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

FORM 10-K

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

For the fiscal year ended December 31, 2022

OR

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

For the transition period from_____to_____
Commission file number: 001-38853

NGM BIOPHARMACEUTICALS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**26-1679911**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

333 Oyster Point Boulevard
South San Francisco, California 94080
(Address of principal executive offices and zip code)
Registrant's telephone number, including area code: (650) 243-5555
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class of Securities Registered	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	NGM	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $699 million, calculated based on the closing price of the registrant's common stock as reported by the Nasdaq Global Select Market. Excludes shares of the registrant's common stock held as of such date by officers, directors and stockholders that the registrant has concluded are or were affiliates of the registrant. Exclusion of such shares should not be construed to indicate that the holder of any such shares possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of February 22, 2023, the number of outstanding shares of the registrant's common stock, par value $0.001 per share, was 82,046,499.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2023 Annual Meeting of Stockholders to be filed with the U.S. Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K are incorporated by reference in Part III, Items 10-14 of this Annual Report on Form 10-K.

NGM BIOPHARMACEUTICALS, INC.
2022 ANNUAL REPORT ON FORM 10-K
TABLE OF CONTENTS

Unless the context suggests otherwise, references in this Annual Report on Form 10-K (the "Annual Report") to "us," "our," "NGM," "NGM Biopharmaceuticals," "we," the "Company" and similar designations refer to NGM Biopharmaceuticals, Inc. and, where appropriate, its subsidiary.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements that involve risks, uncertainties and assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. The statements contained in this Annual Report on Form 10-K that are not purely historical are 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. Forward-looking statements are often identified by the use of words such as, but not limited to, "aim," “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” "seek," “should,” “will,” “would” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes to identify these forward-looking statements. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements. Forward-looking statements in this Annual Report 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 clinical trials;
- our belief that NGM707 has the potential to reprogram immunoglobulin-like transcript 4-, or ILT4-, and immunoglobulin-like transcript 2-, or ILT2-, expressing myeloid cells to shift them from a suppressive state that restricts anti-tumor immunity to a stimulatory state that may promote anti-tumor immunity;
- our belief that NGM831 has the potential to block the interaction of the Immunoglobulin-like transcript 3, or ILT3 (also known as LILRB4), receptor with fibronectin, as well as other cognate ligands, and mobilize a patient's own immune system to fight tumors by shifting myeloid cells from a suppressive state to a stimulatory state promoting anti-tumor activity;
- our belief that NGM438 has the potential to potently block the binding of all collagens to leukocyte-associated immunoglobulin-like receptor 1, or LAIR1, and to address a key resistance mechanism that limits tumor responses to current immunotherapies;
- our belief that NGM120 may reduce tumor growth and improve survival;
- our belief that MK-3655 (NGM313) has the potential to be a treatment for patients with NASH with early to moderate fibrosis;
- our plans to research, develop and commercialize our key programs in active development, NGM707, NGM831, NGM438 and NGM120, and the therapeutic potential of those product candidates;
- the therapeutic potential of our additional programs currently without significant resource allocation whose further development is primarily dependent on our ability to secure potential future collaboration, out licensing, partnering or other business development arrangements, or BD Arrangements, with third-party partners and our ability to secure such BD Arrangements on beneficial terms, if at all;
- our ability to obtain funding for our operations;
- our estimates regarding future expenses, revenue, capital requirements and needs for additional financing, particularly in light of our estimates of Merck Sharp & Dohme LLC providing further decreased funding in 2023 and minimal funding thereafter;
- our ability to obtain and maintain regulatory approvals for our current and any of our future product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our belief regarding the impact of our product candidates’ side effects and our ability to effectively manage these side effects;
- the commercialization of our product candidates, if approved;
- 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 other countries;
- our beliefs with respect to the availability of the accelerated approval pathway for any marketing applications that we may submit to the U.S. Food and Drug Administration;
- the performance of, and our ability to obtain sufficient supply of clinical trial material in a timely manner from, third-party suppliers and manufacturers;

- our beliefs around the competitive landscape for our product candidates and the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific, development and management personnel;
- our expectations regarding our ability to obtain, maintain, protect and enforce intellectual property protection for our product candidates; and
- the risks, uncertainties and other factors we identify elsewhere in this Annual Report on Form 10-K and in our other filings with the U.S. Securities and Exchange Commission.

RISK FACTOR SUMMARY

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should carefully consider the risks and uncertainties described under “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K as part of your evaluation of an investment in our common stock.

- We need to successfully complete rigorous preclinical and clinical testing of our product candidates before we can seek regulatory approval, and the regulatory approval processes of the U.S. Food and Drug Administration and comparable foreign health authorities are lengthy and inherently unpredictable, and if we are not successful at each step of the process, commercialization of our product candidates will be delayed or prevented.
  - Our product candidates are in early stages of development, with our most advanced product candidates only in Phase 2 development.
  - Our product candidates may fail to demonstrate safety and efficacy in ongoing and future clinical trials, may never achieve regulatory approval and may not be able to be successfully commercialized due to competition or other factors.
- We have incurred net losses every year since our inception, we have no source of product revenue, we expect to continue to incur significant operating losses and we may never become profitable.
- All of our revenue for recent periods has been received from a single collaboration partner, Merck Sharp & Dohme LLC, or Merck, and that revenue will be substantially lower in 2023 and minimal thereafter.
- We will need significant additional capital to proceed with development and commercialization of our current and potential future product candidates and to finance our other operations, and that additional capital may not be available to us on acceptable terms, or at all; as a result, we may be required to delay, scale back or discontinue development of our product candidates or other operations.
- We may depend in the future on BD Arrangements with third-party partners for the development and commercialization of our product candidates and for revenue and, if we are unable to secure those BD Arrangements, or if any future BD Arrangements are not successful, we may not be able to capitalize on the market potential of our product candidates or continue their development.
- We may not be able to obtain and maintain relationships with future partners that are necessary to develop, manufacture and commercialize some or all of our product candidates.
  - While we may opportunistically consider BD Arrangements to advance development of our key solid tumor oncology programs, we are actively seeking, or intend to seek, BD Arrangements with third-party partners to progress, in whole or in part, the development of one or more of our other programs whose further development is primarily dependent on our ability to secure potential future BD Arrangements, and if we are unable to secure BD Arrangements to support these programs, which include NGM621, aldafermin, NGM936, and, once termination of Merck's license is effective, MK-3655, we are unlikely to be able to advance their development unless our portfolio prioritization changes and we have access to the necessary capital to fund such development, and may discontinue or abandon any or all of these programs altogether, in which case we will not realize any return on our investments in those programs.
  - BD Arrangements involve numerous risks, any of which could materially and adversely affect our business and financial condition.

- We rely completely on contract manufacturers for the manufacture of our product candidates and the process of manufacturing, and conducting release testing for, our biologic product candidates is complex, highly regulated and subject to many risks, including our current reliance on single source manufacturers and suppliers, difficulties in supply chain, including procuring raw materials and components and the availability of manufacturing slots, and difficulties in production, including scaling up and validating initial production, contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, turnover of qualified staff or improper storage conditions, or difficulties with quality control, product stability or quality assurance testing, any of which could substantially increase our costs and limit supply of our product candidates and any future products needed for clinical trials and commercialization.

- Our product candidates other than NGM621 and aldafermin are currently manufactured at a facility in Lithuania. The ongoing conflict between Russia and Ukraine and the retaliatory measures taken or that may be taken by the United States, NATO and others against Russia create global security concerns, including the possibility of expanded regional or global conflict, and are likely to have short-term and likely longer-term negative impacts on regional and global economies, any or all of which could disrupt our supply chain and adversely affect our ability to conduct ongoing and future clinical trials of our product candidates and our ability to raise capital on favorable terms.
- We may not successfully identify new product candidates to expand our development pipeline.
- Our future success depends in part on our ability to attract and retain highly skilled employees, including members of our current senior management team, especially our Chief Scientific Officer, Dr. Jin-Long Chen.
- We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, us.
- Our business could be materially and adversely affected in the future by effects of disease outbreaks, epidemics and pandemics, including the COVID-19 pandemic.
- Our success depends in significant part upon our ability to obtain and maintain intellectual property protection for our products and technologies.
- Our principal stockholders, including entities affiliated with The Column Group, Merck and our management, own a substantial percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.
- We or third parties we rely on or partner with could experience a cybersecurity incident that could harm our business.
- 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.
- We continue to incur increased costs as a result of operating as a public company and our management devotes substantial time to public company compliance initiatives; for example, we are obligated to develop and maintain proper and effective internal control over financial reporting and to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

PART I

Item 1. Business.

Overview of Our Business

We are a biopharmaceutical company focused on discovering and developing novel, potentially life-changing medicines based on scientific understanding of key biological pathways underlying grievous diseases with critical unmet or underserved patient need. These diseases represent a significant burden for patients and 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 portfolio of product candidates ranging from early discovery to Phase 2b development. Currently, we have five programs in active clinical development. Our biology-centric drug discovery approach is therapeutic area agnostic and aims to seamlessly integrate interrogation of complex disease-associated biology and protein engineering expertise to unlock proprietary insights that are leveraged to generate promising product candidates and enable their rapid advancement into proof-of-concept studies. As explorers on the frontier of life-changing science, we aspire to operate one of the most productive research and development engines in the biopharmaceutical industry. All therapeutic candidates in our pipeline have been generated by our in-house discovery engine led by biology and motivated by patient need.

For more detailed information about our product candidate pipeline and their targeted therapeutic areas, see "—Our Pipeline Programs."

Our Mission and Strategy

Our mission is to translate complex, powerful biology with rigor and urgency into life-changing medicines. Our strategy is built on a straightforward central premise: create an environment that both allows drug discovery research to thrive by focusing on powerful human biology unconstrained by therapeutic area or technology approach and remain grounded in the singular motivation of delivering impactful medicines to address critical unmet or underserved needs of patients suffering from grievous diseases. All therapeutic candidates in our pipeline have been generated by our in-house discovery engine, led by biology and motivated by patient need.

Our pipeline is currently divided into two categories with separate approaches to development strategy and resource allocation in an effort to enable more of the product candidates in our pipeline to be advanced as effectively and efficiently as possible. To that end, we are currently focusing most of our execution efforts and resources on advancing our clinical-stage solid tumor oncology programs to potentially rapid proof of concept. For our other programs that are in therapeutic areas where clinical development is relatively resource intensive and can have long timelines to generate proof-of-concept data, due to the need to conserve capital and prioritize focused execution, we are actively seeking, or intend to seek, collaboration, out licensing, partnering or other business development arrangements, or BD Arrangements, with third-party partners with sufficient resources and relevant domain expertise to further their development.

Key elements of our strategy are:

- **Systematically and empirically interrogate complex disease-associated biology.** We employ unbiased, systematic investigations of complex disease-associated biology in pursuit of uncovering novel mechanisms of action and identifying proprietary insights into critical biological processes and pathways demonstrating powerful biological effects.
- **Remain biologics-focused, but modality flexible, leveraging a versatile approach to designing unique solutions for complex problems.** Building on these biological insights, we deploy our protein and antibody engineering expertise to create product candidates designed to be highly specific, to modulate targeted processes and to boost therapeutic potential. We have an unbiased antibody generation approach and use an array of modalities and technologies to optimize the properties of our antibody product candidates and native proteins.
- **Urgently advance therapies to meet unmet needs.** We seek to move promising product candidates we have discovered and developed rapidly into proof-of-concept clinical studies and, if warranted, late-stage development.
- **Build a diversified pipeline, honed with disciplined prioritization.** We seek to allocate our capital efficiently and strategically and fund our portfolio based on each program's scientific and other merits. Our discipline has been demonstrated by our decision not to proceed with development activities on multiple potentially viable product candidates for portfolio management and capital conservation reasons and to concentrate our resources and focus our execution on our solid tumor oncology programs.

- **Recruit and retain industry-leading research and development talent.** Our talented and experienced team is the foundation of our company. We aim to attract outstanding individuals with expertise in discovery sciences, protein and antibody engineering, pharmacology, translational medicine and preclinical and clinical development who are committed to sustaining and enhancing our scientific excellence, rigor and innovation, our creative clinical development and our high level of productivity.
- **Pursue BD Arrangements with partners.** Pursuing BD Arrangements has been and is expected to continue to be a key component of our strategy. Given the breadth of opportunities that have been, and may in the future be, produced by our discovery engine, we are actively seeking, or intend to seek, BD Arrangements with third-party partners to progress, in whole or in part, the development of one or more of our product candidates. We believe that this strategy, if successfully implemented, may enable more of the programs in our pipeline, including those in active development by us, to be advanced as effectively and efficiently as possible.

Our Pipeline Programs

Our biology-driven and therapeutic area agnostic discovery engine has produced a diverse pipeline of product candidates spanning oncology, retinal disease and liver and metabolic disease. We have divided our pipeline programs into two distinct categories with separate approaches to development strategy and resource allocation.

Key Programs in Active Development

Our pipeline includes four solid tumor oncology programs in active ongoing clinical development. We are currently focusing most of our execution efforts and resources on these key programs. We have intentionally built our clinical capabilities primarily in areas such as solid tumor oncology that offer development paths that are relatively resource efficient and have the potential to generate clinical proof-of-concept data more rapidly than certain other indications. Subject to our ability to obtain sufficient additional capital, whether through potential future BD Arrangements or otherwise, we may in the future pursue development of programs in other therapeutic areas. While we will opportunistically consider BD Arrangements to advance development of our key programs, we intend to invest our resources in their development even in the absence of BD Arrangements.

ILT2 = immunoglobulin-like transcript 2; ILT4 = immunoglobulin-like transcript 4; ILT3 = immunoglobulin-like transcript 3; LAIR1 = leukocyte-associated immunoglobulin-like receptor 1; GFRAL = glial cell-derived neurotrophic factor receptor alpha-like; PDAC = pancreatic ductal adenocarcinoma; mCRPC = metastatic castration-resistant pancreatic cancer

Therapeutic Area: Solid Tumor Oncology

Cancer Disease Overview

Cancer involving solid tumors is a leading cause of death globally and was responsible for an estimated over nine million deaths in 2020. There were an estimated almost 17 million newly diagnosed cancer cases around the world in 2020, excluding non-melanoma skin cancer. By 2040, the number of new cancer cases globally per year is expected to rise to over 25 million and the number of cancer-related deaths per year to grow to nearly 15 million, excluding non-melanoma skin cancer. Cancer was the second leading cause of death in the United States in 2020, causing over 500,000 deaths that year.

NGM707, NGM831 and NGM438: Our Myeloid Reprogramming and Checkpoint Inhibition Portfolio Designed to Enhance Anti-Tumor Immunity

Over the past decade, advances in cancer immunotherapy have driven significant improvements in clinical outcomes, especially in certain cancer types that are immunogenic, or capable of provoking an immune response. In particular, T cell checkpoint inhibitors, including immune checkpoint inhibitors targeting Programmed Cell Death Protein 1 and Programmed Cell Death Protein Ligand 1, or PD-1 and PD-L1, respectively, are designed to inhibit immune checkpoint pathways. When turned "on," these pathways act as "brakes" on anti-tumor immune responses, enabling tumors to evade detection and destruction by the immune system. T cell checkpoint inhibitors essentially work to "release" the "brakes" by turning off those pathways. However, the overall response rate to PD-1/PD-L1 inhibitors is typically only 20% to 30% and many cancer patients who initially experience a full or partial response using T cell checkpoint inhibitors may eventually experience cancer progression.

Our cancer research is currently focused on an emerging area of immuno-oncology research known as myeloid checkpoint inhibition. The tumor microenvironment, or TME, is composed of both cancerous and non-malignant cells. There is an abundance of myeloid cells present in the TME of many tumor types. While myeloid cells play a critical role in the immune system, in the tumor they can contribute to the inhibition of anti-tumor immune responses using multiple mechanisms, including suboptimal T-cell priming, T-cell suppression and physical exclusion of immune cells from the cancer cells. In essence, they serve as myeloid checkpoints, keeping the "brakes on" and enabling tumors to evade the immune system and drive resistance to cancer therapies. Our focus is on promoting myeloid reprogramming - switching myeloid cells in the TME from an immunosuppressive state to a stimulatory state that enhances anti-tumor immunity by releasing the "brake" and allowing these myeloid cells to potentially play a pivotal role in anti-tumor activity by acting to both kill cancer cells directly as well through the recruitment and activation of tumor-directed T cells.

We have built a portfolio of three myeloid checkpoint inhibitor product candidates, NGM707, NGM831 and NGM438, targeting four receptors whose elevated expression in myeloid cells in the TME has been associated with poor patient responses to T cell checkpoint inhibitors. NGM707, NGM831 and NGM438 are wholly-owned programs. Although all three programs were originally researched and developed under a collaboration agreement with funding from Merck Sharp & Dohme LLC, or Merck, we have had the sole right, at our sole discretion, to independently research, develop and commercialize each of them, at our sole expense, since March 2022, subject to the payment to Merck of low single-digit royalties on commercial sales of any resulting products. See "Licensing and Collaboration Arrangements—Merck Collaboration."

NGM707: ILT2/ILT4 Dual Antagonist Antibody

Overview of NGM707

NGM707, the lead asset in our myeloid reprogramming and checkpoint inhibition portfolio, is a dual antagonist monoclonal antibody that is designed to improve patient immune responses to tumors by inhibiting both Immunoglobulin-like transcript 2, or ILT2 (also known as LILRB1), and Immunoglobulin-like transcript 4, or ILT4 (also known as LILRB2), receptors. We believe NGM707 has the potential to reprogram ILT4- and ILT2-expressing myeloid cells to shift them from a suppressive state that restricts anti-tumor immunity to a stimulatory state that may promote anti-tumor immunity. Blocking ILT2 also may reverse inhibition of ILT2-expressing lymphoid cells to further stimulate anti-tumor immune responses.

Clinical Development of NGM707

We are conducting an open-label Phase 1/2 clinical trial evaluating NGM707 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab) for the treatment of patients with advanced or metastatic solid tumors. We expect to enroll approximately 220 patients in this trial. A Phase 1, Part 1a cohort evaluating NGM707 as a monotherapy was initiated in the second quarter of 2021. A Phase 1, Part 1b cohort evaluating NGM707 in combination with pembrolizumab was initiated in the second quarter of 2022. Both Phase 1 cohorts are ongoing and will be followed by Phase 2 expansion cohorts evaluating NGM707 in combination with pembrolizumab in specific tumor types. In December 2022, we presented initial data from the Phase 1, Part 1a cohort at the European Society for Medical Oncology Immuno-Oncology, or ESMO I-O, Annual Congress. The data indicated that NGM707 was generally well tolerated across all dose cohorts and demonstrated promising early signals of anti-tumor activity. In the presentation, we disclosed that of 24 response-evaluable patients as of November 23, 2022, best overall responses were a partial response in one patient, stable disease in six patients and non-complete response/non-progressive disease in one patient, and that potential proof-of-mechanism (myeloid reprogramming) was observed in peripheral blood and tumor biopsies.

NGM707 Patent Portfolio

As of December 31, 2022, we did not own or have a license to any issued patent that covers NGM707. However, NGM707 and related compositions-of-matter and methods of use are disclosed in pending U.S. and international patent applications we have filed. Any patent that may issue from these applications or any related applications we file is expected to expire no earlier than 2041, including any patent issued in the United States, if any, not including any patent term adjustments and any patent term extensions.

NGM707 Competition

We believe NGM707 is the most advanced candidate currently in clinical development targeting both ILT2 and ILT4. We are aware that ImmunOs Therapeutics AG announced in January 2023 that it will conduct a Phase 1 trial of its lead program IOS-1002, which demonstrated the ability to bind to three different immune checkpoint targets, LILRB1 (ILT2), LILRB2 (ILT4) and KIR3DL1 in preclinical trials. Additionally, there are several products in development that target either ILT4 or ILT2. We are aware of four clinical stage anti-ILT4 programs from Merck, Jounce Therapeutics, Inc., or Jounce, Immune-Onc Therapeutics, Inc., or Immune-Onc, and Bristol-Myers Squibb. In September 2020, Merck presented interim findings from a Phase 1 dose-escalation study evaluating its investigational anti-ILT4 therapeutic candidate, MK-4830, and Phase 1 results were published in January 2022. Jounce is developing an anti-ILT4 monoclonal antibody, JTX-8064, and clinical data from its Phase 1 trial were presented in December 2022. In February 2023, Jounce announced that as part of a corporate restructuring and business combination with Redx Pharma Plc it would be seeking business development opportunities for the future development of JTX-8064. In September 2021, Immune-Onc initiated a Phase 1 study of its anti-ILT4 therapeutic candidate, IO-108. OncoResponse, Inc., Celldex Therapeutics, Inc. and Invectys Inc. have preclinical programs targeting ILT4. Biond Biologics Ltd., or Biond, has an antagonist antibody targeting ILT2, BND-22, which has been licensed by Sanofi, and a Phase 1 trial commenced in 2021. Agenus Inc. has an antagonist antibody targeting ILT2, AGEN1571, that entered Phase 1 clinical development in August 2022. Jounce also has a preclinical program targeting ILT2. Finally, Adanate, Inc. has an antibody, ADA-01, in early clinical development targeting LILRB family receptors that may include ILT4 and ILT2.

NGM831: ILT3 Antagonist Antibody

Overview of NGM831

NGM831 is an antagonist antibody that is designed to block the interaction of Immunoglobulin-like transcript 3, or ILT3 (also known as LILRB4) receptor, with fibronectin, as well as other cognate ligands. ILT3 is a fibronectin-binding inhibitory immune receptor that receives signals from the extracellular matrix to directly promote myeloid cell suppression. ILT3 is expressed on a variety of immune cells including tumor-associated myeloid cells, with particularly high expression on tolerogenic dendritic cells, or DCs, myeloid-derived suppressor cells and M2 macrophages. High ILT3 expression is associated with poor survival. Moreover, fibronectin has been shown to be upregulated in multiple cancers and associated with tumor progression. For tumors in which both ILT3 and fibronectin are upregulated, the ILT3-fibronectin signaling pathway may act as a "stromal checkpoint" to repress myeloid cell function and inhibit anti-tumor immunity. By inhibiting ILT3's interaction with fibronectin and its other ligands, we believe NGM831 has the potential to mobilize a patient's own immune system to fight tumors by shifting myeloid cells from a suppressive state to a stimulatory state and promoting anti-tumor activity. Our scientists have made discoveries related to this pathway, including the discovery of fibronectin as ILT3's functional ligand, as described in a publication in *Cancer Immunology Research*, a journal of the American Association for Cancer Research, in 2021.

Clinical Development of NGM831

In 2022, we initiated an open-label Phase 1/1b clinical trial to evaluate NGM831 as a monotherapy and in combination with pembrolizumab for the treatment of patients with advanced or metastatic solid tumors. A Phase 1, Part 1a cohort evaluating NGM831 as a monotherapy was initiated in the first quarter of 2022 and is ongoing. In addition, a Phase 1, Part 1b cohort evaluating NGM831 in combination with pembrolizumab was initiated in the third quarter of 2022 and is ongoing. We expect to enroll up to approximately 80 patients in these two cohorts.

NGM831 Patent Portfolio

As of December 31, 2022, we did not own or have a license to any issued patent that covers NGM831. However, NGM831 and related compositions-of-matter and methods of use are disclosed in pending U.S. and international patent applications we have filed. Any patent that may issue from these or related applications or any related applications we file is expected to expire no earlier than 2040, including any patent issued in the United States, if any, not including any patent term adjustments and any patent term extensions.

NGM831 Competition

We are aware of only one other antibody being pursued clinically for the treatment of solid tumors that is intended to block the interaction of Immunoglobulin-like transcript 3, or ILT3, with fibronectin, as well as other cognate ligands, which is Immune-Onc's Phase 1 asset, IO-202. However, there are other programs that target ILT3 in the clinic. Merck, Immune-Onc and Carbiogene Therapeutics Co. Ltd., or Carbiogene, all have clinical stage anti-ILT3 programs. Merck's anti-ILT3 program, MK-0482, is currently in Phase 2 development. Carbiogene's ILT3 program is in Phase 1 development for acute myeloid leukemia. We are aware of four additional preclinical anti-ILT3 candidates in development: Biond has BND-35, Jounce has JTX-1484, and Immune-Onc has both an ILT3 CAR-T and an ILT3 bispecific under development.

NGM438: LAIR1 Antagonist Antibody

Overview of NGM438

NGM438 is an antagonist antibody that is designed to inhibit leukocyte-associated immunoglobulin-like receptor 1, or LAIR1, and thereby promote anti-tumor immune responses. NGM438 has the potential to potently block the binding of all collagens to LAIR1, including tumor-derived collagens. Collagens produced by the tumor stroma, meaning the non-malignant, non-immune components of the tumor, are believed to bind LAIR1 to create an immuno-suppressive TME. The interaction of collagens from the tumor stroma with LAIR1 on immune cells represents a "stromal checkpoint" that restrains anti-tumor immune responses. Reinvigoration of these collagen-suppressed immune cells by blocking the binding of collagens to LAIR1 may address a key resistance mechanism that limits tumor responses to current immunotherapies.

Clinical Development of NGM438

In 2022, we initiated an open-label, Phase 1/1b clinical trial to evaluate NGM438 as a monotherapy and in combination with pembrolizumab for the treatment of patients with advanced or metastatic solid tumors. A Phase 1, Part 1a cohort evaluating NGM438 as a monotherapy commenced in the second quarter of 2022 and is ongoing. In addition, a Phase 1, Part 1b cohort evaluating NGM438 in combination with pembrolizumab commenced in the fourth quarter of 2022 and is ongoing. We expect to enroll up to approximately 80 patients in these two cohorts.

NGM438 Patent Portfolio

As of December 31, 2022, we did not own or have a license to any issued patent that covers NGM438. However, NGM438 and related compositions-of-matter and methods of use are disclosed in pending U.S. and international patent applications we have filed. Any patent that may issue from these applications or any related applications we file is expected to expire no earlier than 2041, including any patent issued in the United States, if any, not including any patent term adjustments and any patent term extensions.

NGM438 Competition

We are aware of only two other anti-LAIR1 antibodies currently in development, Immune-Onc's preclinical-stage asset, IO-106, and NextCure, Inc.'s, or NextCure's, NC525. NextCure also has a Phase 1 product candidate in the clinic, NC410, a LAIR2 fusion protein designed to mimic the natural decoy effects of LAIR2, which binds to collagens and blocks the activity of LAIR1.

NGM120: The Potential of GDF15/GFRAL Inhibition to Treat Cancer and Cancer-Related Cachexia

Our scientists have made several discoveries related to growth differentiation factor 15, or GDF15, including identifying its cognate receptor glial cell-derived neurotrophic factor receptor alpha-like, or GFRAL. GFRAL is expressed in a specific region of the hindbrain, partially outside the blood brain barrier. Our preclinical research suggests the central role of the GDF15/GFRAL pathway in promoting tumor-associated appetite suppression, metabolic regulation and immune modulation. *In vivo* screening of human genes shows that GDF15 expression leads to an outsized effect on weight loss and, in animal models, elevated serum levels of GDF15 are a regulator of immune function, metabolism and feeding. In addition, elevated serum levels of GDF15 have been shown to be associated with cachexia, a disorder that causes extreme weight loss and muscle wasting. Evidence has shown that serum levels of GDF15 are elevated in patients across a number of tumor types and are associated with a worse prognosis in prostate, colorectal, esophageal and ovarian cancers. As a result of our identification of GFRAL, we developed novel insights into the mechanism of action of GDF15 and the structure and function of the GDF15/GFRAL interaction.

Overview of NGM120

NGM120 is an antagonist antibody that binds to GFRAL and is designed to block the effects of elevated serum levels of GDF15. We designed NGM120 as a potent, humanized monoclonal antibody inhibitor of GFRAL

with the potential for once-monthly or less frequent dosing. Preclinical studies suggest that NGM120 may reduce tumor growth and improve survival in syngeneic orthotopic pancreatic tumor models in mice.

Although NGM120 was originally researched and developed under a collaboration agreement with funding from Merck, we have had the sole right, at our sole discretion, to independently research, develop and commercialize NGM120, at our sole expense, since March 2022, subject to the payment to Merck of low single-digit royalties on commercial sales of any resulting products. See “Licensing and Collaboration Arrangements—Merck Collaboration.”

Clinical Development of NGM120

We are currently conducting a Phase 1/2 clinical trial to assess NGM120’s effect on cancer and cancer-related cachexia in patients with select advanced solid tumors, metastatic pancreatic cancer and metastatic castration-resistant prostate cancer, or mCRPC. The trial includes:

- a Phase 1a cohort evaluating NGM120 as a monotherapy in patients with select advanced solid tumors,
- a Phase 1b cohort evaluating NGM120 in combination with gemcitabine and Nab-paclitaxel in patients with metastatic pancreatic cancer,
- an additional Phase 1b cohort testing NGM120 in combination with one or more lines of hormone therapies in patients with mCRPC, and
- a Phase 2 cohort evaluating NGM120 in combination with gemcitabine and Nab-paclitaxel as first-line treatment in patients with metastatic pancreatic cancer (referred to as the PINNACLES trial).

In August 2022, we initiated the Phase 1b cohort testing NGM120 in combination with one or more lines of hormone therapies in patients with mCRPC.

In September 2022, at the European Society for Medical Oncology, or ESMO, Annual Congress, we reported updated preliminary findings for a subgroup of patients with advanced prostate cancer from the Phase 1a cohort evaluating NGM120 as a monotherapy in patients with select advanced solid tumors. The updated preliminary results reported at ESMO demonstrated that NGM120 was well tolerated with no dose-limiting toxicities and provided encouraging signals of anti-cancer activity in patients with advanced prostate cancer.

In September 2022, at the American Association for Cancer Research, or AACR, Special Conference: Pancreatic Cancer, we reported updated preliminary findings from the Phase 1b cohort evaluating NGM120 in combination with gemcitabine and Nab-paclitaxel in patients with metastatic pancreatic cancer. The updated preliminary results reported at AACR demonstrated that NGM120 was well tolerated with no dose-limiting toxicities and provided encouraging signals of anti-cancer activity in patients with metastatic pancreatic cancer.

NGM120 Patent Portfolio

As of December 31, 2022, we owned two issued patents in the United States, as well as six issued foreign patents covering NGM120 and related compositions-of-matter and methods of use. We also own pending patent applications covering similar subject matter in the United States and multiple jurisdictions outside of the United States. The issued patents are expected to expire in 2037, not including any patent term adjustments and any patent term extensions.

NGM120 Competition

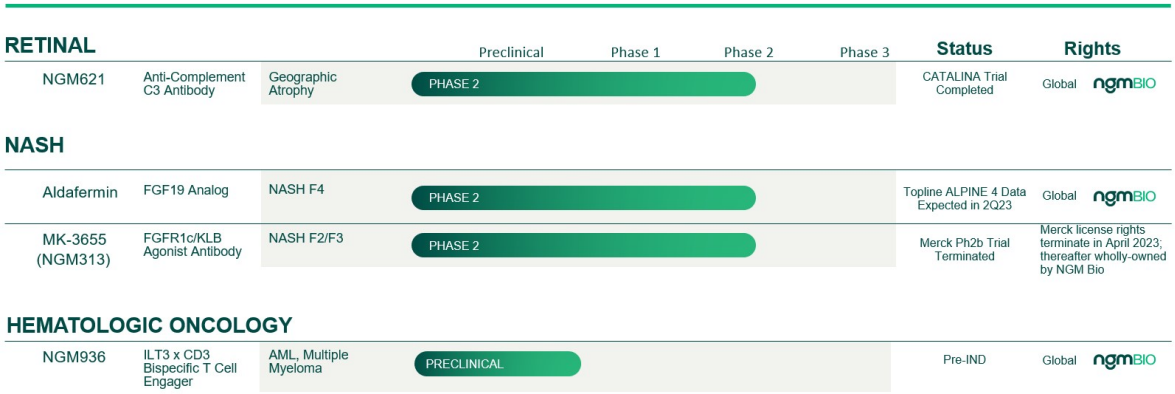
We are not aware of any publicly disclosed program other than NGM120 that targets GFRAL. There are three Phase 1 programs we are aware of that target GDF15: AVEO Pharmaceuticals, Inc.’s AV-380 is in a Phase 1 trial in healthy volunteers, Pfizer’s monoclonal antibody PF-06946860 is in Phase 1 trials in solid tumors assessing various cachexia-related measures and anti-tumor effects and CatalYm GmbH, or CatalYm, has initiated a Phase 1 clinical trial of visugromab (formerly known as CTL-002) in Europe to explore the treatment of cancer in solid tumors, and initial results from this trial were presented in September 2022. AstraZeneca also has a preclinical program, AZD8853, an antibody targeting GDF15, and CatalYm has an additional discovery program targeting the GDF15 pathway.

The current standard of care for first-line metastatic pancreatic cancer is chemotherapy with gemcitabine and Nab-paclitaxel or a combination chemotherapy regimen referred to as FOLFIRINOX. No new treatments have been FDA-approved for this population since Abraxane® (paclitaxel protein bound), or Nab-paclitaxel, in 2013 and several programs have failed in Phase 3 development in recent years. We are aware of three programs in Phase 3 trials in combination with chemotherapy in first-line metastatic pancreatic cancer: Novartis’ NIS793, a monoclonal antibody targeting transforming growth factor beta, or TGFβ, FibroGen Inc.’s pamrevlumab targeting connective tissue growth factor, and Novocure GmbH’s Tumor Treating Fields device. Over 50 therapies are in Phase 1 and

Phase 2 trials for pancreatic cancer, spanning multiple mechanisms of action, including immune checkpoint inhibitors, cancer vaccines, tyrosine kinase inhibitors and chemokine receptor antagonists.

