

None

SCHEDULE III

Name of Stockholder

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

Jin-Long Chen, Ph.D., Chief Scientific Officer and Director

Carole Ho, M.D., Director

William J. Rieflin, Executive Chairman and Director

David Schnell, M.D., Director

David V. Goeddel, Ph.D., Director

Mark Leschly, Director

McHenry T. Tichenor, Jr., Director

Shelly D. Guyer, Director

Suzanne Sawochka Hooper, Director

Siobhan Nolan Mangini, Chief Financial Officer

Hsiao D. Lieu, M.D., Chief Medical Officer and Senior Vice President

ANNEX I

FORM OF LOCK-UP AGREEMENT

NGM Biopharmaceuticals, Inc.

Lock-Up Agreement

_____, 20__

Goldman Sachs & Co. LLC
Citigroup Global Markets Inc.
Cowen and Company, LLC

c/o Goldman Sachs & Co. LLC
200 West Street
New York, NY 10282

c/o Citigroup Global Markets Inc.
388 Greenwich Street
New York, NY 10013

c/o Cowen and Company, LLC
599 Lexington Avenue
New York, NY 10022

Re: NGM Biopharmaceuticals, Inc.—Lock-Up Agreement

Ladies and Gentlemen:

The undersigned understands that you, as representatives (the "Representatives"), propose to enter into an Underwriting Agreement (the "Underwriting Agreement") on behalf of the several Underwriters to be named in Schedule I to such agreement (collectively, the "Underwriters"), with NGM Biopharmaceuticals, Inc., a Delaware corporation (the "Company"), providing for a public offering (the "Offering") of the common stock, par value $0.001 per share, (the "Common Stock") of the Company (the "Shares") pursuant to a Registration Statement on Form S-3 (the "Registration Statement") filed with the Securities and Exchange Commission (the "SEC").

In consideration of the agreement by the Underwriters to offer and sell the Shares, and of other good and valuable consideration the receipt and sufficiency of which is hereby acknowledged, the undersigned agrees that, during the period beginning from the date hereof and continuing to and including the date 60 days after the date of the final prospectus covering the public offering of the Shares (the "Lock-Up Period"), the undersigned shall not, and shall not cause or direct any of its affiliates to, (i) offer, sell, contract to sell, pledge, grant any option to purchase, lend, make any short sale or otherwise dispose of any shares of Common Stock of the Company, or any options or warrants to purchase any shares of Common Stock of the Company, or any securities convertible into, exchangeable for or that represent the right to receive shares of Common Stock of the Company (such options, warrants or other securities,

collectively, "Derivative Instruments"), including without limitation any such shares or Derivative Instruments, whether now owned or hereafter acquired, owned directly by the undersigned (including holding as a custodian) or with respect to which the undersigned has beneficial ownership within the rules and regulations of the SEC (collectively the "Undersigned's Shares"), (ii) engage in any hedging or other transaction or arrangement (including, without limitation, any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward, swap or any other derivative transaction or instrument, however described or defined) which is designed to or which reasonably could be expected to lead to or result in a sale, loan, pledge or other disposition (whether by the undersigned or someone other than the undersigned), or transfer of any of the economic consequences of ownership, in whole or in part, directly or indirectly, of any shares of Common Stock of the Company or Derivative Instruments, whether any such transaction or arrangement (or instrument provided for thereunder) would be settled by delivery of Common Stock or other securities, in cash or otherwise (any such sale, loan, pledge or other disposition, or transfer of economic consequences, a "Transfer") or (iii) otherwise publicly announce any intention to engage in or cause any action or activity described in clause (i) above or transaction or arrangement described in clause (ii) above. The undersigned represents and warrants that the undersigned is not, and has not caused or directed any of its affiliates to be or become, currently a party to any agreement or arrangement that provides for, is designed to or which reasonably could be expected to lead to or result in any Transfer during the Lock-Up Period. For the avoidance of doubt, the undersigned agrees that the foregoing provisions shall be equally applicable to any issuer-directed or other Shares the undersigned may purchase in the offering.

If the undersigned is not a natural person, the undersigned represents and warrants that no single natural person, entity or "group" (within the meaning of Section 13(d)(3) of the Securities Exchange Act of 1934, as amended), other than a natural person, entity or "group" (as described above) that has executed a Lock-Up Agreement in substantially the same form as this Lock-Up Agreement, beneficially owns, directly or indirectly, 50% or more of the common equity interests, or 50% or more of the voting power, in the undersigned.

Notwithstanding the foregoing, the undersigned may:

(1) transfer the Undersigned's Shares:

(i) as a *bona fide* gift or gifts,

(ii) to an immediate family member of the undersigned, or to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned, or if the undersigned is a trust, to any beneficiary (including such beneficiary's estate) of the undersigned or otherwise for *bona fide* estate planning purposes,

(iii) by will or under the laws of descent,

(iv) to affiliates (within the meaning set forth in Rule 405 promulgated by the SEC under the Securities Act of 1933, as amended, and including subsidiaries of the undersigned if the undersigned is a corporation), limited partners, general partners, limited liability company members or stockholders of the undersigned to the extent that the undersigned is a partnership, limited liability company or corporation,

(v) any transfer pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction made to all holders of the Shares involving a change in control of the Company,

(vi) in connection with a sale of (a) any of the Undersigned's Shares acquired in open market transactions after the Public Offering Date and, (b) unless the undersigned is a director or officer of the Company, any Shares the undersigned may purchase in the Offering, whether or not issuer-directed,

(vii) to the Company (a) as forfeitures to satisfy tax withholding and remittance obligations of the undersigned in connection with the vesting, settlement or exercise of equity awards granted pursuant to an employee benefit plan described in the Registration Statement, or (b) in connection with the repurchase of shares of Common Stock issued pursuant to an employee benefit plan described in the Registration Statement or pursuant to the agreements pursuant to which such shares were issued as disclosed in the Registration Statement,

(viii) pursuant to a trading plan established pursuant to Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the "Exchange Act") that has been disclosed to the Representatives prior to the date hereof, or

(ix) with the prior written consent of the Representatives on behalf of the Underwriters;

provided, that in the case of (i), (ii), (iii), (iv) and (v) above, it shall be a condition to the transfer that the donee, trustee, legatee, heir, distribute or other transferee, as the case may be, agrees to be bound in writing by the restrictions set forth herein; provided, further, that in the case of (i), (ii), (iii) and (iv) above, (a) no public announcement or filing under Section 16 of the Exchange Act shall be required or shall be voluntarily made during the Lock-up Period with respect to such transfers and (b) such transfers shall not involve a disposition for value; provided, further, that in the case of (vi) and (vii) above, no public announcement or filing under Section 16(a) of the Exchange Act) shall be required or shall be voluntarily made during the Lock-up Period with respect to such transfers; provided, further, that in the case of (viii) above, that any public reports or filings, including filings under Sections 13 or 16 of the Exchange Act that shall be required to be made or voluntarily made shall clearly indicate in the footnotes that such sale was made pursuant to a trading plan established pursuant to Rule 10b5-1 under the Exchange Act; or

(2) exercise any stock options issued pursuant to the Company's equity incentive plans or warrants (including, in each case, by way of net exercise, but for the avoidance of doubt, excluding all manners of exercise that would involve a sale of any securities relating to such options or warrants, whether to cover the applicable aggregate exercise price, withholding tax obligations or otherwise), which equity incentive plans and stock options or warrants are described in the Registration Statement; provided, that any securities received upon such exercise will also be subject to this Lock-Up Agreement. For purposes of this Lock-Up Agreement, "immediate family" shall mean any relationship by blood, marriage or adoption, not more remote than first cousin. The undersigned now has, and, except as contemplated by clause (1) and (2) above, for the duration of this Lock-Up Agreement will have, good and marketable title to the Undersigned's Shares, free and clear of all liens, encumbrances, and claims whatsoever. The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the Undersigned's Shares except in compliance with the foregoing restrictions. In addition, the undersigned agrees that, without the prior written consent of the Representatives on behalf of the Underwriters, it will not, during the Lock-Up Period, make any demand for or exercise any right with respect to, the registration of any shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock.

The restrictions set forth in this Lock-Up Agreement shall not apply to the conversion of outstanding shares of preferred stock of the Company into shares of Common Stock, provided, that any securities received upon such conversion will also be subject to this Lock-Up Agreement. In addition, nothing in this Lock-Up Agreement shall preclude the establishment of a new trading plan meeting the requirements of Rule 10b5-1 under the Exchange Act; provided, that (i) no public announcement or filing under Section 16(a) of the Exchange Act) regarding the establishment of such plan shall be required or shall be voluntarily made during the Lock-Up Period and (ii) no sales are made during the Lock-Up Period pursuant to such new plan.

The undersigned acknowledges and agrees that none of the Underwriters has made any recommendation or provided any investment or other advice to the undersigned with respect to this Lock-Up Agreement or the subject matter hereof, and the undersigned has consulted its own legal, accounting, financial, regulatory, tax and other advisors with respect to this Lock-Up Agreement and the subject matter hereof to the extent the undersigned has deemed appropriate.

The undersigned understands that the Company and the Underwriters are relying upon this Lock-Up Agreement in proceeding toward consummation of the offering. The undersigned further understands that this Lock-Up Agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representatives, successors, and assigns.

It is understood that, if (i) the Company notifies the Representatives, in writing, prior to the execution of the Underwriting Agreement, that it does not intend to proceed with the proposed public offering of Common Stock, (ii) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Shares to be sold thereunder, or (iii) the proposed public offering of Shares shall not have been completed by January 31, 2021, this Lock-Up Agreement shall immediately be terminated and the undersigned shall be released from all obligations under this Lock-Up Agreement.

[*Signature page follows*]

Very truly yours,

IF AN INDIVIDUAL:

_____

(signature)

Name: _____

(please print full name)

Email Address:

_____

Address:

_____

_____

IF AN ENTITY:

_____

(please print complete name of entity)

By: _____

(duly authorized signature)

Name: _____

(please print full name of signatory)

Email Address:

_____

Address:

_____

_____

Exhibit 5.1

Cooley

Carlton Fleming
+1 650 843 5865
cfleming@cooley.com

January 6, 2021

NGM Biopharmaceuticals, Inc.
333 Oyster Point Blvd
South San Francisco, CA 94080

Ladies and Gentlemen:

We have represented NGM Biopharmaceuticals, Inc., a Delaware corporation (the "***Company***"), in connection with the offering by the Company of up to 5,324,074 shares of the Company's common stock, par value $0.001 (the "***Shares***"), including up to 694,444 Shares that may be sold pursuant to the exercise of an option to purchase additional shares, pursuant to a Registration Statement on Form S-3 (Registration Statement No.333-238991) (**the "*Registration Statement*"**), filed with the Securities and Exchange Commission (the "***Commission***") under the Securities Act of 1933, as amended (the "***Act***"), the base prospectus included in the Registration Statement (the "***Base Prospectus***"), and the prospectus supplement relating to the Shares filed with the Commission pursuant to Rule 424(b) under the Act (together with the Base Prospectus, the "***Prospectus***").

In connection with this opinion, we have examined and relied upon the Registration Statement, the Prospectus, the Company's Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, each as currently in effect, and such other documents, records, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as copies, the accuracy, completeness and authenticity of certificates of public officials and the due authorization, execution and delivery of all documents by all persons other than the Company where authorization, execution and delivery are prerequisites to the effectiveness thereof. As to certain factual matters, we have relied upon a certificate of an officer of the Company and have not independently verified such matters.

Our opinion is expressed only with respect to the General Corporation Law of the State of Delaware. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state securities law, rule or regulation.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Shares, when sold in accordance with the Registration Statement and the Prospectus, will be validly issued, fully paid and nonassessable.

We consent to the reference to our firm under the caption “Legal Matters” in the Prospectus and to the filing of this opinion as an exhibit to a Current Report on Form 8-K to be filed with the Commission for incorporation by reference in the Registration Statement.

Sincerely,

Cooley LLP

By: /s/ Carlton Fleming
Carlton Fleming

Unless the context otherwise requires, the terms "NGM Biopharmaceuticals", "NGM", "we", "us" and "our" in this Exhibit 99.1 refer to NGM Biopharmaceuticals, Inc. and its wholly-owned subsidiary, taken as a whole. This Exhibit 99.1 includes trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included in this Exhibit 99.1 are the property of their respective owners.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Exhibit 99.1 contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Forward-looking statements may include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials, and the initiation of, enrollment in, availability of data for and other events related to such trials;
- our or our partners' ability to obtain and maintain regulatory approval for aldafermin (NGM282), MK-3655 (NGM313), NGM621, NGM120, NGM707, NGM438 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 aldafermin may have the potential to be a treatment for non-alcoholic steatohepatitis, or NASH, patients with moderate to advanced fibrosis;
- the potential roles of immunoglobulin-like transcript 2, or ILT2, immunoglobulin-like transcript 4, or ILT4, and leukocyte-associated immunoglobulin-like receptor 1, or LAIR1, in cancer and the potential consequences of ILT2, ILT4 and LAIR1 blockade;
- our belief regarding the impact of our product candidate side effects and our ability to effectively manage these side effects;
- our belief that MK-3655 (NGM313) may have the potential to be a treatment for NASH patients with early to moderate fibrosis;
- of our research collaboration, product development and license agreement, or the Collaboration Agreement, with Merck Sharp & Dohme Corp., or Merck, and the possibility that Merck will decide 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 potential commercialization of aldafermin, MK-3655 (NGM313), NGM621, NGM120, NGM707, NGM438 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, and our ability to obtain sufficient supply of clinical trial material in a timely manner from, third-party suppliers and manufacturers;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific, development and management personnel;
- our estimates regarding future expenses, revenue, capital requirements and needs for additional financing;

- our expectations regarding the period during which we qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act; and
- our expectations regarding our ability to obtain, maintain, protect and enforce intellectual property protection for our product candidates.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events and are based on assumptions and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss in greater detail many of these risks under the heading “Risk Factors” below. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this Exhibit 99.1. Unless required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. We qualify all of the forward-looking statements in this Exhibit 99.1 by these cautionary statements.

*****

RISK FACTORS

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

Risks Related to Our Financial Results and Capital Needs

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

We are a biopharmaceutical company that was incorporated in 2007 and commenced operations in early 2008. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect and/or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each year since commencing operations. For the three and nine months ended September 30, 2020, our net losses were $29.8 million and $74.5 million, respectively, compared to net losses of $10.9 million and $26.9 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $270.6 million.