Additional Programs Currently Without Significant Resource Allocation

Due to the need to conserve capital and prioritize focused execution, the remainder of our pipeline includes programs whose further development is primarily dependent on our ability to secure potential future BD Arrangements. These programs are in therapeutic areas where clinical development is relatively resource intensive and can have long timelines to generate proof-of-concept data. As a result, we are actively seeking, or intend to seek, BD Arrangements with third-party partners possessing sufficient resources and relevant domain expertise in the relevant therapeutic area in order to further clinical development of these programs. In the absence of such BD Arrangements for these programs, we are unlikely to be able to advance their development unless our portfolio prioritization changes and we have access to the necessary capital to fund such development. These programs are set forth below:



C3 = component 3; NASH = non-alcoholic steatohepatitis; FGF19 = fibroblast growth factor 19; FGFR1c = fibroblast growth factor receptor 1c; KLB = beta-klotho; F2/3/4 = stage 2/3/4 liver fibrosis; ILT3 = immunoglobulin-like transcript 3; CD3 = cluster of differentiation 3; AML = acute myeloid leukemia

Therapeutic Area: Retinal Diseases

Geographic Atrophy Disease Overview

Geographic atrophy, or GA, is an advanced form of age-related, dry macular degeneration characterized by progressive retinal degeneration associated with irreversible loss of vision and is a major cause of blindness for elderly patients. GA afflicts over one million patients in the United States and approximately five million patients worldwide. One in six people with GA becomes legally blind within six years of diagnosis. The decline in visual function experienced by patients with GA is typically bilateral and directly related to the progressive loss of retinal photoreceptors, retinal pigment epithelium, or RPE, and choriocapillaris in the macular, or central, region of the retina. GA disease progression, and the patient's accompanying visual decline, can have significant consequences for the patient, which can include the inability to drive, read and perform activities of daily living, a reduction in quality of life and increased likelihood of accidents or injuries and loss of independence. Dysregulated activation of the complement system, a key component of the immune system, including complement C3, has been implicated in the onset and progression of GA.

NGM621: A Potential Treatment for Geographic Atrophy

NGM621 is a humanized Immunoglobulin 1, or IgG1, monoclonal antibody administered via intravitreal, or IVT, injection. NGM621 was engineered to potently bind to, and be a long-acting inhibitor of, complement C3 with the treatment goal of reducing the rate of disease progression in patients with geographic atrophy, or GA, secondary to age-related macular degeneration, or AMD.

In October 2022, we announced topline results from the Phase 2 CATALINA clinical trial, which evaluated the efficacy and safety of NGM621 when given to patients with GA every four weeks or every eight weeks via IVT injections compared to sham control. The trial did not meet its primary endpoint of a statistically significant reduction in the rate of change in GA lesion area growth using slope analysis over 52 weeks of treatment with NGM621 versus sham. NGM621 demonstrated a favorable safety profile, with no evidence of increased choroidal

neovascularization in NGM621-treated patients compared to sham. In addition, there were no serious adverse events deemed by an investigator to be treatment-related.

In November 2022, we presented additional findings from the CATALINA trial at The Retina Society Annual Scientific Meeting. One of the post-hoc analyses presented at the Retina Society meeting involved the evaluation of a sub-population of patients least likely to be impacted by fundus autofluorescence, or FAF, grading methodology limitations: those in the middle two quartiles of a quartile analysis based on baseline lesion area. The patients in this sub-group had baseline GA lesions measuring 4.17 – 9.64 mm^2 as compared to study inclusion criteria of baseline GA area between ≥2.5 mm^2 and ≤17.5 mm^2. In this analysis, NGM621 demonstrated a reduction in the rate of change in GA lesion area (slope) of 21.9% (Q4W) (n=55) and 16.8% (Q8W) (n=52), compared to sham (n=53). Using MMRM analysis, a mixed effects model for repeated measures, to evaluate the change from baseline in GA area at weeks 24 and 52 for this subgroup, the reduction in GA growth (change from baseline vs sham) at 52 weeks was 20.6% (Q4W) and 16.6.% (Q8W).

Merck had a one-time option to license NGM621 and its related compounds upon completion of the CATALINA trial. In December 2022, Merck notified us that it would not exercise its option to license NGM621 and its related compounds, nor would Merck exercise the related ophthalmology bundle option; accordingly, these options expired unexercised in January 2023 and the program is now wholly-owned by us. Further development of NGM621 is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of NGM621 unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

NGM621 Patent Portfolio

As of December 31, 2022, we owned one issued United States patent covering NGM621, and the product and related compositions-of-matter and methods of use are disclosed and claimed in other patent applications pending in the United States and in multiple jurisdictions outside of the United States. The current patent and any patent that may issue from any of the pending applications would be expected to expire no earlier than 2039, not including any patent term adjustments and any patent term extensions.

Geographic Atrophy Competition

Current Treatments

There is currently only one medicine approved by the FDA and none approved by the EMA for the treatment of GA. Patients with GA have very limited options other than SYFOVRE™ (pegcetacoplan injection) approved by the FDA in February 2023 for the treatment of GA secondary to AMD. Patients are observed by their ophthalmologist or retina specialist for the purposes of documenting disease worsening, through imaging and visual acuity testing, and to monitor for any conversion to wet age-related macular degeneration, or wet AMD (which is treatable with anti-VEGFs). Some patients with GA take AREDS formula vitamins which have been shown to reduce the risk of progression to advanced forms of AMD; however, results from the AREDS trials have shown that there is no benefit to reducing the rate of existing GA progression. As their vision declines, patients with GA can receive visual rehabilitation and instruction on adaptive tools, like magnifiers, to help manage their disability as well as possible.

Treatments in Development

Given the large market opportunity in GA, there are multiple programs in clinical development for GA. The landscape can be subdivided into either agents targeting the complement pathway or agents targeting other pathways implicated in AMD pathogenesis and different modes of action. Most treatment approaches for GA have focused on reducing the rate of GA lesion area progression, as assessed by retinal imaging. For the complement-targeted approaches, some therapeutics focus on inhibiting key points in the complement pathway with targeted inhibitors, while others are replacing regulatory proteins that modulate the complement cascade activity. Additionally, the product administration approaches vary and include oral pills, subcutaneous injections, IVT injections and surgical approaches like gene therapy. GA is a chronic, progressive disease and, currently, many believe that slowing the progression of disease requires treatment periods of at least 12 months to show a meaningful treatment benefit relative to sham control.

Multiple complement inhibition therapies are under clinical evaluation in patients with GA, and one has received regulatory approval from the FDA. In February 2023, Apellis Pharmaceuticals, Inc., or Apellis, announced that the FDA approved SYFOVRE™ (pegcetacoplan injection) for the treatment of GA secondary to AMD. With reference to other therapies currently in clinical development, Iveric bio, Inc.'s, or Iveric's, avacincaptad pegol, a PEGylated aptamer inhibitor of complement C5, completed a Phase 2/3 clinical trial that demonstrated statistically significant reductions in the rate of GA lesion area growth in the avacincaptad pegol arm versus the sham arm. In

February 2023, Iveric announced that the FDA had accepted its NDA of avacincaptad pegol. Other agents in development targeting the complement pathway include: Ionis Pharmaceuticals, Inc.'s IONIS-FB-LRx, a factor B inhibitor in Phase 2 development; Hemera Biosciences, LLC's HMR59, a gene therapy in development that produces CD59 to inhibit the complement membrane attack complex formation; Gemini Therapeutics, Inc.'s complement factor H replacement agent in Phase 2 development, GEM103; and Gyroscope Therapeutics Holdings plc's gene therapy GT-005, replacing complement factor I in patients with genetically defined GA in Phase 2 development; and Alexion Pharmaceuticals, Inc.'s ALXN2040 and Annexon, Inc.'s ANX007, both in Phase 2 development.

There are multiple product candidates in development that target other pathways implicated in AMD pathogenesis, including visual cycle modulators (for example, ALK001 in Phase 3 development by Alkeus Pharmaceuticals, Inc.), an NLRP3 inflammasome-targeting molecule, Xiflam, in Phase 2 development by InflammX Therapeutics, and others with undeclared targets (for example, EG-301 moving into Phase 2 development in early 2023 by Evergreen Therapeutics). Additionally, there are stem cell products being developed with the potential to replace RPE cells in late-stage GA and with the intent of preserving or improving visual function (for example, OpRegen in development by Lineage Cell Therapeutics, Inc.; CPCB-RPE1 in development by Regenerative Patch Technologies LLC; and ASP7217 in development by Astellas Pharma Inc.).

Therapeutic Area: Liver and Metabolic Diseases

We have spent more than a decade discovering and developing a portfolio of clinical-stage drug candidates that target various forms of cardio-metabolic and liver diseases, most specifically nonalcoholic steatohepatitis, or NASH. We have identified multiple hormonal pathways of interest and our drug candidates stem from novel insights we have made in the regulation of cardio-metabolic processes and liver function.

NASH Disease Overview

NASH and metabolic diseases are among the largest unmet medical needs globally and represent a leading cause of morbidity and mortality and a significant burden for patients and healthcare systems. They also represent areas of underinvestment by the pharmaceutical industry, driven in part by the biological complexity of the diseases and the substantial costs necessary to develop new therapeutics. Metabolic syndrome is exhibited by approximately 35% of adults in the United States and comprises a constellation of co-morbid conditions, including type 2 diabetes, obesity, high blood pressure, poorly regulated lipids and non-alcoholic fatty liver disease, or NAFLD, a precursor to NASH. NAFLD is characterized by abnormal amounts of fat in the liver, a condition known as steatosis. This abnormal fat in the liver contributes to the progression in certain NAFLD patients to NASH by developing a necroinflammatory state in the liver that ultimately drives scarring, also known as fibrosis, and, for many, progresses to cirrhosis, liver cancer and liver failure.

The estimated global prevalence of NAFLD and NASH has risen rapidly in parallel with the dramatic rise in obesity and diabetes. In the United States alone, the prevalence of NASH was estimated to total 19.3 million cases in 2020 and is expected to reach 27 million cases in the United States by 2030, with similar trends occurring globally. Patients with NASH with F2, F3 or F4 fibrosis were believed to encompass approximately 8.3 million patients in the United States in 2020 and that number is expected to grow to 14.1 million by 2030. The population of cirrhotic patients with NASH in the United States is expected to reach 3.5 million in 2030.

In addition to living with the burden of illness, NASH with advanced fibrosis can be very expensive for patients, their families and society. Advanced liver fibrosis is generally considered fibrosis stages F3 and F4. The annual economic burden associated with NAFLD and NASH in the United States was estimated to be over $100 billion in 2016. If a patient progresses through the earlier stages of fibrosis to F4 fibrosis, or cirrhosis, there is an increased occurrence of negative liver-related outcomes, including a more than 60% risk of cirrhosis-related complications such as ascites, jaundice, hepatic encephalopathy, variceal bleeds, liver cancer or liver transplant. The median survival for a cirrhotic NASH patient is approximately seven years.

Our NASH Product Candidates

Aldafermin

Aldafermin is an engineered analog of human hormone fibroblast growth factor 19, or FGF19, that is administered through a once-daily subcutaneous injection. Aldafermin is wholly-owned by us. Further development of aldafermin is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of aldafermin unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

Clinical Development of Aldafermin

To date, aldafermin has been dosed in over 700 patients and healthy volunteers across multiple liver and metabolic diseases, including more than 300 patients with NASH. In May 2021, we announced that the Phase 2b ALPINE 2/3 trial of aldafermin in patients with NASH and liver fibrosis stage 2 or 3, or F2 or F3, did not meet its primary endpoint evaluating a dose response at week 24 on liver fibrosis improvement by >1 stage with no worsening of NASH. As a result, we decided to suspend further development of aldafermin in patients with F2/F3 NASH, allowing for the reallocation of resources to advancing our other programs.

Aldafermin remains in Phase 2b development for the treatment of patients with compensated cirrhosis due to NASH (liver fibrosis stage 4, or F4, by the NASH Clinical Research Network classification). The Phase 2b ALPINE 4 clinical trial, which is fully enrolled, is designed to evaluate the treatment effect of aldafermin over 48 weeks in a population of patients with NASH with F4 liver fibrosis and well-compensated cirrhosis. We initiated the ALPINE 4 trial in February 2020 and completed enrollment of 160 patients across 80 sites in the United States, Europe, Hong Kong and Australia in January 2022. The objective of the trial is to evaluate whether fibrosis regression can be achieved in compensated cirrhotic patients with NASH, for whom liver mortality rates are high and liver transplant is the only option. The primary endpoint for the trial is the Enhanced Liver Fibrosis, or ELF, test, a reproducible, quantitative non-invasive liver prognostic test that evaluates liver fibrosis and correlates to liver-related outcomes. The ELF test is a composite blood test measuring the presence of three biomarkers associated with liver matrix metabolism. Liver biopsy data will also be measured and reported as a secondary endpoint upon completion of the trial. We expect to report topline data from the ALPINE 4 trial in the second quarter of 2023.

Aldafermin has been generally well tolerated in clinical trials to date. In patients with NASH receiving various doses of aldafermin (between 0.3 mg and 6 mg) in our completed Phase 2 trials, the most common reported adverse events occurring in more than 10% of patients included diarrhea, headache, abdominal distension, nausea, fatigue, vomiting, constipation, frequent bowel movements, injection site bruising, urinary tract infection, nasopharyngitis, abdominal pain, injection site reaction, vitamin D deficiency, injection site symptoms (such as pruritus, erythema or swelling), cough, fecal color discoloration, cholesterol and low-density lipoprotein cholesterol increase, with the majority of adverse events classified as mild or moderate. SAEs included one case of acute pancreatitis, as well as pleurisy, vertigo, headache, hypertension, cardiac arrest, chest pain, pneumonia, kidney mass, rectal bleeding and liver biopsy complication, none of which were considered related to study drug.

In patients with NASH and stage 2 or 3 liver fibrosis receiving various doses of aldafermin (between 0.3 mg and 3 mg) in the completed Phase 2b ALPINE 2/3 trial, results showed that the most common reported adverse events occurring in more than 10% of patients included diarrhea, nausea, headache, upper abdominal pain, injection site erythema, constipation and sinusitis with the majority of adverse events classified as mild or moderate. SAEs included osteoarthritis, uterine cancer, suicide attempt, small bowel obstruction, cholecystitis, cardiac hypertrophy and obesity, none of which were considered related to study drug.

Aldafermin Patent Portfolio

As of December 31, 2022, we owned 27 issued patents in the United States, as well as issued patents in more than 40 foreign countries, including various member states of the European Patent Office, or EPO, covering aldafermin, related compositions-of-matter and methods of use. We also own patent applications covering similar subject matter in the United States and multiple foreign jurisdictions including Europe. The earliest issued patents in the United States are expected to expire in 2032, not including any patent term adjustments and any patent term extensions.

MK-3655 (NGM313): An Insulin Sensitizer for the Treatment of NASH

MK-3655, also known as NGM313, is an agonistic antibody discovered by us that selectively activates fibroblast growth factor receptor 1c-beta-klotho, or FGFR1c/KLB, which regulates insulin sensitivity, blood glucose and liver fat and is administered every four weeks through a subcutaneous injection. We believe that MK-3655 has the potential to be a treatment for those patients with NASH with early to moderate fibrosis with or without type 2 diabetes.

In November 2018, Merck exercised its option for a license to conduct research upon, develop and commercialize MK-3655 and other FGFR1c/KLB agonists. As described below, in January 2023, Merck provided us with the required 90-days' notice of partial termination of our collaboration with Merck as it relates to MK-3655 and its related compounds. As a result, in late April 2023, the license rights granted to Merck in 2018 with respect to MK-3655 will revert to us and the program will become wholly-owned by us. Further development of MK-3655, once the termination is effective, is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of MK-3655 unless our

portfolio prioritization changes and we have access to the necessary capital to fund such development. See “Licensing and Collaboration Arrangements—Merck Collaboration.”

Clinical Development of MK-3655

At the end of 2020, Merck initiated a Phase 2b clinical trial of MK-3655 for the treatment of patients with NASH with F2 or F3 fibrosis. The trial was a multi-center, double-blind, placebo-controlled trial administering 50 mg, 100 mg and 300 mg doses of MK-3655 every four weeks compared to placebo for 52 weeks. The primary objective of the Phase 2b trial was NASH resolution without worsening of fibrosis at 52 weeks. In January 2023, we announced that Merck notified us of its decision to terminate the Phase 2b trial based on the results of an interim analysis of safety and reduction in liver fat at Week 24. Although it was not the primary endpoint of the trial, the percent reduction from baseline in liver fat for MK-3655, while greater than placebo across multiple dose arms, did not reach Merck’s threshold for continuing the trial through to completion. The trial was not discontinued for safety concerns.

In the Phase 1 and Phase 1b clinical trials we conducted, MK-3655 was generally well tolerated and data has shown the agent is capable of reducing liver fat content and improving metabolic biomarkers in obese, insulin resistant subjects with NAFLD after a single dose. In the Phase 1 trial, there were two SAEs reported in the MK-3655 treatment group, lower gastrointestinal, or GI, hemorrhage due to hemorrhoids and cholecystitis, both of which were deemed by the investigators to be unrelated to treatment with MK-3655. The majority of adverse events were mild to moderate in severity, and treatment-related events with the greatest proportion of subjects were GI disorders, injection site reactions, upper respiratory tract infections, headache and increased appetite. In the Phase 1b trial, all adverse events observed during the course of the study were deemed mild, with increased appetite (12%) and injection site reaction (12%) being the only adverse events reported in at least 10% of MK-3655-treated subjects.

MK-3655 Patent Portfolio

As of December 31, 2022, we owned three issued patents in the United States, which were licensed to Merck in connection with Merck's exercise of its license option for MK-3655, as well as pending patent applications in the United States and granted patents and pending patent applications in multiple jurisdictions outside of the United States covering MK-3655, related compositions-of-matter and methods of use. The earliest issued patents in the United States are expected to expire in 2035, not including any patent term adjustments and any patent term extensions. Once the partial termination of our collaboration with Merck as it relates to MK-3655 and its related compounds becomes effective, the license rights to these patents will revert to us.

NASH Competition

Current Treatments

Currently, there are no therapeutic agents approved by the FDA or the EMA for the treatment of NASH. Weight loss through diet and lifestyle management is currently considered the first-line treatment strategy for NASH and is associated with improvement in liver histology and a reduction in cardiovascular and metabolic complications. However, fewer than 10% of patients are successful in achieving or maintaining at least a 10% total body weight loss that is sufficient to improve fibrosis and, therefore, require other interventions. In cases of morbid obesity, gastric bypass surgery has been successful in resolving NASH in a majority of patients; however, the effect on fibrosis improvement was less substantial and the risk of complications and expense of the surgery limit more widespread use.

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

Treatments in Development

Certain NASH drug development candidates are focused on the metabolic components of the disease, such as insulin resistance and lipotoxicity, that are associated with the inception and early stages of the disease pathology. Metabolically-oriented mechanism of action classes that have product candidates with histological proof-of-concept data include: Madrigal Therapeutic, Inc.’s, or Madrigal's, resmetirom and Viking Therapeutic Inc.’s VK2809, both thyroid hormone receptor β-selective (THRβ) agonists; Novo Nordisk AS’s glucagon-like peptide (GLP)-1 agonist, semaglutide; the stearyl-CoA desaturase inhibitor aramchol from Galmed Pharmaceuticals Ltd.; Inventiva SA’s pan-peroxisome proliferator-activated receptors (PPAR) agonist, lanifibranor; Akero Therapeutics, Inc.’s efruxifermin and 89 Bio Inc.'s BIO89-100, both analogs of fibroblast growth factor 21 (FGF21); and

Genentech/Roche's BFKB8488A, an FGFR1c/KLB bi-specific agonistic antibody. In December 2022, Madrigal announced positive topline results from the pivotal Phase 3 MAESTRO-NASH biopsy clinical trial of resmetirom. MAESTRO-NASH, a registrational Phase 3 trial, achieved both liver histological improvement endpoints that FDA proposed as reasonably likely to predict clinical benefit to support accelerated approval for the treatment of NASH with liver fibrosis.

Product candidates targeting various mechanisms with possible anti-inflammatory and anti-fibrotic effects are also in clinical testing for NASH. These classes of compounds have shown mixed results in meaningfully improving the fibrosis score of patients. Where fibrosis improvements have been shown, results have either been transient or not accompanied by significant improvements in other histological measures of the disease, which may reflect the difficulty in treating the disease without removing the underlying insult of lipotoxicity or the challenge of impinging on the complex process of hepatocellular death and fibrosis from collagen deposition by intervention through a single pathway. Members of the "anti-inflammatory" or "anti-fibrotic" mechanism of action classes with compounds that have histological proof-of-concept data include farnesoid X receptor, or FXR, agonists, such as Intercept Pharmaceuticals, Inc.'s, or Intercept's, obeticholic acid. A new drug application, or NDA, for obeticholic acid was filed with the FDA by Intercept in September 2019 and received a complete response letter in June 2020. In December 2021, Intercept withdrew its marketing authorization application from the EMA. In December 2022, Intercept resubmitted an NDA with the FDA and in January 2023, Intercept announced that the FDA had accepted its NDA with a Prescription Drug User Fee Act, or PDUFA, target action date of June 22, 2023.

An ongoing consideration in NASH clinical development is pursuing combination treatments in an attempt to combine agents with less than optimal activity on their own to achieve a more clinically meaningful result. Combinations currently being evaluated in proof-of-concept trials include: metabolic/anti-fibrotic combinations such as semaglutide/cilofexor/firsocostat and tropifexor/licogliflozin (FXR agonist/SGLT-2, both from Novartis AG) and anti-inflammatory/anti-fibrotic duos such as cenicriviroc/tropifexor.

Therapeutic Area: Hematologic Oncology

Hematologic Cancer Disease Overview

Hematologic cancer, also referred to as blood cancer, refers to various forms of cancer that lead to uncontrolled growth or dysregulation of blood cells or blood-forming tissues. Examples of hematologic cancer include leukemia, lymphoma and multiple myeloma.

NGM936: ILT3xCD3 Bispecific T Cell Engager

Overview of NGM936

NGM936 is a bispecific T cell engager therapeutic candidate for the treatment of hematologic malignancies that targets ILT3 and cluster of differentiation 3, or CD3. NGM936 is designed to direct T cell mediated killing of ILT3-positive cancer cells while sparing normal hematopoietic stem cells, or HSCs, and minimizing CD3-driven cytokine release. ILT3, a myeloid-cell restricted receptor, has enriched expression in myelomonocytic leukemia, monocytic leukemia and leukemia stem cells but is not expressed on healthy HSCs. The expression profile of ILT3 may make it a potential target for the treatment of monocytic acute myeloid leukemia, or AML, and multiple myeloma.

Preclinical Development of NGM936

NGM936 has been evaluated in preclinical studies, where it has demonstrated *in vitro* the ability to potently kill ILT3+ AML cells, kill ILT3+ multiple myeloma cells and preserve healthy bone marrow cells. Further development of NGM936 is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of NGM936 unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

NGM936 Patent Portfolio

As of December 31, 2022, we did not own or have a license to any issued patent that covers NGM936. However, NGM936 and related compositions-of-matter and methods of use are disclosed in pending U.S. provisional patent applications we have filed. Any patent that may issue from these applications or any related applications we file is expected to expire no earlier than 2043, including any patent issued in the United States, if any, not including any patent term adjustments and any patent term extensions.

NGM936 Competition

We are not aware of any publicly disclosed program other than NGM936 that targets ILT3 and CD3 using a bispecific T cell engager. Immune-Onc has a bispecific antibody, IO-312, in preclinical development which targets ILT3 and is being pursued for cancer. The identity of the target of the second arm of IO-312 has not been disclosed.

Manufacturing

We do not own, and have no plans to establish, any manufacturing facilities. We currently use third-party contract development and manufacturing organizations or contract manufacturing organizations, which we refer to collectively as CMOs, to manufacture and supply all of the raw materials, drug substances and drug products for our R&D programs, including all the clinical trial materials used in the clinical trials of our clinical-stage product candidates. We have established relationships with several CMOs, including Lonza Ltd and Biotechpharma UAB. The activities of our CMOs are overseen by an experienced group of employees and third-party consultants.

We plan to continue to rely on CMOs to manufacture commercial quantities of any products for which we successfully obtain regulatory approval, as well as to provide packaging, storage and distribution of any approved products. We have not entered into long-term clinical or commercial supply agreements with any of our CMOs. In addition, each of our product candidates relies on a single contract manufacturer for supplies of its drug substance and drug product.

Competition

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Although we believe that we hold a strong position in research in certain areas of cancer, retinal diseases and liver and metabolic diseases, our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies, universities and other research institutions. Smaller or earlier-stage companies also may prove to be significant competitors, particularly through collaboration or partnering arrangements with large, established companies. We believe the key competitive factors that will affect the development and commercial success of our product candidates are their efficacy, safety and tolerability profile, and reliability.

There are many pharmaceutical companies, biotechnology companies, public and private universities and research organizations actively engaged in the R&D of products that may be competitive to our products. A number of pharmaceutical companies, including AbbVie, Allergan, AstraZeneca, Bayer, Boehringer 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, Apellis, Ascletis, Axcella, AVEO, Biond, Bird Rock, Can-Fite, CatalYm GmbH, Cirius, Enanta, Galectin, Galmed, Genfit, Gilead, Glympse, Immune-Onc, ImmunOS, Immuron, Intercept, Inventiva, Iveric, Jounce, Madrigal, MannKind, MediciNova, Mirum, Nalpropion, NextCure, North Sea, Promethera, Salix, Scholar Rock, Seal Rock, Terns, Tiziana, Tizona, Viking and Vivus, are pursuing the development or marketing of pharmaceuticals that target the same diseases that we are targeting. It is probable that the number of companies seeking to develop products and therapies for the treatment of cancer, retinal diseases and liver and metabolic diseases will increase.

For example, in February 2023, Apellis announced that the FDA approved SYFOVRE™ (pegcetacoplan injection) for the treatment of GA secondary to AMD. And in February 2023, Iveric announced that the FDA accepted Iveric's NDA of avacincaptad pegol for the treatment of GA. Many of these and other existing or potential competitors have substantially greater financial, technical, human and other resources than we have and may be better equipped to develop, manufacture and market 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. In addition, other technologies or products may be developed that have an entirely different approach or means of accomplishing the intended purposes of our products, which might render our technology and products noncompetitive or obsolete.

For more information regarding the competition that our disclosed product candidates face, or may face, see the discussion of specific competition for each product candidate see “—Our Pipeline Programs.”

Intellectual Property

Our intellectual property is critical to our business and our success depends, in part, on our ability to obtain and maintain intellectual property protection for our product candidates, technology and know-how, to defend and

enforce our intellectual property rights, in particular, our patent rights, to preserve the confidentiality of our trade secrets and to operate without infringing the proprietary rights of others.

We seek to protect the proprietary technology that we believe is important to our business through a variety of methods, including seeking and maintaining patents and patent applications intended to cover our product candidates, their compositions-of-matter, their methods of use and the processes for their manufacture and any other aspects of inventions that are commercially important to the success of our business. We seek to obtain domestic and international patent protection and, in addition to filing and prosecuting patent applications in the United States, we may file counterpart patent applications in additional countries where we believe such foreign filing is likely to be beneficial.

As of December 31, 2022, our patent portfolio includes over 600 patents and applications, including over 50 issued U.S. patents and over 30 pending U.S. patent applications covering our product candidates, certain aspects of our proprietary technology, and related inventions and improvements. Our patent portfolio also includes over 500 patents and patent applications in jurisdictions outside of the United States that, in many cases, are counterparts to our U.S. patents and patent applications. For more information regarding the patents and patent applications relating to eight of our disclosed product candidates, see the discussion of intellectual property protection for each product candidate in "—Our Pipeline Programs." The patent landscape surrounding our product candidates is crowded, and we do not know if our pending patent applications will be issued with the claims we are seeking or if our issued patents will withstand challenges from third parties.

Not all patent applications result in the issuance of patents. Patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially longer, so public disclosure of discoveries via the publication of patent applications or in the scientific literature is often delayed. As a result, we cannot be certain of the priority of inventions covered by our patent applications and may be subject to claims of priority from third parties or the United States Patent and Trademark Office, or USPTO, against which we will need to defend ourselves.

In addition, the scope of claims that may be allowed in any granted patent may be significantly reduced from the coverage claimed in the initial patent application. Further, the scope of the claims in an issued patent may be reinterpreted and, in some cases, narrowed or even cancelled after issuance by courts upon review. In addition, many jurisdictions allow third parties to challenge issued patents in administrative proceedings that may result in further narrowing or cancellation of patent claims. As a result, even issued patents may not provide sufficient protection from competitors.

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

Any changes we make to the composition, formulation, method of delivery or other attributes of our current and future product candidates to cause them to have what we view as more advantageous properties may not be covered by our existing patents and patent applications, and we may be required to file new applications and/or seek other forms of protection.

Even if patents are issued, if a third party engages in activities covered by valid claims of our patents, we may be required to engage in enforcement actions in the courts to enforce our patents. Not all enforcement proceedings are successful. We also must take care not to infringe the valid patents of third parties. Third-party patent rights that purport to cover our product candidates or their discovery, use or manufacture may require us to challenge their validity in court or administrative proceedings and prevail in such challenges, to alter our development or commercial strategy or our product candidates or their uses and manufacture, to obtain licenses to such patents and/or to stop certain activities altogether. We hold various licenses with third parties to their intellectual property, including those with Horizon Discovery Ltd. and, as described below, Lonza Sales AG, or Lonza, for the use of their cell lines. The patent positions of biotechnology companies like ours are generally uncertain and involve complex legal, scientific and factual questions. We may not obtain or maintain adequate patent protection for any of our programs and product candidates.

In addition to patent protection, we also rely on trademark registration, trade secrets, know-how, other proprietary information and continuing scientific innovation to develop and maintain our competitive position. We seek to maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. As a part of these efforts, it is our policy

to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of their respective relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. Although we take these and other steps to safeguard our proprietary information and trade secrets, these agreements may be breached or third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our proprietary information that is not otherwise protected by patent.

See "Risk Factors—Risks Related to Our Intellectual Property" for information regarding the risks related to our intellectual property.

Licensing and Collaboration Arrangements

Merck Collaboration

In 2015, we entered into a research collaboration, product development and license agreement with Merck, which, together with amendments made prior to June 30, 2021, is referred to as the Original Collaboration Agreement, covering the discovery, development and commercialization of novel therapies across a range of therapeutic areas, including a broad, multi-year drug discovery and early development program financially supported by Merck, but scientifically directed by us with input from Merck. The original research phase of the collaboration was for five years and was extended by Merck for an additional two years through March 2022.

On June 30, 2021, we entered into an amended and restated research collaboration, product development and license agreement with Merck, or the Amended Collaboration Agreement, replacing the Original Collaboration Agreement and extending the research phase of the collaboration, but with a narrower scope than in the Original Collaboration Agreement. Under the Amended Collaboration Agreement, the collaboration was focused primarily on the identification, research and development of collaboration compounds directed to targets of interest to Merck in the fields of ophthalmology and cardiovascular or metabolic, or CVM, disease, including heart failure. The collaboration scope also included certain laboratory testing and other activities on compounds that are directed to one of up to two undisclosed targets outside of the fields of ophthalmology and CVM disease, or the Lab Programs. Currently, the only ongoing research activities funded under the Amended Collaboration Agreement are certain CVM-related activities and remaining activities under the Lab Programs, or the Remaining Research Programs. The ophthalmology compounds in the collaboration under the Amended Collaboration Agreement initially included NGM621 (and its related compounds) and compounds directed against two other undisclosed ophthalmology targets (and their related compounds). Merck had a one-time option to license NGM621 and its related compounds upon completion of the Phase 2 CATALINA trial. In December 2022, Merck notified us that it would not exercise its option to license NGM621 and its related compounds, nor would Merck exercise the related ophthalmology bundle option; accordingly, these options expired unexercised in January 2023 and the programs are now wholly-owned by us. Further, Merck did not elect for us to continue to conduct R&D on any compounds from our other ophthalmology programs that were subject to the collaboration, which are preclinical and directed to undisclosed targets. Such an election would have resulted in an extended or tail period in which Merck would continue to fund our R&D of such ophthalmology compounds. Because Merck did not exercise its ophthalmology license options or make such a tail period election, we do not have any funding from Merck to pursue such ophthalmology programs.

For the period that started on January 1, 2023 and ends on March 31, 2024, we expect to receive funding of approximately $13.0 million in the aggregate from Merck for ongoing activities under the Remaining Research Programs and for certain costs and reimbursements related to the NGM621 program. Funding from Merck after December 31, 2023 is expected to be minimal. The research phase for the CVM-related programs under the Amended Collaboration Agreement will continue through March 31, 2024, unless the parties mutually agree to extend the research phase through March 31, 2026, in which case Merck would provide up to a total of $20.0 million in R&D funding during the additional two years of the CVM program research phase. New CVM-related programs may be added to the collaboration if recommended by us and selected by Merck, although we do not expect any new CVM-related programs to be added. The research phase for the Lab Programs was scheduled to end no later than December 31, 2022, although certain limited activities continue and will be wrapped up in 2023.

In January 2023, we announced that Merck notified us of its decision to terminate the Phase 2b trial of MK-3655 in patients with NASH and liver fibrosis stage 2 or 3 and Merck subsequently provided us with the required

90-days' notice of partial termination of the Amended Collaboration Agreement as it relates to MK-3655 and its related compounds. As a result, in late April 2023, the license rights granted to Merck in 2018 with respect to MK-3655 will revert to us and the program will become wholly-owned by us. Further development of MK-3655, once the termination is effective, is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of MK-3655 unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

During the three-month period before the end of the research phase for the CVM-related programs, Merck has the right to review the product candidates from each applicable program and to elect to have R&D activities continue under the collaboration for an additional period, referred to as a Tail Period. If Merck makes such an election, then the applicable Tail Period will begin at the end of the research phase for the applicable program and will end on the earlier of achievement of the License Option exercise point or three years, except that in certain circumstances a Tail Period may continue beyond three years if the License Option exercise point has not been achieved by such time. All R&D work on CVM-related programs during the applicable Tail Period, if any, will be conducted by Merck or its third-party contractors at Merck's expense. Each Lab Program will enter a Tail Period if Merck elects to continue work on it after we complete specified laboratory and other activities.

Under the Amended Collaboration Agreement, Merck retains License Options to obtain an exclusive, worldwide license, on specified terms, to each collaboration compound (and its related compounds) that remains within the scope of the continuing collaboration under the Remaining Research Programs. Merck generally has a one-time right to exercise its License Option for any product candidate when we or Merck achieve the specified License Option exercise point. The License Option exercise point for a collaboration compound from the CVM-related programs or the Lab Programs will be the designation by Merck of such collaboration compound as a research program development candidate that Merck intends to progress into preclinical development. Upon Merck's exercise of a License Option for any CVM-related program or Lab Program, Merck will pay us an option exercise fee of $6.0 million and we will be eligible to receive a milestone payment of $10.0 million if Merck subsequently completes a proof-of-concept trial for a product candidate from such program.

If Merck exercises its License Option to a product candidate and its related compounds, referred to as a Licensed Program, we will have the option to receive milestones and royalty payments or, in certain cases, prior to Merck initiating any Phase 3 clinical trial of such licensed compound, to co-fund development and participate in a global cost and profit share arrangement of up to 50%, with an additional option to co-detail any such licensed compound in the United States. If we do not elect to exercise our cost and profit share option for a particular licensed compound, we are eligible to receive an aggregate of up to $469.0 million in milestone payments upon the achievement of specific clinical development and regulatory events, commercial milestone payments of up to $125.0 million and royalties from low-double digit to mid-teen percentages of worldwide net sales of such licensed compound.

Merck will be responsible, at its own cost, for all development and commercialization of product candidates from each Licensed Program, subject to our options to cost and profit share worldwide, and to co-detail those compounds in the United States as described above. If Merck does not exercise its License Option with respect to a particular candidate and its related compounds within the applicable time period, in most instances we retain all rights to research, develop and commercialize that candidate and those compounds on a worldwide basis, either alone or in partnership with a third party, subject to the payment to Merck of low single-digit royalties on commercial sales of any resulting products.

Under the Amended Collaboration Agreement, we also granted Merck a worldwide, exclusive right to conduct R&D on, and to manufacture, use and commercialize, small molecule compounds identified or developed by Merck that have specified activity against any target that we are researching or developing under the research phase of the collaboration. Merck's research license for its own small molecule program will become non-exclusive if Merck does not exercise its option to a product candidate against a target at its option exercise point, but Merck will retain an exclusive license to any small molecule compounds that it has already identified and developed. Merck has sole responsibility for R&D of any of these small molecule compounds, at its own cost. We are eligible to receive milestone and royalty payments on small molecule compounds that are developed by Merck under such a license from us.

In addition to the options and exclusive licenses that we granted or are obligated to grant to Merck, we have the following exclusivity obligations to Merck under the Amended Collaboration Agreement. During the applicable research phase and Tail Period, if any, for the CVM-related programs and Lab Programs, we may not directly or indirectly research, develop, manufacture or commercialize, outside of our collaboration with Merck, any product with specified activity against any target that is being researched or developed under the applicable programs and, if Merck exercises its License Option for a program, we may not directly or indirectly research, develop,

manufacture or commercialize any product with specified activity against the target that is the subject of that Licensed Program for so long as Merck's license to it remains in effect. In addition, we are prohibited from directly or indirectly researching, developing or commercializing any product for the treatment of heart failure with preserved ejection fraction, or HFpEF, during the research phase for the CVM-related programs.

After the research phase, Merck may terminate the overall Amended Collaboration Agreement for convenience upon written notice. Subject to certain limitations, Merck may partially terminate the Amended Collaboration Agreement for convenience as it relates to any Licensed Program or any of its rights to research and develop small molecule compounds.

Either we or Merck may terminate the Amended Collaboration Agreement with respect to a specific Licensed Program or any particular licensed small molecule compound if the other party is in material breach of its obligations regarding that specific program and fails to cure the breach within the specified cure period. If Merck terminates a Licensed Program as a result of our uncured material breach, then we would lose our option to participate in a global cost and profit share 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 candidates arising from the relevant Licensed Program. If Merck terminates a licensed small molecule compound program for our uncured material breach, we would continue to receive the full amount of milestones and royalties we were otherwise eligible for with respect to the relevant small molecule compounds.

Lonza License

In October 2014, we entered into a Multi-Product License Agreement, or the Lonza License, with Lonza under which we obtained a worldwide, non-exclusive license to use Lonza's glutamine synthetase gene expression system, known as GS Xceed™, to manufacture and commercialize our proprietary products.

Pursuant to the Lonza License, we paid Lonza an upfront fee of £250,000. Upon the initiation of the first Phase 2 clinical trial, the first Phase 3 clinical trial and the first commercial sale of any product manufactured using GS Xceed™, we are required to pay Lonza one-time milestone payments of £100,000, £100,000 and £150,000, respectively. We paid a one-time milestone payment to Lonza of £100,000 for each of the Phase 2 trial initiations for MK-3655, NGM621 and NGM120. We are also required to pay low single-digit royalties to Lonza based on net sales of any product manufactured using GS Xceed™. Our royalty obligation to Lonza continues on a product-by-product basis until the later of the expiration of the last-to-expire licensed patent or ten years after the first commercial sale of the product. We are also required to pay an annual license fee to Lonza of up to £300,000 per product if a party other than Lonza, we, our affiliates or our strategic partners (including Merck or any potential future partners) manufactures certain product candidates for commercial activities. We are currently required to pay this fee for MK-3655 and NGM120. In accordance with the Lonza License, for certain additional product candidates, we are instead required to pay an annual license fee to Lonza of £25,000 per product candidate prior to the initiation of clinical development, and following the initiation of clinical development, £100,000, £150,000 or £300,000 annually per product candidate, respectively, if such product candidate is in a Phase 1, Phase 2 and Phase 3 clinical trial. We were required to pay this fee for NGM621 prior to Merck's decision not to exercise its option to license NGM621 and its related compounds in January 2023.

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

Government Regulation

Product Approval in the United States

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

The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Failure

to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions or judicial sanctions. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, the market acceptance of our products and our reputation.

Preclinical and Clinical Development

Prior to beginning the first clinical trial with a product candidate, a sponsor must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an IND product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacology, pharmacokinetics and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions regarding safety or conduct of the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices, or cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an institutional review board, or IRB, for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed.

The FDA, an IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some trials also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee, which provides authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

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

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

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These are called Phase 4 studies and may be made a condition to approval of the BLA. Concurrent with clinical trials, companies may complete additional animal

studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with current Good Manufacturing Practices, or cGMP, requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, for biologics, must develop methods for testing the identity, strength, quality, purity and potency of the product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The submission of a BLA requires payment of a substantial application user fee to FDA, unless a waiver or exemption applies.

Once a BLA has been submitted, the FDA generally makes a decision on the acceptance of the application for filing within 60 days of receipt. The FDA's goal is to review standard applications within ten months after it accepts the application for filing, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCPs. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information.

The FDA may issue an approval letter or a Complete Response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response letter will describe all of the deficiencies that the FDA has identified in the BLA. In issuing the Complete Response letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification, completion of other significant and time-consuming requirements related to clinical trials, and/or conduct of additional preclinical studies or manufacturing activities. Even if such data and information are submitted, the FDA may determine that the BLA does not satisfy the criteria for approval. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States. The FDA may delay or refuse approval of a BLA, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-marketing studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Programs

A sponsor may seek to develop and obtain approval of its product candidates under programs designed to accelerate the FDA review and approval of marketing applications for new drugs and biologics that meet certain criteria, such as the Fast Track program, priority review, accelerated approval, breakthrough therapy designation and Real-Time Oncology Review, or RTOR, Program.

Fast Track Designation

The FDA Fast Track program is intended to facilitate development and expedite review of new drugs and biologics that are intended to treat a serious or life-threatening disease or condition and that demonstrate potential to address an unmet medical need. For a Fast Track-designated product, there may be more frequent meetings and communication with the FDA, and early and frequent communication between the FDA and sponsor is encouraged throughout the entire development and review process. The FDA may consider sections of a BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. The product may also be eligible for priority review and accelerated approval. The sponsor can request the FDA to designate the product for Fast Track status any time before receiving BLA approval, but ideally no later than the pre-BLA meeting.

Priority Review

Generally, the FDA follows a two-tiered system of review times, standard review and priority review. For a product that receives priority review designation, the FDA has the goal of taking action on the marketing application within six months of the 60-day filing date, compared to ten months under standard review. However, the FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and the review process is often extended by FDA requests for additional information or clarification. A priority review designation is applicable for products that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to marketed products. The FDA decides on the review designation for every application; however, an applicant may expressly request priority review. The FDA informs the applicant of a priority review designation within 60 days of the receipt of the original marketing application. If criteria are not met for priority review, the application is subject to the standard FDA review period of ten months after FDA accepts the application for filing. Priority review designation does not change the scientific or medical standard for approval, or the quality of evidence necessary to support approval.

Accelerated Approval

In addition, the FDA may base accelerated approval for drugs and biologics for serious conditions that fill an unmet medical need on whether the drug or biologic has an effect on a surrogate or an intermediate clinical endpoint. A surrogate endpoint used for accelerated approval is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Likewise, an intermediate clinical endpoint is a measure of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a product, such as an effect on irreversible morbidity and mortality, or IMM. The FDA bases its decision on whether to accept the proposed surrogate or intermediate clinical endpoint on the scientific support for that endpoint. As a condition of accelerated approval, the FDA will generally require the sponsor to perform and provide regular updates to the agency on adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on IMM or other clinical benefit. Where confirmatory trials verify clinical benefit, the FDA will generally terminate the requirement. Approval of a product may be withdrawn or the labeled indication of the product changed, if trials fail to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the product, for example, if the product shows a significantly smaller magnitude or duration of benefit than was anticipated based on the observed effect on the surrogate endpoint. In addition, the FDA currently requires as a condition for accelerated approval the pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Breakthrough Therapy Designation

Additionally, a drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less

time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough therapy designation comes with all of the benefits of Fast Track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

Real-Time Oncology Review (RTOR) Program

The RTOR program is for oncology product candidates that are likely to demonstrate substantial improvements over available therapy, which may include drugs previously granted breakthrough therapy designation for the same or other indications and candidates meeting other criteria for other expedited programs, such as Fast Track and priority review. Submissions for RTOR consideration should also have straightforward study designs and endpoints that can be easily interpreted (such as overall survival or progression free survival). Acceptance into the RTOR program does not guarantee or influence approvability of the application, which is subject to the usual benefit-risk evaluation by FDA reviewers, but the program allows FDA to review data earlier, before an applicant formally submits a complete application. The RTOR program does not affect FDA's PDUFA timelines.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or the time period for FDA review or approval may not be shortened. Furthermore, Fast Track designation, priority review, accelerated approval, breakthrough therapy designation and RTOR program acceptance do not change the standards for product approval.

Orphan Drug Designation

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

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

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

Pediatric Information and Pediatric Exclusivity

Under the Pediatric Research Equity Act, or PREA, certain BLAs and certain supplements to a BLA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. A sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan, or PSP. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at

any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials and/or other clinical development programs.

A drug or biologic product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing user fee requirements, under which FDA assesses an annual program fee for each product identified in an approved BLA.

FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with FDA regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. FDA regulations also impose reporting requirements upon sponsors and their third-party manufacturers. Manufacturers and other entities involved in the manufacture and distribution of approved biologics are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws, which impose certain procedural and documentation requirements upon sponsors and their third-party manufacturers. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including recall. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon sponsors and their third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon sponsors and their third-party manufacturers.

The FDA may also place other conditions on approvals including the requirement for a REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in: revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in

accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses and misbranding. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective actions, including corrective advertising, and potential civil and criminal penalties, including monetary penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication (or thirty days in advance of their first use if approved via the accelerated approval pathway). Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new BLA or BLA supplement, which may require the development of additional data or preclinical studies and clinical trials.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the federal Anti-Kickback Statute, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended, as applicable.

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

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

The federal false claims and civil monetary penalty laws, including the FCA, which imposes significant penalties and can be enforced by private citizens through civil *qui tam* actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, including federal healthcare programs, such as Medicare and Medicaid, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the ACA amended the intent standard for

certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements on covered entities (including certain health care providers, health plans and health care clearinghouses, business associates and their covered subcontractors) relating to the privacy, security and transmission of individually identifiable health information. HIPAA may be enforced by several federal agencies as well as state attorneys general. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

Our physician-administered products, once approved, may be eligible for coverage under Medicare through Medicare Part B. As a condition of receiving Medicare Part B reimbursement for a manufacturer's eligible drugs, the manufacturer is required to participate in other government healthcare programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program, and would be subject to those requirements as well.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, as amended, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members.

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

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

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements with third parties comply with applicable healthcare laws and regulations is a costly endeavor. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other current or future governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private *qui tam* actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity

agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The Foreign Corrupt Practices Act

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

Environmental, Health and Safety Regulation

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

European Union Development of Medicinal Products

In the European Economic Area, or EEA, which consists of the 27 Member States of the European Union, or the EU and the EU Member States, as well as Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after a marketing authorization, or MA, has been granted by a competent regulatory authority. This is similar to the approach in the United States. The various phases of preclinical and clinical research in the EEA are currently regulated by Clinical Trials Regulation (EU) No 536/2014, which went into effect on January 31, 2022. The regulation, which is directly applicable in all EEA countries, overhauls the current system of approvals for clinical trials in the EU in an effort to simplify and streamline the approval of clinical trials in the EU.

European Union Review of Marketing Authorization and Approval

Depending on the type of product and its intended therapeutic indication, related MAs may be granted either by the European Commission at the EU level or by the competent authorities of the EEA countries. An EU MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and other immune dysfunctions and viral diseases. The Centralized Procedure is optional, subject to the approval of the EMA, for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

National MAs, which are issued by the competent authorities of the EEA countries, and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in an EEA country, that National MA can be recognized in another EEA country through the Mutual Recognition Procedure. If the product has not received a National MA in any EEA country at the time of application for authorization, it can be approved simultaneously in various EEA countries through the Decentralized Procedure. Under the Decentralized Procedure, an identical dossier is submitted to the competent authorities of each of the EEA countries in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft Summary of Product Characteristics, or SmPC, the document that provides information to physicians concerning the safe and effective use of the product, and a draft of the labeling and package leaflet, which are sent to the other EEA countries, referred to as the Concerned Member States, or CMSs, for their approval. If the CMSs raise no objections to the assessment, SmPC, labeling or packaging proposed by the

RMS, the product is subsequently granted a National MA in the RMS and the Concerned Member States. The RMS or CMSs may only raise objections to authorization that are based on a potential serious risk to public health.

In the EEA, a MA, whether granted through the Centralized, Decentralized or Mutual Recognition Procedures, may be granted only to an MA applicant that is established within the EEA.

In principle, an MA has an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EEA country in which the original MA was granted. The European Commission or the competent authorities of the EEA country may decide, on justified grounds relating to pharmacovigilance, to require one additional five-year period for the MA before it is definitively renewed. Once subsequently definitively renewed, the MA is valid for an unlimited period. Any MA that is not followed by the actual placing of the medicinal product on the EEA market (in case of Centralized Procedure approvals), or on the market of the authorizing EEA country if applicable, within three years after authorization ceases to be valid (the so-called sunset clause).

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the United States. In the EEA, a conditional MA may be granted by the European Commission through the Centralized Procedure in cases where all the required safety and efficacy data are not yet available. The conditional MA is subject to conditions to be fulfilled concerning generation of missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. After this, the conditional MA is converted to a normal MA. An MA may also be granted “under exceptional circumstances” by the European Commission through the Centralized Procedure where the MA applicant can show that it is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use even after the product has been authorized and subject to specific procedures after being introduced. These circumstances may arise in particular when the intended therapeutic indications are very rare and, based on the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles.

Data and Market Exclusivity

The EU legislation governing the grant of marketing authorizations for medicinal products also provides opportunities for data and market exclusivity related to MAs in certain circumstances. Upon grant of an MA, innovative medicinal products generally benefit from eight years of data exclusivity and ten years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the EEA from referencing the innovator’s data to assess a biosimilar application for eight years from the date of authorization of the innovative product, after which a biosimilar application for MA can be submitted, and the innovator’s data may be referenced. The market exclusivity period prevents a successful biosimilar applicant from commercializing its product in the EEA until ten years have elapsed from the initial MA of the innovator product in the EEA. The overall ten-year period may, occasionally, be extended for a further year to a maximum of eleven years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. There is, however, no guarantee that our products will be considered by European regulatory authorities to be a new biological entity. In such circumstances, our products, even if granted MA, may not qualify for data and market exclusivity.

Pediatric Development

Regulation (EC) No 1901/2006 provides that all applicants for MA for new medicinal products have to include the results of trials conducted in the pediatric population in compliance with a pediatric investigation plan, or PIP, agreed to with the EMA’s Pediatric Committee, or PDCO. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. The obligation to provide pediatric clinical trial data can be waived entirely by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EEA countries and study results in compliance with the PIP are included in the product information, even when those results are negative, the product may be eligible for a six-month extension to certain patent protections or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Post-Approval Requirements

Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EEA countries and regional authorities within those countries. Legislation adopted at the EU level, such as Directives, may be implemented differently by individual EEA countries. Examples of post-approval requirements include the obligation on the holder of an MA to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products, establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs. All new applicants for MA must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose risk-minimization measures or post-authorization obligations as a condition of the MA, which may include additional safety monitoring, more frequent submission of PSURs or the conduct of additional clinical trials or post-authorization safety studies.

Marketing of Medicinal Products in the EEA

In the EEA, the advertising and promotion of medicinal products are subject to both EU law and the national law of individual EEA countries governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established at the EU level, the details are governed by rules developed in individual EEA countries and can differ from one country to another. Examples of regulatory obligations include the requirement that promotional materials and advertising in relation to medicinal products comply with the product's SmPC as approved by the competent authorities in connection with an MA. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

Marketed products in the EEA are subject to substantial continuing regulation. This includes, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution and advertising and promotion of the product. For example, much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EEA. The provision of benefits or advantages to physicians is governed by national laws, including anti-bribery laws, industry codes or professional codes of conduct and related national implementing laws. Payments made to physicians in certain EEA countries must also be publicly disclosed, and agreements with physicians are often the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EEA countries. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Regulation in the United Kingdom Following Brexit

The withdrawal of the UK from the EU, commonly referred to as "Brexit," took effect on January 31, 2020. Pursuant to the formal withdrawal arrangements agreed between the UK and the EU, the UK was subject to a transition period that ended December 31, 2020, during which EU rules continued to apply. A Trade and Cooperation Agreement, or the TCA, that outlines the trading relationship between the UK and the EU entered into force provisionally in January 2021, and permanently since May 2021. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Although the body of the TCA includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex. Under the TCA, Great Britain (England, Scotland and Wales) is be treated as a third country, except that Northern Ireland will, with regard to EU regulations on free movement of goods, continue to follow the EU regulatory rules. As part of the TCA, the EU and the UK will mutually recognize cGMP inspections and accept official cGMP documents. The UK has unilaterally agreed to accept EU batch testing and batch release. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures.

With respect to MAs, Great Britain has a separate regulatory submission and approval process and a national MA implemented through its regulator, the Medicines and Healthcare products Regulatory Agency, or

MHRAs, with certain exceptions for Northern Ireland. Companies established in the UK can no longer use the Centralized Procedure for approval by the European Commission to obtain an MA to market products in the UK and instead must follow one of the UK national authorization procedures. Until the end of 2023, the MHRA may rely on a decision made by the European Commission on the approval of a new Centralized Procedure MA when deciding on an application for a Great Britain MA. Thereafter, a new international recognition process, which will take into consideration decisions made by the EMA and certain other regulatory authorities, is anticipated to be in place. The MHRA has also established its own decentralized or mutual recognition procedures enabling MAs approved in EU Member States through decentralized and mutual recognition procedures to be recognized in the United Kingdom or Great Britain. It is currently unclear to what extent the UK will seek to align its regulations with the EU in the future.

The data exclusivity periods in the UK are currently in line with those in the EU, but the TCA provides that the periods for both data and market exclusivity are to be determined by domestic law, so there could be divergence in the future.

Privacy and Data Security Laws and Compliance Obligations

In the ordinary course of our business, we may process personal or sensitive data. Accordingly, we are, or may become, subject to numerous obligations, including U.S. federal, state and local, as well as foreign, data privacy and security laws, regulations, guidance and industry standards, and other legal obligations related to privacy and data security. The regulatory framework with respect to data privacy and security is stringent and constantly evolving. For example, in addition to laws such as HIPAA that govern the processing of health information, we are or may become subject to numerous other data privacy and security laws and legal obligations, which may include laws such as the Federal Trade Commission Act, the California Consumer Privacy Act of 2018, or CCPA, the California Privacy Rights Act of 2020, or CPRA, and similar laws enacted or proposed in other states in the United States, the EU's General Data Protection Regulation 2016/679, or EU GDPR, and the EU GDPR as it forms part of UK law by virtue of section 3 of the European Union (Withdrawal) Act 2018, or UK GDPR. Additionally, we are, or may become, subject to various U.S. federal and state consumer protection laws which require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

These laws and obligations impose on subject entities extensive, costly and complex compliance obligations, which may conflict or be inconsistent with one another, and violations may result in significant fines, penalties and other adverse consequences. The CCPA and EU GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business's collecting, using and disclosing personal data and to respond to certain requests from California residents related to their personal data. Also, the CCPA provides for civil penalties and a private right of action for data breaches which may include an award of statutory damages. In addition, the CPRA, effective January 1, 2023, expanded the CCPA to, among other things, give California residents the ability to limit use of certain sensitive personal data, establish restrictions on personal data retention, expand the types of data breaches that are subject to the CCPA's private right of action and establish a new California Privacy Protection Agency to implement and enforce the new law.

Foreign data privacy and security laws (including but not limited to the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authorities and affected individuals; and mandating the appointment of representatives in the EU in certain circumstances. See "Risk Factors—Risks Related to Our Business and Industry" for additional information about the privacy and data security risks we may face, including in relation to the laws and regulations to which we are or may become subject.

Rest of the World Regulation

For other countries outside of the EU, United Kingdom and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. Failure to comply with applicable foreign laws and regulatory requirements may result in, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products and operating restrictions.

Additional Laws and Regulations Governing International Operations

If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Likewise, the UK Bribery Act of 2010 applies to companies that carry on all or part of their business in the UK, and prohibits bribing another person or being bribed, bribing a foreign public official with the intent to influence and obtain or retain business or an advantage, and failure by a commercial party to prevent bribery, including where the prohibited conduct or its effects occurred entirely outside the UK.

Compliance with the FCPA and anti-corruption and anti-bribery laws in other countries is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry because, in many countries, hospitals are operated by the government and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The U.S. Securities and Exchange Commission, or SEC, also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Coverage, Pricing and Reimbursement

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

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a therapeutic is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Coverage may also be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Reimbursement may impact the demand for, or the price of, any product for which we obtain regulatory approval.

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

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

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

Before products become available to patients in the EEA, they are generally subject to decisions on pricing and reimbursement by the applicable authorities in a Member State. Key criteria to determine the reimbursement status and pricing of a product may include the product's therapeutic value, medical need, safety and cost effectiveness. Obtaining pricing and reimbursement approval of a product from a government is a time-consuming and costly process, and significant uncertainty exists as to the pricing and reimbursement status of any product candidates for which we may seek marketing approval in the EEA. Our ability to commercialize any such products successfully in the EEA will depend, in part, on the outcome of these decisions.

In many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process, which is currently governed by national laws in each EU Member State, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced

by the HTA of the specific medicinal product currently varies between EU Member States. In 2021 the European Union Parliament adopted the HTA regulation which, when it enters into application in 2025, will be intended to harmonize the clinical benefit assessment of HTA across the European Union. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the European Union could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the EU and the UK may continue to propose and implement cost-containing measures to keep healthcare costs down; particularly due to the financial strain that the COVID-19 pandemic has placed on national healthcare systems. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of EU and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Healthcare Reform

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

The ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is unclear. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, (1) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry.

Further, in March 2010, the ACA was signed into law and has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the ACA provisions of importance to the pharmaceutical and biotechnology industries are those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected and annual fees based on pharmaceutical companies’ share of sales to federal healthcare programs.

There have been legal and political challenges to certain aspects of the ACA. For example, former President Trump signed several executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. However, the ACA may be subject to judicial or Congressional challenges in the future. Additionally, on January 28, 2021, President Biden issued an executive order instructing certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. The IRA, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program.

We anticipate that the ACA, if substantially maintained in its current form, will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other

healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the ACA was enacted. Aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013, will stay in effect through 2031 unless additional Congressional action is taken. Under current legislation. the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in later years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several U.S. Congressional inquiries, presidential executive orders and proposed and enacted federal legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer-patient programs and reform government program reimbursement methodologies for drugs. For example, in July 2021, the Biden administration released an executive order, “Promoting Competition in the American Economy,” with multiple provisions aimed at prescription drugs. In response to President Biden’s executive order, on September 9, 2021, the United States Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Human Capital

Our team of talented scientists and industry professionals is the foundation of our company and fuels our historical and prospective achievements for patients. We consider the intellectual capital of our employees to be an essential driver of our business and key to our future opportunities. As of December 31, 2022, we had 239 employees, of which approximately 155 (65%) were engaged in R&D activities, 89 hold Ph.D. and/or M.D. degrees and an additional 52 hold a masters or other post-graduate degree. Every NGM team member plays a vital role in furthering our goals and impacting our progress towards fully realizing our mission to develop transformative therapies for patients.

To succeed in our mission, we must attract, recruit, retain, develop and motivate qualified clinical, nonclinical, scientific, manufacturing, regulatory, management and other personnel needed to support our business and operations. We recruit for talent in the biotechnology and pharmaceutical industry in the San Francisco Bay Area, which is in one of the most competitive and highest cost labor markets in the United States and periodically experiences higher turnover rates than other industries. For example, in 2022, we continued to experience a challenging recruiting environment with relative high rates of employees leaving the company to pursue other opportunities, particularly in the first three quarters of the year. This turnover was mitigated by a robust recruiting effort, including extensive efforts to source and interview a talented and diverse pipeline of candidates. We maintain a comprehensive dashboard of measurements, including recruitment productivity, diversity, equity and inclusion metrics, employee engagement scores, total rewards benchmarking, participation rates and satisfaction scores for internal training, turnover rates and exit interview results, to guide our human capital management efforts.

We believe that we can best address competitive challenges by enhancing the reputation of NGM as a great place to work, which includes nurturing our workplace culture, providing competitive compensation and benefits programs and supporting employee career development and related management training. To that end, we continue to invest resources and energy into being an employer of choice – attracting and engaging individuals who are innovative, curious, driven, diligent, collaborative and of the highest integrity and ethics. Some of our key efforts in this area and management of our human capital assets generally are described here.

Compensation and Benefits

Our compensation philosophy is to provide pay and benefits that are competitive in the biotechnology and pharmaceutical industry where we compete for talent. We monitor our compensation programs closely and review them throughout the year to provide what we consider a very competitive mix of compensation and health, welfare

and retirement benefits for all our employees. Our compensation package for all employees includes market-competitive base salaries, eligibility for annual performance bonuses and equity grants. Our benefits programs include company-sponsored medical, dental and vision health care coverage, life and AD&D insurance, a 401(k) plan with a matching employer contribution, paid time off and family leave and an employee stock purchase plan, among others benefits. Every year, we undertake a detailed review of our compensation by position and level and make adjustments necessary to ensure that we continue to provide competitive compensation. Our hiring practices and annual compensation reviews are designed to ensure fairness in pay equity across gender and ethnicity among similar roles and responsibilities throughout our organization, after accounting for legitimate business factors that can explain differences, such as performance, time at grade level, education and tenure. In conjunction with the California's Pay Transparency law (SB 1162), beginning January 1, 2023, we will publish pay ranges in all job postings and we are proactively providing existing employees with the salary range for their positions. In addition, our efforts extend beyond pay equity to include fairness in gender and ethnic representation at all levels in the organization.

Diversity, Equity and Inclusion

Our goal is to have a diverse, equitable and inclusive workforce – not just because it is the right thing to do, but because we believe this is key to our long-term success. As of December 31, 2022, NGM employed 136 women (57%) and 103 men (43%), and 59% of our employees self-identify as non-white, including 10% that are from traditionally underrepresented groups. Our leadership, including employees at or above the vice president level and members of our board of directors, includes 43% women and 22% who self-identify as non-white. To champion our efforts in this area, a cross-functional team of employees continues to drive our diversity, equity and inclusion initiatives that have focused on awareness and understanding; diverse candidate pipelines; community outreach; advocacy and career advancement; and business impact. Our efforts, which began in 2020 with a focus on anti-Black racism, have included mandatory unconscious bias and discrimination training, an employee-led diversity page on our intranet updated monthly with fresh content, voluntary participation in a program to encourage allyship, guest speaker programs on Diversity, Equity & Inclusion, or DEI, topics, and conducting a survey to understand employee sentiment around race-related issues to establish a baseline for tracking future progress. We implemented an internship program targeted to students from underrepresented minorities and adopted specific quantitative efforts to provide the company with a diverse candidate pipeline and more diverse interview panels. In addition to internal efforts, our research employees volunteer to teach elementary school students various topics in biology.

In 2022, we engaged an external consultant with expertise in DEI to help conduct an assessment to understand where improvements could be made in our culture to drive equitable outcomes and foster an inclusive environment, with a particular focus on women scientists. The assessment included cross-organizational interviews, focus group discussions, a detailed review of our policies, programs and business norms, an all-employee inclusion survey and a review of organizational diversity metrics to determine what are the barriers to success and advancement of women and underrepresented groups. The project identified three areas of action that are being shared across the company, and we plan to begin to implement the recommendations in 2023. In addition, we supported an employee-led effort to develop our first employee resource group, N-GAGE (NGM Gathers to Advance Gender Equity). Since its inception, N-GAGE has supported the DEI assessment, created community spaces for engagement and discussions on current topics disproportionately affecting women, and incubated a company-wide mentorship and professional enrichment program starting with speed-mentoring events and guest speakers with a planned roll-out in 2023.

Communication and Engagement

We believe that part of what sets NGM apart from other companies is our culture and, in particular, our focus on providing timely and transparent communications and creating a strong sense of belonging and inclusiveness. In 2022, after nearly two years of the COVID-19 pandemic, we were able to reinstate many of the traditions and celebrations that contribute to what makes NGM a special place to work: monthly themed happy hours; weekly group lunch programs, often with employee-led lunch-and-learns with scientific and other updates of interest; quarterly all-hands' meetings; regular coffee chats or other gatherings for small groups with our CEO and other members of senior management; and events including a summer family picnic, Thanksgiving potluck and holiday white elephant party, among many others.

We survey our employees each year to measure their level of engagement at NGM. Our employee engagement scores have remained relatively steady over the past three years, despite the challenges we faced through the COVID-19 pandemic and disappointing clinical trial readouts. These surveys provide rich feedback each year that helps us to continue to grow our culture and make NGM a great place to work.

Health, Wellness and Safety

In addition to specific support relating to health and safety during the COVID-19 pandemic, we continue other activities that continue to promote our employees' whole health and wellness, including an on-site gym, external support from our employee assistance program and mental wellness and health advocacy services.

None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relations with our employees to be good.

Corporate and Available Information

We were incorporated in Delaware in December 2007 and commenced operations in 2008. Our principal executive offices are located at 333 Oyster Point Blvd., South San Francisco, CA 94080-7014, and our telephone number is (650) 243-5555. Our website address is http://www.ngmbio.com.

We file or furnish electronically with the U.S. Securities and Exchange Commission, or the SEC, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act. We make copies of these reports available free of charge through the “SEC Filings” tab on the “Investors & Media” page of our website as soon as reasonably practicable after we file or furnish them with the SEC.

Information contained on or accessible through our website is not incorporated into, and does not form a part of, this Annual Report or any other report or document we file with the SEC, and any references to our website are intended to be inactive textual references only.

Item 1A. Risk Factors.

An investment in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below before deciding whether to make an investment decision with respect to our common stock. You should also refer to the other information contained in this Annual Report on Form 10-K, including in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our consolidated financial statements and related notes, as well as our other filings with the U.S. Securities and Exchange Commission, or SEC. Our business, financial condition, results of operations, stock price and prospects could be materially and adversely affected by any of these risks or uncertainties. In any such case, the trading price of our common stock could decline, and you could lose all or part of your investment. We caution you that the risks, uncertainties and other factors referred to below and elsewhere in this Annual Report on Form 10-K may not contain all of the risks, uncertainties and other factors that may affect our future results and operations. 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. Moreover, new risks will emerge from time to time. It is not possible for our management to predict all risks.

Risks Related to Our Financial Condition and Capital Needs

We have incurred net losses every year since our inception and have no source of product revenue. We expect to continue to incur significant operating losses and may never become profitable.

We have no products approved for commercial sale and have not generated any revenue from product sales to date. As a result, we are not profitable and have incurred losses in each year since commencing operations. Our net losses were $162.7 million, $120.3 million and $102.5 million for the years ended December 31, 2022, 2021 and 2020, respectively. As of December 31, 2022, we had an accumulated deficit of $581.6 million.

We expect to continue to incur significant research and development, or R&D, and other expenses related to our ongoing operations for the foreseeable future, particularly to fund R&D of, and seek regulatory approvals for, our product candidates. We incurred substantial net operating losses in 2022 and expect to continue to incur significant operating losses in 2023 and over the next several years as our research, development, manufacturing, preclinical studies, clinical trial and related activities increase. We expect our accumulated deficit will also increase in future periods. The size of our future net losses will depend, in part, on the amount of our expenses and our ability to generate revenue. All of our revenue from recent periods has been provided under our collaboration with Merck Sharp & Dohme LLC, or Merck, under the amended and restated research collaboration, product development and license agreement we entered into with Merck on June 30, 2021, or the Amended Collaboration Agreement. That revenue will be substantially lower in 2023 than in 2022 and prior years and minimal thereafter. See the risk factor titled *"All of our revenue for recent periods has been received from a single collaboration partner, and that revenue will be substantially lower going forward as compared to historical periods."*

Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

In addition, we will not be able to generate product revenue unless and until one of our product candidates successfully completes clinical trials, receives regulatory approval and is successfully commercialized. As our product candidates are in Phase 2 trials or in earlier stages of development, we do not expect to receive product revenue from our product candidates for a number of years, if ever.

Our ability to generate any product revenue from our current or future product candidates also depends on a number of additional factors, including our ability or the ability of any potential future third-party partner to:

- successfully complete research and clinical development of current and future product candidates and obtain regulatory approval for those 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 marketing approval is obtained, if any, and, if launched independently by us without a partner, successfully establish a sales force and marketing and distribution infrastructure;
- demonstrate the necessary safety data (and, if accelerated approval is obtained, verify the clinical benefit) post-approval to ensure continued regulatory approval;

- obtain coverage and adequate product reimbursement from third-party payors, including government payors, for any approved products;
- achieve market acceptance for any approved products;
- establish, maintain, protect and enforce our intellectual property rights; and
- attract, hire and retain qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, including that our product candidates may not advance through development or be approved for commercial sale, we are unable to predict if or when we will generate product revenue or achieve or maintain profitability.