We have spent, and expect to continue to spend, significant resources to fund research and development of, and seek regulatory approvals for, our product candidates. We will require substantial additional capital to achieve our development and commercialization goals for our aldafermin program that is being conducted outside of the Merck collaboration, for any future programs that Merck does not opt to license under the Collaboration Agreement and that we choose to develop, for any Merck-licensed programs that we opt to co-develop and for any programs that Merck chooses to license under the Collaboration Agreement and later elects to terminate. If our research and development expenses for product candidates subject to the Merck collaboration exceed the funding caps provided in our Collaboration

Agreement, which happened in the fiscal year ended December 31, 2020 and could potentially happen in the future, we will be required to devote our own financial resources toward the development of such product candidates or pause or suspend such development to remain within the funding caps. We expect to incur substantial and increasing operating losses over the next several years as our research, development, manufacturing, preclinical studies, clinical trial and related activities increase. As a result, our accumulated deficit will also increase significantly. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business, including those resulting from the evolving effects of the COVID-19 pandemic. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to continue to generate revenue under the Merck collaboration and to generate revenue outside of the Merck collaboration. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Even if we eventually generate product revenue, we may never be profitable and, if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

Since 2017, all of our revenue has been from our collaboration partner, Merck. Under the collaboration, Merck initially committed to reimburse us for research and development activities 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 investigational new drug application-, or 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. In March 2019, Merck exercised its option to extend the initial five-year research and early development program, which we refer to as the research phase of the collaboration, for an additional two years through March 16, 2022. In connection with this extension, Merck agreed to continue to fund our research and development efforts during the extension at the same levels as existed during the five-year initial term and, in lieu of a $20.0 million extension fee that would have otherwise been payable to us, Merck agreed to make additional payments totaling up to $20.0 million in support of our research and development program activities under the collaboration across 2021 and the first quarter of 2022. Accordingly, the total Merck reimbursement for our research and development activities could reach up to $75.0 million per year through the current two-year extension of the research phase of the collaboration, plus up to $20.0 million in support of our research and development activities across 2021 and the first quarter of 2022. During the fiscal years ended December 31, 2019 and 2020, the total Merck reimbursement reached $75.0 million per year. Merck has the right to extend the research phase of the collaboration again through March 16, 2024. If our research and development expenses for product candidates subject to the Merck collaboration exceed the funding caps provided in our Collaboration Agreement, which happened in the fiscal year ended December 31, 2020 and could potentially happen in the future, we will be required to devote our own financial resources toward the development of such product candidates or pause or suspend such development to remain within the funding caps. For example, in 2020 we decided to suspend activities related to NGM386, NGM395 and NGM217 to concentrate our resources on our other Merck collaboration product candidates and aldafermin. In addition, if Merck elects not to exercise its remaining option to extend the research phase of the collaboration beyond March 16, 2022, which Merck may unilaterally elect to do at its sole discretion at any time before March 16, 2021, we would require significant additional capital in order to proceed with development and commercialization of any product candidates that had been subject to the Merck collaboration but Merck decides not to proceed with after termination of the research phase, or we will need to enter into additional collaboration or license agreements in order to fund such development and commercialization, which may not be possible, or we may be required to delay, scale back or discontinue development of such product candidates.

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

Our product candidates are in the early stages of development. To date, we have not generated any revenue from commercialization of our product candidates. We will not be able to generate product revenue unless and until one of our product candidates successfully completes clinical trials, receives

regulatory approval and is successfully commercialized. As our product candidates are in Phase 2 trials or in earlier stages of development, we do not expect to receive revenue from those product candidates for a number of years, if ever. We may seek to obtain revenue from collaboration or licensing agreements with third parties. Other than our agreement with Merck, we currently have no such agreements that could provide us with material, ongoing future revenue and we may never enter into any such agreements.

Our ability to generate future product revenue from our current or future product candidates also depends on a number of additional factors, including our or our current collaborator's and potential future collaborators' ability to:

- successfully complete research and clinical development of current and future product candidates;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate, scaled up and legally compliant manufacturing of bulk drug substances and drug products to maintain sufficient supply;
- launch and commercialize any product candidates for which we obtain marketing approval, if any, and, if launched independently by us without a collaborator, successfully establish a sales force and marketing and distribution infrastructure;
- demonstrate the necessary safety data (and, if accelerated approval is obtained, verify the clinical benefit) post-approval to ensure continued regulatory approval;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors, for any approved products;
- achieve market acceptance for any approved products;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

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

Even if we generate revenue from the sale of any of our products that may be approved, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or do not sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or cease our operations.

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

As a research and development company, our operations have consumed substantial amounts of cash since inception and we will require additional capital to finance our operations and pursue our strategy, which may not be available to us on acceptable terms, or at all. We expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly to the extent that product candidates whose costs are not included in the Merck collaboration, such as aldafermin, advance in clinical development. In addition, we may be required to develop and implement additional clinical study policies and procedures to mitigate the evolving effects of the COVID-19 pandemic, which could significantly increase our research and development expenses. We believe that our existing cash, cash equivalents and short-term marketable securities, together with the anticipated net proceeds from our recently-announced public offering of common stock, will be sufficient to fund our operations for at least the next twelve months. We plan to continue to fund our operations and pursue our strategy through the Sales Agreement or other public or private equity or debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements or a combination of these. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section.

We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Our future funding requirements, both short- and long-term, will depend on many factors, including:

- the initiation, progress, timing, delays, costs and results of preclinical studies and clinical trials for our current product candidates and any future product candidates we may develop;
- whether Merck exercises its option to license product candidates upon our completion of proof-of-concept studies for each such candidate in humans;
- whether Merck terminates the research phase of the collaboration under pre-specified circumstances set forth in the Collaboration Agreement or terminates a program that it has licensed (such as Merck's termination of its license for NGM395 and NGM386);
- whether Merck exercises its remaining option to extend the research phase of the collaboration, which would trigger an extension payment to us;
- whether we exceed the funding caps provided in our Collaboration Agreement, which happened in the fiscal year ended December 31, 2020 and could potentially happen in the future, which would require us to devote our own financial resources toward the development of programs and product candidates subject to the Merck collaboration during the current two-year extension of the research phase (and during a second extension should Merck unilaterally determine to trigger a second extension) or delay, scale back or discontinue such development to remain within the funding caps;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the U.S. Food and Drug Administration, or FDA, and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more studies than those that we currently expect or to change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of products that may compete with our product candidates or other market developments;
- market acceptance of any approved product candidates, including product pricing and product reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for commercial-scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for our product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with partners; and
- the extent to which any of the foregoing costs are the responsibility of Merck.

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

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

We plan to finance our future cash needs through the Sales Agreement or other public or private equity or debt offerings, government or other third-party funding, product collaborations, strategic alliances, licensing arrangements or a combination of these. Additional capital may not be available in sufficient amounts, on reasonable terms or when we need it, if at all, including pursuant to the Sales Agreement, and our ability to raise additional capital may be adversely impacted by worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from, among other things, the evolving effects of the COVID-19 pandemic. Our existing stockholders could suffer dilution or be negatively affected by fixed payment obligations we may incur if we raise additional funds through the issuance of additional equity securities or debt, including equity securities already sold and that may in the future be sold pursuant to the Sales Agreement as well as the equity securities to be sold in connection with our recently-announced public offering of common stock. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants or protective rights that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

If we are unable to raise adequate additional capital, including pursuant to the Sales Agreement, we may not be able to expand our operations or otherwise capitalize on our business opportunities, our business and financial condition will be negatively impacted, and we may need to:

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

Accordingly, if we are unable to raise adequate additional capital, we may be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

Our ability to use net operating loss carryforwards to offset taxable income could be limited.

We plan to use our current year operating losses to offset taxable income from any revenue generated from operations, including corporate collaborations. To the extent that our taxable income exceeds any current year operating losses, we plan to use our net operating loss carryforwards to offset income that would otherwise be taxable. Our net operating loss carryforwards generated in tax years ending on or prior to December 31, 2017 are only permitted to be carried forward for 20 years under applicable U.S. tax law. Under the Tax Cuts and Jobs Act, or the 2017 Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, our federal net operating losses generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating losses generated in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the 2017 Tax Act or the CARES Act.

In addition, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, if we experience an “ownership change,” generally defined as a greater than 50% change, by value, in equity ownership over a three-year period, our ability to use our pre-change net operating loss carryforwards to offset our post-change income may be limited. Due to our initial public offering, or the IPO, and subsequent shifts in our stock ownership, we have experienced ownership changes in the past and may experience ownership changes in the future as a result of our recently-announced public offering of our common stock and other subsequent shifts in our stock ownership, some of which are outside our control. As a result, our use of federal net operating loss carryforwards could be limited. State net operating loss carryforwards may be similarly limited. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Any such limitations may result in greater tax liabilities than we would incur in the absence of such limitations and any increased liabilities could adversely affect our business, results of operations, financial position and cash flows.

Risks Related to Our Business and Industry

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

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

- ongoing discussions with the FDA or comparable foreign authorities regarding the scope or design of our clinical trials, including discussions with the FDA regarding initiation of our planned Phase 3 trial of aldafermin;
- delays in obtaining, or the inability to obtain, required approvals from institutional review boards, or IRBs, or other governing entities at clinical trial sites selected for participation in our clinical trials;
- delays in enrolling participants into clinical trials, such as the slower pace of enrollment we have experienced, from time to time, in our ALPINE 4 and CATALINA trials, including as a result of the evolving effects of the COVID-19 pandemic;
- delays in key trial activities and patient enrollment or diversion of healthcare resources as a result of the evolving effects of the COVID-19 pandemic, such as the slower pace of clinical trial site initiation in our ALPINE 4, CATALINA and NGM120 trials;
- lower than anticipated retention rates of participants in clinical trials;
- implementation of new, or changes to, guidance or interpretations from the FDA or comparable foreign authorities with respect to approval pathways for product candidates we are pursuing, such as draft guidance documents from the FDA for the development of products for the treatment of NASH that issued in 2018 and 2019 and from the European Medicines Agency, or EMA, that issued in 2018;
- the need to repeat clinical trials as a result of inconclusive or negative results, poorly executed testing or changes in required endpoints by the FDA or comparable foreign authorities;
- insufficient supply or deficient quality of drug substance, drug product or other clinical trial material necessary to conduct our clinical trials;
- unfavorable FDA or comparable foreign authority inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- serious and unexpected drug-related adverse effects experienced by participants in our clinical trials; or
- the placement of a clinical hold on a trial by the FDA or comparable foreign authorities.

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

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

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

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we or our collaborators must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Preclinical studies and clinical trials are expensive, take several years to complete and may not yield results that support further clinical development or product approvals. A failure of one or more clinical trials can occur at any stage of testing.

To date, the data supporting our drug discovery and development programs are derived from laboratory and preclinical studies and earlier-stage clinical trials. Despite the results reported in our Phase 1 and 2 clinical trials for aldafermin, in Phase 1 clinical trials for MK-3655 (NGM313), NGM621 and NGM120 and in preclinical studies for our other product candidates, including NGM707 and NGM438, future clinical trials in humans may show that one or more of our product candidates are not safe and effective, in which event we may need to abandon development of such product candidates. It is impossible to predict when or if any of our product candidates will prove safe and effective in humans or will receive regulatory approval. Owing in part to the complexity of biological pathways, these compounds might not demonstrate in patients the biochemical and pharmacological properties we anticipate based on laboratory studies or earlier-stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways.

Further, we expect that certain of our current product candidates will, and future product candidates may, require chronic administration. The need for chronic administration increases the risk that participants in our clinical trials will fail to comply with our dosing regimens. If participants fail to comply, we may not be able to generate clinical data in our trials acceptable to the FDA or foreign regulatory authorities. The need for chronic administration also increases the risk that our clinical drug development programs may not uncover all possible adverse events that patients who take our products may eventually experience. The number of patients exposed to treatment with, and the average exposure time to, our product candidates in clinical development programs may be inadequate to detect rare adverse events or chance findings that may only be detected once our products are administered to more patients and for longer periods of time.

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

Success in preclinical studies or earlier-stage clinical trials may not be indicative of results in future clinical trials.

Success in preclinical studies and earlier-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of our product candidates. Similarly, preliminary data and interim results from clinical trials may not be predictive of final results. Frequently, product candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. For example, the results we obtained in our Phase 1 trials of aldafermin and in our completed Phase 2 trial, including the data from the fourth and final 24-week expansion cohort of that trial in patients with fibrosis stage F2 or F3 NASH, may not be indicative of the future results we obtain from our ongoing ALPINE 2/3 and ALPINE 4 trials and any Phase 3 trial.

Some of our clinical trials involve small patient populations, sometimes at single sites, and the results of these clinical trials may be subject to substantial variability and may not be indicative of either future interim results or final results. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Because we have limited experience designing clinical trials, we may be unable to design and execute a clinical trial to support regulatory approval.

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

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

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

We cannot guarantee that we will be able to successfully accomplish required regulatory activities or all of the other activities necessary to initiate and complete clinical trials. As a result, our preclinical studies and clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approvals or successfully commercialize our products. For example, we have experienced, from time to time, a slower pace of clinical trial site initiation and enrollment than originally anticipated in certain of our clinical trials, including the ALPINE 4, CATALINA and NGM120 trials, as a result of the evolving effects of the COVID-19 pandemic, and if the evolving effects of the COVID-19 pandemic become more severe, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects. In any event, we do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Our product development costs will increase if we continue to experience delays in clinical testing. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects. Events that may result in a delay or failure to successfully complete clinical development include:

- delays in reaching agreement on acceptable terms with prospective clinical 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 to clinical trial sites of the product candidates or other study materials;
- delays in key trial activities, clinical trial site initiation and patient enrollment or diversion of healthcare resources as a result of the evolving effects of the COVID-19 pandemic;

- for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected patients and test any patient samples;
- delays in patient enrollment, such as the slower pace of enrollment we have experienced, from time to time, in our ALPINE 4 and CATALINA trials, including as a result of the evolving effects of the COVID-19 pandemic;
- delays in patients completing a trial or returning for post-treatment follow-up;
- delays caused by patients dropping out of a trial, including due to side effects, disease progression or concerns about the COVID-19 pandemic;
- demonstration of a significant adverse safety or tolerability signal limiting the utility of the product candidate;
- changes in regulatory authority recommendations or guidance regarding development of drugs for a particular indication that we are pursuing, such as draft guidance documents from the FDA for the development of NASH that issued in 2018 and 2019 and from the EMA that issued in 2018;
- withdrawal of clinical trial sites or investigators from our clinical trials for any reason, including as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials; or
- changes in government regulations or administrative actions or lack of adequate funding to continue the clinical trials.