Even if we successfully complete development and regulatory processes for any product candidates that we take forward, we anticipate incurring significant costs associated with launching and commercializing any products. If we fail to become profitable or do not sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or cease our operations.

All of our revenue for recent periods has been received from a single collaboration partner, and that revenue will be substantially lower going forward as compared to historical periods.

We do not have any committed external source of funds, other than pursuant to our collaboration with Merck, which has provided us with substantial financial support since 2015. However, as described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Overview of Our Business—Licensing and Collaboration Updates” in Part II, Item 7 of this Annual Report on Form 10-K, in 2023 the R&D funding we receive from Merck under the collaboration will be substantially lower on an annual basis than the research funding previously provided by Merck. In this regard, for the period that started on January 1, 2023 and ends on March 31, 2024, we expect to receive funding of approximately $13.0 million in the aggregate from Merck for the ongoing activities under the Amended Collaboration Agreement and for certain costs and reimbursements related to the NGM621 program. Funding from Merck after December 31, 2023 is expected to be minimal.

In any event, we need to devote a substantial amount of our own financial resources to our R&D programs, particularly with respect to our wholly-owned programs that now include all of our ophthalmology programs and, as described below, once Merck's termination of its license with respect to MK-3655 is effective, MK-3655 (NGM313). In addition, our funding requirements would increase for any preclinical programs that remain within the scope of the collaboration in the event Merck does not elect to license these programs and we decide to continue them, in the event Merck elects to terminate its license to any program it licenses and we decide to continue it or in the event we opt to co-develop any Merck-licensed programs. For example, as a result of Merck’s decision not to exercise its option to license NGM621 and its related compounds, as described below, NGM621 and its related compounds are now wholly-owned by us. Further development of NGM621 is primarily dependent on our ability to secure potential future collaboration, out licensing, partnering or other business development arrangements, or BD Arrangements, with third-party partners and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of NGM621 unless our portfolio prioritization changes and we have access to the necessary capital to fund such development. In addition, as a result of Merck's decision to terminate its license to MK-3655 and its related compounds, once the termination is effective, the license rights granted to Merck in 2018 with respect to MK-3655 will revert to us and the program will become wholly-owned by us. Further development of MK-3655, once the termination is effective, is also primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of MK-3655 unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

Other than our Amended Collaboration Agreement with Merck, which is limited in scope and duration, and may be unilaterally terminated by Merck under certain circumstances, we are not party to any agreements that could provide us with future revenue. Accordingly, we will need to raise significant additional capital and we will need to enter into additional partnering arrangements in order to proceed with development through regulatory approval and commercialization of our current and potential future product candidates. Neither may be possible and, as a result, if adequate funds are not available when we need them, we may need to significantly delay, scale back or discontinue development of or abandon some or all of our product candidates or scale back or discontinue discovery efforts, which could have a material adverse effect on our business, operating results and prospects, or we may be required to cease operations altogether.

We will need significant additional capital to proceed with development and commercialization of our current and potential future product candidates and our other operations. We may not be able to access sufficient capital on acceptable terms, if at all, and, as a result, we may be required to delay, scale back or discontinue development of such product candidates or other operations.

As an R&D company, our operations have consumed substantial amounts of cash since inception, and we will require substantial additional capital to finance our operations and pursue our strategy, both in the short and the long term, and the amount of funding we will need depends on many factors, including:

- the initiation, progress, timing, delays, costs and results of preclinical studies and clinical trials for our current and future product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the United States Food and Drug Administration, or FDA, and comparable foreign health authorities, including the potential for such authorities to require that we perform more studies than those that we currently expect or to change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the cost and timing of selecting, auditing and potentially validating a manufacturing site for later-stage clinical and commercial-scale manufacturing;
- 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;
- whether Merck exercises its option to license any preclinical candidates that remain within the scope of the collaboration at the license option point as specified in the Amended Collaboration Agreement for each such candidate;
- whether Merck terminates the research phase of the collaboration under pre-specified circumstances set forth in the Amended Collaboration Agreement or terminates a program that it has licensed, such as its decision to terminate its license for MK-3655 and its related compounds;
- the cost of potentially acquiring, licensing or investing in additional businesses, products, product candidates and technologies; and
- the cost of establishing sales, marketing and distribution capabilities for any of our product candidates for which we may receive regulatory approval and that we determine to commercialize ourselves or in collaboration with partners.

We believe that our existing cash, cash equivalents and short-term marketable securities will be sufficient to fund our operations for at least the twelve months from the date of filing of this Annual Report on Form 10-K. Moreover, based on our current development plans and related assumptions, we believe our current cash position is sufficient to fund our key solid tumor oncology programs through generation of proof-of-concept data. We have based these estimates on plans and assumptions that may prove to be insufficient or inaccurate (for example, with respect to anticipated costs, timing or success of certain activities), and we could utilize our available capital resources sooner than we currently expect. In addition, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section.

We plan to finance our future cash needs through public or private equity or debt offerings, including under the Open Market Sale Agreement℠, or the Sales Agreement, we entered into with Jefferies LLC in June 2020, BD Arrangements or a combination of these potential financing sources. Additional capital may not be available in sufficient amounts, on reasonable terms or when we need it, if at all. While the long-term economic impact of either the COVID-19 pandemic or the conflict between Russia and Ukraine is difficult to assess or predict, each of these events has caused significant disruptions to the global financial markets and contributed to a general global economic slowdown. Furthermore, inflation rates, particularly in the United States and the U.K., have increased recently to levels not seen in decades. Increased inflation may result in increased operating costs (including labor costs) and may affect our operating budgets. In addition, the U.S. Federal Reserve has raised, and is expected to further raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty

and heighten these risks. If the financial market disruptions and economic slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could in the future negatively affect our financial condition and our ability to pursue our business strategy.

If adequate funds are not available from public or private equity or debt offerings on acceptable terms when needed, in order to continue the development of product candidates outside of the scope of the collaboration with Merck we may need to:

- seek strategic alliances for R&D 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 BD Arrangements that could require us to relinquish, or license, on potentially unfavorable terms, our rights to intellectual property, product candidates or products that we otherwise would develop or seek to commercialize ourselves.

In this regard, due to the need to conserve capital and prioritize focused execution, we are actively seeking, or intend to seek, BD Arrangements with third-party partners with sufficient resources and relevant domain expertise in order to further the clinical development, if any, of NGM621, aldafermin, NGM936 and, once termination of Merck's license is effective, MK-3655. Further development of these programs, which are in therapeutic areas where clinical development is relatively resource intensive and can have long timelines to generate proof-of-concept data, is primarily dependent on our ability to secure potential future BD Arrangements. However, we may not be able to enter into such BD Arrangements on acceptable terms, if at all. We face significant competition in seeking appropriate partners. Whether we reach a definitive agreement for a BD Arrangement will depend, among other things, upon the potential partner’s evaluation of the subject product candidate and its market opportunity, our assessment of the partner’s resources and expertise and the terms and conditions of the potential BD Arrangement. In the absence of such BD Arrangements for these programs, we are unlikely to be able to advance their development unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

We are also restricted under our existing Amended Collaboration Agreement with Merck, and may be restricted under future BD Arrangements, from entering into additional agreements on certain terms with potential partners. For example, under the current terms of the Amended Collaboration Agreement, we may not directly or indirectly research, develop, manufacture or commercialize, except pursuant to the Amended Collaboration Agreement, any medicine or product candidate that modulates a target then subject to the collaboration with specified activity. In addition, under the Amended Collaboration Agreement, we are prohibited from, directly or indirectly, researching, developing or commercializing any product for the treatment of heart failure with preserved ejection fraction, or HFpEF, during the research phase for the CVM-related programs.

We may not be able to raise adequate additional capital or negotiate potential future BD Arrangements on a timely basis, on acceptable terms or at all. If we are unable to do so, we may need to significantly delay, scale back or discontinue development of or abandon some or all of our product candidates, or scale back or discontinue discovery research efforts, which could have a material adverse effect on our business, operating results and prospects, or we may be required to cease operations altogether.

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

If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Our ability to raise capital may be adversely impacted by the trading prices of our common stock following the announcement in October 2022 that the CATALINA trial did not meet its primary endpoint. Furthermore, any securities that we may issue may have rights senior to those of our common stock and could contain covenants or protective rights that would lead to restrictions on our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

Risks Related to Our Dependence on Third Parties

Funding from Merck under the collaboration after December 31, 2023 is expected to be minimal, and we may never realize the anticipated benefits to us of the collaboration.

As described in more detail under “Business—Licensing and Collaboration Arrangements—Merck Collaboration” in Part I, Item 1 of this Annual Report on Form 10-K and under “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Overview of Our Business—Business Development and Merck Collaboration Updates” in Part II, Item 7 of this Annual Report on Form 10-K, our continuing Merck collaboration involves a complex allocation of rights, provides for certain limited R&D funding and, for remaining collaboration preclinical candidates for which Merck exercises its license option, if any, 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 share 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.

The level of R&D funding we expect to receive from Merck will be limited and substantially lower on an annual basis than the funding previously provided by Merck. In this regard, for the period that started on January 1, 2023 and ends on March 31, 2024, we expect to receive funding of approximately $13.0 million in the aggregate from Merck for the ongoing activities under the Amended Collaboration Agreement and for certain costs and reimbursements related to the NGM621 program. Funding from Merck after December 31, 2023 is expected to be minimal.

In addition, in January 2023, we announced that Merck notified us of its decision to terminate the Phase 2b trial of MK-3655 in patients with nonalcoholic steatohepatitis, or NASH, and liver fibrosis stage 2 or 3, or F2/F3, and Merck subsequently provided us with the required 90-days' notice of partial termination of the Amended Collaboration Agreement as it relates to MK-3655 and its related compounds. As a result, in late April 2023, the license rights granted to Merck in 2018 with respect to MK-3655 will revert to us and the program will become wholly-owned by us. Further development of MK-3655, once the termination is effective, is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of MK-3655 unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

Similarly, in October 2022, we announced that our Phase 2 CATALINA trial evaluating NGM621 in patients with geographic atrophy, or GA, secondary to age-related macular degeneration, or AMD, did not meet its primary endpoint and, in December 2022, Merck notified us that it would not exercise its option to license NGM621 and its related compounds or the related ophthalmology bundle option and, as a result, those options expired unexercised in January 2023. Further, Merck did not elect for us to continue to conduct R&D on any compounds from our other ophthalmology programs that were subject to the collaboration, which are preclinical and directed to undisclosed targets. Such an election would have resulted in an extended or tail period in which Merck would continue to fund our R&D of such ophthalmology compounds. Because Merck did not make such an election, we do not have any funding from Merck to pursue such ophthalmology programs after we complete certain wind down activities related to NGM621, and if we choose to develop these programs further, we will be responsible for funding them. As a result, while our ophthalmology programs, including NGM621, are now wholly-owned by us, further development of those programs is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of NGM621 or the preclinical ophthalmology programs unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

We do not know whether Merck will elect to exercise its option to license any CVM-related preclinical candidates that remain subject to the collaboration. Accordingly, the anticipated benefits to us of the collaboration with Merck may never be realized and it possible that the Amended Collaboration Agreement will be terminated without Merck exercising its option to license any other programs or product candidates.

Moreover, under the Amended Collaboration Agreement, Merck has the unilateral right to terminate all or part of the agreement at certain times and under certain circumstances. Merck also may unilaterally terminate its R&D funding for programs that remain within the scope of the collaboration if we are acquired by a third party or in the event of an uncured material breach by us. Subject to certain limitations, Merck may partially terminate the Amended Collaboration Agreement for convenience as it relates to any future licensed program, as they did with respect to MK-3655 in January 2023 (effective in late April 2023) and with respect to our growth differentiation factor 15, or GDF15, agonist program, which included product candidates NGM395 and NGM386, in 2019. Merck may also unilaterally terminate the Amended Collaboration Agreement as it relates to its rights to research and develop

small molecule compounds. It may also unilaterally terminate the Amended Collaboration 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 a global cost and profit share arrangement if not yet exercised as of the time of termination and lose our co-detailing option (whether or not exercised as of that time) for the relevant licensed program.

If Merck terminates funding or terminates the Amended Collaboration Agreement, it could delay or preclude our ability to further our CVM-related research programs, which could materially and adversely affect our business. In addition, in the event that Merck decides to take over any CVM-related preclinical candidates that remain within the scope of the collaboration for development during any tail period, or exercises its license option for any such preclinical candidate, we could be subject to disputes with Merck with respect to their obligation to use commercially reasonable efforts with respect to the development and commercialization of the affected product candidate, and we could otherwise be subject to disputes with Merck over the scope of the parties' respective rights under the Amended Collaboration Agreement, any of which could delay or preclude the development or commercialization of the affected product candidate and involve us in costly and time-consuming arbitration and litigation, which could divert management attention and resources and otherwise negatively affect our business and operations.

We may depend in the future on BD Arrangements with third-party partners for the development and commercialization of our product candidates and for revenue. If we are unable to secure those BD Arrangements on beneficial terms, if at all, or if any such future arrangements are not successful, we may not be able to capitalize on the market potential of our product candidates or continue their development.

Pursuing BD arrangements has been and is expected to continue to be a key component of our strategy, and we are actively seeking, or intend to seek, BD Arrangements with third-party partners to progress, in whole or in part, the development of one or more of our product candidates. While we may opportunistically consider BD Arrangements to advance development of our key solid tumor oncology programs, the further development of other programs in our pipeline, including NGM621, aldafermin, NGM936 and, once termination of Merck's license is effective, MK-3655, is primarily dependent on our ability to secure potential future BD Arrangements for these programs. Due to the need to conserve capital and prioritize focused execution and unless our portfolio prioritization changes, if we are unable to secure BD Arrangements for these programs on beneficial terms, if at all, we are unlikely to be able to advance their development unless our portfolio prioritization changes and may discontinue or abandon any or all of these programs altogether, in which case we will not realize any return on our investments in these programs. Even if we are successful in entering into any BD Arrangements with third-party partners for our programs, we will likely have limited control over the amount and timing of resources that our partners dedicate to the development or commercialization of the applicable product candidates. Our ability to generate revenue from any such arrangement will depend on the specific financial terms we reach with any partner, as well as each of our partners' abilities to successfully perform the functions assigned to them in such arrangement towards developing, seeking regulatory approval for and commercializing our product candidates.

BD Arrangements involving our product candidates pose risks to us, including the following:

- Partners have significant discretion in determining the efforts and resources that they will apply to these arrangements. For example, under the terms of the collaboration with Merck, if Merck exercises its option to acquire an exclusive license for any CVM-related preclinical candidate that remains within the scope of the collaboration, our ability to influence the resources Merck devotes to such candidate are substantially reduced until such time, if any, that we exercise our right to participate in a cost and profit share arrangement. Even after we exercise that right to participate in a cost and profit share arrangement, our ability to influence Merck will be limited.
- Partners 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 partner's strategic focus or available funding or external factors, such as an acquisition that diverts resources or creates competing priorities. For example, in June 2021, we and Merck entered into the Amended Collaboration Agreement that covers a narrower scope, focused primarily on ophthalmology- and CVM-related therapeutic areas, than had been covered under the original collaboration agreement we entered into with Merck in 2015. In addition, under the terms of the Amended Collaboration Agreement, it is possible for Merck to unilaterally terminate and any other future licensed program, if any, (whether or not we have exercised our cost and profit share option) upon prior written notice, such as it did for NGM386 and NGM395 in 2019 and most recently in its notice of termination for MK-3655 (effective late April 2023), without triggering a termination of the remainder of the Amended Collaboration Agreement. Moreover, Merck might also opt not to designate any collaboration preclinical candidates for further development

during the tail period following the end of the research phase or exercise any of its options to acquire a license to a product candidate, as it did with respect to the preclinical ophthalmology product candidates.

- Partners may delay clinical trials, provide insufficient funding for a clinical trial program, request the suspension or termination of 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.
- Partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the partners 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 partner with marketing and distribution rights might not commit sufficient resources to the marketing and distribution of our product candidates.
- Partners might not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation.
- Disputes may arise between the partners and us that result in the delay or termination of the research, development or commercialization of our 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 BD Arrangements, including, in the case of our collaboration with Merck, if we undergo a change in control.
- BD Arrangements 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.
- BD Arrangements might not lead to development or commercialization of product candidates in the most efficient manner, or at all. If a present or future partner of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such arrangement could be delayed, diminished or terminated.

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 any potential future partners, we expect to depend on other third parties, including contract research organizations, or CROs, clinical data management organizations, clinical investigators, contract manufacturing organizations/contract development and manufacturing organizations, or CMOs, and other third-party partners and service providers to support our discovery efforts, to formulate product candidates, to conduct our clinical trials and certain aspects of our research and preclinical studies, to manufacture clinical and commercial-scale quantities of our drug substances and drug products and to market, sell and distribute any products we successfully develop and for which we obtain regulatory approval. Any problems we experience with any of these third parties could delay our research efforts or the development, manufacturing or commercialization of our product candidates or any future products, which could harm our results of operations. For more information, see the risk factors titled *“We rely completely on CMOs for the manufacture of our product candidates, and 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"* and *“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 cannot guarantee that we or, as applicable, any of our partners will be able to successfully negotiate agreements for, and maintain relationships with, third-party partners and service providers on favorable terms, if at all. If we or any of our partners are unable to obtain and maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our product candidates, which will, in turn, adversely affect our business. If we or any of our partners need to enter into alternative arrangements, it would delay our product development and, if applicable, commercialization activities and such alternative arrangements may not be available on terms acceptable to us.

We expect to continue to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, our reliance on these third parties for R&D activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. However, we cannot control the amount or timing of resources our partners will devote to our R&D programs, product candidates or potential product

candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials or other R&D activities in accordance with regulatory requirements, 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 any approved products. In addition, we base our expense accruals related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf and, if their estimates are not accurate, it could negatively affect the accuracy of our financial statements.

Any agreements we have or may enter into with third-party partners and service providers 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 R&D, 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 and time-consuming arbitration or litigation.

In addition, we are less knowledgeable about the reputation and quality of third-party contractors in countries outside of the United States where we conduct discovery research or preclinical and clinical development and manufacturing of our product candidates and, therefore, we may not choose the best parties for these relationships.

We rely completely on CMOs for the manufacture of our product candidates, and we are subject to many manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates and any future products.

We have limited process development capabilities and require the services of third-party CMOs to provide additional process development and 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. As a result, we rely completely on CMOs, which entails risks to which we would not be subject if we manufactured product candidates or products ourselves, including risks related to reliance on third parties for availability of drug product to use in our clinical trials and for regulatory compliance and quality assurance with respect to such drug product, the possibility of breach of the manufacturing agreement by third parties because of factors beyond our control (including a failure to manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications) and the possibility of termination or nonrenewal of agreements by third parties, based on their own business priorities, at a time that is costly or damaging to us.

Our product candidates are biologics, and the manufacture of biologic products is complex, highly regulated and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. As a result, the manufacture of our product candidates is subject to many risks, including the following, some of which we have experienced:

- product loss or other negative consequences due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, shortages of qualified personnel or improper delivery or storage conditions;
- difficulties with production costs and yields, quality control, product stability and quality assurance testing, including challenges related to bioanalytical method development and the qualification and implementation of those methods for release testing, which can delay availability of clinical trial materials;
- the negative consequences of failure to comply with strictly enforced federal, state and foreign regulations;
- minor deviations from normal manufacturing processes, which have in the past and may in the future result in reduced production yields, product defects and other supply disruptions;
- the presence of microbial, viral or other contaminants discovered in our product candidates or in the manufacturing facilities in which they are made, which can necessitate closure of facilities for an extended period of time to investigate and eliminate the contamination;
- the negative consequences of our CMOs' failure to qualify upon an audit by regulatory authorities, by us or by our partners;

- our CMOs' changing strategies and business priorities, which can affect the availability of facilities where we intend to manufacture our product candidates; and
- our CMOs' manufacturing facilities being adversely affected by labor, raw material and component shortages, turnover of qualified staff or financial difficulties of their owners or operators, including as a result of the effects of the ongoing COVID-19 pandemic, or by natural disasters, power failures, local political unrest or other factors.

We cannot ensure that issues relating to the manufacture or testing of our product candidates, such as those described above, will not occur or continue to occur in the future and if we or our CMOs experience any such issues there could be a shortage of drug substance or drug product for use in our clinical trials, which could delay clinical and regulatory timelines significantly and have an adverse effect on our business.

In addition, to date our product candidates have been manufactured by CMOs solely for preclinical studies and relatively small clinical trials. We intend to continue to use CMOs for these purposes, and also for the supply of larger quantities that may be required to conduct accelerated or expanded early clinical trials or larger, later clinical trials and for commercialization if we advance any of our product candidates through regulatory approval and to commercialization. These manufacturers may not have sufficient manufacturing capacity and may not be able to scale up the production of drug substance or drug product in the quantities we need and at the level of quality required in a timely or effective manner, or at all. In particular, there is increased competition in the biotechnology industry for CMO manufacturing slots and other capabilities generally, which has had, and may continue to have, a negative impact on the availability of manufacturing capacity and therefore our ability to supply clinical trial materials for planned, ongoing or expanded clinical trials.

The transfer of our small-scale manufacturing processes to CMOs for scale up and validation and any later scale up and validation of the manufacturing process in the CMOs' facilities to manufacture larger quantities, involve difficult and complex processes. We may not be successful in transferring our production system to a CMO, either because it is unable to implement the process successfully in its facilities or for other reasons. Later scale-up activities are also difficult and costly and entail risks such as process reproducibility, stability, consistency and other technical challenges. If we are unable to adequately validate or scale up the manufacturing processes for our product candidates, we would need to undertake a transfer to another third party and repeat the manufacturing validation process, which can be expensive and time-consuming and could delay the initiation or completion of our clinical trials.

Similarly, we or our CMOs may make changes to our product candidates' manufacturing processes at various points in product development for many reasons, including scaling up, facility fit, raw material or component availability, decreasing costs or timing of production, improving processing robustness and reliability, decreasing processing times or others. Such changes require further validation and may have unintended consequences, which could include causing our product candidates to perform differently when administered in clinical trials and affecting clinical trial results. In some circumstances, we may be required to perform comparability or other studies to demonstrate that the product used in earlier clinical trials or at earlier stages of a trial are comparable to the product we intend to use in later trials or later stages of an ongoing trial. These efforts are expensive and there is no assurance that they will be successful, which could impact our ability to continue or initiate clinical trials in a timely manner, or at all.

Any future adverse developments affecting manufacturing operations or the scale up or validation of manufacturing processes for our product candidates may result in shipment delays, lot failures, clinical trial delays or discontinuations, or, if we are commercializing products, inventory shortages, product withdrawals or recalls or other interruptions in supply. We may also have to record inventory write-offs and incur other charges and expenses for drug substance or drug product that fails to meet specifications or cannot be used before its expiration date. In addition, for out of specification materials, we may need to undertake costly remediation efforts or manufacture new batches at considerable cost and time delays or, in the longer run, seek more expensive 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 CMOs, who may take advantage of our reliance on them to increase the pricing of their manufacturing services or require us to change our intended manufacturing plans based on their strategies and priorities. Single sourcing also imposes a risk of interruption or delays in supply in the event of manufacturing, quality or compliance difficulties and/or other difficulties in timely supplying us with materials. For example, our investigational new drug application, or IND, submissions for NGM438 and NGM831 were delayed due to challenges at one of our CMOs, primarily related to analytical method qualification and release testing for those product candidates. It is possible that we could experience further supply-related delays that would adversely affect our ability to commence first-in-human testing of product candidates on

our anticipated timing. Moreover, we do not currently have arrangements in place for redundant supply for drug substance or drug product. If one of our suppliers fails or refuses to supply us for any reason or we otherwise choose to engage a new supplier for one or more of our product candidates, including a second source supplier to mitigate the risks of single-source supply, it would take a significant amount of time and cost to implement and execute the necessary technology transfer to, and qualification of, a new supplier. The FDA or comparable foreign health authority must approve manufacturers of drug substance and drug product. If there are any delays in qualifying new suppliers or facilities or a new supplier is unable to meet the requirements of the FDA or comparable foreign health authority for approval, there could be a shortage of drug substance or drug product for use in clinical trials with respect to the affected product candidates.

Our product candidates use certain raw materials for their production, such as reagents that support cell growth, purification materials and testing and manufacturing supplies. Some of these materials only have a single supplier and are purchased as necessary without a long-term supply agreement in place. In addition, our drug products may require the use of syringe or other components, some of which have been the subject of shortages amplified by the COVID-19 pandemic due to their use in, among other things, COVID-19 vaccine production. If our CMOs are required to obtain an alternative source of certain raw materials and components, additional testing, validation activities and regulatory approvals may be required, which may negatively impact manufacturing and other development timelines. For example, one of our CMOs experienced shortages of the specific cell culture media used to manufacture one of our products due to global supply chain challenges and, while we have been successful in obtaining a replacement product, these types of substitutions may require additional and unplanned testing, qualification or validation activities. Any significant delay in the acquisition or decrease in the availability of these materials, components or other items, or failure to successfully qualify or validate alternative materials or components, could considerably delay the manufacture of our product candidates, which could adversely impact the timing or completion of any ongoing and planned trials or the timing of regulatory approvals, if any, of our product candidates.

In addition, our CMOs' facilities and operations have been adversely affected by labor, raw material and component shortages, high turnover of staff and difficulties in hiring trained and qualified replacement staff and the operations of our CMOs 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. For a discussion of how the COVID-19 pandemic has affected or may affect drug or related component supplies for our clinical trials, refer to the risk factor titled *"Our business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics, including the COVID-19 pandemic."* Changes in economic conditions, supply chain constraints, labor, raw material and component shortages and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic as well as other stimulus and spending programs, could also lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs.

Our product candidates other than NGM621 and aldafermin are currently solely manufactured at a facility in Lithuania. Following Russia's invasion of Ukraine in February 2022, the response from the United States and its allies has included both significant sanctions and NATO's deployment of additional military forces to Eastern Europe, including to Lithuania. The ongoing conflict between Russia and Ukraine and the retaliatory measures taken or that may be taken by the United States, NATO and others, including significant sanctions against Russia, create global security concerns and regional instability, including due to the possibility of expanded regional or global conflict, and are likely to have short-term and likely longer-term negative impacts on regional and global economies, any or all of which could disrupt our supply chain and adversely affect our ability to conduct ongoing and future clinical trials of our product candidates and our ability to raise capital on favorable terms.

Any further delays or interruptions in the supply of clinical trial material could delay the completion or initiation of our 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, terminate ongoing clinical trials or abandon planned clinical trials or expansions or accelerations of clinical trials completely.

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, if any, or for which Merck decides not to exercise its license option, we must either develop our own sales, marketing and distribution capabilities or make

arrangements with third parties to perform these services for us. If we exercise our co-detailing rights in the United States with respect to the Merck collaboration, we will be responsible for the costs of fielding such a sales force, subject to partial offset pursuant to the formula by which profits are allocated, and the risks of attracting, retaining, motivating and ensuring the compliance of such a sales force with the various requirements of the Merck collaboration and applicable law. If we decide to market any of our products on our own, we will have to commit significant resources to developing a marketing and sales force and supporting distribution capabilities. If we decide to enter into arrangements with third parties for performance of these services, we may find that they are not available on terms acceptable to us, or at all. If we are not able to establish and maintain successful arrangements with third parties or build our own sales and marketing infrastructure, we may not be able to commercialize our product candidates, which would adversely affect our business, operating results and prospects.

Risks Related to Our Business and Industry

Our product candidates must undergo rigorous clinical trials before seeking regulatory approvals, and clinical trials may be delayed, suspended or terminated at any time for many reasons, any of which could delay or prevent regulatory approval and, if approval is granted, commercialization of our product candidates.

All of our product candidates are subject to rigorous and extensive clinical trials before we can seek regulatory approval from the FDA and comparable foreign health authorities such as the European Commission. Clinical trials may be delayed, suspended or terminated at any time for reasons including but not limited to:

- ongoing discussions with the FDA or comparable foreign health authorities regarding the scope or design of our clinical trials;
- delays in obtaining, or the inability to obtain, required approvals from IRBs and ethics committees or other governing entities at clinical trial sites selected for participation in our clinical trials;
- delays in patient enrollment and other key trial activities, including as a result of the effects of the ongoing COVID-19 pandemic and of the significant competition for recruiting patients with cancer in clinical trials;
- delays in reaching agreement on acceptable terms with prospective CROs and the failure of CROs, testing laboratories and other third parties to satisfy their contractual duties to us or meet expected deadlines;
- deviations from the trial protocol by clinical trial sites and investigators, or failures to conduct the trial in accordance with regulatory requirements;
- lower than anticipated retention rates of participants in clinical trials, including patients dropping out due to side effects, disease progression or concerns about the COVID-19 pandemic;
- failure of enrolled patients to complete treatment or to return for post-treatment follow-up;
- for clinical trials in selected patient populations, delays in identification and auditing of central or other laboratories and the transfer and validation of assays or tests to be used to identify selected patients and test any patient samples;
- implementation of new, or changes to, guidance or interpretations from the FDA or comparable foreign health authorities with respect to approval pathways for product candidates we are pursuing;
- the need to repeat clinical trials as a result of inconclusive or negative results, poorly executed testing or changes in required endpoints;
- insufficient supply or deficient quality of drug substance, drug product or other clinical trial material necessary to conduct our clinical trials, as well as delays in the testing, validation, manufacturing and delivery to clinical trial sites of such material;
- withdrawal of clinical trial sites or investigators from our clinical trials for any reason, including as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- unfavorable FDA or comparable foreign health authority inspection or review of a clinical trial site or records of any clinical or preclinical investigation;
- drug-related adverse effects or tolerability issues experienced by participants in our clinical trials;
- changes in government regulations or administrative actions;
- lack of adequate funding to continue the clinical trials;
- our ability to hire and retain key R&D personnel; or
- the placement of a clinical hold on a trial by the FDA or comparable foreign health authorities.

We cannot guarantee that we will be able to successfully accomplish required regulatory and/or manufacturing activities or all of the other activities necessary to initiate and complete clinical trials in a timely fashion, if at all. 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. In addition, we have only limited experience in conducting late-stage clinical trials required to obtain regulatory approval. In any event, we do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all.

Our product development costs will increase if we continue to experience delays in clinical testing. Significant clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business, results of operations and prospects. Our or our partners' inability to timely complete clinical development could result in additional costs to us or impair our ability to generate product revenue or development, regulatory, commercialization and sales milestone payments and royalties on product sales.

If clinical trials of our product candidates fail to produce positive results or to demonstrate safety and efficacy to the satisfaction of the FDA or comparable health authorities or sufficient to demonstrate differentiation from other approved therapies or therapies in development, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Our product candidates are in early stages of development, with our most advanced product candidates only in Phase 2 development. Before obtaining marketing approval from health authorities for the sale of our product candidates, we or our partners must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Preclinical studies and clinical trials are expensive, take several years to complete and may not yield results that support further clinical development or product approvals. 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 and failure can occur at any stage of testing. For example, despite the results of preclinical and Phase 1 studies of NGM621, our Phase 2 CATALINA clinical trial evaluating NGM621 in patients with GA secondary to AMD did not meet its primary endpoint. Since Merck did not elect to exercise its option to license NGM621 and its related compounds, further development of NGM621 is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of NGM621 unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

Similarly, our Phase 2b ALPINE 2/3 trial evaluating aldafermin in patients with F2/F3 NASH did not meet its primary endpoint and, as a result, we decided to suspend further development of aldafermin in patients with F2/F3 NASH, allowing for the reallocation of resources to advancing our other programs. While we continued, and have completed, enrollment in our Phase 2b ALPINE 4 clinical trial of aldafermin in patients with compensated cirrhosis due to NASH (liver fibrosis stage 4, or F4, by the NASH Clinical Research Network classification), we updated the design of the ALPINE 4 trial, elevating the Enhanced Liver Fibrosis, or ELF, test, a reproducible, quantitative non-invasive liver prognostic test that evaluates liver fibrosis and correlates to liver-related outcomes, to be the primary endpoint for the trial. The ELF test is a composite blood test measuring the presence of three biomarkers associated with liver matrix metabolism. Liver biopsy data will also be measured and reported as a secondary endpoint upon completion of the trial. For more information, refer to the risk factor titled "*Aldafermin is, and MK-3655 was, being developed, for the treatment of NASH, an indication for which there are no approved products. This makes it difficult to predict the timing, cost and potential success of their continued clinical development, if any, and regulatory approval for the treatment of NASH, or otherwise.*"

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 comparable foreign health authorities. The need for chronic administration also increases the risk that our clinical drug development programs may not uncover all possible adverse events that patients who take our products may eventually experience. The number of patients exposed to

treatment with, and the average exposure time to, our product candidates in clinical development programs may be inadequate to detect rare adverse events or chance findings that may only be detected once our products are administered to more patients and for longer periods of time.

We may also not be successful in generating clinical data sufficient to differentiate our product candidates from other products in the same therapeutic area. If our competitors' products are, or are perceived to be, more effective, more convenient, less costly or safer than our products, or we are unable to demonstrate differentiation in any of those factors, we may not be able to achieve a competitive position in the market. For more information, refer to the risk factor titled "*We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than us."*

In addition, data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In any event, it is impossible to predict when or if any of our product candidates will prove safe and effective in humans or will receive regulatory approval. If we are unable to successfully discover, develop or enable our partners to develop drugs that regulatory authorities deem 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.

To date, the data supporting our drug discovery and development programs are derived from laboratory and preclinical studies and earlier-stage clinical trials. Owing in part to the complexity of biological pathways, when used to treat human patients, our product candidates might not demonstrate 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. Success in preclinical studies and earlier-stage clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the effectiveness and safety of our product candidates. In this regard, the data supporting our drug discovery and development programs are derived from laboratory and preclinical studies, and future clinical trials in humans may show that one or more of our product candidates are not safe and effective, in which event we may need to abandon development of such product candidates. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical studies and earlier-stage clinical trials. Similarly, preliminary data and interim results from clinical trials may not be predictive of final results. For example, despite the results of preclinical and Phase 1 studies of NGM621, our Phase 2 CATALINA clinical trial evaluating NGM621 in patients with GA secondary to AMD did not meet its primary endpoint. Similarly, in spite of the results we had obtained in our Phase 1 trials of aldafermin and in our first Phase 2 trial, in May 2021, we announced that our Phase 2b ALPINE 2/3 trial evaluating aldafermin in patients with F2/F3 NASH did not meet its primary endpoint. For more information, refer to the risk factor titled "*If clinical trials of our product candidates fail to produce positive results or to demonstrate safety and efficacy to the satisfaction of the FDA or comparable health authorities or sufficient to demonstrate differentiation from other approved therapies or therapies in development, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates."* There can be no assurance that any clinical testing of our product candidates will be successful or will otherwise be supportive of continued development and/or regulatory approvals of such product candidates.

In addition, some of our earlier-stage 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. As a general matter, there is also a substantial risk that Phase 3 trials with larger numbers of patients and/or longer durations of therapy will fail to replicate efficacy and safety results observed in earlier clinical trials.

Our product candidates may cause undesirable side effects or adverse events or have other properties or safety risks, which could delay or prevent continued clinical development or their regulatory approval or limit the commercial profile of any approved label.

Adverse events, undesirable side effects or similar safety issues caused by our product candidates could cause us or health authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign health authorities. Additional clinical trials may be required to further evaluate the safety profile of our product candidates. Patients in certain of our ongoing or planned clinical trials, particularly patients with cancer or with NASH with more advanced fibrosis, often enter our trials with significant comorbidities or advanced life-threatening illness and/or are treated in the trial

with our product candidate in combination with other medications, including, in cancer patients, chemotherapy or other approved cancer treatments. As a result, patients in our clinical trials can be expected to experience some adverse events, including death, or side effects that are not or may not be related to treatment with our product candidates. Nonetheless, the occurrence of adverse events or side effects, whether or not related to our product candidates, could impact the success of our clinical trials.

Patients experienced, and we reported, serious adverse events, or SAEs, in the treatment arms of our completed trials of MK-3655, NGM621 and aldafermin. We expect that patients in our clinical trials, including those that are sham- or placebo-controlled with some patients not receiving study drug, will continue to experience adverse events and SAEs and we will continue to monitor those SAEs for any signals of concern regarding the safety and tolerability of our product candidates. For example, cancer patients enrolled in our ongoing clinical trials of NGM120, NGM707, NGM831 and NGM438, many of whom are suffering from advanced life-threatening illness, have experienced, and we expect will continue to experience, SAEs and other adverse events, which may or may not be drug-related. If patients in any of our clinical trials experience a high or unacceptable severity and prevalence of side effects, including particularly SAEs, it could affect patient recruitment or the ability of enrolled patients to complete their treatment in a clinical trial, it may result in a regulatory authority putting a clinical hold on the clinical trial or it may result in failure to obtain regulatory approval for our product candidates or product liability claims.

In addition, significant increases in serum levels of low-density lipoprotein cholesterol, or LDL-C, were observed in clinical trials of aldafermin in patients with NASH and type 2 diabetes. Serum levels of LDL-C were brought back to baseline levels with concomitant statin use in patients with NASH; however, the impact of these drug-induced changes in LDL-C are unknown. Generally, sustained and prolonged LDL-C elevations in untreated patients are associated with cardiovascular disease through atherosclerotic plaque development. While data from our completed Phase 2b ALPINE 2/3 clinical trial and earlier trials of aldafermin demonstrated the ability of concomitant statin use to mitigate the serum LDL-C elevations driven by aldafermin activity, aldafermin's impact on LDL-C may negatively impact market acceptance of an approved aldafermin product.

Our product candidates are protein or antibody therapeutics. Protein and antibody therapeutics can sometimes induce host immune responses that can cause the production of anti-drug antibodies, or ADAs. In some cases, ADAs have no effect. In other cases, ADAs may neutralize the effectiveness of the product candidate, can require that higher doses be used to obtain a therapeutic effect or can cross react with substances naturally occurring in a subject's body, which can cause unintended effects, including potential impacts on efficacy and adverse events. Some patients treated with aldafermin in our completed clinical trials have developed ADAs against aldafermin and, in some cases, those antibodies were neutralizing or appeared to cross react with the patient's naturally occurring FGF19. We developed an assay to measure the presence of ADAs against aldafermin for our ongoing NASH program, which we are using to test patient samples and which will need to be evaluated by regulatory agencies. The presence of ADAs was also observed in our Phase 1 MK-3655 trial. If we are required to undertake substantial additional testing as a result of the detection of ADAs in subjects using aldafermin, MK-3655 or any other product candidate, the costs of our clinical trials may increase. If we determine that ADAs are causing safety or efficacy concerns when using any of our product candidates, we may need to delay or halt clinical trials of our product candidates and the affected product candidates may never obtain regulatory approval. We cannot provide assurance that the detection of ADAs will not be higher than we have observed historically or that observed rates will not later be found to limit drug exposure or cause adverse safety events, or that the detection of ADAs will not otherwise result in the non-approvability of any of our product candidates.

NGM621 had been delivered to clinical sites in vials and then administered to patients using commercially available single-use syringes. The manufacturer of a commercially available single-use syringe widely used by ophthalmologists for intravitreal, or IVT, injections, including investigators in the Phase 2 CATALINA trial, issued a notice that such single-use syringes should not be used for ocular medications due to an increased potential for adverse eye conditions. While we have not experienced any safety concerns in our completed NGM621 clinical trials relating to syringe use, we communicated with the FDA and our study investigators regarding this issue and this issue could preclude or delay any efforts to partner our NGM621 program.

Future results of our trials could reveal a high and unacceptable severity and prevalence of side effects, SAEs, ADAs, safety issues or other negative or otherwise unexpected characteristics. The occurrence of those issues could affect patient recruitment or the ability of enrolled patients to complete their treatment in a clinical trial, result in failure to obtain regulatory approval for our product candidates or product liability claims or impact market acceptance of our products. Any of these occurrences could materially and adversely affect our business, financial condition and prospects.

Aldafermin is, and MK-3655 was, being developed for the treatment of NASH, an indication for which there are no approved products. This makes it difficult to predict the timing, cost and potential success of their continued clinical development, if any, and regulatory approval for the treatment of NASH, or otherwise.

We are developing aldafermin, and MK-3655 was in development by Merck, for the treatment of NASH, an indication for which there are no approved products. Implementation of new, or changes to, guidance or interpretations from the FDA or comparable foreign health authorities with respect to approval pathways, such as draft guidance documents from the FDA for the development of products for the treatment of NASH that issued in 2018 and 2019 and from the European Medicines Agency, or EMA, that issued in 2018, may impact the path for regulatory approval for NASH therapies. Further, as we and other companies advance clinical trials for potential NASH therapies, we expect that the path for regulatory approval for NASH therapies may continue to evolve as companies refine their regulatory approval strategies and interact with health authorities. Such evolution may impact our future clinical trial designs, including trial size and endpoints, in ways that we cannot currently predict. We updated the design of the ALPINE 4 trial of aldafermin, elevating the ELF test to be the primary endpoint for the trial. Neither the ELF test, nor any other surrogate biomarker endpoints, are currently endorsed by the FDA or EMA as sufficient for granting regulatory approval of products being developed for the treatment of compensated cirrhosis due to NASH (stage F4) and therefore may not be able to be used as a primary endpoint in potential future Phase 3 trials to support regulatory approval for aldafermin.

In addition, certain of our competitors have experienced regulatory setbacks for NASH therapies following communications from the FDA. We currently do not know the impact, if any, that these setbacks could have on the path for regulatory approval for NASH therapies generally or for aldafermin and MK-3655 in particular. If the clinical trials for aldafermin and MK-3655 are not designed in a manner that, even if successful, support regulatory approval due to shifting approval pathways or for other reasons, those product candidates may be delayed in obtaining approval or may never be approved, which could have a material adverse effect on our business, operating results and prospects. Moreover, the above factors could make it difficult or preclude altogether our ability to secure potential future partners necessary to further the development of aldafermin and MK-3655 in NASH or otherwise.

As a result of the above, the future development of aldafermin and MK-3655 in patients with NASH is substantially uncertain and could be discontinued altogether, in which case, we will not receive any return on our investments in these programs.

Aldafermin is a modified version of a human hormone that has been associated with liver cancer in rodent testing.

The IND application we filed for aldafermin in February 2014 for type 2 diabetes was placed on clinical hold by the FDA Division of Metabolism and Endocrinology Products pending receipt of additional information relating to the potential risk of proliferative effects of aldafermin in the livers of non-human primates and mice based on concerns relating to the observation that human FGF19 can induce hepatocellular proliferation in rodents. We withdrew this IND in January 2015, as we determined that we would not further study aldafermin in type 2 diabetes after we analyzed the results of the Phase 2 clinical trial of aldafermin in type 2 diabetes and made the determination to pursue NASH and other liver indications. To date, the FDA Division of Hepatology and Nutrition, which is responsible for the NASH indication, has not requested any additional information regarding the potential for aldafermin to induce hepatocellular proliferation. We have received feedback from the FDA Carcinogenicity Assessment Committee that our preclinical data through six-month chronic toxicology studies in mice and monkeys support a single species, two-year carcinogenicity assessment in rats. The human hormone and the rodent ortholog for FGF19 share a sequence identity of approximately 50%, which means that the results of these studies of aldafermin in rats are not necessarily predictive of the potential risk of carcinogenicity in humans. To our knowledge, neither FGF19 nor any variant thereof other than aldafermin has ever been tested in humans. Concerns about the association between FGF19 and liver cancer could have an adverse effect on our ability to develop and commercialize aldafermin.

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

The success of our business over the longer term depends upon our ability to identify and validate new potential protein and antibody therapeutics. Research programs to identify new product candidates require substantial technical, financial and human resources, and our research methodology may not successfully identify medically relevant protein or antibody therapeutics to be developed as product candidates. In addition, our drug discovery efforts often identify and select novel, untested proteins in the particular disease indication we are pursuing, which we may fail to validate after further research work. Moreover, our research efforts may initially show promise in discovering potential new protein and antibody therapeutics yet fail to yield product candidates for clinical

development for multiple reasons. For example, potential product candidates may, on further study, be shown to have inadequate efficacy, harmful side effects, suboptimal drug profiles or other characteristics suggesting that they are unlikely to be commercially viable products. Our inability to successfully identify additional new product candidates to advance into clinical trials could have a material adverse effect on our business, operating results and prospects.

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

We have limited technical, managerial and financial resources to determine which of our product candidates should proceed to initial clinical trials, later-stage clinical development and potential commercialization. We may make incorrect determinations in allocating resources among these product candidates. Our decisions to allocate our R&D, 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. For example, our key pipeline programs in active development include product candidates in solid tumor oncology, and we are focusing most of our execution efforts and resources on these programs, intending to mainly advance them in generation of proof-of-concept data internally. However, our focus on the solid tumor oncology therapeutic area may be unsuccessful and may never lead to the development of viable commercial products. Similarly, our decisions to delay or terminate drug development programs, such as our decision to suspend development activities related to multiple metabolic disease product candidates and for aldafermin in patients with F2/F3 NASH to concentrate our resources elsewhere, also may be incorrect and could cause us to miss valuable opportunities.

Under the terms of our Amended 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 share 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 our Chief Scientific Officer, Dr. Jin-Long Chen, or to 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 R&D and other 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.

There is intense competition for qualified personnel, including management, in the technical fields in which we operate, particularly in the oncology field, 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. We recruit for talent in the biotechnology and pharmaceutical industry in the San Francisco Bay Area, which is one of the most competitive and highest cost labor market in the United States and periodically experiences higher turnover rates than other industries. For example, in 2022, we continued to experience a challenging recruiting environment with relatively high rates of employees leaving the company to pursue other opportunities, particularly in the first three quarters of the year.

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. The labor market tightened significantly after the beginning of the ongoing COVID-19 pandemic. During the first couple of years of the COVID-19 pandemic, we experienced employee attrition at rates higher than we experienced historically, which may recur and could have

a negative impact on our productivity. If we are unable to attract and retain high-quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited.

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

The biopharmaceutical industry is intensely competitive and subject to rapid and significant technological change. Our competitors include multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. A number of pharmaceutical and biotechnology companies are pursuing the development or marketing of pharmaceuticals that seek to treat the same diseases that we are pursuing with our most advanced product candidates, particularly in the oncology field. Some of these pharmaceuticals in development are active, or seek to be active, against the same targets that our product candidates are engineered to effect, including the targets that are the focus of our immuno-oncology candidates, ILT2, ILT3, ILT4 and LAIR1. It is probable that the number of companies seeking to develop products and therapies for the treatment of cancer, retinal diseases and liver and metabolic diseases will increase. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly greater experience than we have in undertaking preclinical 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 and approval or marketing authorization from comparable health authorities such as the European Commission 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 collaboration or partnering relationships. Smaller and earlier-stage companies may also prove to be significant competitors, particularly through collaboration or partnering arrangements with large, established companies.

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

Although we believe there are no FDA- or European Commission-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 or GA) for which our product candidates may be useful and many of these currently approved therapies act through mechanisms similar to our product candidates. Many of these approved drugs are well-established therapies or products and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded products. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products, including branded generic products. This may make it difficult for us to differentiate our products from currently approved therapies, which may adversely impact our business strategy. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will be as our product candidates progress through clinical development. For more information regarding the competition that our most advanced product candidates face, or may face, see the discussion of specific competition for each product candidate in “Business-Our Pipeline Programs” in this Annual Report on Form 10-K.

In February 2023, Apellis Pharmaceuticals, Inc., or Apellis, announced that the FDA approved SYFOVRE™ (pegcetacoplan injection) for the treatment of GA secondary to AMD. Apellis' regulatory approval for pegcetacoplan injection may affect future late-stage clinical trial designs, if any, and require added clinical development expense. Iveric bio, Inc.’s, or Iveric's, avacincaptad pegol, a PEGylated aptamer inhibitor of complement C5, completed a Phase 2/3 clinical trial that demonstrated statistically significant reductions in the rate of GA lesion area growth in the avacincaptad pegol arm versus the sham arm. In February 2023, Iveric announced that the FDA had accepted its NDA for avacincaptad pegol. Even if we are successful in securing a future BD Arrangement for the NGM621 program, which may not occur in a timely manner or at all, and our partner obtains regulatory approval of NGM621,

which is substantially uncertain given the failure to meet the primary endpoint in the CATALINA trial, NGM621 may not be able to compete effectively against pegcetacoplan and avacincaptad pegol, which could adversely affect our future revenues and business prospects in the event we are able to successfully partner the program.

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

Demonstrating the safety and efficacy of our product candidates and obtaining regulatory approvals will not guarantee future revenue. 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. 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 physicians and patients;
- the actual and perceived advantages of the product candidate over alternative treatments, including any similar generic treatments;
- the viewpoints of influential physicians with respect to the product candidate;
- the inclusion or exclusion of the product candidate from treatment guidelines established by various physician groups;
- the cost of treatment relative to alternative treatments;
- our pricing and the availability of coverage and adequate reimbursement by third parties and government authorities as described in the risk factor titled "*Even if we obtain approval to market our products, these products may become subject to unfavorable pricing regulations, reimbursement practices from third-party payors or healthcare reform initiatives in the United States and abroad, which could harm our business*";
- the relative convenience and ease of administration;
- the frequency and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- any unfavorable publicity relating to the product candidate.

For example, aldafermin is currently administered via a once-daily subcutaneous injection, which may negatively impact market acceptance of an approved aldafermin product, if any. In addition, refer to the risk factor titled "*Our product candidates may cause undesirable side effects or adverse events or have other properties or safety risks, which could delay or prevent continued clinical development or their regulatory approval or limit the commercial profile of any approved label."* 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 obtain approval to market our products, these products may become subject to unfavorable pricing regulations, reimbursement practices from third-party payors or healthcare reform initiatives in the United States and abroad, 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 the European Union, or EU, Japan and Canada, the pricing of prescription drugs is controlled by the government and 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 regulatory approval for the product 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. 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. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. 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 drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drug 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 regulatory approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we and our partners may not be able to successfully commercialize any product candidate for which marketing approval is obtained.

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

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

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

For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or the IRA, into law, which among other things, (1) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was enacted, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers. There have been executive, judicial and congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive legislation repealing the ACA, such legislation may be reintroduced. Members of Congress have introduced legislation to modify or replace certain provisions of the ACA. It is unclear how these efforts to repeal and/or replace the ACA will impact the ACA and our business. For example, the Tax Cuts and Jobs Act, or 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.” On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Prior to the United States Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage

through Medicaid or the ACA. The IRA also, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025 and eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is possible that the ACA and IRA may be subject to judicial or Congressional challenges in the future. It is unclear how any additional healthcare reform measures may impact the ACA or IRA, increase the pressure on drug pricing or limit the availability of coverage and adequate reimbursement for our product candidates, which would adversely affect our business.

There has also been increasing executive, legislative and enforcement interest in the United States with respect to drug pricing practices. There have been U.S. congressional inquiries, presidential executive orders and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, in an executive order, the administration of President Biden expressed its intent to pursue certain policy initiatives to reduce drug prices and, in response, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to lower drug prices. Further, the Biden administration released an additional executive order on October 14, 2022, directing HHS to submit a report on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. 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. 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.

In many countries outside the United States, government-sponsored healthcare systems are the primary payors for drugs. With increasing budgetary constraints and/or difficulty in understanding the value of medicines, governments and payors in many countries are applying a variety of measures to exert downward price pressure and we expect that legislators, policy makers and healthcare insurance funds in the EU Member States will continue to propose and implement cost cutting measures. These measures include mandatory price controls, price referencing, therapeutic-reference pricing, increases in mandates, incentives for generic substitution and biosimilar usage, government-mandated price cuts, limitations on coverage of target population and introduction of volume caps.

Many countries implement health technology assessment, or HTA, procedures that use formal economic metrics such as cost-effectiveness to determine prices, coverage and reimbursement of new therapies. These assessments are increasingly implemented in established and emerging markets. In the EU, the newly-adopted Regulation (EU) 2021/2282 on Health Technology Assessment, or HTA Regulation, which will become effective in January 2025, will allow EU member states to use common HTA tools, methodologies and procedures to conduct joint clinical assessments and joint scientific consultations whereby HTA authorities may provide advice to health technology developers. Each EU member state will, however, remain exclusively competent for assessing the relative effectiveness of health technologies and making pricing and reimbursement decisions. Given that the extent to which pricing and reimbursement decisions are influenced by the HTA process currently varies between EU member states, it is possible that our products may be subject to favorable pricing and reimbursement status only in certain EU countries. If we are unable to maintain favorable pricing and reimbursement status in EU member states that represent significant markets, including following periodic review, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected. Moreover, in order to obtain reimbursement for our products in some EU member states, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Efforts to generate additional data for the HTA process will involve additional expenses which may substantially increase the cost of commercializing and marketing our products in certain EU member states.

We expect that countries will continue taking aggressive actions to seek to reduce expenditures on drugs. Similarly, fiscal constraints may also affect the extent to which countries are willing to approve new and innovative therapies and/or allow access to new technologies.

We cannot predict the likelihood, nature or extent of healthcare reform initiatives that may arise from future legislation or administrative action. 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 partner succeeds in developing any of our product candidates, we intend to market them in the EU and other jurisdictions in addition to the United States. If approved, we, Merck or any future partner 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 and data protection 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 or component 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 inflation and local and regional financial crises on demand and payment for our products and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political, geopolitical and economic instability, including wars such as the conflict between Russia and Ukraine, terrorism and political unrest, disease outbreaks, epidemics and pandemics, 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 partner 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 partner 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 partner obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program, such as Medicare and Medicaid;
- the federal False Claims Act, or FCA, imposes criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act, or HIPAA, imposes criminal liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense or knowingly and willfully making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, or HITECH, 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, processing and transmission of individually identifiable health information;

- the federal Physician Payments Sunshine Act, as amended, 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 HHS information related to "payments or other transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and 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 and other processing 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, litigation, 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.

Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of EU member states, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Our business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics, including the COVID-19 pandemic.

Disease outbreaks, epidemics and pandemics, such as the COVID-19 pandemic, in regions where we have concentrations of clinical trial sites or other business operations 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. Disease outbreaks, epidemics and pandemics have negative impacts on our ability to initiate new clinical trial sites, to enroll new patients and to maintain existing patients who are participating in our clinical trials, which may include increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of our product candidates, if at all. For example, 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 was impacted by COVID-19 quarantines, shelter-in-place and similar restrictions imposed by federal, state and local governments. In addition, during the COVID-19 pandemic, we experienced, from time to time, a slower pace of clinical site initiation and clinical trial enrollment and a higher subject dropout rate than originally anticipated in certain of our clinical trials, which we believe may have been due to factors such as the vulnerability of our studied patient populations, site staff shortages, clinical trial site suspensions, reallocation of medical resources and the challenges of working remotely due to shelter-in-place and similar government orders and guidelines, among other factors.

General supply chain issues may be exacerbated during disease outbreaks, epidemics and pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. For example, in 2022 we were made aware of a shortage of tubes required for taking blood samples, requiring the use of tubes of a different size from those specified in one of our protocols. In addition, our CMOs' facilities and operations have been adversely affected by labor, raw material and component shortages, high

turnover of staff and difficulties in hiring trained and qualified replacement staff during the COVID-19 pandemic. These difficulties have resulted in some delays in early development timelines and we could experience more significant disruptions to our supply chain and operations as a result of disease outbreaks, epidemics or pandemics in the future. If our CMOs are required to obtain an alternative source of certain raw materials and components, for example, additional testing, validation activities and regulatory approvals may be required which can also have a negative impact on timelines. Any associated delays in the manufacturing and supply of drug substance and drug product for our clinical trials could adversely affect our ability to conduct ongoing and future clinical trials of our product candidates on our anticipated development timelines. 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. For example, early in the COVID-19 pandemic, our aldafermin drug product CMO advised us that it could be required under orders of the U.S. government to allocate manufacturing capacity to the manufacture or distribution of COVID-19 vaccines. If any of our CMOs or raw materials or components suppliers become subject to acts or orders of U.S. or foreign government entities to allocate or prioritize manufacturing capacity, raw materials or components to the manufacture or distribution of vaccines or medical supplies needed to test or treat patients in a disease outbreak, epidemic or pandemic, this could delay our clinical trials, perhaps substantially, which could materially and adversely affect our business.

Moreover, COVID-19 continues to evolve, and the extent to which COVID-19 may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the emergence, infectiousness and severity of new variants, travel restrictions, quarantines and social distancing in the United States and other countries, business closures or business disruptions, global supply challenges, and the effectiveness of actions in the United States and other countries to contain and treat the disease. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business. To the extent the effects of the continuing COVID-19 pandemic, or any future disease outbreak, epidemic or pandemic, adversely affects our business and results of operations, it also may have the effect of heightening many of the other risks and uncertainties described elsewhere in this "Risk Factors" section.

Risks Related to Regulatory Approvals

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

Currently, none of our product candidates has received regulatory approval and we do not expect our product candidates to be commercially available for several years, if at all. The time required to obtain approval from the FDA and comparable foreign health authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the health authorities. In addition, approval policies, regulations or the type and amount of preclinical and clinical data necessary to gain approval may change during the course of a product candidate's development and may vary among jurisdictions. It is possible that none of our existing or future product candidates will ever obtain regulatory approval.

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

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

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

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

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 or a future partner seek accelerated approval for one of our product candidates based on a surrogate endpoint, the FDA may not accept such endpoint, may require additional studies or analysis or may not approve our product candidate on an accelerated basis, or at all. For example, in June 2020, Intercept Pharmaceuticals, Inc., or Intercept, announced that it had received a complete response letter regarding its new drug application, or NDA, for obeticholic acid for the treatment of NASH, in which the FDA indicated that it had determined that the predicted benefit of obeticholic acid based on a surrogate histopathologic endpoint was uncertain and did not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommended that Intercept submit additional post-interim analysis efficacy and safety data from its ongoing Phase 3 study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue. In addition, if full approval is granted for another product in the same indication for which we are seeking accelerated approval for one of our product candidates, the accelerated approval pathway may no longer be available to us or a future partner for our product candidate.

In the EU, innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the United States.

Sponsors that benefit from PRIME designation are potentially eligible for accelerated assessment of their marketing authorization applications, although this is not guaranteed. If a product for which PRIME designation was granted is the subject of an accelerated assessment, the product may be placed on the market in the EU before our product candidate with a similar therapeutic indication.

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

If we or our partners 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 pricing and reimbursement approvals before health authorities will approve the product for sale in that country. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by health authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we fail to obtain approval of any of our product candidates by health authorities in another country, we will be unable to commercialize our product in that country, and the commercial prospects of that product candidate and our business prospects could decline.

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

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign health authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. The FDA and comparable foreign health authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign health authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a Risk Evaluation and Mitigation Strategy, or REMS, 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. Failure to comply with any related obligations may result in the suspension or withdrawal of an obtained approval and in civil and/or criminal penalties. Receipt of approval for narrower indications than sought, restrictions on marketing through a REMS or similar strategy imposed in an EU member state or other foreign country, or significant labeling restrictions or requirements in an approved label such as a boxed warning, could have a negative impact on our ability to recoup our R&D costs and to successfully commercialize that product, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects. In any event, if we are unable to comply with our post-marketing obligations imposed as part of the marketing approvals in the United States, the EU, or other countries, our approval may be varied, suspended or revoked, product supply may be delayed and our sales of our products could be materially adversely affected.

In addition, manufacturers of drug substance and drug products and their facilities are subject to continual review and periodic inspections by the FDA and comparable foreign health authorities for compliance with current Good Manufacturing Practices, or 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 or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, or if our product candidates are found to cause undesirable or unacceptable side effects, 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 and complete post-marketing studies;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend marketing of, withdraw regulatory approval of or initiate a recall of such product;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or refuse to permit the import or export of products.

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

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

In the United States, engaging in the impermissible promotion of our products for off-label uses can subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines

and agreements that materially restrict the manner in which a company promotes or distributes drug products. These false claims statutes include the federal FCA, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these FCA lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label drug uses involving fines in excess of $1 billion. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations.

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

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU member state laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each member state and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities in connection with a marketing authorization. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Direct-to-consumer advertising of prescription medicinal products is also prohibited in the EU.

Failure to comply with EU, EU member state, and other country laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of a marketing authorization, or with other applicable regulatory requirements, may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties. In addition, legislation adopted at the EU level may be implemented differently by individual member states. These regulations, and their differing implementations in member states, increase our legal and financial compliance costs and may make some activities more time-consuming and expensive.

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

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

Risks Related to Our Intellectual Property

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

Our success depends in significant part on our ability and the ability of our current or future licensors, licensees, partners or collaborators to establish and maintain adequate intellectual property covering the product candidates that we plan to develop. In addition to taking other steps designed to protect our intellectual property, we have applied for, and intend to continue applying for, patents with claims covering our technologies, processes and product candidates when and where we deem it appropriate to do so. However, the patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees, partners 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, partners 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', partners' or collaborators' may not result in patents being issued that protect our technology or product candidates, or products resulting therefrom, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products.

We have filed numerous patent applications both in the United States and in certain foreign jurisdictions to obtain patent rights to our inventions, with claims directed to compositions-of-matter, methods of use, formulations, combination therapy and other technologies relating to our product candidates. There can be no assurance that any of these patent applications will issue as patents or, for those applications that do mature into patents, whether the claims of the patents will exclude others from making, using or selling our product or product candidates, or products or product candidates that are substantially similar to ours. In countries where we have not and do not seek patent protection, third parties may be able to manufacture and sell products that are substantially similar or identical to our products or product candidates without our permission, and we may not be able to stop them from doing so.

Similar to other biotechnology companies, our patent position is generally highly uncertain and involves complex legal and factual questions. In this regard, we cannot be certain that we or our current or future licensors, licensees, partners or collaborators were the first to make an invention, or the first inventors to file a patent application claiming an invention in our owned or licensed patents or pending patent applications. In addition, even if patents are issued, given the amount of time required for the development, testing and regulatory review of our product candidates, any patents protecting such candidates might expire before or shortly after the resulting products are commercialized. Moreover, the laws and regulations governing patents could change in unpredictable ways that could weaken the ability of us and our current or future licensors, licensees, partners or collaborators to obtain new patents or to enforce existing patents and patents we may obtain in the future. In any event, the issuance, scope, validity, enforceability and commercial value of our patent rights and those of our current or future licensors, licensees, partners or collaborators are highly uncertain and may not effectively prevent others from commercializing competitive technologies and products.

In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees, partners 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, partners 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, partners or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised.

In addition, the legal protection afforded to inventors and owners of intellectual property in countries outside of the United States may not be as broad or effective as that in the United States and we may be unable to acquire and enforce intellectual property rights outside the United States to the same extent as in the United States, if at all. Accordingly, our efforts, and those of our licensors, licensees, partners or collaborators, to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

We own one issued United States patent that covers our NGM621 product candidate, although the product and related compositions-of-matter and methods of use are disclosed and claimed in other pending U.S. non-provisional and/or national stage applications in particular foreign countries. We do not currently own or have a

license to any issued patents that cover our NGM707, NGM831 and NGM438 product candidates, although these product candidates are disclosed and claimed in our pending U.S. non-provisional and international applications. The patent landscape surrounding all of our product candidates is crowded, and there can be no assurance that we will be able to secure patent protection that would adequately cover such product candidates, that we will obtain sufficiently broad claims to be able to prevent others from selling competing products or that we will be able to protect and maintain any patent protection that we initially secure.

Any changes we make to our product candidates to cause them to have what we view as more advantageous properties may not be covered by our existing patents and patent applications, and we may be required to file new patent applications and/or seek other forms of protection for any such altered product candidates. The patent landscape surrounding the technology underlying our product candidates is crowded, and there can be no assurance that we would be able to secure patent protection that would adequately cover an alternative to any of our product candidates.

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

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

Depending on what patent claims ultimately issue and how courts construe the issued patent claims, as well as the ultimate formulation and method of use of our product candidates, we may need to obtain a license to practice the technology claimed in such patents. There can be no assurance that such licenses will be available on commercially reasonable terms, or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing rights to third-party intellectual property rights we have, we might be unable to develop and commercialize one or more of our product candidates, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

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

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

Third parties may infringe patents or misappropriate or otherwise violate intellectual property rights owned or controlled by us or our current or future licensors, licensees, partners 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, partners 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, partners or collaborators initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office, or USPTO, or made a misleading statement during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us or our current or future licensors, licensees, partners 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, partners 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, partners or collaborators. These proceedings can be expensive 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, partners 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, partners 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, partners or collaborators could be dissuaded from collaborating with us to license, develop or commercialize current or future product candidates if the breadth or strength of protection provided by our patents and patent applications is threatened. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees.

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

Third parties may initiate legal proceedings against us or our current or future licensors, licensees, partners or collaborators alleging that we infringe their intellectual property rights. Alternatively, we may initiate legal proceedings to challenge the validity or scope of intellectual property rights controlled by third parties, including in

oppositions, interferences, revocations, reexaminations, *inter partes* review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. In this regard, we are aware of several third-party patents and patent applications containing claims directed to compositions-of-matter, methods of use and related subject matter, some of which pertain, at least in part, to subject matter that might be relevant to our product candidates. These proceedings can be expensive and time-consuming, and many of our adversaries may have the ability to dedicate substantially greater resources to prosecuting these legal actions than us.

In addition, we may be subject to claims that we or our employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer, or that third parties have an interest in our patents as an inventor or co-inventor. Likewise, we and our current or future licensors, licensees, partners or collaborators may be subject to claims that former employees, partners, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. Litigation may be necessary to defend against these claims.

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

An unfavorable outcome in any such proceeding could require us and our current or future licensors, licensees, partners 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 may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or our licensors' inventions in all countries outside the United States, even in jurisdictions where we or our licensors do pursue patent protection. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own competing products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

In Europe, expected by the end of 2023, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or the UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. It is our initial belief that the UPC, while offering a cheaper streamlined process, has potential disadvantages to patent holders, such as making a single European patent vulnerable in all jurisdictions when challenged in a single jurisdiction.

Risks Related to Ownership of Our Common Stock

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

The market price for our common stock has fluctuated significantly from time to time, for example, varying between a high of $32.12 on March 17, 2021 and a low of $2.92 on October 17, 2022. 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:

- results of clinical trials of our product candidates or those of our competitors;
- our ability to raise adequate capital through public or private equity or debt offerings or negotiate potential future BD Arrangements;
- the success of competitive products or technologies, including disclosure of data by our competitors;
- regulatory actions with respect to our product candidates or our competitors’ product candidates or products;
- timeline delays in our clinical trials, including delays resulting from the effects of the ongoing global COVID-19 pandemic or otherwise;
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us or our competitors or partners of significant acquisitions, strategic collaborations, joint ventures 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;
- purchases or 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 and the conflict between Russia and Ukraine, 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 effects of the ongoing COVID-19 pandemic, macroeconomic factors including inflation and rising interest rates, and geopolitical instability, including instability resulting from the conflict between Russia and Ukraine and the related sanctions imposed against Russia, 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 elsewhere in this “Risk Factors” section, could have a dramatic and material adverse impact on the market price of our common stock.

Because of 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 to the risk factor titled “*An active trading market for our common stock may not be sustained and sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.*”

Our principal stockholders, including entities affiliated with The Column Group, Merck and management, own a substantial percentage of our stock and collectively 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 collectively may be able to determine all matters requiring stockholder approval. For example, these stockholders collectively 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 our common stock, our stock price could fall.

An active trading market for our common stock may not be sustained and sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

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.

For the trading days during the nine months ended September 30, 2022, the average daily trading volume for our common stock on The Nasdaq Global Select Market was only 376,739 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 by any of our large stockholders, or even the perception in the market that we or the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. In addition, as a result of the low trading volume of our common stock, the trading of relatively small quantities of shares by our stockholders could disproportionately influence the market price of our common stock in either direction. The price for our shares could, for example, decline significantly in the event that a large number of shares of our common stock are sold on the market without commensurate demand, as compared to an issuer with a higher trading volume that could better absorb those sales without an adverse impact on its stock price. Moreover, certain holders of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

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

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

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

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

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

- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law 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 Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, which is generally a person that together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Certain provisions in our agreement with Merck may also deter a change of control. For example, under the Amended Collaboration Agreement, 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, if any.