Our or our collaborators' inability to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenue or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

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

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

- the size and nature of the patient population we enroll;
- the number and location of clinical trial sites;
- delays in enrollment due to travel or quarantine policies, behaviors or other factors related to COVID-19;
- competition with other companies for clinical trial sites or patients;
- the eligibility and exclusion criteria for the trial;
- the design of the clinical trial;
- inability to obtain and maintain patient consents;
- risk that enrolled participants will drop out before completion; and
- competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

In particular, there is significant competition for recruiting NASH patients in clinical trials. In the first quarter of 2020, we announced that enrollment in our ALPINE 2/3 clinical trial of aldafermin had been delayed beyond our initial projections. In addition, clinical trial enrollment generally continues to be affected by the effects of the COVID-19 pandemic, including in our ongoing ALPINE 4 and CATALINA trials, including due to delays in additional clinical trial site initiation, suspension of enrollment at clinical trial sites or patient reluctance to participate in a clinical trial during quarantines or shelter-in-place orders or otherwise, particularly in medically vulnerable patient populations. We or our partners may be unable to enroll the patients we need to complete clinical trials on a timely basis, or at all.

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

The success of our business depends primarily upon our ability to identify and validate new therapeutic candidates, and to identify, develop and commercialize protein and antibody therapeutics.

Research programs to identify new product candidates require substantial technical, financial and human resources. Our research efforts may initially show promise in discovering potential new protein and antibody therapeutics, yet fail to yield product candidates for clinical development for a number of reasons, including:

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

If any of these events occur, we may be forced to abandon our development efforts for one or more programs, which could have a material adverse effect on our business, operating results and prospects and could potentially cause us to cease operations. For example, we have suspended activities related to NGM386 and NGM217, and will be suspending activities related to NGM395 after the ongoing Phase 1 trial is completed, in all cases to concentrate our resources on our other product candidates. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

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

To date, aldafermin and our other product candidates have been manufactured by third-party manufacturers solely for preclinical studies and relatively small clinical trials. These manufacturers may not be able to scale production to the larger quantities required for large clinical trials and for commercialization. The process of manufacturing aldafermin and our other product candidates is complex, highly regulated and subject to several risks, including:

- the process of manufacturing biologics is susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error and improper storage conditions. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, the manufacturing facilities may need to be closed for an extended period of time to investigate and eliminate the contamination;
- a third-party manufacturer of a product candidate subject to our collaboration with Merck may fail to qualify upon an audit by Merck;
- the manufacturing facilities in which our products are made could be adversely affected by equipment failures, labor and raw material shortages, financial difficulties of our contract manufacturers, including as a result of the evolving effects of the COVID-19 pandemic, natural disasters, power failures, local political unrest and numerous other factors; and
- any adverse developments affecting manufacturing operations or the scale up of manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our product candidates. We may also have to record inventory write-offs and incur other charges and expenses for product candidates or drug substances that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

We also have a single source of supply for most of our product candidates, including the drug substances used in manufacturing them. Single sourcing minimizes our leverage with our contract manufacturers, who may take advantage of our reliance on them to increase the pricing of their manufacturing services. Single sourcing also imposes a risk of interruption in supply in the event of manufacturing, quality or compliance difficulties. If one of our suppliers fails or refuses to supply us for any reason, it would take a significant amount of time and cost to implement and execute the necessary technology transfer to, and to qualify, a new supplier. The FDA or comparable foreign regulatory authority must approve manufacturers of drug substance and drug product. If there are any delays in qualifying new suppliers or facilities or a new supplier is unable to meet the requirements of the FDA or comparable foreign regulatory authority for approval, there could be a shortage of drug substance or drug product for use in clinical trials with respect to the affected product candidates.

In addition, the operations of our third-party manufacturers may be requisitioned, diverted or allocated by U.S. or foreign government orders such as under emergency, disaster and civil defense declarations in connection with the COVID-19 pandemic or otherwise. As an example, President Trump has invoked the Defense Production Act pursuant to which the U.S. government may, among other things, require domestic industries to provide essential goods and services needed for the national defense, such as drug material or other supplies needed to treat COVID-19 patients or to produce or distribute vaccines, which could require our third-party manufacturers to allocate manufacturing capacity in a way that delays or interrupts our supply of clinical trial material.

Specifically, we have entered into a Development and Manufacturing Services Agreement with Lonza Sales AG, or Lonza, for the production of Phase 3 and commercial supplies of the aldafermin drug substance. If Lonza or our drug product manufacturer are not able to provide us with sufficient quantities of aldafermin for our clinical trials on a timely basis, or at all, whether due to production shortages or other supply delays or interruptions resulting from the ongoing COVID-19 pandemic or otherwise, our clinical trials or regulatory approval may be delayed. In this regard, although significant portions of our research and development resources are focused, and will continue to be focused, on activities required to prepare aldafermin for potential regulatory approval for the treatment of NASH, including manufacturing of clinical trial material and preparation for potential Phase 3 testing, if Lonza and/or our drug product manufacturer experience difficulties in scaling production or experience product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error or improper storage conditions, the potential Phase 3 testing of aldafermin would be delayed, perhaps substantially, which could materially and adversely affect our business. Moreover, our aldafermin drug product manufacturer has advised us that it could be required under orders of the U.S. government to allocate manufacturing capacity to the manufacture or distribution of COVID-19 vaccines. If Lonza Sales AG and/or our aldafermin drug product manufacturer become subject to acts or orders of U.S. or foreign government entities to allocate manufacturing capacity to the manufacture or distribution of COVID-19 vaccines or medical supplies needed to treat COVID-19 patients, this could also delay, perhaps substantially, the potential Phase 3 testing of aldafermin which could materially and adversely affect our business. Refer also to the risk factor entitled “Our business is currently adversely affected and could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics, including by the evolving effects of the COVID-19 pandemic. The COVID-19 pandemic continues to adversely impact our business and could materially and adversely affect our operations, as well as the businesses or operations of our manufacturers, CROs or other third parties with whom we conduct business.”

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

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

We have limited process development capabilities and have access only to external manufacturing capabilities. We do not have, and we do not currently plan to acquire or develop, the facilities or capabilities to manufacture bulk drug substance or filled drug product for use in clinical trials or commercialization. Any delay or interruption in the supply of clinical trial material could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval or limit the commercial profile of an approved label.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Additional clinical trials may be required to evaluate the safety profile of our product candidates. Serious adverse events that were reported in the aldafermin treatment arms from our completed Phase 1 and Phase 2 clinical trials of aldafermin include: moderate dizziness, community acquired pneumonia, iron deficiency anemia, fractured finger, pneumonitis/alveolitis, acute pancreatitis, pneumonia, pleurisy, non-myocardial infarction cardiac arrest, chest pain, vertigo, headache, accelerated hypertension, kidney mass, bowel obstruction, bilirubin increase, cholangitis, progression of primary sclerosing cholangitis, or PSC, intervertebral discitis, rectal bleeding and post-biopsy bleeding. Serious adverse events, or SAEs, reported in our ongoing Phase 2 trials with aldafermin include gallbladder injury due to biopsy, suicide attempt and bronchogenic cyst, and no SAEs were deemed by investigators to be related to the treatment with aldafermin. In our completed Phase 1 and Phase 1b clinical trials of MK-3655 (NGM313), there were two reported SAEs in the MK-3655 (NGM313) treatment arms: cholecystitis and rectal bleeding due to hemorrhoids, both of which were deemed by the investigators to be unrelated to treatment with MK-3655 (NGM313). In our completed Phase 1 clinical trial of NGM120, there were two reported SAEs in the NGM120 treatment arms: renal colic and bipolar disorder, both of which were deemed by the investigators to be unrelated to treatment with NGM120. In our ongoing Phase 1a/1b trial of NGM120 evaluating NGM120 as a monotherapy in patients with select advanced tumors and in combination with two chemotherapeutic agents in patients with metastatic pancreatic cancer, there have been a number of SAEs, including sepsis, neutropenia, pulmonary embolism, pleural effusion, non-cardiac chest pain, renal failure, acute kidney injury and encephalopathy, none of which were deemed related to treatment with NGM120 after medical safety review. In our completed Phase 1 and ongoing Phase 2 clinical trials of NGM621, there have been no reported SAEs deemed related to treatment with NGM621.

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

Protein and antibody therapeutics can sometimes induce host immune responses that can cause the production of anti-drug-antibodies, or ADA. Our product candidates, including aldafermin, which is an engineered variant of the human hormone fibroblast growth factor 19, or FGF19, protein, are protein and antibody therapeutics. In some instances, certain ADA called neutralizing antibodies can neutralize the therapeutic effects of the treatment. ADA can also sometimes cross react with substances naturally occurring in a subject’s body (in the case of aldafermin, FGF19), which can cause unintended effects, including potential impacts on efficacy and, in rare cases, even adverse events. One subject in a Phase 2

clinical trial investigating aldafermin as an intervention for type 2 diabetes developed ADA against aldafermin; however, this patient did not demonstrate any biochemical or clinically relevant safety concerns while in the study, and we have not identified any safety concerns while monitoring the subject following the study. In the Phase 2 PBC extension clinical trial of aldafermin, 18 of the 36 subjects tested positive for aldafermin-specific ADA at one or more time points using a preliminary assay. Six of these 36 subjects tested positive for neutralizing antibodies using an assay that was subsequently validated, of which two subjects developed antibodies that appeared to cross-react with their naturally occurring FGF19. These subjects have not demonstrated any biochemical or clinically relevant safety signals that were different from observations in subjects that did not generate ADA against aldafermin. We are developing an assay to measure the presence of ADA against aldafermin for our ongoing NASH program, which will need to be evaluated by regulatory agencies. The subjects who were found to develop ADA in both the type 2 diabetic and PBC populations may not be predictive of future test results in NASH patients due to differences in disease setting, study design, dose regimen and the use of a different ADA assay. If we are required to do substantial additional testing as a result of the detection of high amounts of ADA in subjects using aldafermin or any other product candidate, the costs of our clinical trials may increase.

Future results of our trials could reveal a high and unacceptable severity and prevalence of side effects or ADA that have negative effects or other unexpected characteristics. In such an event, we may need to suspend or terminate our trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could affect patient recruitment, the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences could materially and adversely affect our business, financial condition and prospects.

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

Aldafermin is an engineered variant of the human hormone FGF19 that has been associated with liver cancer in rodent testing. The IND that we filed in February 2014 for type 2 diabetes was placed on clinical hold by the FDA Division of Metabolism and Endocrinology Products pending receipt of additional information relating to the potential risk of proliferative effects of aldafermin in the livers of non-human primates and mice based on concerns relating to the observation that human FGF19 can induce hepatocellular proliferation in rodents. We withdrew this IND in January 2015, as we determined that we would not further study aldafermin in type 2 diabetes after we analyzed the results of the Phase 2 clinical trial of aldafermin in type 2 diabetes and made the determination to pursue NASH and other liver indications. To date, the FDA Division of Hepatology and Nutrition, which is responsible for the NASH indication, has not requested any additional information regarding the potential for aldafermin to induce hepatocellular proliferation. We have received feedback from the FDA Carcinogenicity Assessment Committee that our preclinical data through six-month chronic toxicology studies in mice and monkeys support a single species, two-year carcinogenicity assessment in rats. The human hormone and the rodent ortholog for FGF19 share a sequence identity of approximately 50%, which means that the results of these studies of aldafermin in rats are not necessarily predictive of the potential risk of carcinogenicity in humans. To our knowledge, neither FGF19 nor any variant thereof other than aldafermin has ever been tested in humans. We believe we have identified a modified version of FGF19 that does not exhibit the cancer-causing effects of native human FGF19 in rodents. We believe that aldafermin will have a superior therapeutic profile to FGF19 based on preclinical data showing reduced fasting blood glucose levels, fed insulin levels and bile acid suppression in animals. However, we may be incorrect in these beliefs, and we cannot be sure that regulators will view our product candidate as safe or that physicians will view our product candidates as superior to alternative treatments. Concerns about the association between FGF19 and liver cancer could have an adverse effect on our ability to develop and commercialize aldafermin.

We have no experience in sales, marketing and distribution and may have to enter into agreements with third parties to perform these functions, which could prevent us from successfully commercializing our product candidates.

We currently have no sales, marketing or distribution capabilities. To commercialize our product candidates outside of the Merck collaboration, or to commercialize products subject to the Merck collaboration for which we may in the future exercise our co-detailing rights in the United States, we must either develop our own sales, marketing and distribution capabilities, which will be expensive and time-consuming, or make arrangements with third parties to perform these services for us. If we exercise our co-detailing rights in the United States with respect to the Merck collaboration, we will be responsible for the costs of fielding such a sales force, subject to partial offset pursuant to the formula by which profits are allocated, and the risks of attracting, retaining, motivating and ensuring the compliance of such a sales force with the various requirements of the Merck collaboration and applicable law. If we decide to market any of our products on our own, we will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all. If we are not able to establish and maintain successful arrangements with third parties or build our own sales and marketing infrastructure, we may not be able to commercialize our product candidates, which would adversely affect our business and financial condition.

We may fail to select or capitalize on the most scientifically, clinically and commercially promising or profitable product candidates.

We have limited technical, managerial and financial resources to determine which of our product candidates should proceed to initial clinical trials, later-stage clinical development and potential commercialization. We may make incorrect determinations in allocating resources among these product candidates. Our decisions to allocate our research and development, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources from better opportunities. Similarly, our decisions to delay or terminate drug development programs, such as our decision to suspend activities related to NGM386, NGM395, NGM621 administered systemically and NGM217 to concentrate our resources on our other product candidates, may also be incorrect and could cause us to miss valuable opportunities.

Under our Collaboration Agreement with Merck, we have the right, exercisable during a specified period prior to the commencement of Phase 3 clinical testing of the applicable product candidate, to convert our economic participation from a milestones and net sales royalty arrangement into a cost and profit share arrangement. If we exercise the cost and profit share right, we have the ability to participate in a co-detailing relationship in the United States. Due to the limited exercise period, we may have to choose whether a product candidate will be subject to a cost and profit share arrangement before we have as much information as we would like, including whether and when such program may receive FDA approval of the applicable biologics license application, or BLA. As a result of such incomplete information or due to incorrect analysis by us, we may select a cost and profit share program that later proves to have less commercial potential than an alternative, or none at all, or may pass on a cost and profit sharing program that proves commercially successful.

We must attract and retain highly skilled employees in order to succeed. If we are not able to retain our current senior management team, especially Dr. Jin-Long Chen, or continue to attract and retain qualified scientific, technical and business personnel, our business will suffer.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel and we face significant competition for experienced personnel. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. An important element of our strategy is to take advantage of the research and development expertise of our current management. The loss of any one of our executive officers, including, in particular, Dr. Jin-Long Chen, our Chief Scientific Officer, could result in a significant loss in the knowledge and experience that we, as an organization, possess and could cause significant delays, or outright failure, in the development and further commercialization of our product candidates.