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 owed by any director, officer or other employee to us or our stockholders; any action asserting a claim against us or any director or officer or other employee arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws; any action with respect to the validity of our amended and restated certificate of incorporation or amended and restated bylaws; any action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; or any action asserting a claim against us or any director or officer or other employee that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Securities and Exchange Act of 1934, as amended, or the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act of 1933, as amended, or the Securities Act, creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

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

General Risk Factors

We, our CROs, our CMOs, our current and potential future partners and other third parties we rely on or partner with could experience a cybersecurity incident that could harm our business.

We collect, store and transmit proprietary, confidential and sensitive information, including personal information (such as health-related data), in the course of our business. Our technology systems and the information and data processed and stored in our technology systems or otherwise by us or on our behalf, and the technology systems of, and data accessed on our behalf by, our research collaborators, partners, CROs, CMOs, contractors, consultants and other third parties on which we depend to operate our business, may be vulnerable to security breaches, loss, damage, corruption, unauthorized access, use or disclosure or misappropriation. Such incidents may result from the actions of a wide variety of actors, including traditional hackers, our personnel or the personnel of the third parties we work with, sophisticated nation-states and nation-state-supported actors. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. Threats we and third parties on which we rely may face are constantly evolving and include (without limitation) malware, viruses, software vulnerabilities and bugs, software or hardware failure, hacking, denial of service attacks, social engineering (including phishing), ransomware, inside threats, credential stuffing or other cyberattacks, telecommunications failures, earthquakes, fires, floods and similar threats. Threats such as ransomware attacks, for example, are becoming increasingly prevalent and severe. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Supply-chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. Our ability to monitor third parties on whom we rely to operate our business is limited, and these third parties may be subject to, and may expose us to, cyberattacks and other security incidents.

We may, under certain data privacy and security obligations, be required to, or we may choose to, expend significant resources or modify our business activities (including our clinical trial activities) in an effort to protect against security incidents. While we have developed systems and processes designed to protect the integrity, confidentiality and security of the confidential and personal information under our control, we cannot assure you that any security measures that we or our third-party service providers implement will be effective in preventing cybersecurity incidents. There are many different cyber-crime and hacking techniques, and as such techniques continue to evolve, we may be unable to anticipate attempted security breaches, identify them before our information is exploited or react in a timely manner.

Certain functional areas of our workforce work remotely on a full- or part-time basis outside of our corporate network security protection boundaries or otherwise utilize network connections, computers and devices outside of our premises or network, which imposes additional risks to our business, including increased risk of industrial espionage, phishing and other cybersecurity attacks, and unauthorized dissemination of proprietary or confidential information, including personal information, any of which could have a material adverse effect on our business.

Despite our efforts to strengthen security and authentication measures, we have not always been able in the past, and may be unable in the future, to detect vulnerabilities in our information technology systems. We have experienced an overall increase in cybersecurity incidents since 2020, none of which, to date, have caused material disruption to our business, or to our knowledge, involved a material security breach. For example, in December 2020, we detected that an attacker had gained access to a single system on our network and unsuccessfully attempted to use that access to stage a broader attack against us. We or the third parties we rely on or partner with could experience a material system failure, security breach or other cybersecurity incident, including any related to or in connection with any of the aforementioned threats, in the future, which could interrupt our operations, disrupt our development programs and have a material adverse effect on our business, financial condition and results of operations. For example, the loss or corruption of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates, to analyze clinical trial samples and to conduct clinical trials, and cybersecurity incidents experienced by these third parties could have a material adverse effect on our business. Security breaches and other cybersecurity incidents affecting us or the third parties we rely on or partner with could also result in substantial remediation costs and expose us to litigation (including class claims), regulatory enforcement action (for example, investigations, fines, penalties, audits and inspections), additional reporting requirements and/or oversight, fines, penalties, indemnification obligations, negative publicity, reputational harm, monetary fund diversions, interruptions in our operations (including availability of data), financial loss and other liabilities and harms. Additionally, such incidents may trigger data privacy and

security obligations requiring us to notify relevant stakeholders. These disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from claims related to our data privacy and security obligations. Additionally, we cannot be certain that our insurance coverage will be adequate for data security liabilities actually incurred, will continue to be available to us on economically and commercially reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could adversely affect our reputation, business, financial condition and results of operations.

The withdrawal of the United Kingdom from the EU, commonly referred to as Brexit, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our business and our financial results.

The United Kingdom's, or UK, withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created significant uncertainty concerning the future relationship between the UK and the EU. The Medicines and Healthcare products Regulatory Agency, or MHRA, is now the UK's standalone regulator.

On December 24, 2020, the EU and UK reached an agreement in principle on the framework for their future relationship, the EU-U.K. Trade and Cooperation Agreement, or the TCA. The TCA primarily focuses on ensuring free trade between the EU and the UK in relation to goods, including medicinal products. Although the body of the TCA includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the TCA.

Among the changes that are now applied are that Great Britain (England, Scotland and Wales) are treated as a third country. Northern Ireland, with regard to EU regulations, continues to follow many aspects of EU regulatory rules. As part of the TCA, the EU and the UK recognize GMP inspections carried out by the other party and accept official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The eventual adoption of the Retained EU Law (Revocation and Reform) Bill that is currently going through the UK adoption procedure may, however, result in substantial change to the extent to which EU laws influence these and other actions in the UK.

After running a public consultation which ended in December 2022, the UK government unilaterally agreed to permanently accept EU batch testing and batch release. However, it is not certain whether the UK will continue this approach, particularly following adoption of the current Retained EU Law (Revocation and Reform) Bill. If the UK were to adopt an approach whereby re-testing and/or re-release in the UK would be required, this could result in increased costs. Furthermore, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the UK must be retested and re-released when entering the EU market for commercial use. As regards marketing authorizations, Great Britain has a separate regulatory submission process, approval process and a national marketing authorization. Northern Ireland, however, continues to be covered by the marketing authorizations granted by the European Commission.

The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation) and, as such, it falls within the scope of the Retained EU Law (Revocation and Reform) Bill as currently drafted. Adoption of the Retained EU Law (Revocation and Reform) Bill as currently drafted would result in the regulatory framework governing clinical trials in the UK being revoked unless Ministerial action were taken to retain or replace it. It is currently unclear to what extent the UK will seek to align its regulations with the EU following entry into application of the Clinical Trials Regulation in the EU which occurred on January 31, 2022.

Since January 1, 2021, an applicant for a marketing authorization granted by the European Commission in accordance with the centralized procedure based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA can no longer be established in the UK. Since this date, companies established in the UK cannot use the centralized procedure and instead must follow one of the UK national authorization procedures to obtain a marketing authorization to market products in the UK. For an initial two-year period from January 1, 2021, MHRA could rely on a decision taken by the European Commission on the approval of a new centralized procedure marketing authorization when determining an application for a Great Britain marketing

authorization, or use the MHRA's decentralized or mutual recognition procedures which enable marketing authorizations approved in EEA countries to be granted in Great Britain. Post Brexit, the MHRA has been updating various aspects of the regulatory regime for medicinal products in the UK. These include: introducing the Innovative Licensing and Access Procedure to accelerate the time to market and facilitate patient access for innovative medicinal products; updates to the UK national approval procedure, introducing a 150-day objective for assessing applications for marketing authorizations in the UK, Great Britain and Northern Ireland and a rolling review process for marketing authorization applications (rather than a consolidated full dossier submission). In September 2022, the MHRA extended the procedure whereby it may rely on a decision taken by the European Commission when determining an application for a Great Britain marketing authorization until December 31, 2023.

Orphan designation in Great Britain following Brexit is, unlike in the EU, not a pre-marketing authorization. Applications for orphan designation are made at the same time as an application for a marketing authorization. The criteria to be granted an orphan drug designation are essentially identical to those in the EU but based on the prevalence of the condition in Great Britain. It is therefore possible that medical conditions that were or would have been designated as orphan conditions in Great Britain prior to the end of the Transition Period are or would no longer be and that conditions that were not or would not have been designated as orphan conditions in the EU will be designated as such in Great Britain.

Since a significant part of the regulatory framework in the UK applicable to our business and our product candidates is derived from EU legislation, Brexit has the potential of materially impacting the regulatory framework with respect to the development, manufacture, approval, import and placement of our product candidates on the market in the UK and the EU. The changes effected by the TCA, as well as any future changes in the regulatory framework governing medicinal products, including the adoption of the Retain EU Law (Revocation and Reform) Bill, could increase the costs and complexity of doing business in or with the UK, which could adversely affect our business.

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

We may collect, use, transfer or otherwise process proprietary, confidential and sensitive information, including personal information (including health-related data), which subjects us to numerous evolving and complex data privacy and security obligations, including various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts and other obligations that govern the processing of such information by us and on our behalf. Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, and the United Kingdom's GDPR, or UK GDPR, impose strict requirements for processing personal information. For example, the EU GDPR, UK GDPR and other relevant laws that govern patient confidentiality and storage of personal health data may apply to our processing of personal information from clinical trials participants and other individuals located in the European Economic Area, or EEA, and/or the UK and, if any of our product candidates are approved, we may seek to commercialize those products in the EEA and/or the UK (as applicable). Companies that violate the EU GDPR can face private litigation, prohibitions on data processing, other administrative measures, reputational damage and fines of up to the greater of 20 million Euros or 4% of their worldwide annual revenue. The EU GDPR requires us to, among other things: give detailed disclosures about how we collect, use and share personal information; contractually commit to data protection measures in our contracts with vendors; maintain adequate data security measures; notify regulators and affected individuals of certain data breaches; meet extensive privacy governance and documentation requirements; and honor individuals' data protection rights, including their rights to access, correct and delete their personal information. The UK has incorporated an amended version of the EU GDPR into UK law, commonly referred to as the UK GDPR, which is independent from, but at present materially aligned with, the EU GDPR, which together with the UK Data Protection Act of 2018, or UK DPA, covers the processing of personal information of UK residents. Non-compliance with UK GDPR may result in substantially similar adverse consequences to those in relation to the EU GDPR, including monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher.

On June 28, 2021, the European Commission adopted an adequacy decision permitting flows of personal data between the EU and the UK to continue without additional requirements. The UK Government also adopted a reciprocal adequacy decision in respect of EEA member states permitting flows of personal data from the UK to the EEA. However, the European Commission's UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/extends that decision and remains under review by the European Commission during this period. The entry into force of the US-UK Data Access Agreement on October 3, 2022 may put at risk the European Commission's adequacy decision granted to the UK. If such adequacy decision were to be

withdrawn, personal data could not flow freely between the UK and the EU and additional safeguards would need to be adopted, which could result in additional costs for us.

The relationship between the UK and the EU in relation to certain aspects of data protection laws remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the UK will be regulated in the long term. The UK's Data Protection and Digital Information Bill, or the Bill, was laid before the UK Parliament on July 18, 2022, introducing reforms intended to update and simplify the UK's data protection framework, deviating from the EU GDPR. However, the Bill's progress through Parliament is currently on pause following changes to the UK Government's leadership. The Bill is expected to re-enter the legislative process in due course.

Certain jurisdictions have enacted data localization laws and laws restricting cross-border transfers of personal information. In particular, regulators and courts in the EEA and the UK have significantly restricted the transfer of personal information to the United States and other countries whose privacy laws it believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal information from the EEA and UK to the United States in compliance with law, such as the EEA's standard contractual clauses and the UK's international data transfer agreement, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal information to the United States.

We continue to monitor changes in data protection laws related to the cross-border transfer of personal information; however, uncertainty remains regarding any future regulations, interpretations of existing law or guidance that may be issued, particularly by the EU authorities. If we are unable to implement a valid compliance solution for cross-border transfers of personal information, or if the requirements for a legally-compliant transfer are too onerous, we will face increased exposure to significant adverse consequences, including substantial fines, regulatory actions, as well as injunctions against the export and processing of personal information from the EEA. Our inability to import personal information from the EEA, UK or Switzerland or other countries may also restrict or prohibit our clinical trial activities in those countries; limit our ability to collaborate with CROs, service providers, contractors and other companies subject to laws restricting cross-border data transfers; require us to increase our data processing capabilities in other countries at significant expense and may otherwise negatively impact our business operations. We may also become subject to new laws in the EEA that regulate cybersecurity and non-personal data, such as data collected through the internet of things. Depending on how these laws are interpreted, we may have to make changes to our business practices and products to comply with such obligations.

Additionally, other countries have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of delivering our services and operating our business.

Privacy and data security laws in the United States at the federal, state and local level are increasingly complex and changing rapidly. For example, at the federal level, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information. Additionally, at the state level, the privacy and data protection landscape is changing rapidly. For example, the California Consumer Privacy Act of 2018, or CCPA, took effect on January 1, 2020. The CCPA gives California residents certain rights similar to the individual rights given under the EU GDPR, including the right to access and delete their personal information, opt-out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, including statutory fines for noncompliance and a limited private right of action in connection with certain data breaches. In addition, the California Privacy Rights Act of 2020, or CPRA, which becomes operative January 1, 2023, will expand the CCPA's requirements, including in that it applies to personal information of business representatives and employees and establishes a new regulatory agency to implement and enforce the law. While the CCPA contains an exemption for certain personal information processed in connection with clinical trials, we may process other personal information that is subject to the CCPA and forthcoming CPRA. Other states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. The evolving patchwork of differing state and federal privacy and data security laws increases the cost and complexity of operating our business and increase our exposure to liability.

We may also be bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. We may publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive,

unfair or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion. These obligations may be subject to differing applications and interpretations, which may be inconsistent or in conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources). These obligations may necessitate changes to our information technologies, systems and practices and to those of any third parties that process personal information on our behalf. In addition, these obligations may require us to change aspects of our business model. Although we endeavor to comply with applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could impact whether or not we are in compliance.

If we (or third parties on which we rely) fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences, including (without limitation): government enforcement actions (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

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

Our facilities have experienced electrical blackouts as a result of a shortage of available electrical power. Future blackouts, which may be implemented by the local electricity provider in the face of high winds and dry conditions, could disrupt our operations. Our facility is located in a seismically active region. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major earthquake, fire, power loss, terrorist activity or other disasters and do not have a comprehensive recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. In addition, the sole supplier of clinical drug substances for NGM120, NGM707, NGM831, NGM438 and MK-3655 is located in Lithuania, a region that has experienced political unrest. Refer to the risk factor titled "*We rely completely on CMOs for the manufacture of our product candidates and 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*." If our operations or the operations of third parties providing services to us are disrupted by any such occurrences, our business and future prospects may be negatively affected.

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.

Our ability to use net operating loss carryforwards and certain other tax attributes 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 BD Arrangements. 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 federal net operating loss carryforwards generated in tax years beginning before January 1, 2018 are only permitted

to be carried forward for 20 years under applicable U.S. tax law. Under the 2017 Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, our federal net operating losses generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the ability to deduct such federal net operating losses generated in tax years beginning after December 31, 2020 is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the 2017 Tax Act or the CARES Act.

In addition, under Sections 382 and 383 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 and certain other pre-change tax attributes (such as R&D tax credits) to offset our post-change income may be limited. Due to our initial public offering and other shifts in our stock ownership, we have experienced ownership changes in the past and may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our use of federal net operating loss carryforwards and certain other tax attributes 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.

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 tax laws, statutes, rules, regulations, directives, decrees or ordinances could be enacted at any time. Further, existing tax laws, statutes, rules, regulations, directives, decrees or ordinances could be interpreted, changed or modified. Any such enactment, interpretation, change or modification could adversely affect us, possibly with retroactive effect. For example, the recently enacted IRA imposes, among other rules, a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases. In addition, for certain research and experimental, or R&E, expenses incurred in tax years beginning after December 31, 2021, the 2017 Tax Act requires the capitalization and amortization of such expenses over five years if incurred in the United States and fifteen years if incurred outside the United States, rather than deducting such expenses currently. Although there have been legislative proposals to repeal or defer the capitalization requirement, there can be no assurance that such requirement will be repealed, deferred or otherwise modified. 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, as amended by the CARES Act or any future tax reform legislation could have a material impact on the value of our deferred tax assets, result in significant one-time charges and 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 continue to incur increased costs as a result of operating as a public company, and our management devotes substantial time to compliance initiatives. In addition, we are obligated to develop and maintain proper and effective internal control over financial reporting. In the future, we may not complete our analysis of our internal control over financial reporting in a timely manner, or our internal control over financial reporting may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

As a public company, we incur significant legal, accounting, insurance and other expenses, and these expenses further increased in connection with our loss of "emerging growth company" status as of December 31, 2021. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley

Act of 2002, or 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 maintaining effective internal controls and procedures. The Sarbanes-Oxley Act requires, among other things, 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. In addition, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting, as required by Section 404(b) of the Sarbanes-Oxley Act, and to allow our independent registered public accounting firm to issue an attestation report on the effectiveness of our internal control over financial reporting. Our compliance with Section 404(b) of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit staff and outsource this function to a third party. We have hired and will need to retain our current accounting and financial staff who have the appropriate public company experience and technical accounting knowledge. If we or our independent registered public accounting firm identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, 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 ability to successfully implement our business plan and comply with Section 404(b) of the Sarbanes-Oxley Act requires us to be able to prepare timely and accurate financial statements. We expect that we will need to continue to improve existing, and implement new operational and financial systems, procedures and controls to manage our business effectively. Any delay in the implementation of, or disruption in the transition to, new or enhanced systems, procedures or controls may cause our operations to suffer, and we may be unable to conclude that our internal control over financial reporting is effective and to obtain an attestation report from our independent registered public accounting firm as required under Section 404(b) of the Sarbanes-Oxley Act. This, in turn, could have an adverse impact on the price for our common stock and could adversely affect our ability to access the capital markets.

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 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, any BD Arrangements we may enter into, our financial information and other disclosures. If securities or industry analysts do not publish research or reports about our business, delay publishing reports about

our business or publish negative reports about our business, regardless of accuracy, our stock price and trading volume could decline.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease and occupy approximately 122,000 square feet of office space and facilities in South San Francisco, California. In July 2022, we entered into an operating lease agreement, or the 2024 Lease Agreement, for our existing corporate office space and facilities at 333 Oyster Point Boulevard, South San Francisco, California, that we currently occupy pursuant to a sublease agreement scheduled to expire on December 31, 2023. The initial term of the 2024 Lease Agreement will commence on January 1, 2024 and expire on December 31, 2033.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

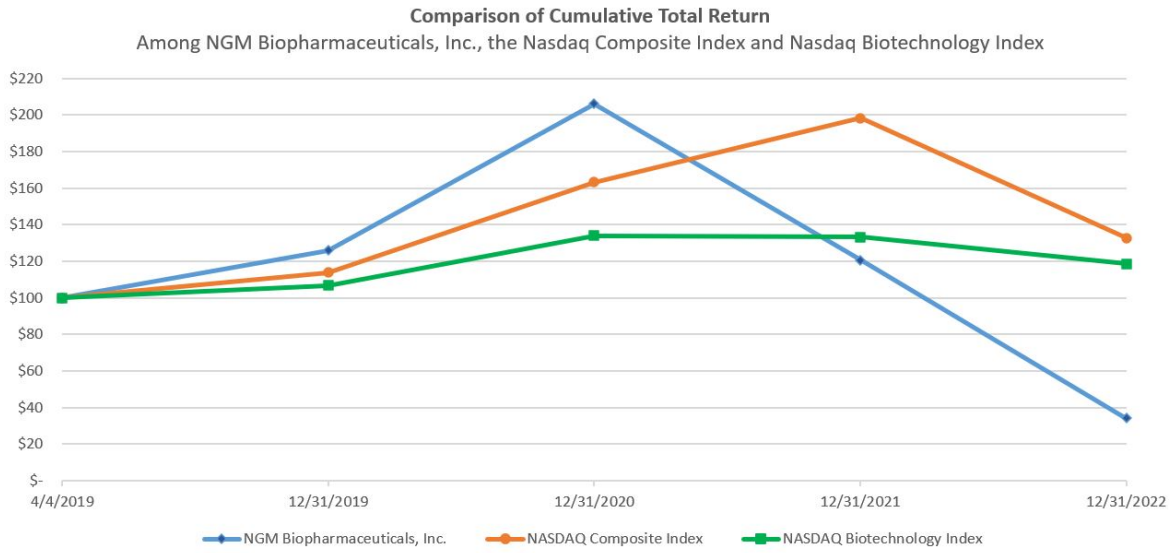
Our common stock has been listed on the Nasdaq Global Select Market under the symbol "NGM" since April 4, 2019.

Holders of Record

As of the close of business on February 22, 2023, there were 38 stockholders of record of our common stock. The actual number of stockholders is greater than the number of stockholders of record and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of stockholders of record also does not include stockholders whose shares may be held in trust by other entities.

Performance Graph

The following stock performance graph compares the value of an investment in (i) our common stock, (ii) the Nasdaq Composite Index and (iii) the Nasdaq Biotechnology Index for the period from April 4, 2019 (the date our common stock commenced trading on the Nasdaq Global Select Market) through December 31, 2022. The figures represented below assume an investment of $100 in our common stock at the closing price on April 4, 2019 and in the Nasdaq Composite Index and Nasdaq Biotechnology Index on April 4, 2019 and the reinvestment of dividends into shares of common stock. However, no dividends have been declared on our common stock to date. The comparisons in the table are required by the Securities and Exchange Commission, or SEC, and are not intended to forecast or be indicative of possible future performance of our common stock.



	4/4/2019	12/31/2019	12/31/2020	12/31/2021	12/31/
NGM Biopharmaceuticals, Inc.	$ 100.00	$ 125.78	$ 206.09	$ 120.48	$
NASDAQ Composite Index	100.00	113.70	163.31	198.24	
NASDAQ Biotechnology Index	100.00	106.66	134.05	133.20	

The information under "Performance Graph" is not deemed to be "soliciting material" or "filed" with the SEC or subject to Regulation 14A or 14C, or to the liabilities of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and is not to be incorporated by reference in any filing of NGM under the Securities

Act of 1933, as amended, or the Securities Act, or the Exchange Act, whether made before or after the date of this Annual Report on Form 10-K and irrespective of any general incorporation language in those filings.

Recent Sales of Unregistered Securities

During the year ended December 31, 2022, we did not issue or sell any unregistered securities.

Issuer Purchases of Equity Securities

During the three-month period ended December 31, 2022, we did not repurchase shares of our common stock.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and related notes appearing elsewhere in this Annual Report. This discussion and analysis contains forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors that could impact our business, including those set forth in the section titled "Risk Factors" under Part I, Item 1A in this Annual Report on Form 10-K. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "aspire," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "should," "will" or the negative of these terms or other similar expressions. See "Special Note Regarding Forward-Looking Statements" in this Annual Report on Form 10-K.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate we have conducted exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

Overview of Our Business

We are a biopharmaceutical company focused on discovering and developing novel, potentially life-changing medicines based on scientific understanding of key biological pathways underlying grievous diseases with critical unmet or underserved patient need. These diseases represent a significant burden for patients and 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 portfolio of product candidates ranging from early discovery to Phase 2b development. Currently, we have five programs in active clinical development. Our biology-centric drug discovery approach is therapeutic area agnostic and aims to seamlessly integrate interrogation of complex disease-associated biology and protein engineering expertise to unlock proprietary insights that are leveraged to generate promising product candidates and enable their rapid advancement into proof-of-concept studies. As explorers on the frontier of life-changing science, we aspire to operate one of the most productive research and development engines in the biopharmaceutical industry. All therapeutic candidates in our pipeline have been generated by our in-house discovery engine, led by biology and motivated by patient need.

Our pipeline is currently divided into two categories with separate approaches to development strategy and resource allocation in an effort to enable more of the product candidates in our pipeline to be advanced as effectively and efficiently as possible. To that end, we are currently focusing most of our execution efforts and resources on advancing our clinical-stage solid tumor oncology programs to potentially rapid proof of concept. For our other programs that are in therapeutic areas where clinical development is relatively resource intensive and can have long timelines to generate proof-of-concept data, due to the need to conserve capital and prioritize focused execution, we are actively seeking, or intend to seek, collaboration, out licensing, partnership or other business development arrangements, or BD Arrangements, with third-party partners with sufficient resources and relevant domain expertise in order to further their development.

Pipeline Programs and Operational Updates

Key Programs in Active Development

Our pipeline includes four solid tumor oncology programs in active ongoing clinical development. We are currently focusing most of our execution efforts and resources on these key programs. We have intentionally built our clinical capabilities primarily in areas such as solid tumor oncology that offer development paths that are relatively resource efficient and have the potential to generate clinical proof-of-concept data more rapidly than certain other indications, although we may in the future pursue development of programs in other therapeutic areas. While we will opportunistically consider BD Arrangements to advance development of our key programs, we intend to invest our resources in their development even in the absence of BD Arrangements.

- **Solid Tumor Oncology**. Our solid tumor oncology product candidates NGM707, NGM831, NGM438 and NGM120 and their related compounds are wholly-owned by us.
  - **NGM707**. NGM707, the lead asset in our myeloid reprogramming and checkpoint inhibition portfolio, is a dual antagonist monoclonal antibody that is designed to improve patient immune responses to tumors by inhibiting both Immunoglobulin-like transcript 2, or ILT2 (also known as LILRB1), and Immunoglobulin-like transcript 4, or ILT4 (also known as LILRB2) receptors. We believe NGM707 has the potential to reprogram ILT4- and ILT2-expressing myeloid cells to shift them from a suppressive state that restricts anti-tumor immunity to a stimulatory state that may promote anti-tumor immunity. Blocking ILT2 also may reverse inhibition of ILT2-expressing lymphoid cells to further stimulate anti-tumor immune responses.
    - We are conducting an open-label Phase 1/2 clinical trial evaluating NGM707 as a monotherapy and in combination with KEYTRUDA® (pembrolizumab) for the treatment of patients with advanced or metastatic solid tumors. We expect to enroll approximately 220 patients in this trial.
    - A Phase 1, Part 1a cohort evaluating NGM707 as a monotherapy was initiated in the second quarter of 2021. A Phase 1, Part 1b cohort evaluating NGM707 in combination with pembrolizumab was initiated in the second quarter of 2022. Both cohorts are ongoing and will be followed by Phase 2 expansion cohorts evaluating NGM707 in combination with pembrolizumab in specific tumor types.
    - In December 2022, we presented initial data from the Part 1a cohort at the European Society for Medical Oncology Immuno-Oncology, or ESMO I-O, Annual Congress. The data indicated that NGM707 was generally well tolerated across all dose cohorts and demonstrated promising early signals of anti-tumor activity. In the presentation, we disclosed that of 24 response-evaluable patients as of November 23, 2022, best overall responses were a partial response in one patient, stable disease in six patients and non-complete response/non-progressive disease in one patient, and that potential proof-of-mechanism (myeloid reprogramming) was observed in peripheral blood and tumor biopsies.
  - **NGM831**. NGM831 is an antagonist antibody that is designed to block the interaction of the Immunoglobulin-like transcript 3, or ILT3 (also known as LILRB4) receptor, with fibronectin, as well as other cognate ligands. For tumors in which both ILT3 and fibronectin are upregulated, the ILT3-fibronectin signaling pathway may act as a stromal checkpoint to repress myeloid cell function and inhibit anti-tumor immunity. By inhibiting ILT3's interaction with fibronectin and its other ligands, we believe NGM831 has the potential to mobilize a patient's own immune system to fight tumors by shifting myeloid cells from a suppressive state to a stimulatory state and promoting anti-tumor activity.
    - In the first quarter of 2022, we initiated an open-label Phase 1/1b clinical trial to evaluate NGM831 as a monotherapy and in combination with pembrolizumab for the treatment of patients with advanced or metastatic solid tumors. A Phase 1, Part 1a cohort evaluating NGM831 as a monotherapy was initiated in the first quarter of 2022 and is ongoing. In addition, a Phase 1, Part 1b cohort evaluating NGM831 in combination with pembrolizumab was initiated in the third quarter of 2022 and is ongoing. We expect to enroll up to approximately 80 patients in these two cohorts.
  - **NGM438**. NGM438 is an antagonist antibody that is designed to inhibit leukocyte-associated immunoglobulin-like receptor 1, or LAIR1, and thereby promote anti-tumor immune responses. NGM438 has the potential to potently block the binding of all collagens to LAIR1, including tumor-derived collagens. Collagens produced by the tumor stroma, meaning the non-malignant, non-

immune components of the tumor, are believed to bind LAIR1 to create an immuno-suppressive tumor microenvironment. The interaction of collagens from the tumor stroma with LAIR1 on immune cells represents a “stromal checkpoint” that restrains anti-tumor immune responses. Reinvigoration of these collagen-suppressed immune cells by blocking the binding of collagens to LAIR1 may address a key resistance mechanism that limits tumor responses to current immunotherapies.

- In the second quarter of 2022, we initiated an open-label, Phase 1/1b clinical trial to evaluate NGM438 as a monotherapy and in combination with pembrolizumab for the treatment of patients with advanced or metastatic solid tumors. A Phase 1, Part 1a cohort evaluating NGM438 as a monotherapy commenced in the second quarter of 2022 and is ongoing. In addition, a Phase 1, Part 1b cohort evaluating NGM438 in combination with pembrolizumab commenced in the fourth quarter of 2022 and is ongoing. We expect to enroll up to approximately 80 patients in these two cohorts.

- **NGM120**. NGM120 is an antagonist antibody that binds to glial cell-derived neurotrophic factor receptor alpha-like, or GFRAL, and is designed to block the effects of elevated serum levels of growth differentiation factor 15, or GDF15. We designed NGM120 as a potent, humanized monoclonal antibody inhibitor of GFRAL with the potential for once-monthly or less frequent dosing. Preclinical studies suggest that NGM120 may reduce tumor growth and improve survival in syngeneic orthotopic pancreatic tumor models in mice.
  - We are currently conducting a Phase 1/2 clinical trial to assess NGM120’s effect on cancer and cancer-related cachexia in patients with select advanced solid tumors, metastatic pancreatic cancer and metastatic castration-resistant prostate cancer, or mCRPC.

    The trial includes:
    - a Phase 1a cohort evaluating NGM120 as a monotherapy in patients with select advanced solid tumors,
    - a Phase 1b cohort evaluating NGM120 in combination with gemcitabine and Nab-paclitaxel in patients with metastatic pancreatic cancer,
    - an additional Phase 1b cohort testing NGM120 in combination with one or more lines of hormone therapies in patients with mCRPC, and
    - a Phase 2 cohort evaluating NGM120 in combination with gemcitabine and Nab-paclitaxel as first-line treatment in patients with metastatic pancreatic cancer (referred to as the PINNACLES trial).
  - In August 2022, we initiated the Phase 1b cohort testing NGM120 in combination with one or more lines of hormone therapies in patients with mCRPC.
  - In September 2022, at the European Society for Medical Oncology, or ESMO, Annual Congress, we reported updated preliminary findings for a subgroup of patients with advanced prostate cancer from the Phase 1a cohort evaluating NGM120 as a monotherapy in patients with select advanced solid tumors. The updated preliminary results reported at ESMO demonstrated that NGM120 was well tolerated with no dose-limiting toxicities and provided encouraging signals of anti-cancer activity in patients with advanced prostate cancer.
  - In September 2022, at the American Association for Cancer Research, or AACR, Special Conference: Pancreatic Cancer, we reported updated preliminary findings from the Phase 1b cohort evaluating NGM120 in combination with gemcitabine and Nab-paclitaxel in patients with metastatic pancreatic cancer. The updated preliminary results reported at AACR demonstrated that NGM120 was well tolerated with no dose-limiting toxicities and provided encouraging signals of anti-cancer activity in patients with metastatic pancreatic cancer.

Additional Programs Currently Without Significant Resource Allocation

Due to the need to conserve capital and prioritize focused execution, the remainder of our pipeline includes programs whose further development is primarily dependent on our ability to secure potential future BD Arrangements. These programs are in therapeutic areas where clinical development is relatively resource intensive and can have long timelines to generate proof-of-concept data. As a result, we are actively seeking, or intend to seek, BD Arrangements with third-party partners possessing sufficient resources and relevant domain expertise in the relevant therapeutic area in order to further clinical development of these programs. In the absence of such BD Arrangements for these programs, we are unlikely to be able to advance their development unless our portfolio

prioritization changes and we have access to the necessary capital to fund such development. These programs are set forth below:

- **Retinal diseases**.
  - **NGM621**. NGM621 is a humanized Immunoglobulin 1, or IgG1, monoclonal antibody administered via intravitreal, or IVT, injection. NGM621 was engineered to potently bind to, and be a long-acting inhibitor of, complement C3 with the treatment goal of reducing the rate of disease progression in patients with geographic atrophy, or GA, secondary to age-related macular degeneration, or AMD.
    - In October 2022, we announced topline results from the Phase 2 CATALINA clinical trial, which evaluated the efficacy and safety of NGM621 when given to patients with GA every four weeks or every eight weeks via IVT injections compared to sham control. The trial did not meet its primary endpoint of a statistically significant rate of change in GA lesion area using slope analysis over 52 weeks of treatment with NGM621 versus sham. NGM621 demonstrated a favorable safety profile, with no evidence of increased choroidal neovascularization in NGM621-treated patients compared to sham. In addition, there were no serious adverse events deemed treatment-related by an investigator.
    - In November 2022, we presented additional findings from the CATALINA trial at The Retina Society Annual Scientific Meeting and we intend to continue to evaluate various pre-specified secondary endpoints and post-hoc analyses relating to NGM621.
    - Merck had a one-time option to license NGM621 and its related compounds upon completion of the CATALINA trial. In December 2022, Merck notified us that it would not exercise its option to license NGM621 and its related compounds, nor would Merck exercise the related ophthalmology bundle option; accordingly, these options expired unexercised in January 2023 and these programs are now wholly-owned by us.
    - Further development of NGM621 is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of NGM621 unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.
- **Liver and metabolic diseases.**
  - **Aldafermin**. Aldafermin is an engineered analog of human hormone fibroblast growth factor 19, or FGF19, that is administered through a once-daily subcutaneous injection. Aldafermin is wholly-owned by us. Aldafermin remains in Phase 2b development for the treatment of patients with compensated cirrhosis due to non-alcoholic steatohepatitis, or NASH (liver fibrosis stage 4, or F4, by the NASH Clinical Research Network classification). The Phase 2b ALPINE 4 clinical trial, which is fully enrolled, is designed to evaluate the treatment effect of aldafermin over 48 weeks. The primary endpoint for the trial is the Enhanced Liver Fibrosis, or ELF, test, a reproducible, quantitative non-invasive liver prognostic test that evaluates liver fibrosis and correlates to liver-related outcomes. The ELF test is a composite blood test measuring the presence of three biomarkers associated with liver matrix metabolism. Liver biopsy data will also be measured and reported as a secondary endpoint upon completion of the trial.
    - Further development of aldafermin is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of aldafermin unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.
    - ***Looking forward:*** We expect to report topline data from the Phase 2b ALPINE 4 trial in the second quarter of 2023.
  - **MK-3655 (NGM313)**. MK-3655 is an agonistic antibody discovered by us that selectively activates fibroblast growth factor receptor 1c-beta-klotho, or FGFR1c/KLB, which regulates insulin sensitivity, blood glucose and liver fat and is administered every four weeks through a subcutaneous injection. MK-3655 was licensed by Merck in November 2018.
    - In January 2023, we announced that Merck notified us of its decision to terminate the Phase 2b trial of MK-3655 in patients with NASH and liver fibrosis stage 2 or 3 based on the results of an interim analysis of safety and reduction in liver fat at Week 24. Although it was not the primary endpoint of the trial, the percent reduction from baseline in liver fat for MK-3655,

while greater than placebo across multiple dose arms, did not reach Merck's threshold for continuing the trial. The trial was not discontinued for safety concerns. Later in January 2023, Merck also provided us with the required 90-days' notice of partial termination of our collaboration with Merck as it relates to MK-3655 and its related compounds. As a result, in late April 2023, the license rights granted to Merck in 2018 with respect to MK-3655 will revert to us and the program will become wholly-owned by us.