To fully realize the research and development support committed under our collaboration with Merck, we will need to maintain a significant number of qualified research and development personnel. There is intense competition for qualified personnel, including management, in the technical fields in which we operate, and we may not be able to attract and retain qualified personnel necessary for the successful research, development and future commercialization, if any, of our product candidates. In particular, the hiring environment in the San Francisco Bay Area, where we are headquartered, is extremely competitive. Many of the other pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

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

Any agreements we have or may enter into with third parties, such as collaboration, license, supplier, manufacturing, sponsored research, CRO or clinical trial agreements, may give rise to disputes regarding the rights and obligations of the parties. Disagreements could develop over contract interpretation, rights to ownership or use of intellectual property, the scope and direction of research and development, the approach for regulatory approvals or commercialization strategy. We are conducting research programs in a range of therapeutic areas, and our pursuit of these opportunities could result in conflicts with the other parties to these agreements that may be developing or selling pharmaceuticals or conducting other activities in these same therapeutic areas. Any disputes or commercial conflicts could lead to the termination of our agreements, delay progress of our product development programs, compromise our ability to renew agreements or obtain future agreements, lead to the loss of intellectual property rights, result in increased financial obligations for us or result in costly litigation.

We work with outside scientific advisors and collaborators at academic and other institutions that assist us in our research and development efforts. Our scientific advisors are not our employees and may have other commitments that limit their availability to us. If a conflict of interest between their work for us and their work for another entity arises, we may lose their services.

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

Since executing the Collaboration Agreement in 2015, we have significantly increased our headcount and advanced our pipeline and the complexity of our operations, which has placed a strain on our administrative and operational infrastructure. We expect this strain to continue as we seek to maintain our growth and seek to obtain and manage relationships with third parties. Our ability to manage our operations and growth effectively depends upon the continual improvement of our procedures, remote work policies, reporting systems and operational, financial and management controls, particularly in light of the evolving effects of the COVID-19 pandemic. We may not be able to expand or identify sufficiently-sized facilities to accommodate our growth, particularly given our location in South San Francisco, California and the current high demand for, and restricted supply of, research and development facilities in this market. We may not be able to implement administrative and operational improvements in an efficient or timely manner and may discover deficiencies in existing systems and controls. If we do not meet these challenges, we may be unable to take advantage of market opportunities, execute our business strategies or respond to competitive pressures, which in turn may slow our growth or give rise to inefficiencies that would increase our losses.

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

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us.

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. A number of pharmaceutical companies, including AbbVie, Allergan, AstraZeneca, Bayer, Boerhinger Ingelheim, Bristol-Myers Squibb, Eisai, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi and Takeda, as well as large and small biotechnology companies such as 89Bio, Akero, Albireo, Alentis, Amgen Inc., or Amgen, Apellis, Ascletis, Axcella, Bird Rock, Can-Fite, Cirius, Enanta, Galectin, Galmed, Gilead, Glympse, Immuron, Intercept, Inventiva, Iveric, Madrigal, MannKind, MediciNova, Metacrine, Mirum, North Sea, Promethera, Salix, Scholar Rock, Seal Rock, Terns, Tiziana, Viking and Vivus, are pursuing the development or marketing of pharmaceuticals that target the same diseases that are targeted by our most advanced product candidates. It is probable that the number of companies seeking to develop products and therapies for the treatment of liver and metabolic diseases, retinal diseases and cancer will increase. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical studies and human clinical trials of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Accordingly, our competitors may succeed in obtaining FDA approval for superior products or for other products that would compete with our product candidates. Many of our competitors have established distribution channels and commercial infrastructure to support the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies.

Our competitors may obtain regulatory approval of their products more rapidly than us or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than us in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

There are no currently approved therapies for NASH. Although we believe there are no approved therapies that specifically target the signaling pathways that our current product candidates are designed to modulate or inhibit, there are numerous currently approved therapies for treating the same diseases or indications, other than NASH, for which our product candidates may be useful and many of these currently approved therapies act through mechanisms similar to our product candidates. Many of these approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products, including branded generic products. This may make it difficult for us to differentiate our products from currently approved therapies, which may adversely impact our business strategy. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development.

If aldafermin or MK-3655 (NGM313) were approved for the treatment of NASH, future competition could also arise from products currently in development, including: cenicriviroc, an immunomodulator that blocks CCR2 and CCR5, from Allergan; firsocostat, an ACC inhibitor, and cilofexor, an FXR agonist, both from Gilead; OCA, an FXR agonist, from Intercept; resmetirom, a beta-thyroid hormone receptor agonist, from Madrigal; pegbelfermin, a PEGylated FGF21 analog, from Bristol-Myers Squibb; AKR-001, an Fc conjugated FGF21 analog, from Akero; FXR agonists from Metacrine; FXR agonists from Novartis; a beta-thyroid hormone receptor agonist from Viking; semaglutide, a GLP-1 analog, from Novo Nordisk; and lanifibranor, a pan-PPAR agonist from Inventiva. The foregoing competitive risks apply to aldafermin, any variants of aldafermin, including the second-generation, half-life extended version of FGF19 we are currently developing, and MK-3655 (NGM313).

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

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. Demonstrating the safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile of the product candidate as demonstrated in clinical trials;
- the timing of market introduction of the product candidate, as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance of the product candidate as a safe and effective treatment by clinics and patients;
- the potential and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the cost of treatment relative to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third parties and government authorities as described below;
- the relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- any unfavorable publicity relating to the product candidate.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our products are safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Even if we commercialize any of our product candidates, alone or with our partners, these products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. In many regions, including Europe, Japan and Canada, the pricing of prescription drugs is controlled by the government. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. Regulatory agencies in those countries could determine that the pricing for our products should be based on prices of other commercially available drugs for the same disease, rather than allowing us to market

our products at a premium as new drugs. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Our commercial success also depends on coverage and adequate reimbursement of our product candidates by third-party payors, including government payors, private health insurers, health maintenance organizations and other organizations, which may be difficult or time-consuming to obtain, may be limited in scope and may not be obtained in all jurisdictions in which we may seek to market our products. Governments and private insurers closely examine medical products to determine whether they should be covered by reimbursement and, if so, the level of reimbursement that will apply. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we or our partners commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we or our partners obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our partners may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

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

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

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

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or, collectively, the ACA, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There remain executive, judicial and congressional challenges to certain aspects of the ACA.

In addition, while Congress has not passed comprehensive legislation repealing the ACA, it has introduced legislation to modify certain provisions. Congress will likely consider other legislation to modify or replace additional elements of the ACA. It is unclear how these efforts to repeal and replace the ACA, or other appeals, will impact the ACA and our business. For example, the 2017 Tax Act repealed the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage that is commonly referred to as the "individual mandate." In December 2019, a U.S. District Court upheld a ruling that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. The Supreme Court of the United States is currently reviewing this case, although it is unclear when a decision will be made. It is also unclear how such litigation and other efforts to challenge, repeal, or replace the ACA will impact the ACA or our business.

Other legislative changes that have affected or may affect our industry include the Budget Control Act of 2011 which has triggered automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year through 2030 unless Congress takes additional action.

Recently, there has also been increasing executive, legislative and enforcement interest in the United States with respect to drug pricing practices. There have been several recent U.S. congressional inquiries, presidential executive orders, and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. We expect that the healthcare reform measures that have been adopted and may be adopted in the future may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

We cannot predict the likelihood, nature or extent of healthcare reform initiatives that may arise from future legislation or administrative action, particularly as a result of the recent presidential election. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our international operations may expose us to business, regulatory, political, operational, financial, pricing and reimbursement risks associated with doing business outside of the United States.

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and clinical trial sites are located outside of the United States. Furthermore, if we, Merck or any future collaborator succeeds in developing any of our product candidates, we intend to market them in the European Union, or the EU, and other jurisdictions in addition to the United States. If approved, we, Merck or any future collaborator may hire sales representatives and conduct physician and patient association outreach activities outside of the United States. Doing business internationally involves a number of challenges and risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our products in various countries;
- rejection or qualification of foreign clinical trial data by the competent authorities of other countries;
- delays or interruptions in the supply of clinical trial material resulting from any events affecting raw material supply or manufacturing capabilities abroad, including those that may result from the ongoing COVID-19 pandemic;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining, maintaining, protecting and enforcing our intellectual property;
- difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- limits on our ability to penetrate international markets;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, including COVID-19 and related shelter-in-place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to anti-corruption compliance and record-keeping that may fall within the purview of the U.S. Foreign Corrupt Practices Act, its accounting provisions or its anti-bribery provisions or provisions of anti-corruption or anti-bribery laws in other countries.

Any of these factors could harm our ongoing international clinical operations and supply chain, as well as any future international expansion and operations and, consequently, our business, financial condition, prospects and results of operations.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we or our collaborator commercializes any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial subjects or patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize any products that we may develop.

Our clinical trial liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for

products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician endorsement of our products or expand our business.

Our relationships with healthcare providers, customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, including physicians, and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we or our collaborator obtains marketing approval. Our arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products for which we or our collaborator 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, or FCA, imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act, or HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, also imposes obligations on certain covered entity healthcare providers, health plans and healthcare clearinghouses, and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, created under Section 6002 of the ACA and its implementing regulations, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to the HHS ownership and investment interests held by physicians (as defined above) and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, anesthesiologist assistants, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and local laws requiring the registration of pharmaceutical sales representatives; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or pricing; and state and foreign laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, additional regulatory oversight, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our operations are vulnerable to interruption by fire, earthquake, power loss, telecommunications failure, terrorist activity and other events beyond our control, which could harm our business.

Our former facility was subject to electrical blackouts as a result of a shortage of available electrical power. Future blackouts, which may be implemented by the local electricity provider in the face of high winds and dry conditions, could disrupt the operations of our current facility. Our facility is located in a seismically active region. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disasters and do not have a complete recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. Our sole supplier of clinical drug substance for MK-3655 (NGM313), NGM120, NGM621, NGM707 and NGM438 is located in a region that has experienced recent political unrest.

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

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

Remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the COVID-19 pandemic could materially and adversely affect our operations. Based on guidance issued by federal, state and local authorities, we transitioned to a remote work environment for a vast majority of our employees in March 2020, while maintaining essential in-person laboratory functions in order to advance key research and development initiatives, supported by the implementation of updated onsite safety procedures. In June 2020, following updated guidance issued by federal, state and local authorities, we re-opened our laboratory facilities for research activities that cannot be conducted remotely with heightened safety measures designed to minimize occupational exposure and reduce transmission of COVID-19 within our workplace. Although we have re-opened our laboratory facilities under these heightened safety measures, we may be forced to, or determine that we should, resume a more restrictive remote work model. In connection with these measures, we may be subject to claims based upon, arising out of, or related to COVID-19 and our actions and responses thereto, including any determinations that we have made and may make in the future with respect to our onsite operations. Further, the effects of current and future governmental shelter-in-place orders and our remote work policies may materially and adversely impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could materially and adversely impact our business, financial condition, results of operations and growth prospects.

As the pandemic continues, there may be continuing negative impacts on our ability to initiate new clinical trial sites, maintain enrollment of existing patients and enroll new patients, which may impact timelines in the future. Our ability to attract additional clinical trial sites and principal investigators to conduct our clinical trials and to conduct the necessary clinical trial site initiation procedures has been and may continue to be impacted by quarantines, shelter-in-place and similar restrictions imposed by federal, state and local governments. These restrictions may also continue to prohibit or discourage patients from enrolling in, or continuing to participate in, our clinical trials. Principal investigators and clinical trial site staff, as healthcare providers, may have heightened exposure to COVID-19 and if their health is impacted by COVID-19 it could adversely impact the conduct of our clinical trials at their sites. Similarly, potential participants in our clinical trials, many of whom are particularly vulnerable, may be unwilling to enroll in, and enrolled patients may be unwilling to continue to participate in, our clinical trials due to concerns about traveling to sites for required screening and clinical trial visits and procedures. In this regard, we have experienced, from to time, a slower pace of clinical site initiation and enrollment than anticipated in certain of our clinical trials, including the ALPINE 4, CATALINA and NGM120 trials, and may experience higher dropout rates than normal, due to factors such as the vulnerability of our studied patient populations, clinical trial site suspensions, reallocation of medical resources and the challenges of working remotely due to shelter-in-place and similar government orders, among other factors. Enrolled patients may be unable to comply with clinical trial protocols if quarantines, shelter-in-place and similar restrictions continue to impede patient movement or interrupt healthcare services. Accordingly, we have developed and implemented additional clinical study policies and procedures designed to help protect

patients from COVID-19 exposure as a result of their trial participation, which include the use of telemedicine visits, remote monitoring of patients and clinical trial sites, and other measures designed to ensure that data from clinical trials that may be disrupted as result of the pandemic are collected pursuant to the study protocol and consistent with current Good Clinical Practices, or cGCPs, with any material protocol deviation reviewed and approved by the clinical trial site IRB. If any of the foregoing efforts to mitigate the impact of the COVID-19 pandemic are not successful, or if the effects of the COVID-19 pandemic become more severe, it could materially and adversely affect our clinical development timelines and our ability to obtain regulatory approvals of our product candidates and could significantly increase our costs.

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

In addition, quarantines, shelter-in-place and similar government orders could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Likewise, the operations of our third-party manufacturers may be requisitioned, diverted or allocated by U.S. or foreign government orders such as under emergency, disaster and civil defense declarations in connection with the COVID-19 pandemic or otherwise. In particular, some of our suppliers of certain materials used in the production of our drug products are located in Europe. In this regard, any manufacturing supply interruption of aldafermin, which is currently manufactured by Lonza at facilities in Switzerland, or our other product candidates, which are currently manufactured at a facility in Lithuania, could adversely affect our ability to conduct ongoing and future clinical trials of aldafermin and our other product candidates. For example, although significant portions of our research and development resources are focused, and will continue to be focused, on activities required to prepare aldafermin for potential regulatory approval for the treatment of NASH, including manufacturing of clinical trial material and preparation for potential Phase 3 testing, if Lonza and/or our drug product manufacturer experience difficulties in scaling production or experience product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error or improper storage conditions, the potential Phase 3 testing of aldafermin would be delayed, perhaps substantially, which could materially and adversely affect our business. Moreover, our aldafermin drug product manufacturer has advised us that it could be required under orders of the U.S. government to allocate manufacturing capacity to the manufacture or distribution of COVID-19 vaccines. If Lonza Sales AG and/or our aldafermin drug product manufacturer become subject to acts or orders of U.S. or foreign government entities to allocate manufacturing capacity to the manufacture or distribution of COVID-19 vaccines or medical supplies needed to treat COVID-19 patients, this could also delay, perhaps substantially, the potential Phase 3 testing of aldafermin which could materially and adversely affect our business. In any event, if the evolving effects of the COVID-19 pandemic become more severe or more acutely impact geographies with particular relevance to our business, we could experience significant disruptions to our current and potential future clinical development timelines, impacts on our ability to obtain regulatory approvals of our product candidates and increases in our costs, all or any of which would adversely affect our business, financial condition, results of operations and growth prospects.