- Further development of MK-3655 once termination of Merck's license is effective is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of MK-3655 unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

- **Hematologic cancer diseases.**
  - **NGM936.** NGM936 is a bispecific T cell engager therapeutic candidate for the treatment of hematologic malignancies that targets ILT3 and cluster of differentiation 3, or CD3. NGM936 is designed to direct T cell mediated killing of ILT3-positive cancer cells while sparing normal hematopoietic stem cells, or HSCs, and minimizing CD3-driven cytokine release. ILT3, a myeloid-cell restricted receptor, has enriched expression in myelomonocytic leukemia, monocytic leukemia and leukemia stem cells but is not expressed on healthy HSCs. This expression profile of ILT3 may make it an effective target for the treatment of monocytic acute myeloid leukemia, or AML, and multiple myeloma.
    - NGM936 has been evaluated in preclinical studies, where it has demonstrated the ability to potently kill ILT3+ AML cells, kill ILT3+ multiple myeloma cells and preserve healthy bone marrow cells.
    - Further development of NGM936 is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of NGM936 unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

We have additional programs that are in various stages of development ranging from functional validation to preclinical development.

The success of each of our product candidates may be affected by numerous factors, including preclinical data, clinical data, competition, manufacturing capability, sales capability, any future partners, the sufficiency of our cash resources, regulatory matters, third-party payor matters and commercial viability. We do not have any products approved for sale and do not anticipate generating revenue from product sales for the foreseeable future, if ever.

Business Development and Merck Collaboration Updates

Pursuing BD Arrangements has been and is expected to continue to be a key component of our strategy. Given the breadth of opportunities that have been, and may in the future be, produced by our discovery engine, we are actively seeking, or intend to seek, BD Arrangements with third-party partners to progress, in whole or in part, the development of one or more of our product candidates. We believe that this strategy, if successfully implemented, may enable more of the programs in our pipeline, including those in active development by us, to be advanced as effectively and efficiently as possible. Further development of NGM621, aldafermin, NGM936 and, once termination of Merck's license is effective, MK-3655, is primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of those programs unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

Our collaboration with Merck, described in "Business — Licensing and Collaboration Arrangements — Merck Collaboration" in Part I, Item 1 of this Annual Report on Form 10-K and Note 5, "Research Collaboration and License Agreements," of the notes to audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K, historically provided us with robust financial support that enabled us to broaden and accelerate our research efforts and to develop more product candidates for major indications than we likely could have advanced on our own. We do not have any committed external source of funds, other than pursuant to our collaboration with Merck under the amended and restated research collaboration, product development and license agreement we entered into with Merck on June 30, 2021, or the Amended Collaboration Agreement. Currently, the only ongoing activities funded under the Amended Collaboration Agreement are ongoing cardiovascular or metabolic-, or CVM-, related activities and remaining laboratory testing and other activities on compounds that are

directed to one of up to two undisclosed targets outside of the fields of ophthalmology and CVM disease, or the Lab Programs, collectively referred to as the Remaining Research Programs. In 2023, the R&D funding we receive from Merck under the Amended Collaboration Agreement will be limited and substantially lower on an annual basis than the research funding previously provided by Merck. In this regard, for the period that started on January 1, 2023 and ends on March 31, 2024, we expect to receive funding of approximately $13.0 million in the aggregate from Merck for activities under the Remaining Research Programs and for certain costs and reimbursements related to the NGM621 program. Funding from Merck after December 31, 2023 is expected to be minimal. The research phase for the CVM-related programs under the Amended Collaboration Agreement will continue through March 31, 2024, unless the parties mutually agree to extend the research phase through March 31, 2026, in which case Merck would provide up to a total of $20.0 million in R&D funding during the additional two years of the CVM program research phase.

In December 2022, Merck notified us that it would not exercise its option to license NGM621 and its related compounds or the related ophthalmology bundle option and, as a result, those options expired unexercised in January 2023. Further, Merck did not elect for us to continue to conduct R&D on any compounds from our other ophthalmology programs that were subject to the collaboration, which are preclinical and directed to undisclosed targets. Such an election would have resulted in an extended or tail period in which Merck would continue to fund our R&D of such ophthalmology compounds. Because Merck did not make such an election, we do not have any funding from Merck to pursue such ophthalmology programs. Similarly, in January 2023, as described above, we announced that Merck notified us of its decision to terminate the Phase 2b trial of MK-3655. Later in January 2023, Merck provided us with the required 90-days' notice of partial termination of the Amended Collaboration Agreement as it relates to MK-3655 and its related compounds. After the license rights granted to Merck with respect to MK-3655 revert to us, we will be responsible for funding further development of the program, if any.

Other Operational Updates

We do not own, and have no plans to establish, any manufacturing facilities. All of our manufacturing activities are outsourced to third-party contract development and manufacturing organizations or third-party contract manufacturing organizations, which we refer to collectively as CMOs, which are generally single-source suppliers of the drug product or drug substance they are manufacturing for us. We also utilize third-party contract research organizations, or CROs, to carry out many of our clinical development activities. We expect to be reliant on CMOs and CROs for these activities for the foreseeable future. Significant portions of our research and development, or R&D, resources are focused, and will continue to be focused, on the manufacture and testing of clinical trial materials. If our CROs and CMOs fail to satisfy their contractual duties to us or meet expected deadlines or if our CMOs experience difficulties in scaling production, higher than anticipated costs or lower than anticipated yields, product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, turnover of qualified staff or improper storage conditions, difficulties with quality control, product stability or quality assurance testing, or difficulties procuring raw materials or components as a result of the ongoing COVID-19 pandemic or otherwise, our ongoing and planned trials and possible acceleration or expansion of those trials may be delayed, perhaps substantially, or abandoned, which could materially and adversely affect our business. For example, while we initiated the Phase 1/1b clinical trial of NGM831 in March 2022 and the Phase 1/1b clinical trial of NGM438 in May 2022, our planned individual new drug application, or IND, submissions for NGM831 and NGM438 were delayed due to challenges at one of our CMOs with respect to the manufacture of those product candidates, primarily related to analytical method qualification and release testing. It is possible that we could experience further supply-related delays that would create supply challenges and possible timing delays for ongoing and planned clinical trials or delay the commencement of first-in-human testing of future product candidates. In addition, there is increased competition in the biotechnology industry for CMO manufacturing slots and other capabilities generally, which has had, and may continue to have, a negative impact on the availability of manufacturing capacity and therefore our ability to supply clinical trial materials for planned, ongoing, accelerated or expanded clinical trials. Our CMOs' facilities and operations have also been adversely affected by labor, raw material and component shortages, high turnover of staff and difficulties in hiring trained and qualified replacement staff. Changes in economic conditions, supply chain constraints, labor, raw material and component shortages and steps taken by governments and central banks, particularly in response to the COVID-19 pandemic as well as other stimulus and spending programs, could lead to higher inflation than previously experienced or expected, which could, in turn, lead to an increase in costs. These supply chain effects, increased competition and higher costs of acquired goods and services may negatively impact our business operations and our financial results.

In addition, all of our product candidates other than NGM621 and aldafermin are currently manufactured solely at a facility in Lithuania. Following Russia's invasion of Ukraine in February 2022, NATO deployed additional military forces to Eastern Europe, including to Lithuania. The ongoing conflict between Russia and Ukraine and the

retaliatory measures taken or that may be taken by the United States, NATO and others, including significant sanctions against Russia, create global security concerns and regional instability, including due to the possibility of expanded regional or global conflict, and are likely to have short-term and likely longer-term negative impacts on regional and global economies, any or all of which could disrupt our supply chain and adversely affect our ability to conduct ongoing and future clinical trials of our product candidates and our ability to raise capital on favorable terms.

In July 2022, we entered into an operating lease agreement, or the 2024 Lease Agreement, for our existing corporate office space and facilities at 333 Oyster Point Blvd., South San Francisco, California, which allows us to remain in our existing facilities through December 31, 2033, subject to our compliance with the 2024 Lease Agreement. We also have an option to extend the 2024 Lease Agreement for a period of either eight or ten years after the initial ten-year term of January 1, 2024 to December 31, 2033.

We seek to allocate our capital efficiently and strategically and fund our portfolio based on each program's scientific and other merits. Our discipline has been demonstrated by our decision not to proceed with development activities on multiple potentially viable product candidates for portfolio management and capital conservation reasons to concentrate our resources and focus our execution on our solid tumor oncology programs. Given the substantial decrease in research funding, we will now receive from Merck as compared to historical periods commensurate with the decreased collaboration scope described below, going forward we will need to devote a substantial amount of our own financial resources to fund our R&D programs, and we may need to delay or suspend development activities on product candidates that we consider promising unless and until we are able to raise sufficient additional capital and/or we will need to enter into additional BD Arrangements in order to proceed with such development through to regulatory approval.

Financial Highlights

Since inception, we have funded our operations primarily through:

- fees received from collaboration partners which since inception through December 31, 2022 includes reimbursement of R&D expenses of $533.0 million, and upfront cash licensing fees of $123.0 million, primarily from Merck, and a payment of $20.0 million from Merck to license MK-3655 and related compounds;
- proceeds from private placements of convertible preferred stock prior to our initial public offering, or IPO, including approximately $106.0 million of our Series E convertible preferred stock purchased by Merck;
- net proceeds from our IPO in 2019 of approximately $107.8 million, together with proceeds from the concurrent private placement of shares of common stock to Merck of $65.9 million;
- net proceeds of $134.6 million from the sale of 5,324,074 shares of our common stock in January 2021 upon completion of an underwritten public offering of our common stock, or the follow-on offering, which included the full exercise by the underwriters of their option to purchase additional shares; and
- net proceeds of $71.5 million through December 31, 2022 from sales of approximately 4.1 million shares of our common stock under an Open Market Sale Agreement[SM], or the Sales Agreement, we entered into with Jefferies LLC, or Jefferies, in June 2020.

At December 31, 2022, we had $271.5 million in cash, cash equivalents and short-term marketable securities.

We have incurred net losses each year since our inception. As of December 31, 2022, we had an accumulated deficit of $581.6 million. Substantially all of our net losses have resulted from costs incurred in connection with our R&D programs and general and administrative, or G&A, costs associated with our operations. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenses on other R&D activities, and the amount of R&D funding we receive from future BD Arrangements, if any. For further discussion of our financial position and future sources of funding, see "Liquidity and Capital Resources" below.

Financial Operations Overview

Related Party Revenue

Our revenue to date has been generated primarily from recognition of license fees and R&D service funding pursuant to our collaboration with Merck. Merck is also a significant stockholder and, as such, collaboration revenue from Merck is referred to as related party revenue.

Since the Company's inception through December 31, 2022, Merck paid us $608.2 million pursuant to the terms of our collaboration. Due to the nature of our collaboration with Merck and the timing of related revenue recognition, our revenue has fluctuated from period to period in the past and we expect that it will continue to fluctuate in 2023 given the substantial decrease in the level of funding we will receive from Merck in 2023. After December 31, 2023, we expect funding, and revenue recognized, from Merck to be minimal. As a result, we believe that period-to-period comparisons of our revenue may not be meaningful and should not be relied upon as being indicative of future performance.

We use the cost-based input method in accordance with Accounting Standards Codification 606, or ASC 606, to calculate the corresponding amount of revenue to recognize at each reporting period. In applying the cost-based input measure of revenue recognition, we measure actual costs incurred relative to budgeted costs to fulfill our performance obligation. We apply considerable judgment when we re-evaluate the estimate of expected costs to satisfy the performance obligation each reporting period and make adjustments for any significant changes. A significant change in the estimate of expected costs under the Amended Collaboration Agreement could have a material impact on revenue recognized (including the possible reversal of previously recognized revenue) at each reporting period.

In the past three years, our related party revenue was as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Related party revenue	$ 55,333	$ 77,882	$ 87,368

Research and Development Expenses

R&D efforts include drug discovery and other research activities and development activities relating to our product candidates, such as manufacturing drug substance, drug product and other clinical trial materials, conducting preclinical studies and clinical trials and providing support for these operations. Our R&D expenses consist of both internal and external costs. Our internal costs include employee, consultant, facility and other R&D operating expenses. Our external costs include fees paid to CROs and other service providers in connection with our clinical trials and preclinical studies, third-party license fees and CMO costs related to manufacturing drug substance, drug product and other clinical trial materials.

Our R&D efforts are extensive and costly. Our R&D expenses related to the development of our product candidates consist primarily of:

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

We need to devote a substantial amount of our own financial resources to our wholly-owned development programs, primarily our solid tumor oncology programs in active ongoing clinical development. In addition, because Merck declined to exercise its license to option NGM621, decided not to continue funding further research on the other preclinical ophthalmology compounds and provided notice of termination of its existing its license to MK-3655 and in prior years other product candidates, our funding requirements would increase even further if our portfolio

prioritization changes and we decide to continue to develop those programs on our own. As a result, further development of NGM621, aldafermin, NGM936 and, once termination of Merck's license is effective, MK-3655, is currently primarily dependent on our ability to secure potential future BD Arrangements and, in the absence of such BD Arrangements, we are unlikely to be able to advance development of those programs unless our portfolio prioritization changes and we have access to the necessary capital to fund such development. For the foreseeable future, we anticipate a significant portion of our financial resources, other than those received from Merck which are dedicated to activities under the Amended Collaboration Agreement, will be directed to activities required to initiate and advance clinical trials of our solid tumor oncology programs and complete the Phase 2b ALPINE 4 clinical trial of aldafermin.

The successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of our product candidates or if we will be able to enter into BD Arrangements or otherwise raise adequate additional capital to meet our funding requirements to support such efforts, particularly outside of our key solid tumor oncology programs. This is due to the numerous risks and uncertainties associated with developing medicines, including the uncertainty of:

- the scope, rate of progress, results and expense of our ongoing, as well as any future, clinical trials and other R&D-related activities;
- the impact and timing of any interactions with regulatory authorities, including timing and receipt of regulatory approvals:
- our ability to hire and retain key R&D personnel;
- manufacturing scale-up challenges, production shortages or other supply disruptions for clinical trial materials, including raw materials and components;
- the effects of the continuing COVID-19 pandemic on our employees, patients, clinical trial sites and our CROs, CMOs and other service providers;
- the timely and quality performance of our CROs, CMOs and other service providers;
- whether Merck will elect to license, or to terminate its license, to any of our preclinical programs remaining within the scope of the collaboration and the timing of such election or termination;
- the effect of products that may compete with our product candidates or other market developments; and
- our ability to expand and enforce our intellectual property portfolio.

A change in the outcome of any of the risks and uncertainties associated with the development of a product candidate could mean a significant change in the costs, as well as the timing, associated with the development of that product candidate. For example, if the FDA or a comparable foreign health authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. For additional discussion of the risks and uncertainties associated with our R&D efforts, see “Risk Factors—Risks Related to Our Business and Industry,” “—Risks Related to Our Dependence on Third Parties,” “—Risks Related to Regulatory Approvals” and "—Risks Related to Our Intellectual Property” in Part I, Item 1A of this Annual Report on Form 10-K.

General and Administrative Expenses

G&A expenses consist primarily of salaries and other related costs, including stock-based compensation and benefits. Other significant costs include legal fees relating to patent and corporate matters, facility costs not otherwise included in R&D expenses and fees for accounting and other consulting services.

We anticipate that our G&A expenses in 2023 will remain relatively consistent with 2022 in support of our narrowed R&D activities. Beginning in 2024, our G&A expenses will include an increase in operating lease expenses under the 2024 Lease Agreement. Additionally, we anticipate continued costs associated with being a public company, including expenses related to services associated with maintaining compliance with Nasdaq listing rules and related SEC requirements and costs related to insurance, investor relations and compliance with Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. In addition, we may incur expenses associated with negotiating and entering into BD Arrangements.

Results of Operations

Our results of operations were as follows (in thousands):

	Year Ended December 31,			Change	
	2022	2021	2020	2022 vs 2021	2021 vs 2020
Related party revenue	$ 55,333	$ 77,882	$ 87,368	$ (22,549)	$ (9,486)
Operating expenses:					
Research and development	181,067	161,712	163,972	19,355	(2,260)
General and administrative	40,515	36,865	27,229	3,650	9,636
Total operating expenses	221,582	198,577	191,201	23,005	7,376
Loss from operations	(166,249)	(120,695)	(103,833)	(45,554)	(16,862)
Interest income, net	3,714	420	1,939	3,294	(1,519)
Other expense, net	(132)	(60)	(593)	(72)	533
Net loss	$ (162,667)	$ (120,335)	$ (102,487)	$ (42,332)	$ (17,848)

Related Party Revenue from Merck

Revenue decreased $22.5 million in the year ended December 31, 2022 compared to the same period in 2021 primarily due to a decrease in R&D revenue under the Amended Collaboration Agreement with Merck. Revenue in the year ended December 31, 2022 includes $4.75 million in reimbursable expenses by Merck related to a third-party manufacturer for NGM621.

Revenue decreased $9.5 million in the year ended December 31, 2021 compared to the same period in 2020 primarily due to a reduction in revenue of $4.6 million for an amount we had recorded under the prior two-year extension of the research phase that was no longer billable to Merck under the Amended Collaboration Agreement as of June 30, 2021 and a $3.9 million decrease related to the recognition of the remaining portion of an upfront payment in the first quarter of 2020.

Due to the nature of our collaboration with Merck and the timing of related revenue recognition, our revenue has fluctuated from period to period in the past and we expect that it will continue to fluctuate in 2023 given the substantial decrease in the level of funding we will receive from Merck in 2023. After December 31, 2023, we expect funding, and revenue recognized, from Merck to be minimal.

Research and Development Expenses

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

	Year Ended December 31,		
	2022	2021	2020
External R&D expenses:			
NGM707 (Anti-ILT2/ILT4 dual antagonist)	$ 24,333	$ 5,521	$ 4,817
NGM621 (C3 inhibitor)	23,738	20,415	13,126
Aldafermin (FGF19 analog)	13,665	31,766	50,553
NGM438 (LAIR1 antagonist)	8,504	4,074	3,586
NGM120 (GFRAL antagonist)	7,183	6,856	5,606
NGM831 (ILT3 antagonist)	6,832	2,377	4,756
Other external R&D expenses	1,186	1,437	4,822
Total external R&D expenses	85,441	72,446	87,266
Personnel-related expenses	62,151	56,209	43,811
Internal and unallocated R&D expenses (1)	33,475	33,057	32,895
Total R&D expenses	$ 181,067	$ 161,712	$ 163,972

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

R&D expenses increased $19.4 million in the year ended December 31, 2022 compared to the same period in 2021 primarily due to increases in external expenses, driven by our ongoing clinical trials of NGM707, NGM831, NGM438 and NGM120, our completed trial of NGM621, and personnel-related expenses including an increase in share-based compensation expense of $3.6 million, partially offset by a decrease in expenses for our manufacturing activities and our clinical trials of aldafermin.

R&D expenses decreased $2.3 million in the year ended December 31, 2021 compared to the same period in 2020 primarily due to a decrease in expenses for our manufacturing activities and our clinical trials of aldafermin, partially offset by an increase in personnel-related expenses, including an increase in share-based compensation expense of $5.8 million, and an increase in external expenses driven by our ongoing clinical trials of NGM621, NGM120 and NGM707 and our preclinical studies of NGM438 and NGM831.

We expect our R&D expenses will decrease moderately in 2023 compared to 2022 as we suspend development activities related to NGM621 and aldafermin and focus on the continued advancement of our solid tumor oncology portfolio, including:

- NGM707: continuing enrollment in the ongoing Phase 1/2 clinical trial;
- NGM831: continuing enrollment in the Phase 1/1b clinical trial;
- NGM438: continuing enrollment in the Phase 1/1b clinical trial, and
- NGM120: continuing enrollment in the Phase 2 PINNACLES portion of the Phase 1/2 clinical trial and the Phase 1b cohort of patients with mCRPC.

General and Administrative Expenses

G&A expenses increased $3.7 million in the year ended December 31, 2022 compared to the same period in 2021 primarily due to an increase in personnel-related expenses due to increased headcount and an increase in share-based compensation expense of $2.5 million.

G&A expenses increased $9.6 million in the year ended December 31, 2021 compared to the same period in 2020 primarily due to an increase in personnel-related expenses due to increased headcount, an increase in share-based compensation expense of $4.7 million and a $2.5 million increase in fees paid to outside consultants, lawyers and accountants.

We anticipate that our G&A expenses in 2023 will remain relatively consistent compared to 2022 as we continue to support our oncology program and operate as a public company.

Interest Income, net

Interest income, net increased $3.3 million in the year ended December 31, 2022 compared to 2021 primarily due to higher yielding investments.

Interest income, net decreased $1.5 million in the year ended December 31, 2021 compared to 2020 primarily due to an increase in unrealized losses in marketable securities, offset by an increase in interest income due to an increase in our average cash balance.

Liquidity and Capital Resources

Funding Requirements

We have no products approved for commercial sale, have not generated any revenue from product sales to date and we are not and may never be profitable. We have incurred losses in each year since commencing operations, and we expect to incur significant operating losses in 2023 and over the next several years. As of December 31, 2022, we had an accumulated deficit of $581.6 million, and we expect our accumulated deficit will continue to increase over time.

We have an active discovery research group and have spent significant resources to fund R&D of multiple pipeline programs. Our pipeline includes four key solid tumor oncology programs, NGM707, NGM831, NGM438 and NGM120, in active ongoing clinical development. We are currently focusing most of our execution efforts and resources on these programs as our substantial research, development, clinical trial and related activities continue. While we will opportunistically consider BD Arrangements to advance development of these key programs, we intend to invest our resources in their development even in the absence of BD Arrangements.

Due to the need to conserve capital and prioritize focused execution, the remainder of our pipeline includes programs whose further development is primarily dependent on our ability to secure potential future BD Arrangements. We are actively seeking, or intend to seek, BD Arrangements with third-party partners possessing sufficient resources and relevant domain expertise in the relevant therapeutic area in order to further clinical development of these programs. In the absence of such BD Arrangements for these programs, we are unlikely to be able to advance their development unless our portfolio prioritization changes and we have access to the necessary capital to fund such development.

Prior to 2022, we received substantial R&D funding from our collaboration with Merck. However, under the narrower scope of the Amended Collaboration Agreement, R&D funding from Merck beginning April 2022 was and is expected to be substantially lower than the R&D funding previously provided by Merck. For the period that started on January 1, 2023 and ends on March 31, 2024, we expect to receive funding of approximately $13.0 million in the aggregate from Merck for activities remaining under the Amended Collaboration Agreement and for certain costs and reimbursements related to the NGM621 program. Funding from Merck after December 31, 2023 is expected to be minimal.

Our cash requirements for fiscal year 2023 will continue to be driven by our R&D and G&A expenses. In 2022 and 2021, our R&D expenses were $181.1 million and $161.7 million, respectively. In 2023, we expect our R&D expenses to decrease moderately compared to 2022 as we suspend development activities related to NGM621 and our other preclinical ophthalmology programs and focus on the continued advancement of our solid tumor oncology portfolio, as well as completion of development activities related to ALPINE 4. In 2022 and 2021, our G&A expenses were $40.5 million and $36.9 million, respectively. In 2023, we expect our G&A expenses will remain relatively consistent compared to 2022 in support of our narrowed R&D activities and expenses associated with being a public company. Beginning in 2024, our operating lease costs will increase pursuant to the 2024 Lease Agreement we entered into in July 2022 for our current corporate office space and facilities in South San Francisco, California. Our current sublease will expire on December 31, 2023. The 2024 Lease Agreement will commence on January 1, 2024 and expire on December 31, 2033. We will pay an initial monthly base rent of approximately $0.9 million for the first year, which is subject to increase at an annual rate of 3.5% each year thereafter, plus certain operating and tax expenses.

We believe that our existing cash, cash equivalents and short-term marketable securities will be sufficient to fund our operations for at least twelve months from the date this Annual Report on Form 10-K is filed. Moreover, based on our current development plans and related assumptions, we believe our current cash position is sufficient to fund our key solid tumor oncology programs through generation of proof-of-concept data. We have based these estimates on plans and assumptions that may prove to be insufficient or inaccurate (for example, with respect to anticipated costs, timing or success of certain activities), and we could utilize our available capital resources sooner than we currently expect. In addition, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially as a result of a number of factors, including the factors discussed under “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K. Nonetheless, in order to advance our current and potential future product candidates through development and to regulatory approval and commercialization, we will need to raise significant additional capital and we will need to enter into BD Arrangements for one or more of our wholly-owned programs and obtain funding or other resources through such BD Arrangements. Neither may be possible and, as a result, we may be required to delay, scale back or discontinue development of such product candidates, which could have a material adverse effect on our business, operating results and prospects.

Sources of Liquidity

Cash and Investments

As of December 31, 2022, we had cash and cash equivalents of $73.5 million and short-term marketable securities of $198.0 million.

Merck Collaboration

The revenue we receive under the Amended Collaboration Agreement with Merck is currently our only source of revenue. For the period that started on January 1, 2023 and ends on March 31, 2024, we expect to receive funding of approximately $13.0 million in the aggregate from Merck for the ongoing CVM-related activities, the remaining activities under the Lab Programs and for certain costs and reimbursements related to the NGM621 program. See “Overview of Our Business—Business Development and Merck Collaboration Updates” above.

Other Sources of Capital

In June 2020, we entered into the Sales Agreement with Jefferies. In accordance with the terms of the Sales Agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to $150.0 million from time to time through Jefferies, acting as our sales agent. As of December 31, 2022, $76.2 million of our common stock remained available to be sold under the Sales Agreement, subject to conditions specified in the Sales Agreement.

We plan to finance our future cash needs through public or private equity or debt offerings, including under the Sales Agreement, BD Arrangements or a combination of these potential financing sources. Additional capital may not be available in sufficient amounts, on reasonable terms or when we need it, if at all.

Our ability to raise additional capital through public or private equity or debt offerings 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, and in the biotechnology industry specifically. While the long-term economic impact of either the COVID-19 pandemic or the conflict between Russia and Ukraine is difficult to assess or predict, each of these events has caused significant disruptions to the global financial markets and contributed to a general global economic slowdown. Furthermore, inflation rates across the globe have increased to levels not seen in decades. Increased inflation may result in increased operating costs (including labor costs) and may affect our operating budgets. In addition, the U.S. Federal Reserve has raised, and is expected to further raise, interest rates in response to concerns about inflation. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. If the financial market disruptions and economic slowdown deepen or persist, we may not be able to access additional capital on favorable terms, or at all, which could negatively affect our financial condition and our ability to pursue our business strategy.

In addition, if we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Furthermore, any securities that we may issue may have rights senior to those of our common stock and could contain covenants or protective rights that would lead to restrictions on our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

While we may opportunistically consider BD Arrangements to advance development of our key solid tumor oncology programs, we are actively seeking, or intend to seek, BD Arrangements with third-party partners to progress, in whole or in part, the development of one or more of our other programs whose further development is primarily dependent on our ability to secure potential future BD Arrangements. We believe that this strategy, if successfully implemented, may enable more of the product candidates in our pipeline to be advanced as effectively and efficiently as possible. If we are unable to secure BD Arrangements for NGM621 and our preclinical ophthalmology programs, aldafermin, NGM936 and, once termination of Merck's license is effective, MK-3655, we may discontinue or abandon any or all of them altogether, in which case we will not realize any return on our investments in these programs. Even if we are successful in securing BD Arrangements for these programs, we will likely have limited control over the amount and timing of resources that our partners dedicate to the development or commercialization of the applicable product candidates. Our ability to generate revenue from any such BD Arrangement will depend on the specific terms of the BD Arrangement.

If we are unable to raise adequate additional capital through public or private equity or debt offerings, BD Arrangements or otherwise, on acceptable terms or at all, we may be delayed in or prevented from pursuing our planned and any future development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

Cash Flow Activity

The following table summarizes our cash flow activity for the periods indicated (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Net cash provided by (used in):			
Operating activities	$ (144,439)	$ (73,229)	$ (83,496)
Investing activities	14,322	(71,650)	(50,998)
Financing activities	54,233	149,657	35,538
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (75,884)	$ 4,778	$ (98,956)

Operating Activities

Cash used in operating activities in 2022 was $144.4 million, which consisted of a net loss of $162.7 million, adjusted for non-cash charges of $39.0 million and a change in operating assets and liabilities of $20.7 million. The non-cash charges consisted primarily of stock-based compensation expense of $32.4 million, depreciation expense of $4.0 million and noncash lease expense of $1.9 million. The change in operating assets and liabilities was mainly driven by decreases in contract liabilities of $17.4 million, operating lease liabilities of $5.1 million, prepaid expenses and other current assets of $1.8 million and accrued liabilities of $0.6 million, partially offset by increases in accounts payable of $3.2 million and related party receivable of $2.6 million.

Cash used in operating activities in 2021 was $73.2 million, which consisted of a net loss of $120.3 million, adjusted for non-cash charges of $42.9 million and a change in operating assets and liabilities of $4.2 million. The non-cash charges consisted primarily of stock-based compensation expense of $26.2 million, depreciation expense of $6.1 million, a decrease in related party contract assets due to the Amended Collaboration Agreement with Merck of $4.6 million, amortization of a premium on marketable securities of $3.5 million and noncash lease expense of $1.8 million. The change in operating assets and liabilities was mainly driven by increases in contract liabilities of $17.8 million, related party receivable of $4.6 million, prepaid expenses and other current assets of $4.1 million and accrued liabilities of $2.9 million, partially offset by decreases in operating lease liabilities of $4.8 million, accounts payable of $4.4 million and related party contract assets of $1.5 million.

Cash used in operating activities in 2020 was $83.5 million, which consisted of a net loss of $102.5 million, adjusted for non-cash charges of $22.3 million and net cash used in operating assets and liabilities of $3.3 million. The non-cash charges consisted primarily of stock-based compensation expense of $15.7 million and depreciation expense of $6.6 million. The change in operating assets and liabilities was mainly driven by increases in accrued expenses of $6.2 million, prepaid expenses and other current assets of $1.9 million, accounts payable of $0.9 million and a related party contract asset of $6.1 million. These increases were offset by a decrease in deferred rent of $2.8 million.

Investing Activities

Cash provided by investing activities in 2022 was $14.3 million, which consisted primarily of $289.0 million in net proceeds on maturity of marketable securities offset by purchases of marketable securities of $272.9 million. Cash used in investing activities in 2021 was $71.7 million, which consisted of purchases of marketable securities of $293.5 million primarily from the net proceeds of the follow-on offering, partially offset by $223.5 million in net proceeds on maturity of marketable securities. Cash used in investing activities in 2020 was $51.0 million, which consisted of purchases of marketable securities of $177.7 million and purchases of property and equipment of $1.9 million partially offset by net proceeds on maturity of marketable securities of $128.5 million.

Financing Activities

Cash provided by financing activities in 2022 was $54.2 million, which consisted of net proceeds of $49.4 million from the sale of shares of our common stock under the Sales Agreement and proceeds from our employee equity incentive and purchase plans of $4.8 million. Cash provided by financing activities in 2021 was $149.7 million, which consisted of net proceeds from the follow-on offering of $134.6 million and proceeds from employee equity incentive and purchase plans of $14.9 million. Cash provided by financing activities in 2020 was $35.5 million and primarily related to net proceeds from the sale of shares of our common stock under the Sales Agreement of $21.9 million and proceeds from employee equity incentive and purchase plans of $14.2 million.

Contractual Obligations

We have contractual obligations related to our lease liabilities. In July 2022, we entered into the 2024 Lease Agreement for the corporate office space and facilities in South San Francisco, California that we currently occupy pursuant to a sublease agreement scheduled to expire on December 31, 2023. The initial term of the 2024 Lease Agreement will commence on January 1, 2024 and expire on December 31, 2033. Base rent during the initial ten-year term of the 2024 Lease Agreement will total $124.1 million. See Note 6 to our consolidated financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data,” of this Annual Report on Form 10-K for information regarding our lease commitments.

We enter into agreements in the normal course of business with CROs for clinical trials, CMOs and other vendors for preclinical studies, supplies, manufacturing and other services and products for operating purposes. These agreements are generally cancellable at any time by us, upon prior written notice, and may or may not include cancellation fees. Given that the amount and timing related to such payments are uncertain, they are not considered to be contractual obligations. Following Merck's decision to not exercise its NGM621 option and our decision not to proceed with further development of NGM621, we cancelled future Phase 3 manufacturing activities for NGM621 and recorded approximately $3.0 million for cancellation charges as of December 31, 2022. No other termination or cancellation charges have been recorded as they were not considered probable. Significant portions of our R&D resources are focused, and will continue to be focused, on the manufacture and testing of clinical trial materials. See "Funding Requirements" above for information regarding our expected R&D spend.

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, low single-digit royalties and payments that become due and payable on the achievement of certain development and commercialization milestones. As the amount and timing of sublicense fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on our consolidated balance sheets and are not considered to be contractual obligations. See "Business— Licensing and Collaboration Arrangements" in Part I, Item 1 of this Annual Report on Form 10-K for additional information regarding our current in-license agreements.