In addition, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the pandemic could result in significant and prolonged disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect the financial resources available to us. In addition, the current recession or additional market corrections resulting from, among other things, the spread of COVID-19 could materially affect our business and the value of our common stock. We also cannot predict how the evolving effects of the COVID-19 pandemic may influence the future decisions of Merck to license any programs available to it under the Collaboration Agreement or to exercise its remaining option to extend the research phase of the collaboration beyond March 16, 2022.

While we expect the COVID-19 pandemic to continue to affect our business operations, the extent of the impact on our clinical development and regulatory efforts, our ability to raise sufficient additional capital on acceptable terms, if at all, the decisions of Merck and the value of and market for our common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. Such developments include the ultimate duration and severity of the pandemic, travel restrictions, quarantines, social distancing and business closure requirements in the United States and in other countries, and the effectiveness of actions taken globally to contain and treat COVID-19. In addition, to the extent the evolving effects of the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this ‘‘Risk Factors’’ section.

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

Similar to other companies in our industry, we face substantial cybersecurity risk. Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors, collaborators and consultants may fail and are vulnerable to damage from computer viruses and unauthorized access. While we have not, to our knowledge, experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates, to analyze clinical trial samples and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

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

In 2017, a security breach of the internal computer systems of our collaborator, Merck, caused material damage to its operations, but did not affect our internal operations. In June 2019, a vendor that conducted bioanalytical services for some of our aldafermin clinical trials was affected by a ransomware attack that resulted in a significant disruption to its IT systems. This cybersecurity incident at our vendor did not result in an integrity loss of certain clinical sample data for aldafermin, as verified by independent vendors. More recently, an attacker gained access to a single system on our network and attempted to use that access to stage a broader attack against us. We detected the suspicious activity on the night of December 15, 2020 and believe we fully contained the incident the next day. The event had minimal impact on our operations and we have no evidence suggesting any ongoing threat or data exfiltration. However, to the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material costs, be exposed to liability, our competitive position could be harmed and the further development and commercialization of our product candidates could be hindered or delayed.

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

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

European data protection laws, including the GDPR, generally restrict the transfer of personal information from Europe, including the European Economic Area, United Kingdom and Switzerland, to the United States and most other countries unless the parties to the transfer have implemented specific safeguards to protect the transferred personal information. One of the primary safeguards allowing United States companies to import personal information from Europe has been certification to the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield frameworks administered by the United States Department of Commerce. However, the Court of Justice of the EU recently invalidated the EU-U.S. Privacy Shield. The same decision also raised questions about whether one of the primary alternatives to the EU-U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, can lawfully be used for personal information transfers from Europe to the United States or most other countries. At present, there are few, if any, viable alternatives to the EU-U.S. Privacy Shield and the Standard Contractual Clauses. Although we rely primarily on individuals' explicit consent to transfer their personal information from Europe to the United States and other countries, in certain cases we have relied or may rely on the Standard Contractual Clauses. Authorities in the United Kingdom and Switzerland, whose data protection laws are similar to those of the EU, may similarly invalidate use of the EU-U.S. Privacy Shield and Swiss-U.S. Privacy Shield, respectively, as mechanisms for lawful personal information transfers from those countries to the United States. As such, if we are unable to rely on explicit consent to transfer individuals' personal information from Europe, which can be revoked, or implement another valid compliance solution, we will face increased exposure to substantial fines under European data protection laws as well as injunctions against processing personal information from Europe. Inability to import personal information from the European Economic Area, United Kingdom or Switzerland may also restrict our clinical trial activities in Europe; limit our ability to collaborate with CROs, service providers, contractors and other companies subject to European data protection laws; and require us to increase our data processing capabilities in Europe at significant expense. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

We use and generate materials that may expose us to material liability.

Our research programs involve the use of hazardous materials, chemicals and radioactive and biological materials. We are subject to foreign, federal, state and local environmental and health and safety laws and regulations governing, among other matters, the use, manufacture, handling, storage and disposal of hazardous materials and waste products. We may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. In addition, we cannot completely eliminate the risk of contamination or injury from hazardous materials and may incur material liability as a result of such contamination or injury. In the event of an accident, an injured party may seek to hold us liable for any damages that result. Any liability could exceed the limits or fall outside the coverage of our workers' compensation, property and business interruption insurance and we may not be able to maintain insurance on acceptable terms, if at all. We currently carry no insurance specifically covering environmental claims.

Risks Related to Our Dependence on Merck and Other Third Parties

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

In February 2015, we entered into a collaboration with Merck focused on the discovery, development and commercialization of biologics, excluding aldafermin, and including a license to our GDF15 receptor agonist program product candidates, NGM386 and NGM395. In November 2018, Merck exercised its option to license MK-3655 (NGM313). In 2019, Merck exercised its option to extend the research phase of the collaboration for an additional two years, from March 17, 2020 through March 16, 2022, and terminated its license to the GDF15 receptor agonist program in May 2019.

The Merck collaboration involves a complex allocation of rights, provides for substantial research and development support, provides for additional payments upon Merck's election, if exercised in its unilateral discretion, to further extend the term of the research program for an additional two years and provides us with either milestone payments based on the achievement of specified clinical development, regulatory and commercial milestones and royalty-based revenue if certain product candidates are successfully commercialized or a cost and profit sharing arrangement with the possibility that we would provide sales representatives to co-detail the product candidates that Merck elects to advance in the United States. We cannot predict the success of the collaboration, whether Merck will exercise its remaining option to extend the research phase of the collaboration or whether Merck will exercise its option to license additional product candidates or whether Merck will terminate its license to a licensed program.

We may seek other third-party collaborators for the development and commercialization of any product candidates that are not subject to the Merck collaboration, including aldafermin, NGM395 and NGM386. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

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

- Collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations. For example, under our collaboration with Merck, once proof-of-concept data in humans has been generated and Merck has exercised its option to acquire an exclusive license for a product candidate, our ability to influence the resources Merck devotes to such product candidate are substantially reduced until such time, if any, that we exercise our right to participate in a cost and profit-sharing arrangement. Even after we exercise that right to participate in a cost and profit-sharing arrangement, our ability to influence Merck will be limited.

- Collaborators might opt not to pursue development and commercialization of our product candidates or not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors, such as an acquisition that diverts resources or creates competing priorities. For example, under our agreement with Merck, it is possible for Merck to unilaterally terminate the MK-3655 (NGM313) program and any other program (whether or not we have exercised our cost and profit-sharing option) upon prior written notice, such as it did for NGM386 and NGM395, without triggering a termination of the remainder of the collaboration arrangement. In addition, Merck might opt not to exercise its option to acquire a license to a product candidate that has generated proof-of-concept data.
- Collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing.
- Collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our medicines or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours.
- A collaborator with marketing and distribution rights to one or more medicines might not commit sufficient resources to the marketing and distribution of our product candidates.
- Collaborators might not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation. For example, Merck has the first right to maintain or defend our intellectual property rights under the Collaboration Agreement with respect to certain licensed programs and, although we may have the right to assume the maintenance and defense of our intellectual property rights if Merck does not, our ability to do so may be compromised by Merck's actions.
- Disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our medicines or product candidates or that result in costly litigation or arbitration that diverts management attention and resources.
- We may lose certain valuable rights under circumstances identified in our collaborations, including, in the case of our agreement with Merck, if we undergo a change in control.
- Collaborations might be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.
- Collaboration agreements might not lead to development or commercialization of product candidates in the most efficient manner, or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated.

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

Under the Collaboration Agreement, Merck has the unilateral right to terminate all or part of the agreement at certain times and under certain circumstances. Merck may unilaterally terminate the research phase of the collaboration program effective March 17, 2022 by providing notice to us prior to March 17, 2021. Merck may also unilaterally terminate its annual funding of the research program prior to March 17, 2022 if we are acquired by a third party or if we are in material uncured breach of our obligations under the research and early development program. After the current research phase of the collaboration or, if Merck again exercises its option to extend the research phase of the collaboration, after such extension period, Merck may unilaterally terminate the overall agreement for convenience upon written notice and subject to certain limitations.

Subject to certain limitations, Merck may partially terminate the Collaboration Agreement for convenience as it relates to MK-3655 (NGM313) or any future licensed program. For example, Merck terminated its license to our GDF15 receptor agonist program, including NGM395 and NGM386, in May 2019. Merck may also unilaterally terminate the agreement as it relates to its rights to research and develop small molecule compounds. It may also unilaterally terminate the agreement with respect to a specific licensed program in the event of an uncured material breach by us. If Merck terminates a program as a result of our uncured material breach, then we would lose our option to participate in global cost and profit sharing if not yet exercised as of the time of termination, and lose our co-detailing option (whether or not exercised as of that time) for the relevant licensed program.

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

We may not be able to obtain and maintain the relationships with third parties that are necessary to develop, commercialize and manufacture some or all of our product candidates.

In addition to our dependence on our collaboration with Merck, we expect to depend on other collaborators, partners, licensees, CROs, clinical investigators, manufacturers and other third parties to support our discovery efforts, to formulate product candidates, to conduct clinical trials for some or all of our product candidates, to manufacture clinical and commercial scale quantities of our drug substances and drug products and to market, sell and distribute any products we successfully develop and for which we obtain regulatory approval. Any problems we experience with any of these third parties could delay our research efforts or the development, commercialization and manufacturing of our products or product candidates, which could harm our results of operations.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including reliance on third parties for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by third parties because of factors beyond our control (including a failure to manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of agreements by third parties, based on its own business priorities, at a time that is costly or damaging to us.

If any of our product candidates are approved by the FDA or other regulatory agencies for commercial sale, we or our collaborator may need to manufacture it in larger quantities. We intend to use third-party manufacturers for commercial quantities of aldafermin, NGM120, NGM621, NGM707 and NGM438, to the extent we advance these product candidates, and will rely on Merck to determine whether to utilize a third-party manufacturer or internal manufacturing capacity for MK-3655 (NGM313) and other licensed product candidates. Our or our collaborator's manufacturers may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or efficient manner, or at all. If we or our collaborator are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in the supply of the product candidate. Our or our collaborator's failure or the failure of third-party manufacturers to comply with the FDA's current Good Manufacturing Practices, or cGMP, and to pass inspections of the manufacturing facilities by the FDA or other regulatory agencies could seriously harm our business.

We cannot guarantee that we or, as applicable, our collaborator will be able to successfully negotiate agreements for, or maintain relationships with, collaborators, partners, licensees, CROs, clinical investigators, manufacturers and other third parties on favorable terms, if at all. If we or our collaborator are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates, which will, in turn, adversely affect our business.

We expect to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, substantial capital will be paid to third parties in these relationships. However, we cannot control the amount or timing of resources our contract partners will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. In addition, we are less knowledgeable about the reputation and quality of third-party contractors in countries outside of the United States where we conduct discovery research or preclinical and clinical development and manufacturing of our product candidates and, therefore, we may not choose the best parties for these relationships.

We may seek to establish additional collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For product candidates not partnered with Merck, such as aldafermin, NGM395 and NGM386, we may decide to collaborate with other pharmaceutical and biotechnology companies for their development and potential commercialization.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to our ownership of intellectual property, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. Potential collaborators may also consider alternative product candidates or intellectual property for similar indications that may be available for collaboration and whether such an alternative collaboration could be more attractive than the one with us for our product candidate.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. For example, under our Collaboration Agreement with Merck, we may not directly or indirectly research, develop, manufacture or commercialize, except pursuant to the Collaboration Agreement, any medicine or product candidate that modulates a target then subject to the collaboration with specified activity. The FGF19 program, including aldafermin, is excluded from this provision, notwithstanding that both aldafermin and MK-3655 (NGM313) signal, in part, through the FGFR1c pathway. During the tail period following the research term of the collaboration, we may not directly or indirectly research, develop or commercialize, outside of the collaboration, any medicine or product candidate with specified activity against any collaboration target that has been designated a tail target.

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

We may not be able to negotiate collaborations on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to delay, scale back or discontinue the development of any product candidate for which we are seeking a collaboration, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

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

We currently rely on, and expect to continue to rely on, third parties, such as CROs, clinical data management organizations, medical institutions, consultants and clinical investigators, to conduct our clinical trials and certain aspects of our research and preclinical studies. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it would delay our product development activities and such alternative arrangements may not be available on terms acceptable to us.

Our reliance on these third parties for research and development activities will reduce our control over these activities, but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as cGCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines. In this regard, we cannot guarantee that these third parties will continue to perform their contractual duties in a timely and satisfactory manner as a result of the COVID-19 pandemic or otherwise.

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

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

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

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party manufacturers for the manufacture of our product candidates for preclinical and clinical studies and for commercial supply of any of these product candidates for which we or our collaborator obtains marketing approval. To date, we have obtained aldafermin, MK-3655 (NGM313), NGM120, NGM621, NGM707 and NGM438 for preclinical and clinical studies from third-party manufacturers. Other than our supply agreement with Lonza for aldafermin drug substance, we do not have a long-term supply agreement with any third-party manufacturer.

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

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

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

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

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

Our current and anticipated future dependence upon others for the manufacture of our product candidates or any future products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis. Refer also to the risk factor entitled “We are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates and any future products.”

Risks Related to Regulatory Approvals

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

We do not expect our product candidates to be commercially available for several years, if at all. Our product candidates are subject to strict regulation by regulatory authorities in the United States and in other countries. We cannot market any product candidate until we have completed all necessary preclinical studies and clinical trials and have obtained the necessary regulatory approvals. The approval

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

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable. Our inability to obtain regulatory approval for our product candidates would substantially harm our business.

Currently, none of our product candidates has received regulatory approval. The time required to obtain approval from the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions. It is possible that none of our existing or future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of results of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data, to support approval, which may delay or prevent approval and commercialization, or we may decide to abandon the development program for other reasons. If we obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition, and the FDA may grant accelerated approval based on a surrogate endpoint reasonably likely to predict clinical benefit. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a Fast Track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable and the sponsor pays any required user fees upon submission of the first section of the BLA. Fast Track designation does not change the standards for product approval.

Although aldafermin has received Fast Track designation from the FDA for NASH and PBC, we may not necessarily experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Many agents in development for NASH have, or are expected to, opt for an accelerated approval pathway and rely on surrogate endpoints for initial approval. If we seek accelerated approval for one of our product candidates, including aldafermin for NASH, based on a surrogate endpoint, the FDA may not accept such endpoint, may require additional studies or analysis or may not approve our product candidate on an accelerated basis, or at all. For example, in June 2020, Intercept announced that it had received a complete response letter regarding its New Drug Application for OCA for the treatment of NASH, in which the FDA indicated that it had determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint was uncertain and did not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommended that Intercept submit additional post-interim analysis efficacy and safety data from its ongoing Phase 3 study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue.

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

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

If we or our collaborators succeed in developing any products, we intend to market them in the EU and other foreign jurisdictions in addition to the United States. In order to market and sell our products in other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, we must secure product reimbursement approvals before regulatory authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our product candidates may be withdrawn if we fail to comply with regulatory requirements, if problems occur after the product candidate reaches the market or for other reasons. If we fail to comply with the regulatory requirements in international markets and fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions. Approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. If we fail to obtain approval of any of our product candidates by regulatory authorities in another country, we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtained regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategy or similar strategy, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may:

- issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require that we conduct post-marketing studies;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw regulatory approval of or initiate a recall of such product;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or refuse to permit the import or export of products.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenue.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, Department of Justice, HHS, Office of Inspector General, state attorneys general, members of Congress and the public. Violations, including promotion of our products for unapproved (or off-label) uses, are subject to enforcement letters, inquiries and investigations and civil and criminal sanctions by the government. Additionally, comparable foreign regulatory authorities will heavily scrutinize advertising and promotion of any product candidate that obtains approval outside of the United States.

In the United States, engaging in the impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal FCA, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these FCA lawsuits against

pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines in excess of $1 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Even if we are able to obtain regulatory approvals for any of our product candidates, if they exhibit harmful side effects after approval, our regulatory approvals could be revoked or otherwise negatively impacted, and we could be subject to costly and damaging product liability claims.

Even if we receive regulatory approval for aldafermin or any of our other product candidates, we will have tested them in only a small number of patients during our clinical trials. If our applications for marketing are approved and more patients begin to use our product, new risks and side effects associated with our products may be discovered. As a result, regulatory authorities may revoke their approvals. If aldafermin is approved by the FDA based on a surrogate endpoint pursuant to accelerated approval regulations (Subpart E regulations), we will be required to conduct additional clinical trials establishing clinical benefit on the ultimate outcome of NASH. Additionally, we may be required to conduct additional clinical trials, make changes in labeling of our product, reformulate our product or make changes and obtain new approvals for our and our suppliers' manufacturing facilities for aldafermin and our other product candidates. We might have to withdraw or recall our products from the marketplace. We may also experience a significant drop in the potential sales of our product if and when regulatory approvals for such product are obtained, experience harm to our reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of our approved product or substantially increase the costs and expenses of commercializing and marketing our product.

Risks Related to Our Intellectual Property

Our success depends upon our ability to obtain and maintain intellectual property protection for our products and technologies.

Our success depends in significant part on our ability and the ability of our current or future licensors, licensees or collaborators to establish and maintain adequate intellectual property covering the product candidates that we plan to develop. In addition to taking other steps to protect our intellectual property, we have applied for, and intend to continue applying for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. However, the patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current or future licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Pending and future patent applications filed by us or our current or future licensors', licensees' or collaborators' may not result in patents being issued that protect our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products.

We have filed numerous patent applications both in the United States and in certain foreign jurisdictions to obtain patent rights to our inventions, with claims directed to compositions of matter, methods of use, formulations, combination therapy and other technologies relating to our product candidates. However, patent applications cannot be enforced against third parties practicing the technology that is currently claimed in such applications unless and until a patent issues from such applications, and then only to the extent the claims that issue are broad enough to cover the technology being practiced by third parties. There can be no assurance that any of these patent applications will issue as patents or, for those applications that do mature into patents, whether the claims of the patents will exclude others from making, using or selling our product or product candidates, or products or product candidates that are substantially similar to ours. In countries where we have not and do not seek patent protection, third parties may be able to manufacture and sell products that are substantially similar or identical to our products or product candidates without our permission, and we may not be able to stop them from doing so.

Similar to other biotechnology companies, our patent position is generally highly uncertain and involves complex legal and factual questions. The patent examination process may require us or our current or future licensors, licensees or collaborators to narrow the scope of the claims of pending and future patent applications, which would limit the scope of patent protection that is obtained, if any. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. In recent years, these areas have been the subject of much litigation in the industry. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights and those of our current or future licensors, licensees or collaborators are highly uncertain and may not effectively prevent others from commercializing competitive technologies and products.

Success in obtaining and maintaining patents and other intellectual property rights may depend upon being the first to make a particular invention or being the first inventor to file a patent application on that invention. However, the publication of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all until they are issued as a patent. Therefore, we cannot be certain that we or our current or future licensors, licensees or collaborators were the first to make an invention, or the first inventors to file a patent application claiming an invention in our owned or licensed patents or pending patent applications.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees or collaborators to perform these activities, which means that these patent applications may not be prosecuted, and these patents may not be enforced, in a manner consistent with the best interests of our business. If our current or future licensors, licensees or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current or future licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

We do not currently own or have a license to any issued patents that cover our NGM621 product candidate, although it is disclosed and claimed in our pending U.S. non-provisional and/or national stage applications in particular foreign countries. Likewise, we do not currently own or have a license to any issued patents that cover our NGM707 and NGM438 product candidates, although these product candidates are disclosed and claimed in our pending U.S. provisional applications. The patent landscape surrounding NGM621, NGM707 and NGM438 are crowded, and there can be no assurance that we will be able to secure patent protection that would adequately cover such product candidates, nor can there be any assurance that we would obtain sufficiently broad claims to be able to prevent others from selling competing products.

Any changes we make to our product candidates, including aldafermin, MK-3655 (NGM313), NGM120, NGM621, NGM707 and NGM 438, to cause them to have what we view as more advantageous properties may not be covered by our existing patents and patent applications, and we may be required to file new patent applications and/or seek other forms of protection for any such altered product candidates. The patent landscape surrounding the technology underlying our product candidates is crowded, and there can be no assurance that we would be able to secure patent protection that would adequately cover an alternative to our aldafermin molecule, including half-life extending formulation enhancements or the half-life extended variants of FGF19 that we are developing, MK-3655 (NGM313), NGM120, NGM621, NGM707 and NGM438 or any of our other product candidates.

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

The legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as broad or effective as that in the United States and we may be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States, if at all. Thus, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our inventions or technologies, or from developing or commercializing competing products.

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

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

India, certain countries in Europe, and certain developing countries, including Thailand, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Additionally, many countries limit the enforceability of patents against government agencies or government contractors. We or our licensors, licensees or collaborators may have limited remedies if patents are infringed or if compelled to grant a license to a third party, which could materially diminish the value of those patents and could limit our potential revenue opportunities. Accordingly, our efforts, and those of our licensors, licensees or collaborators, to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

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

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

The duration of our intellectual property rights is limited.

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

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

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

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

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

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

We may be unable to obtain intellectual property rights or technologies necessary to develop and commercialize our product candidates.

Several third parties are actively researching and seeking and obtaining patent protection in the liver and metabolic diseases, retinal diseases and cancer fields, and there are issued third-party patents and published third-party patent applications in these fields. The patent landscape around our aldafermin, MK-3655 (NGM313), NGM120, NGM621, NGM707 and NGM438 product candidates is complex, and we are aware of several third-party patents and patent applications containing claims directed to compositions of matter, methods of use and related subject matter, some of which pertain, at least in part, to subject matter that might be relevant to our product candidates. However, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates and technologies.

Depending on what patent claims ultimately issue and how courts construe the issued patent claims, as well as the ultimate formulation and method of use of our product candidates, we may need to obtain a license to practice the technology claimed in such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If a third party does not offer us a necessary license or offers a license only on terms that are unattractive or unacceptable to us, we might be unable to develop and commercialize one or more of our product candidates, which would have a material adverse effect on our business, financial condition and results of operations.

Moreover, even if we obtain licenses to such intellectual property, but subsequently fail to meet our obligations under our license agreements, or such license agreements are terminated for any other reason, we may lose our rights to in-licensed technologies.

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

We could lose the ability to continue the development and commercialization of our products or product candidates if we breach any license agreement related to those products or product candidates.

Our commercial success depends upon our ability, and the ability of our current and future licensors, licensees and collaborators, to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. A third party may hold intellectual property rights, including patent rights that are important or necessary to the development of our products. As a result, we are a party to a number of technology and patent licenses that are important to our business and we expect to enter into additional licenses in the future. If we fail to comply with the obligations under these agreements, including payment and diligence obligations, our licensors may have the right to terminate these agreements, in which event we may not be able to develop, manufacture, market or sell any product that is covered by these agreements or to engage in any other activities necessary to our business that require the freedom-to-operate afforded by the agreements, or we may face other penalties under the agreements. For example, we are party to license agreements with multiple vendors under which we license cell lines used to produce multiple product candidates, including some that are currently subject to our collaboration with Merck. We require prior consent from some of these vendors to grant sub-licenses under these agreements. Therefore, these vendors may be able to prevent us from granting sub-licenses to third parties, which could affect our ability or Merck's ability to use certain desired manufacturers in order to manufacture our product candidates.

Any of the foregoing could materially adversely affect the value of the product or product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or amended agreements, which may not be available to us on equally favorable terms, or at all, or cause us to lose our rights under these agreements, including our rights to intellectual property or technology important to our development programs.

We may become involved in lawsuits or other proceedings to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe patents or misappropriate or otherwise violate intellectual property rights owned or controlled by us or our current or future licensors, licensees or collaborators. In the future, it may be necessary to initiate legal proceedings to enforce or defend these intellectual property rights, to protect trade secrets or to determine the validity or scope of intellectual property rights that are owned or controlled by us or our current or future licensors, licensees or collaborators. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results.

If we or our current or future licensors, licensees or collaborators initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us or our current or future licensors, licensees or collaborators is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent does not cover the technology in question. An adverse result in any litigation proceeding could put one or more of the patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would not preclude third parties from entering the market with competing products.

Third parties may initiate legal proceedings against us or our current or future licensors, licensees or collaborators to challenge the validity or scope of intellectual property rights we own or control. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of patents owned or controlled by us or our current or future licensors, licensees or collaborators. These proceedings can be expensive, lengthy and time-consuming, and many of our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us. Accordingly, despite our efforts, we or our current or future licensors, licensees or collaborators may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or have rights to, particularly in countries where the laws may not protect those rights as fully as in the United States.

There is a risk that some of our confidential information could be compromised by disclosure during litigation because of the substantial amount of discovery required. Additionally, many foreign jurisdictions have rules of discovery that are different than those in the United States and that may make defending or enforcing our patents extremely difficult. There also could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

Third-party pre-issuance submission of prior art to the USPTO, opposition, derivation, revocation, reexamination, inter partes review or interference proceedings, or other pre-issuance or post-grant proceedings, as well as other patent office proceedings or litigation in the United States or other jurisdictions brought by third parties against patents or patent applications owned or controlled by us or our current or future licensors, licensees or collaborators, may be necessary to determine the inventorship, priority, patentability or validity of these patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection and allow third parties to commercialize our technology or product candidates without payment to us. Additionally, potential licensees or collaborators could be dissuaded from collaborating with us to license, develop or commercialize current or future product candidates if the breadth or strength of protection provided by our patents and patent applications is threatened. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees.

Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights or we may initiate legal proceedings against third parties to challenge the validity or scope of the third-party intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and that of our current or future licensors, licensees or collaborators to develop, manufacture, market and sell any product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. Third parties may initiate legal proceedings against us or our current or future licensors, licensees or collaborators alleging that we infringe their intellectual property rights. Alternatively, we may initiate legal proceedings to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, revocations, reexaminations, inter partes review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. These proceedings can be expensive, lengthy and time-consuming, and many of our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us.

Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity in favor of the granted third party patent. This is a high burden, requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim.

An unfavorable outcome in any such proceeding could require us and our current or future licensors, licensees or collaborators to cease using the related technology or developing or commercializing the product or product candidate, or to attempt to license rights to it from the prevailing party, which may not be available on commercially reasonable terms, or at all. Additionally, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business.

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

We are aware of several third-party patents and patent applications containing claims directed to compositions of matter, methods of use and related subject matter, some of which pertain, at least in part, to subject matter that might be relevant to our aldafermin, MK-3655 (NGM313), NGM120, NGM621 NGM707 and NGM438 product candidates. We are not aware of any facts that would lead us to conclude that the valid and enforceable claims of any third-party patents would reasonably be interpreted to encompass our product candidates, unless we are unsuccessful in our opposition of any of the granted European patents that are discussed below, or any appeals stemming therefrom. As to pending third-party applications, we cannot predict with any certainty the claims that will issue, if any, or the scope of such issued claims.

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

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

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

In addition to seeking patents for some of our technology and products, we also rely substantially on trade secrets in our activities, including unpatented know-how, technology and other proprietary materials and information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers,

consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. However, these steps may be inadequate, we may fail to enter into agreements with all such parties or any of these parties may breach the agreements and disclose our proprietary information and there may be no adequate remedy available for such breach of an agreement. We cannot assure that our proprietary information will not be disclosed or that we can meaningfully protect our trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing, or unwilling, to protect trade secrets. If a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

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

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

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

We and our current or future licensors, licensees or collaborators may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. Litigation may be necessary to defend against these and other claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our products and product candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to any product candidates we may develop or utilize similar technologies that are not covered by the claims of the patents that we license or may own in the future;
- we, or our current or future licensors, licensees or collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we license or may own in the future;
- we, or our current or future licensors, licensees or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our pending patent applications or those that we may own in the future will not lead to issued patents;
- issued patents to which we hold rights may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

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

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been and may continue to be volatile, and you could lose all or part of your investment.

The market price for our common stock has fluctuated significantly from time to time, for example, varying between a high of $32.05 on December 30, 2020 and a low of $8.81 on October 7, 2019. The trading price of our common stock has been and may continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. In addition to the factors discussed in this “Risk Factors” section, these factors include:

- developments associated with our collaboration with Merck, including Merck’s failure to exercise its remaining unilateral option to extend the research phase of the collaboration, any termination of the collaboration or other change in our relationship with Merck;
- the success of competitive products or technologies, including disclosure of interim data by our competitors;
- regulatory actions with respect to our product candidates or our competitors’ product candidates or products;
- results of clinical trials of our product candidates or those of our competitors;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors or collaborators of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- regulatory, legal or payor developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to in-license or acquire additional product candidates or products;

- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors; and
- general economic, industry and market conditions.

In addition, the stock market in general, and The Nasdaq Global Select Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including worsening economic conditions and other adverse effects or developments relating to the evolving effects of the COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and material adverse impact on the market price of our common stock.

Because of potential volatility in our trading price and trading volume, we may incur significant costs from class action securities litigation.

Holders of stock in companies that have a volatile stock price frequently bring securities class action litigation against the company that issued the stock. We may be the target of this type of litigation in the future. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, we could incur substantial costs defending the lawsuit and the time and attention of our management could be diverted from other business concerns, either of which could seriously harm our business. Refer also to the risk factor entitled “Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.”

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

Our common stock is currently listed on The Nasdaq Global Select Market under the symbol “NGM” and trades on that market. We cannot ensure that an active trading market for our common stock will be sustained. Accordingly, we cannot ensure the liquidity of any trading market, your ability to sell your shares of our common stock when desired or the prices that you may obtain for your shares.

Our principal stockholders, including entities affiliated with The Column Group, Merck and management, own a substantial percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, significant stockholders, including entities affiliated with The Column Group and Merck, and their respective affiliates beneficially own a substantial amount of our
voting stock. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders. In addition, if any of our significant stockholders decide to sell a meaningful amount of their ownership position and there is not sufficient demand in the market for such stocks, our stock price could fall.

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

For so long as we remain an "emerging growth company" as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not "emerging growth companies" including:

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

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

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

With respect to the JOBS Act, we are also taking advantage of some, but not all, of the reduced regulatory and reporting requirements that are available to us so long as we qualify as an "emerging growth company." For example, we are not subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies." As a result, changes in U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

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

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

For the trading days during the three months ended September 30, 2020, the average daily trading volume for our common stock on The Nasdaq Global Select Market was only 180,030 shares. As a result, sales of a substantial number of shares of our common stock in the public market, including pursuant to the Sales Agreement or the perception in the market that we or the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. In addition, as a result of the low trading volume of our common stock, the trading of relatively small quantities of shares by our stockholders could disproportionately influence the market price of our common stock in either direction. The price for our shares could, for example, decline significantly in the event that a large number of shares of our common stock are sold on the market without commensurate demand, as compared to an issuer with a higher trading volume that could better absorb those sales without an adverse impact on its stock price. Moreover, certain holders of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Shares issued to Merck in the private placement that occurred concurrently with our IPO became available for sale in the public market beginning on March 17, 2020, subject to the conditions of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, if any.

Some provisions of our charter documents, Delaware law and our agreement with Merck may have anti-takeover effects or could otherwise discourage an acquisition of us by others, even if an acquisition would benefit our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or to remove our current management. These provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- authorizing the issuance of “blank check” preferred stock, the terms of which we may establish and shares of which we may issue without stockholder approval;
- prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. In addition, Section 203 of the DGCL prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, which is generally a person that together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Certain provisions in our agreement with Merck may also deter a change of control. For example, under our agreement with Merck, a change of control gives Merck the right to terminate the research phase of the collaboration as well as additional rights if our acquirer is a qualifying large pharmaceutical company or has a research, development or commercialization program that competes with a program licensed by Merck.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws, Delaware law or our agreement with Merck that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a breach of a fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

New tax laws or regulations, changes to existing tax laws or regulations or changes in their application to us or our customers may have a material adverse effect on our business, cash flows, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business and financial condition. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the 2017 Tax Act sanctioned many significant changes to the U.S. tax laws. Future guidance from the U.S. Internal Revenue Service, or IRS, and other tax authorities with respect to the

2017 Tax Act may affect us, and certain aspects of the 2017 Tax Act may be repealed or modified in future legislation. For example, the CARES Act modified certain provisions of the 2017 Tax Act. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings and the deductibility of expenses under the 2017 Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges and could increase our future U.S. tax expense.

Future changes in financial accounting standards or practices may cause adverse and unexpected revenue fluctuations and adversely affect our reported results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our reported financial position or results of operations. Financial accounting standards in the United States are constantly under review and new pronouncements and varying interpretations of pronouncements have occurred frequently in the past and are expected to occur again in the future. As a result, we may be required to make changes in our accounting policies. Those changes could affect our financial condition and results of operations or the way in which such financial condition and results of operations are reported. Compliance with new accounting standards may also result in additional expenses. As a result, we intend to invest all reasonably necessary resources to comply with evolving standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from business activities to compliance activities.

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

As a public company, we incur significant legal, accounting, insurance and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an “emerging growth company.” As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the Dodd-Frank Act, as well as rules adopted, and to be adopted, by the SEC and The Nasdaq Global Select Market. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and may make some activities more time-consuming and costly. The increased costs will increase our net loss. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur in the future to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

Specifically, in order to comply with the requirements of being a public company, we need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on The Nasdaq Global Select Market.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

Our stock price and trading volume is heavily influenced by the way analysts and investors interpret our clinical trial results, financial information and other disclosures. If securities or industry analysts do not publish research or reports about our business, delay publishing reports about our business or publish negative reports about our business, regardless of accuracy, our stock price and trading volume could decline. The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. A limited number of analysts are currently covering our company. If the number of analysts that cover us declines, demand for our common stock could decrease and our common stock price and trading volume may decline. Even if our common stock is actively covered by analysts, we do not have any control over the analysts or the measures that analysts or investors may rely upon to forecast our future results. Over-reliance by analysts or investors on any particular metric to forecast our future results may result in forecasts that differ significantly from our own.

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NGM BUSINESS OVERVIEW

We are a biopharmaceutical company focused on discovering and developing novel therapeutics based on scientific understanding of key biological pathways underlying liver and metabolic diseases, retinal diseases and cancer. These diseases represent a significant burden for healthcare systems and, in some cases, are leading causes of morbidity and mortality. Since the commencement of our operations in 2008, we have generated a robust portfolio of product candidates. Our six most advanced product candidates are presented below:

NASH = non-alcoholic steatohepatitis; FGF = fibroblast growth factor; GDF = growth differentiation factor; KLB = beta-klotho; C3 = Component 3; GFRAL = glial cell-derived neurotrophic factor receptor alpha-like; CACS = Cancer Anorexia/Cachexia Syndrome; ILT2 = Immunoglobulin-like transcript 2; ILT4 = Immunoglobulin-like transcript 4; LAIR1 = Leukocyte-associated immunoglobulin-like receptor 1

In 2015, we entered into the Collaboration Agreement with Merck, which allows us to develop multiple product candidates in parallel without bearing substantially greater costs or incurring significantly greater risk compared to developing product candidates, such as aldafermin (formerly NGM282), an engineered version of FGF19 on our own. In March 2019, Merck exercised its option to extend the research phase of the collaboration through March 16, 2022 and has the unilateral right to extend it again through March 16, 2024. As part of the extension through March 16, 2022, Merck agreed to continue to fund our research and development efforts up to $75.0 million each year consistent with the initial five-year term and, in lieu of a $20.0 million extension fee payable to us, Merck agreed to make additional payments totaling up to $20.0 million in support of our research and development activities across 2021 and the first quarter of 2022.

Merck generally has a one-time right to exercise its option to an exclusive, worldwide license when a program completes a human proof-of-concept trial. In November 2018, Merck exercised its option to license MK-3655 (formerly NGM313), an agonistic antibody selectively activating fibroblast growth factor receptor 1c/beta-klotho, or FGFR1c/KLB, which is a potential treatment for non-alcoholic steatohepatitis, or NASH. The collaboration enables us to develop more product candidates for major indications than we could likely advance on our own. We retain an option, when a product candidate has advanced to Phase 3 clinical trials, to participate in up to 50% of the economic return from that product candidate if it becomes an approved medicine by agreeing to share up to 50% of the costs of development. If we do not elect this option, we will instead receive milestone and royalty payments and we will not be required to share in development costs. Overall, the Merck collaboration provides us with robust research and development support, while allowing us to retain our research independence and the option to split costs and profits on individual product candidates Merck elects to advance.

In 2020, we suspended development activities related to multiple product candidates for portfolio management considerations in order to concentrate our resources on aldafermin and certain other product candidates subject to our Merck collaboration. Most recently, in December 2020, based on the overall clinical experience with both NGM386 (a once-daily growth differentiating factor 15, or GDF15, agonist product candidate we suspended development of earlier in 2020) and NGM395 (a long-acting GDF15 agonist product candidate), we decided to suspend development of the NGM395 program after we have completed the ongoing Phase 1 clinical trial evaluating safety, tolerability and pharmacokinetics, or PK, in obese but otherwise healthy adults. We remain interested in the potential applications of a GDF15 agonist, but we believe antagonizing the GDF15 receptor, glial-cell derived neurotropin factor receptor alpha-like, or GFRAL, with NGM120, one of our product candidates described below, in patients with cancer has a stronger near-term rationale for development.

All of our product candidates other than aldafermin, NGM395 and NGM386 are subject to our Merck collaboration.

Aldafermin in NASH

Aldafermin, an engineered version of the 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 aldafermin 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. Aldafermin is currently being tested in the ongoing Phase 2b ALPINE 2/3 trial in patients with NASH with stage 2 and 3, or F2-F3, liver fibrosis, which completed enrollment in September 2020, and in the ongoing ALPINE 4 trial in patients with NASH with stage 4, or F4, liver fibrosis and well-compensated cirrhosis, which commenced enrollment in February 2020. We expect to report topline data from the ALPINE 2/3 trial in the second quarter of 2021. Aldafermin was excluded from the Merck collaboration at the inception of the collaboration and remains wholly-owned by us.

In August 2020, we announced final data from our completed double-blind, randomized, placebo-controlled Phase 2 clinical study (Cohort 4) of aldafermin, which enrolled patients with biopsy-confirmed NASH with F2-F3 liver fibrosis, including a new analysis of Cohort 4 data from NASH patients with F3 liver fibrosis. Cohort 4 was the final reported cohort from our adaptive Phase 2 clinical study of aldafermin in NASH.

Cohort 4 was statistically powered to demonstrate the effect of 1 mg aldafermin treatment versus placebo on the primary endpoint of change in absolute liver fat content, or LFC, which achieved statistical significance. In addition, the study assessed secondary and exploratory endpoints of liver histology and biomarkers of disease activity. The histology results revealed that treatment with aldafermin led to clinically meaningful improvements at 24 weeks versus placebo in fibrosis improvement of ³1 stage with no worsening of NASH (38% of aldafermin-treated patients vs. 18% placebo) and in resolution of NASH with no worsening of liver fibrosis (24% of aldafermin-treated patients vs. 9% placebo). The study also demonstrated a statistically significant impact on the combined endpoint of both fibrosis improvement and resolution of NASH (22% in aldafermin-treated patients vs. 0% placebo), which the FDA has indicated in draft industry guidance may be an acceptable development pathway.

Summary of Cohort 4 Histology Data1

Proportion of Patients Achieving Endpoints	Aldafermin 1 mg (n=50)	Placebo (n=22)
Fibrosis improvement (>1 stage) with no worsening of NASH2	38%	18%
Resolution of NASH with no worsening of liver fibrosis3	24%	9%
Fibrosis improvement and resolution of NASH4	22%*	0%
NAS reduction of >2 points with no worsening of liver fibrosis	62%***	9%

* p=0.015; ***p<0.001

1 Per protocol, analyzed using the “liver histologic population,” defined as the subset of enrolled patients who had valid, non-missing biopsy data at both baseline and week 24 (n=72).

2 Defined as patients having an improvement in liver fibrosis >1 stage and having no worsening of hepatocellular ballooning, no worsening of lobular inflammation and no worsening of steatosis from baseline to week 24.

[3] Defined as patients having a non-alcoholic fatty liver disease activity score, or NAS, of 0 or 1 for lobular inflammation and 0 for hepatocellular ballooning, with no worsening of fibrosis (no progression of NASH fibrosis stage) from baseline to week 24 (as defined by Clinical Research Network criteria).

[4] Defined as patients having an improvement in liver fibrosis >1 stage and having a NAS of 0 or 1 for lobular inflammation and 0 for hepatocellular ballooning at week 24.

Efficacy data from a secondary analysis of patients with advanced liver fibrosis enrolled in Cohort 4 was also provided. In this patient population, 30% of patients with F3 liver fibrosis treated with 1 mg aldafermin achieved fibrosis improvement ≥1 stage without worsening of NASH compared to 0% in the placebo arm. A responder analysis conducted in patients with F3 liver fibrosis who achieved >30% LFC reductions showed that 46% of patients treated with 1 mg aldafermin had fibrosis improvement of >1 stage without worsening of NASH compared to 0% of placebo patients.

Similar to what has been observed in prior NASH clinical studies with aldafermin, Cohort 4 findings also demonstrated that patients treated with 1 mg aldafermin experienced a mean increase of 45 mg/dL LDL cholesterol, or LDL-C, at week two of treatment relative to baseline. Under the protocol, patients in both the placebo and aldafermin arms who experienced an increase in mean levels of LDL-C of at least 10 mg/dL at week two of treatment were directed to take rosuvastatin daily during the treatment period. LDL-C was effectively managed with the concomitant statin use and LDL-C levels for both the placebo and aldafermin arms were nearly identical at approximately 77 mg/dL at week 24. In addition, mean serum triglyceride levels were significantly reduced in patients treated with aldafermin versus placebo as early as week two and sustained through week 24.

In Cohort 4, aldafermin had an overall adverse event profile that was similar to that of placebo, with no meaningful difference in gastrointestinal or pruritus adverse events in aldafermin compared to placebo. Serious adverse events, or SAEs, were also similar to placebo (aldafermin 4% versus 12% placebo), with all SAEs determined not to be related to treatment by the site investigator. Aldafermin was generally well tolerated and there were no study withdrawals due to adverse events, or AEs, in the aldafermin arm as compared to one withdrawal due to an adverse event in the placebo arm. Specific AE information is provided in the table below:

TREATMENT EMERGENT ADVERSE EVENTS (TEAE)	Placebo (N=25)	Aldafermin 1 mg (N=53)
Any TEAE	22 (88.0%)	46 (86.8%)
TEAE Leading to Drug Withdrawal	1 (4.0%)	0
Serious Adverse Event (SAE)	3 (12.0%)	2 (3.8%)
Drug-Related TEAE	11 (44.0%)	27 (50.9%)
TEAE Leading to Death	0	0

Most Common (>10%) Adverse Events	Placebo (N=25)	Aldafermin 1 mg (N=53)
Diarrhea	6 (24.0%)	15 (28.3%)
Nausea	6 (24.0%)	5 (9.4.%)
Headache	9 (36.0%)	7 (13.2%)
Fatigue	4 (16%)	3 (5.7%)
Abdominal Distension	3 (12.0%)	7 (13.2%)
Diabetes Mellitus	5 (20.0%)	2 (3.8%)
Peripheral Edema	3 (12.0%)	2 (3.8%)

Finally, in November 2020, additional Cohort 4 data was presented showing that statistically significant reductions in C4, a marker of bile acid synthesis, and bile acids were observed with aldafermin compared to placebo. In patients with NASH, the rate-limiting enzyme for bile acid synthesis, CYP7A1, is upregulated and an associated increase in serum levels of bile acids is also observed.

MK-3655 in NASH

MK-3655 is an 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. In November 2018, Merck exercised its option for a license to further research, develop and commercialize MK-3655 and other FGFR1c/KLB agonists pursuant to our Collaboration Agreement. In Phase 1 clinical testing, MK-3655 demonstrated favorable tolerability and preliminary data has shown the agent is capable of reducing LFC and improving metabolic biomarkers in obese insulin resistant subjects with nonalcoholic fatty liver disease, or NAFLD, after a single dose. We conducted a Phase 1b randomized, open-label, parallel group trial to evaluate the safety, tolerability, PK and pharmacodynamics, or PD, of a single MK-3655 dose or the maximum approved dose of daily oral pioglitazone in 25 obese insulin resistant subjects with NAFLD. The Phase 1b clinical trial evaluated the ability of MK-3655 to decrease LFC to support the clinical development of MK-3655 in NASH. The primary objectives of the study were to evaluate changes from baseline in LFC as measured by magnetic resonance imaging-estimated proton density fat fraction at day 36 and changes from baseline in whole body insulin sensitivity at day 29 in subjects treated with MK-3655 as compared to pioglitazone. This study indicated that MK-3655 was well tolerated, with no SAEs and no AE leading to study discontinuation. All AEs observed during the course of the study were deemed mild, with increased appetite (12%) and injection site reaction (12%) being the only AEs reported in at least 10% of MK-3655-treated subjects.

In the fourth quarter of 2020, Merck initiated a Phase 2b trial of MK-3655 in patients with F2-F3 NASH.

NGM621 in Geographic Atrophy

NGM621 is an inhibitory antibody designed to bind and inactivate complement C3, a protein implicated in the pathology of geographic atrophy, or GA. We initiated a Phase 1 safety, tolerability and PK clinical trial of NGM621, administered via intravitreal, or IVT, injections, in patients with GA in the second half of 2019. NGM621 is currently being tested in the ongoing Phase 2 CATALINA trial in patients with GA to evaluate its effects on disease progression when given every four weeks or every eight weeks. The first patient was dosed in the CATALINA trial in July 2020. Merck has a one-time option to license NGM621 upon our completion of a proof-of-concept study in humans.

In November 2020, we announced results from our completed Phase 1 clinical study of NGM621. The primary objective of the Phase 1 trial was to assess the safety and tolerability of single and multiple IVT injections of NGM621 in patients with GA. Secondary objectives were to characterize the serum PK of single or multiple doses of NGM621. The study enrolled 15 patients across three single-ascending dose cohorts of NGM621, 2 mg, 7.5 mg and 15 mg, the maximum planned dose in the study, and a multiple dose cohort that received two 15 mg doses separated by four weeks. Patients were dosed sequentially and followed closely over 12 weeks. In the study, NGM621 was well tolerated, with no patients experiencing SAEs, drug-related AEs, intraocular inflammation, endophthalmitis or choroidal neovascularization. No dose-related safety patterns or concerns were reported. Ocular AEs observed were mild in severity and representative of those commonly associated with IVT injections. No vision-related safety signals were detected. On average, patients maintained their visual acuity over the 12-week follow-up study duration. The serum PK of NGM621 was linear and dose-proportional. Ocular PK/PD preclinical modeling conducted by Merck and us suggests that NGM621 may potentially achieve >90% reduction in free C3 in the eye for seven weeks following a single IVT dose of 15 mg. Taken together, we believe the PK profile of NGM621 demonstrated in the Phase 1 study and subsequent PK/PD preclinical modeling support the potential for up to an every eight week (or every other month) dosing regimen of NGM621 at the 15 mg dose level. NGM621 serum exposure was below concentrations expected to produce systemic complement inhibition after IVT injection of the 15 mg dose. No anti-drug antibodies were detected in any patient at any timepoint.

NGM120 in CACS and Cancer

NGM120 is an inhibitory antibody binding GFRAL that is designed to block the effects of elevated GDF15 levels on cancer anorexia/cachexia syndrome, or CACS, and potentially on tumors. 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 metabolism to propel the cachectic state, and potentially the tumors, in cancer patients that have high serum levels of GDF15. Merck has a one-time option to license NGM120 upon our completion of a proof-of-concept study in humans.

In 2019, we completed a Phase 1 clinical trial in single (n=48) and multiple (n=44) ascending cohorts of NGM120 in healthy volunteers that assessed its safety, tolerability and PK profile. This clinical trial demonstrated that NGM120 was well tolerated at all doses studied and the pharmacokinetics supported once-monthly dosing. No SAEs or AEs were identified. The PK profile of NGM120 had a terminal half-life of approximately 35 days.

In the first quarter of 2020, we initiated a Phase 1a/1b clinical trial to assess the anti-CACS and anti-cancer effect of NGM120 in patients with advanced solid tumors. We recently completed enrollment in the Phase 1a dose finding portion of the study of NGM120 as a monotherapy in patients with select solid tumors and in the the Phase 1b dose finding portion of the study of NGM120 in combination with gemcitabine and abraxane in patients with metastatic pancreatic cancer. We expect to report data from the Phase 1a/1b dose finding study in the second half of 2021. A Phase 1b placebo-controlled expansion study of gemcitabine and abraxane and either NGM120 or placebo is planned in metastatic pancreatic carcinoma patients, and we anticipate initiating that study in the first quarter of 2021.

NGM707

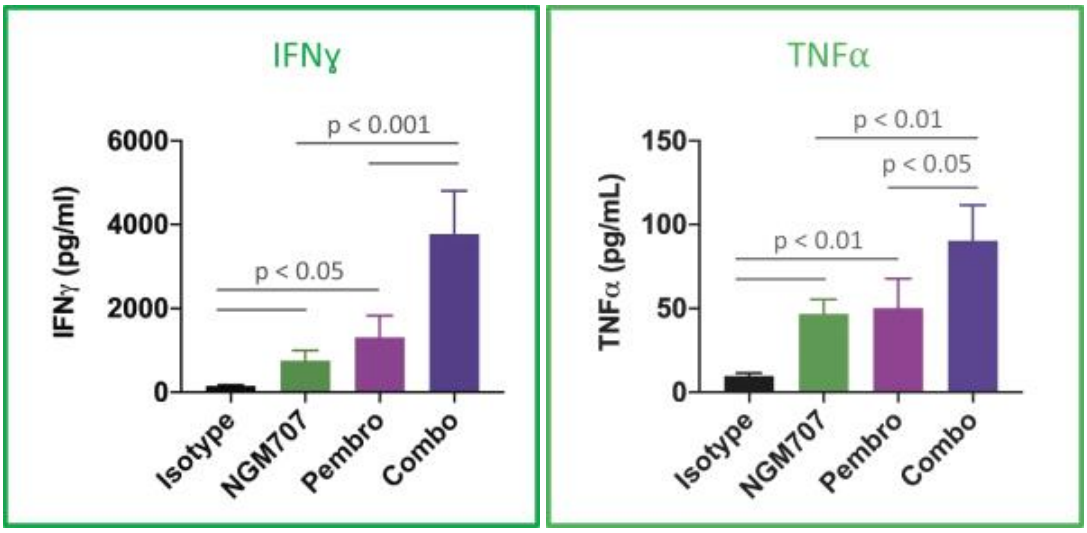
NGM707 is a novel dual antagonist antibody that is designed to improve patient immune responses to tumors by inhibiting both the Immunoglobulin-like transcript 2, or ILT2 (also known as LILRB1), and Immunoglobulin-like transcript 4, or ILT4 (also known as LILRB2), receptors. NGM707 targets an epitope shared by both ILT2 and ILT4 to achieve inhibition of both receptor systems. We believe NGM707 has the potential to both reprogram ILT4-and ILT2-expressing myeloid cells to shift them from suppressing to activating immune detection and attacking tumors. ILT2 blockage may also reverse inhibition of certain ILT2-expressing lymphoid effector cells to promote further tumor response. Reversing myeloid suppression, or myeloid reprogramming, may represent a promising new therapeutic area of immuno-oncology aimed at increasing patient response rates to T cell checkpoint inhibitors.

ILT2/ILT4 receptors

ILT2 and ILT4 receptors expressed on myeloid cells are implicated in suppressing anti-tumor immune responses in the tumor microenvironment and may represent checkpoints that enable tumors to evade immune detection. Suppressive myeloid cells enriched with ILT2 and ILT4 receptors are upregulated in certain cancer types, while ILT2 is also expressed on natural killer, or NK, cells, B cells and a subset of highly cytolytic T cells. Of note, ILT2 and ILT4 are upregulated on macrophages in the tumor microenvironment of certain cancer patients that are non-responders to T cell checkpoint inhibitor therapy and, therefore, implicate them as T cell checkpoint inhibitor resistance mechanisms.

Preclinical Studies and Planned Clinical Trials

Preclinical studies of NGM707 suggest that blockade of ILT4 reverses myeloid cell immune suppression, while blockade of ILT2 promotes NK and CD8+ T cell killing of tumor cells and activates macrophage phagocytosis of tumor cells. In addition, preclinical studies of NGM707 have shown that the dual blockade of ILT2 and ILT4 acts synergistically to reverse suppression of fragment crystallizable, or Fc, receptor signaling. In preclinical tests of monocytes from two individuals, the combination of NGM707 and pembrolizumab acted additively to increase T cell activation and cytokine secretion as shown in the mixed lymphocyte reactions' graphics below.



IFNg = Interferon Gamma; TNFa = Tumor Necrosis Factor alpha; Pembro= pembrolizumab; Combo = pembrolizumab and NGM707

All preclinical studies to enable an IND have been completed. We are preparing the final reports for a planned IND submission in early 2021, and plan to initiate a first-in-human study of NGM707 in mid-2021. Merck has a one-time option to license NGM707 upon our completion of a proof-of-concept study in humans.

NGM438

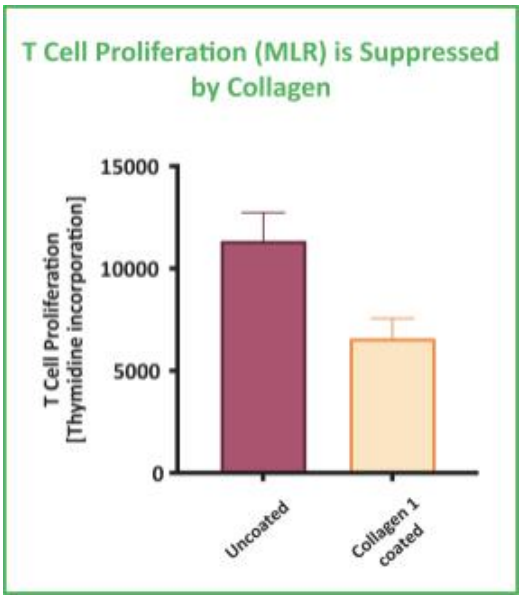
NGM438 is a novel antagonistic antibody that is designed to inhibit leukocyte-associated immunoglobulin-like receptor 1, or LAIR1, and promote immune detection and activation against advanced solid tumors. NGM438 has the potential to block the binding of all collagens tested with high potency, including tumor cell-derived collagens, which are the endogenous natural forms of collagen produced by the tumor that are believed to bind to LAIR1 to drive an immuno-suppressive environment surrounding the tumor. Reinvigoration of these collagen-suppressed immune cells may address a key resistance mechanism that limits responses to current immunotherapies.

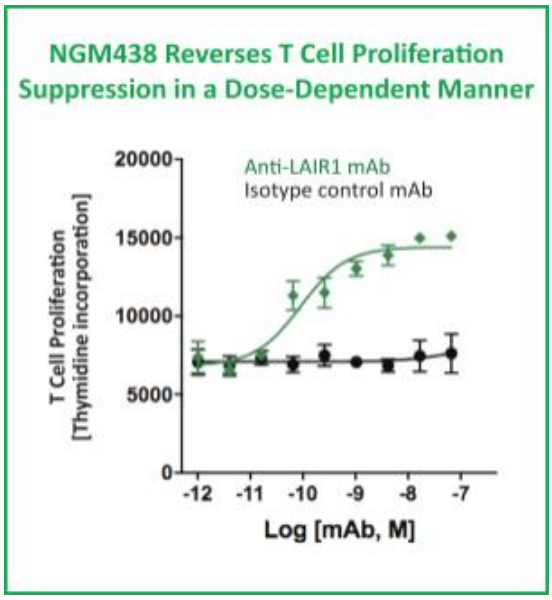
LAIR1 receptor

LAIR1 is a collagen-binding inhibitory receptor expressed on immune cells that is implicated in immune suppression. LAIR1 and collagens are upregulated in multiple cancer types where collagens are produced by activated stromal cells. These stromal-derived suppressive factors are associated with poor responses to checkpoint inhibitors. For such tumors, formation of the LAIR1-collagen complex may act as a stromal checkpoint to both physically exclude immune cells from the tumor and impose signaling-based immune suppression. Inhibiting this stromal checkpoint represents a potentially promising new therapeutic strategy to treat cancer by promoting the remodeling of the tumor architecture that restricts T cell infiltration of the tumor cell mass and reversing immune suppression in the tumor microenvironment.

Preclinical Studies and Planned Clinical Trials

Preclinical studies suggest that NGM438 may have the potential to reprogram collagen-suppressed myeloid cells to a stimulatory phenotype, induce inflammatory cytokine production by myeloid and T cells and relieve collagen-based suppression of T cell proliferation. For example, in a preclinical model as shown in the graphics below, collagen suppressed the mixture of myeloid cells and T cells in mixed lymphocyte reactions while the administration of NGM438 in vitro reversed this T cell suppression in a dose-dependent manner.





MLR = Mixed Lymphocyte Reaction; mAb = monoclonal antibodies

We plan to submit an IND in the second half of 2021 and expect to initiate a first-in-human study of NGM438 in the fourth quarter of 2021. Merck has a one-time option to license NGM438 upon our completion of a proof-of-concept study in humans.