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our consolidated financial statements, as well as revenue and expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. In accordance with U.S. GAAP, we base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in Note 2 to our consolidated financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data,” of this Annual Report on Form 10-K, we believe that the following critical accounting policies are the most important policies in understanding and evaluating our financial condition and results of operations because they are complex and relate to the more significant areas involving management’s judgment.

Revenue Recognition

ASC 606 requires an entity to recognize revenue upon the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. We apply the following five-step revenue recognition model outlined in ASC 606 to adhere to this core principle: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the Company satisfies a performance obligation.

All of our revenue to date has been generated from collaborations, primarily the collaboration agreement with Merck. The terms of these agreements generally require us to provide (i) license options for our compounds, (ii) R&D services and (iii) non-mandatory services in connection with participation in research or steering committees. Payments received under these arrangements may include non-refundable upfront license fees, partial or complete

reimbursement of R&D costs, contingent consideration payments based on the achievement of defined collaboration objectives and royalties on sales of commercialized products.

We assess whether the promises in our arrangements, including any options provided to the partner, are considered distinct performance obligations that should be accounted for separately. Judgment is required to determine whether the license to a compound is distinct from R&D services or participation in research and steering committees, as well as whether options create material rights in the contract. In situations when a contract includes distinct R&D services that are substantially the same and have the same pattern of transfer to the customer over time, they are recognized as a series of distinct services.

The transaction price in each arrangement is generally comprised of a non-refundable upfront fee and unconstrained variable consideration related to the performance of R&D services. The unconstrained variable consideration amount included in the transaction price represents an amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. We typically submit a budget for the R&D services to our partner in advance of performing the services. The transaction price is allocated to the identified performance obligations based on the standalone selling price, or SSP, of each distinct performance obligation. Judgment is required to determine the SSP. In instances where the SSP is not directly observable, such as when a license or service is not sold separately, the SSP is determined using information that may include market conditions and other observable inputs. We utilize judgment to assess the nature of our performance obligations to determine whether they are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress toward completion. We re-evaluate estimated costs to satisfy a performance obligation each reporting period and make adjustments for any significant changes. In applying the cost-based input method, we measure actual costs incurred relative to budgeted costs to fulfill our performance obligation. These budgeted costs consist of our employee full-time equivalent hours plus allowable external (third-party) costs incurred. Management applies considerable judgment in estimating expected costs as such costs are key inputs when applying the cost-based input method. We recognize revenue based on actual costs incurred as a percentage of total budgeted costs as we complete a performance obligation applied to the transaction price. A significant change in the estimate of expected costs for the remainder of a contract term could have a material impact on revenue recognized (including the possible reversal of previously recognized revenue) at each reporting period, as well as a related impact on contract assets and liabilities.

Our collaboration or partnering agreements may include contingent payments related to specified development and regulatory milestones or contingent payments for royalties based on sales of a commercialized product. Milestones can be achieved for such activities in connection with progress in clinical trials, regulatory filings in various geographical markets and marketing approvals from health authorities. Sales-based royalties are generally related to the volume of annual sales of a commercialized product. At the inception of each agreement that includes such payments, we evaluate whether the milestones are considered probable of being achieved and estimate the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or our partner’s control, such as those related to regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation based on a relative SSP basis. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of each such milestone and any related constraint and, if necessary, adjust our estimate of the overall transaction price. Pursuant to the guidance in ASC 606, sales-based royalties are not included in the transaction price. Instead, royalties are recognized at the later of when the performance obligation is satisfied or partially satisfied, or when the sale that gives rise to the royalty occurs.

Contract modifications, defined as changes in the scope or price (or both) of a contract that are approved by the parties to the contract, such as a contract amendment, exist when the parties to a contract approve a modification that either creates new, or changes existing, enforceable rights and obligations of the parties to the contract. Depending on facts and circumstances, we account for a contract modification as one of the following: (i) a separate contract; (ii) a termination of the existing contract and a creation of a new contract; or (iii) a combination of the preceding treatments. A contract modification is accounted for as a separate contract if the scope of the contract increases because of the addition of promised services that are distinct and if the price of the contract increases by an amount of consideration that reflects our standalone selling prices of the additional promised services. When a contract modification is not considered a separate contract and the remaining services are distinct from the services transferred on or before the date of the contract modification, we account for the contract modification as a termination of the existing contract and a creation of a new contract. When a contract modification is not considered a separate contract and the remaining services are not distinct, we account for the contract modification as an add-on to the existing contract and as an adjustment to revenue on a cumulative catch-up basis.

Accrued Research and Development Expenses

As part of the process of preparing these consolidated financial statements, we are required to estimate and accrue expenses, the largest of which are R&D expenses. This process involves:

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

Examples of estimated R&D expenses that we accrue include:

- fees paid to CROs and other service providers in connection with preclinical studies and clinical trials;
- fees paid to investigative sites in connection with clinical trials;
- fees paid to CMOs in connection with the production of clinical trial materials and to procure raw materials and components for manufacture; and
- professional service fees for consulting and other services.

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

All of our clinical trials have been executed with support from CROs and other vendors. We accrue costs for clinical trial activities performed by CROs based upon the estimated amount of work completed on each trial. For clinical trial expenses, the significant factors used in estimating accruals include the number of patients enrolled, the activities to be performed for each patient, the number of active clinical sites and the duration for which the patients will be enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, correspondence with CROs and review of contractual terms. We base our estimates on the best information available at the time.

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

Stock-Based Compensation

We account for stock-based compensation arrangements in accordance with Topic 718, Compensation—Stock Compensation.

Stock-based compensation expense represents the grant-date fair value of stock options granted under our 2008 Equity Incentive Plan, or 2008 Plan, and our 2018 Amended and Restated Equity Incentive Plan, or 2018 Plan, and rights to acquire stock granted under our 2019 Employee Stock Purchase Plan, or ESPP, recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis, net of estimated forfeitures.

We use the Black-Scholes option-pricing model to calculate the grant-date fair value of stock-based compensation awards. The Black-Scholes option-pricing model requires the use of subjective assumptions, including stock price volatility, the expected term that stock options will remain outstanding, risk-free interest rates and expected dividends.

The expected volatility is based on the historical volatility of our stock and the stock of similar entities within our industry over periods commensurate with our expected term assumption. The expected term of stock option grants represents the weighted-average period the options are expected to remain outstanding and is based on the “simplified” method where the expected term is the midpoint between the vesting date and the end of the

contractual term for each option. We base the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term. In reference to the expected dividend yield assumption, we have not historically paid, and do not expect for the foreseeable future to pay, a dividend.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements included in Part II, Item 8, “Financial Statements and Supplementary Data,” of this Annual Report on Form 10-K for a description of recent accounting pronouncements applicable to our business.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

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

Interest Rate Sensitivity

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and short-term marketable securities of $271.5 million as of December 31, 2022, which consisted primarily of money market funds and marketable securities, largely composed of investment grade, short-to-intermediate term fixed income securities.

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

Foreign Currency Sensitivity

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

Item 8. Financial Statements and Supplementary Data.

NGM BIOPHARMACEUTICALS, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of NGM Biopharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of NGM Biopharmaceuticals, Inc. (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 28, 2023 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosures to which it relates.

Accrued clinical trials expenses

Description of the Matter

During the year ended December 31, 2022, the Company incurred $181.1 million in research and development related expenses, and $14.6 million was recorded as accrued clinical trials expenses as of December 31, 2022. As described in Note 2 of the consolidated financial statements, the Company records accruals for its estimated costs of research and development activities, including contract services for clinical trials. Clinical trial activities performed by outside third-party service providers, including those performed by clinical research organizations (CRO), are recorded based upon estimates of the proportion of work completed over the life of the individual clinical trial and patient enrollment rates in accordance with agreements established with third-party service providers. Estimates are determined by reviewing contracts, vendor agreements and purchase orders, and through detailed discussions with internal clinical personnel and external service providers as to the progress or stage of completion of trials or services and then applying these estimates of completion to previously agreed-upon rates and fees to be paid for such services.

Auditing management's accounting estimates of accrued clinical trials expenses was especially challenging, as evaluating the nature, progress, and stage of completion of the activities being performed under the Company's research and development agreements is dependent upon the accumulation of a high volume of information from internal clinical personnel and third-party service providers.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the accounting for accrued clinical trials expenses, including controls over management's review of clinical trial progress and activities in comparison to budgets and invoices received from third-party service providers.

Our audit procedures included, among others, testing the accuracy and completeness of the underlying data used by management to determine the amount of the accrued clinical trials expenses. Additionally, we inspected the terms and conditions of selected service providers' contracts and change orders, assessed patient enrollment as well as the activities to be performed for each patient, and tested the clinical cost models which calculate the costs incurred for the period under audit. We also agreed selected inputs used in a sample of clinical cost models back to contractual terms, performed inquiries with the Company's internal clinical personnel that oversee the clinical trials, as well as inspected information obtained by the Company directly from service providers. For a sample of contracts, we obtained external confirmation from service providers of key inputs to the clinical cost models, such as an amount of unbilled costs as of the balance sheet date, the number of patient visits, the number of sites activated and the progress of contracted clinical activities. Further, we inspected a sample of subsequent payments made and invoices received from service providers after the balance sheet date and compared such information back to the accruals recorded by the Company.

We have served as the Company's auditor since 2008.

/s/ Ernst & Young LLP

San Mateo, California

February 28, 2023

NGM BIOPHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 73,456	$ 151,795
Short-term marketable securities	198,036	214,458
Related party receivable from collaboration	7,580	4,945
Prepaid expenses and other current assets	9,787	8,082
Total current assets	288,859	379,280
Property and equipment, net	8,496	10,071
Operating lease right-of-use asset	2,096	4,045
Restricted cash	3,954	1,499
Other non-current assets	3,997	7,492
Total assets	$ 307,402	$ 402,387
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,453	$ 5,246
Accrued liabilities	33,638	33,258
Operating lease liability, current	5,385	5,077
Contract liabilities	366	17,774
Total current liabilities	47,842	61,355
Operating lease liability, non-current	—	5,385
Total liabilities	47,842	66,740
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000 shares authorized; no shares issued or outstanding as of December 31, 2022 and 2021, respectively	—	—
Common stock, $0.001 par value; 400,000 shares authorized; 81,885 and 77,962 shares issued and outstanding as of December 31, 2022 and 2021, respectively	82	78
Additional paid-in capital	841,413	754,664
Accumulated other comprehensive loss	(302)	(129)
Accumulated deficit	(581,633)	(418,966)
Total stockholders' equity	259,560	335,647
Total liabilities and stockholders' equity	$ 307,402	$ 402,387

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2022	2021	2020
Related party revenue	$ 55,333	$ 77,882	$ 87,368
Operating expenses:			
Research and development	181,067	161,712	163,972
General and administrative	40,515	36,865	27,229
Total operating expenses	221,582	198,577	191,201
Loss from operations	(166,249)	(120,695)	(103,833)
Interest income, net	3,714	420	1,939
Other expense, net	(132)	(60)	(593)
Net loss	$ (162,667)	$ (120,335)	$ (102,487)
Net loss per share, basic and diluted	$ (2.03)	$ (1.56)	$ (1.50)
Weighted average shares used to compute net loss per share, basic and diluted	79,950	77,085	68,475

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,		
	2022	2021	2020
Net loss	$ (162,667)	$ (120,335)	$ (102,487)
Other comprehensive loss, net of tax:			
Net unrealized loss on available-for-sale marketable securities	(173)	(133)	(21)
Total comprehensive loss	$ (162,840)	$ (120,468)	$ (102,508)

See accompanying notes to consolidated financial statements.

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

	Common Stock		Additional Paid-In Capital	Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	66,886	$ 67	$ 526,771	$ 25	$ (196,144)	$ 330,719
Issuance of common stock upon exercise of stock options	2,616	3	11,835	—	—	11,838
Issuance of common stock under Open Market Agreement, net of issuance costs	810	1	21,329	—	—	21,330
Issuance of common stock under employee stock purchase plan	197	—	2,370	—	—	2,370
Vesting of common stock from early exercises	68	—	524	—	—	524
Issuance of common stock to participants in 401(k) Plan	6	—	119	—	—	119
Stock-based compensation expense	—	—	15,651	—	—	15,651
Comprehensive loss	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	(102,487)	(102,487)
Balance at December 31, 2020	70,583	$ 71	$ 578,599	$ 4	$ (298,631)	$ 280,043
Issuance of common stock under offering, net of issuance costs	5,324	5	134,575	—	—	134,580
Issuance of common stock upon exercise of stock options	1,845	2	12,360	—	—	12,362
Issuance of common stock under employee stock purchase plan	193	—	2,519	—	—	2,519
Issuance of common stock under Open Market Agreement, net of issuance costs	7	—	196	—	—	196
Issuance of common stock to participants in 401(k) plan	4	—	125	—	—	125
Vesting of common stock from early exercises	6	—	48	—	—	48
Stock-based compensation expense	—	—	26,242	—	—	26,242
Comprehensive loss	—	—	—	(133)	—	(133)
Net loss	—	—	—	—	(120,335)	(120,335)
Balance at December 31, 2021	77,962	$ 78	$ 754,664	$ (129)	$ (418,966)	$ 335,647
Issuance of common stock under Open Market Sale Agreement, net of issuance costs	3,246	3	49,443	—	—	49,446
Issuance of common stock upon exercise of stock options	426	1	2,983	—	—	2,984
Issuance of common stock under employee stock purchase plan	243	—	1,803	—	—	1,803
Issuance of common stock to participants in 401(k) plan	8	—	137	—	—	137
Stock-based compensation expense	—	—	32,383	—	—	32,383
Comprehensive loss	—	—	—	(173)	—	(173)
Net loss	—	—	—	—	(162,667)	(162,667)
Balance at December 31, 2022	81,885	$ 82	$ 841,413	$ (302)	$ (581,633)	$ 259,560

See accompanying notes to consolidated financial statements.

NGM BIOPHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2022	**2021**	**2020**
Cash flows from operating activities			
Net loss	$ (162,667)	$ (120,335)	$ (102,487)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	32,383	26,242	15,651
Reduction in related party contract asset due to Amended Collaboration Agreement with Merck	—	4,600	—
Depreciation	4,035	6,089	6,555
Amortization of premium (accretion of discount) on marketable securities	69	3,514	(128)
Noncash lease expense	1,949	1,810	—
Other non-cash expenses	504	643	613
Changes in operating assets and liabilities:			
Related party receivable from collaboration	(2,635)	(4,612)	4,873
Related party contract asset	—	1,500	(6,100)
Prepaid expenses and other assets	1,790	(4,145)	(1,864)
Accounts payable	3,207	(4,417)	910
Accrued and other liabilities	(589)	2,893	6,182
Operating lease liability	(5,077)	(4,785)	—
Deferred rent	—	—	(2,829)
Contract liabilities	(17,408)	17,774	(4,872)
Net cash used in operating activities	(144,439)	(73,229)	(83,496)
Cash flows from investing activities			
Purchase of marketable securities	(272,857)	(293,466)	(177,655)
Proceeds from maturities of marketable securities	289,037	223,500	128,536
Purchase of property and equipment	(1,858)	(1,684)	(1,879)
Net cash provided by (used in) investing activities	14,322	(71,650)	(50,998)
Cash flows from financing activities			
Proceeds from Open Market Agreement, net	49,446	196	21,943
Proceeds from exercise of stock options	2,984	12,362	11,838
Proceeds from employee stock purchase plan	1,803	2,519	2,370
Proceeds from follow on offering, net	—	134,580	—
Deferred offering costs paid	—	—	(613)
Net cash provided by financing activities	54,233	149,657	35,538
Net (decrease) increase in cash and cash equivalents	(75,884)	4,778	(98,956)
Cash, cash equivalents and restricted cash, at beginning of period	153,294	148,516	247,472
Cash, cash equivalents and restricted cash, at end of period	$ 77,410	$ 153,294	$ 148,516
Supplemental disclosures of non-cash investing and financing activities:			
Property and equipment purchases not yet paid	$ 606	$ —	$ 20
Right of use asset acquired under operating lease on the adoption of ASC 842	—	5,855	—

See accompanying notes to consolidated financial statements.

NGM BIOPHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of Business

NGM Biopharmaceuticals, Inc. and its wholly-owned subsidiary, NGM Biopharmaceuticals Australia Pty Ltd., NGM Australia, collectively referred to as the Company, is a biopharmaceutical company focused on discovering and developing novel, potentially life-changing medicines based on scientific understanding of key biological pathways underlying grievous diseases with critical unmet or underserved patient need. The Company's portfolio of product candidates range from early discovery to Phase 2b development and includes five programs in active clinical development. The Company has additional programs that are in various stages of development ranging from functional validation to preclinical development.

The Company was incorporated in Delaware in December 2007 and commenced operations in 2008. The Company's headquarters are located at 333 Oyster Point Blvd., South San Francisco, California 94080.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP, and include the consolidated accounts of NGM Biopharmaceuticals, Inc. and its wholly-owned foreign subsidiary, NGM Australia. All intercompany balances and transactions have been eliminated upon consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make judgments, assumptions and estimates that affect the reported amounts of assets, liabilities, revenues and expenses. Specific accounts that require management estimates include, but are not limited to, the valuation of common stock and the associated stock-based compensation expense, contract manufacturing accruals, clinical trial accruals and revenue recognition in accordance with Accounting Standards Update, or ASU, 2014-09, Revenue from Contracts with Customers (Topic 606), or ASC 606. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates, and to the extent that there are differences between management's estimates and actual results, the Company's future financial statement presentation, financial condition, results of operations and cash flows may be affected.

Sources and Uses of Liquidity

Since inception, the Company has incurred net losses and negative cash flow from operations. During the years ended December 31, 2022, 2021 and 2020, the Company incurred net losses of $162.7 million, $120.3 million and $102.5 million, respectively. As of December 31, 2022, the Company had an accumulated deficit of $581.6 million. The Company expects its accumulated deficit will continue to increase over time and does not expect to experience positive cash flows from operations in the near future.

As of December 31, 2022, the Company had $271.5 million of cash, cash equivalents and short-term marketable securities.

In June 2020, the Company entered into an Open Market Sale Agreement℠, or the Sales Agreement, with Jefferies LLC. As of December 31, 2022, $76.2 million of the Company's common stock remained available to be sold under the Sales Agreement, subject to conditions specified in the Sales Agreement.

The Company believes its existing cash, cash equivalents and short-term marketable securities will be sufficient to fund its operations for a period of at least one year from the date of these consolidated financial statements.

To fully implement the Company’s business plan and fund its operations, the Company will need to raise significant additional capital through public or private equity or debt offerings (which may include potential net proceeds from future sales, if any, under the Sales Agreement), collaboration or partnering arrangements, strategic alliances, licensing arrangements or a combination of the foregoing.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, the related party receivable from collaboration and other current assets and liabilities approximate their respective fair values due to their short-term nature.

Cash and Cash Equivalents

Cash and cash equivalents are stated at fair value. Cash equivalents are securities with an original maturity of three months or less at the time of purchase. The Company limits its credit risk associated with cash and cash equivalents by investing in highly rated money market funds and placing its cash with a bank it believes is highly creditworthy in amounts that may at times exceed federally insured limits. As of December 31, 2022 and 2021, cash and cash equivalents consisted of bank deposits and investments in money market funds.

Marketable Securities

The appropriate classification of the Company's marketable securities is determined at the time of purchase and such designations are re-evaluated at each balance sheet date. All of the Company's securities are considered as available-for-sale and carried at estimated fair values and reported in cash equivalents and short-term marketable securities. Unrealized gains and losses on available-for-sale securities are excluded from net loss and reported in accumulated other comprehensive loss as a separate component of stockholders' equity. Interest income, net, includes interest, amortization of purchase premiums and accretion of purchase discounts, realized gains and losses on sales of securities and other-than-temporary declines in the fair value of securities, if any. The cost of securities sold is based on the specific identification method.

The Company's investments are regularly reviewed for other-than-temporary declines in fair value. This review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities and whether it is more likely than not that the Company will be required to sell the securities before the recovery of their amortized cost basis. When the Company determines that the decline in fair value of an investment is below its carrying value and this decline is other-than-temporary, the Company reduces the carrying value of the security it holds and records a loss for the amount of such decline. As of December 31, 2022, the Company did not record any impairment related to other-than-temporary declines in the fair value of securities.

Restricted Cash

The Company's restricted cash balance represents collateral required under the Company's facility lease agreement and is classified as a non-current asset on the consolidated balance sheets, as the collateral will not be returned to the Company within twelve months from the date of these consolidated financial statements.

Concentration of Credit and Other Risks

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

Related party receivables from collaboration and partnering arrangements are typically unsecured. Accordingly, the Company may be exposed to credit risk generally associated with its current amended and restated research collaboration, product development and license agreement, or the Amended Collaboration Agreement, with Merck and any future collaboration or partnering arrangements with other potential future partners. To date, the Company has not experienced any losses related to these receivables.

Amounts recognized as revenue prior to the Company having an unconditional right (other than a right that is conditioned only on the passage of time) to receipt are recorded as contract assets in the Company's consolidated balance sheets. Although the Company expects to have an unconditional right to receive such amounts, the Company may be exposed to the risk of not receiving the recorded amounts under its current collaboration agreement with Merck and any future collaboration or partnering arrangements with other potential future partners. To date, the Company has not experienced any losses related to contract assets.

Merck accounted for 100% of the Company's revenue for the years ended December 31, 2022, 2021 and 2020.

Property and Equipment, Net

Property and equipment are recorded at cost and consists of computer equipment, laboratory equipment and office furniture and leasehold improvements. Maintenance and repairs, and training on the use of equipment, are expensed as incurred. Costs that improve assets or extend their economic lives are capitalized. Depreciation is recognized using the straight-line method based on an estimated useful life of the asset, which is as follows:

Computer equipment	3 years
Laboratory equipment and office furniture	3 years
Leasehold improvement	Shorter of life of asset or lease term

Leases

Effective January 1, 2021, the Company adopted ASU 2016-02, Leases (Topic 842), referred to as ASC 842. Under ASC 842, the Company determines if an arrangement is a lease at inception. Lease assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Lease liabilities are measured at the lease commencement date as the present value of future minimum lease payments over the term of the lease. Lease assets are measured as the lease liability plus initial direct costs and prepaid lease payments less lease incentives. In measuring the present value of the future minimum lease payments, the Company generally uses its incremental borrowing rate. The lease term is the noncancelable period of the lease and includes options to extend or terminate the lease when it is reasonably certain that an option will be exercised. Leases with terms of 12 months or less are not recorded on the Company's balance sheet. Lease expense is recognized on a straight-line basis over the lease terms, or in some cases, the useful life of the underlying asset. The Company accounts for the lease and non-lease components as a single lease component. The Company’s lease agreement for its corporate office space and facilities is classified as an operating lease.

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge is recognized as the amount by which the carrying amount of the asset exceeds the estimated fair value of the asset. As of December 31, 2022 and 2021, no revision to the remaining useful lives or write-down of long-lived assets was required.

Income Taxes

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

Revenue Recognition

Under ASC 606, the Company estimates each arrangement’s total transaction price, which includes unconstrained variable consideration, and the recognition of that transaction price based on a cost-based input method that requires estimates to determine, at each reporting period, the percentage of completion based on the estimated total effort required to complete the project and the total transaction price. The unconstrained variable consideration amount included in the transaction price represents an amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur.

The Company applies the following five-step revenue recognition model outlined in ASC 606 to adhere to this core principle: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the Company satisfies a performance obligation.

All of the Company's revenue to date has been generated from its collaboration agreements, primarily its collaboration agreement with Merck. The terms of these agreements generally require the Company to provide (i) license options for its compounds, (ii) research and development, or R&D, services and (iii) non-mandatory services in connection with participation in research or steering committees. Payments received under these arrangements may include non-refundable upfront license fees, partial or complete reimbursement of R&D costs, contingent consideration payments based on the achievement of defined collaboration objectives and royalties on sales of commercialized products. In some agreements, the collaboration partner is solely responsible for meeting defined objectives that trigger contingent or royalty payments. Often the partner only pursues such objectives subsequent to exercising an optional license on compounds identified as a result of the R&D services performed under the collaboration agreement.

The Company assesses whether the promises in its arrangements, including any options provided to the partner, are considered distinct performance obligations that should be accounted for separately. Judgment is required to determine whether the license to a compound is distinct from R&D services or participation in research or steering committees, as well as whether options create material rights in the contract. In situations when a contract includes distinct R&D services that are substantially the same and have the same pattern of transfer to the customer over time, they are recognized as a series of distinct services.

The transaction price in each arrangement is generally comprised of a non-refundable upfront fee and unconstrained variable consideration related to the performance of R&D services. The unconstrained variable consideration amount included in the transaction price represents an amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. The Company typically submits a budget for the R&D services to the partner in advance of performing the services. The transaction price is allocated to the identified performance obligations based on the standalone selling price, or SSP, of each distinct performance obligation. Judgment is required to determine the SSP. In instances where the SSP is not directly observable, such as when a license or service is not sold separately, SSP is determined using information that may include market conditions and other observable inputs. The Company utilizes judgment to assess the nature of its performance obligations to determine whether they are satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress toward completion. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

The Company's collaboration agreements may include contingent payments related to specified development and regulatory milestones or contingent payments for royalties based on sales of a commercialized product. Milestones can be achieved for such activities in connection with progress in clinical trials, regulatory filings in various geographical markets and marketing approvals from health authorities. Sales-based royalties are generally related to the volume of annual sales of a commercialized product. At the inception of each agreement that includes such payments, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or its partner's control, such as those related to regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is then allocated to each performance obligation based on a relative SSP basis. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of each such milestone and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Pursuant to the guidance in ASC 606, sales-based royalties are not included in the transaction price. Instead, royalties are recognized at the later of when the performance obligation is satisfied or partially satisfied, or when the sale that gives rise to the royalty occurs.

Contract modifications, defined as changes in the scope or price (or both) of a contract that are approved by the parties to the contract, such as a contract amendment, exist when the parties to a contract approve a modification that either creates new, or changes existing, enforceable rights and obligations of the parties to the contract. Depending on facts and circumstances, the Company accounts for a contract modification as one of the following: (i) a separate contract; (ii) a termination of the existing contract and a creation of a new contract; or (iii) a combination of the preceding treatments. A contract modification is accounted for as a separate contract if the scope of the contract increases because of the addition of promised services that are distinct and if the price of the contract increases by an amount of consideration that reflects the Company's standalone selling prices of the additional promised services. When a contract modification is not considered a separate contract and the remaining services are distinct from the services transferred on or before the date of the contract modification, the Company accounts for the contract modification as a termination of the existing contract and a creation of a new contract. When a contract modification is not considered a separate contract and the remaining services are not distinct, the

Company accounts for the contract modification as an add-on to the existing contract and as an adjustment to revenue on a cumulative catch-up basis.

Research and Development

R&D costs are expensed as incurred. R&D expenses primarily include salaries and benefits for medical, clinical, quality, preclinical, manufacturing and research personnel, costs related to research activities, preclinical studies, clinical trials, drug manufacturing expenses and allocated overhead and facility occupancy costs. The Company accounts for non-refundable advance payments for goods or services that will be used in future R&D activities as expenses when the goods have been received or when the service has been performed rather than when the payment is made.

Clinical trial costs are a component of R&D expenses. The Company accrues estimated costs for its clinical trial activities performed by third parties, including clinical research organizations, or CROs, and other service providers based upon estimates of the proportion of work completed over the life of the individual clinical trial and patient enrollment rates in accordance with associated agreements. The Company's estimates are determined through detailed discussions with internal personnel and its service providers as to the progress of each clinical trial and by reviewing contracts, vendor agreements and purchase orders for previously agreed-upon rates and fees to be paid for such services.

Stock-Based Compensation

The Company’s stock-based compensation programs include stock option grants, as well as shares issued under its 2019 Employee Stock Purchase Plan, or ESPP. Grants are awarded to employees, directors and non-employees. The Company measures stock-based compensation expense for all stock-based awards at the grant date based on the fair value measurement of the award. The expense is recorded on a straight-line basis over the requisite service period, which is generally the vesting period, for the entire award. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures materially differ from estimates. The Company calculates the fair value measurement of stock options using the Black-Scholes option-pricing model.

Foreign Currency Transactions

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

The Company is subject to foreign currency risk with respect to its clinical and manufacturing contracts denominated in currencies other than the U.S. dollar, primarily British Pounds, Swiss Francs, Australian dollars and the Euro. Payments on contracts denominated in foreign currencies are made at the spot rate on the day of payment. Changes in the exchange rate between billing dates and payment dates are recorded within other expense, net on the consolidated statements of operations.

Comprehensive Loss

Comprehensive loss is composed of net loss and certain changes in stockholders’ equity that are excluded from net loss, primarily unrealized gains or losses, net of taxes, on the Company’s marketable securities.

Net Loss per Share

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding during the period, less shares subject to repurchase and excludes any dilutive effects of stock-based options and awards. Diluted net income per share is computed by giving effect to all potentially dilutive shares, including common stock issuable upon exercise of stock options. However, where there is a diluted net loss per share, no adjustment is made for potentially issuable shares since their effect would be anti-dilutive. In this case, diluted net loss per share is equal to basic net loss per share.

Net loss per share was computed as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2022	2021	2020
Numerator:			
Net loss	$ (162,667)	$ (120,335)	$ (102,487)
Denominator:			
Weighted average number of shares used in calculating net loss per share—basic and diluted	79,950	77,085	68,475
Net loss per share—basic and diluted	$ (2.03)	$ (1.56)	$ (1.50)

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

	Year Ended December 31,		
	2022	2021	2020
Options to purchase common stock	14,215	10,485	10,018
Shares committed under the ESPP	1,222	390	292
Total	15,437	10,875	10,310

Segment and Geographical Information

The Company operates in one business segment. Substantially all of the Company's long-lived assets, primarily comprised of property and equipment, are based in the United States. For the years ended December 31, 2022, 2021 and 2020, the Company's revenues were entirely within the United States based upon the location of the Company and Merck.

Recent Accounting Pronouncements

New accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's results of operations and financial position upon adoption.

3. Fair Value Measurements

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

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
As of December 31, 2022				
U.S. treasury securities	$ 89,039	$ 7	$ (160)	$ 88,886
Money market funds	62,844	—	—	62,844
Corporate and agency bonds	46,300	—	(200)	46,100
Commercial paper	42,746	—	—	42,746
U.S. government agency securities	20,253	51	—	20,304
Totals	$ 261,182	$ 58	$ (360)	$ 260,880
Classified as:				
Cash and cash equivalents				$ 62,844
Short-term marketable securities (amortized cost of $198,338)				198,036
Total				$ 260,880

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
As of December 31, 2021				
U.S. treasury securities	$ 141,093	$ —	$ (116)	$ 140,977
Money market funds	129,763	—	—	129,763
Corporate and agency bonds	64,997	7	(20)	64,984
Commercial paper	8,497	—	—	8,497
Totals	$ 344,350	$ 7	$ (136)	$ 344,221
Classified as:				
Cash and cash equivalents				$ 129,763
Short-term marketable securities (amortized cost of $214,587)				214,458
Total				$ 344,221

Cash and cash equivalents in the table above excludes cash on deposit with banks of $10.6 million and $22.0 million as of December 31, 2022 and 2021, respectively.

To date, the Company has not recorded any impairment charges against the market value of its marketable securities. In determining whether a decline is other than temporary, the Company considers various factors including the length of time and extent to which the market value has been less than cost, the financial condition and near-term prospects of the issuer and the Company's intent and ability to retain its investment in the issuer for a period of time sufficient to allow for any anticipated recovery in market value.

As of December 31, 2022 and 2021, all of the Company's marketable securities had remaining contractual maturities of less than one year. As of December 31, 2022, the Company had 19 marketable securities in an unrealized loss position compared to 21 marketable securities in an unrealized loss position as of December 31, 2021. Marketable securities that had been in unrealized loss positions as of December 31, 2022 and 2021 were in an unrealized loss position for less than twelve months. The Company does not need to nor does it intend to sell marketable securities that are in an unrealized loss position and it is highly unlikely that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following table summarizes, by major security type, the Company's available-for-sale securities that were measured at fair value on a recurring basis and were categorized using the fair value hierarchy (in thousands):

	Fair Value Measurements			
As of December 31, 2022	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
U.S. treasury securities	$ 88,886	$ —	$ —	$ 88,886
Money market funds	62,844	—	—	62,844
Corporate and agency bonds	—	46,100	—	46,100
Commercial paper	—	42,746	—	42,746
U.S. government agency securities	—	20,304	—	20,304
Totals	$ 151,730	$ 109,150	$ —	$ 260,880

	Fair Value Measurements			
As of December 31, 2021	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
U.S. treasury securities	$ 140,977	$ —	$ —	$ 140,977
Money market funds	129,763	—	—	129,763
Corporate and agency bonds	—	64,984	—	64,984
Commercial paper	—	8,497	—	8,497
Totals	$ 270,740	$ 73,481	$ —	$ 344,221

The Company estimates the fair values of investments in commercial paper, corporate and agency bond securities and U.S. government agency securities using Level 2 inputs by taking into consideration valuations obtained from third-party pricing services.

There were no transfers of assets or liabilities between the fair value measurement levels during the years ended December 31, 2022 and 2021.

4. Balance Sheet Components

Cash, Cash Equivalents and Restricted Cash

A reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets to the amount reported within the consolidated statements of cash flows is as follows (in thousands):

	December 31,	
	2022	**2021**
Cash and cash equivalents	$ 73,456	$ 151,795
Restricted cash	3,954	1,499
Total cash, cash equivalents and restricted cash	$ 77,410	$ 153,294

Property and Equipment

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

	December 31,	
	2022	2021
Leasehold improvements	$ 25,866	$ 25,880
Laboratory equipment and office furniture	23,807	21,916
Computer equipment	1,433	1,225
Construction-in-progress	284	18
Total property and equipment, gross	51,390	49,039
Less: accumulated depreciation and amortization	(42,894)	(38,968)
Total property and equipment, net	$ 8,496	$ 10,071

Depreciation expense for the years ended December 31, 2022, 2021 and 2020 was approximately $4.0 million, $6.1 million and $6.6 million, respectively.

Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Clinical trials and research and development costs	$ 14,597	$ 12,070
Personnel-related costs	9,181	10,298
Manufacturing costs (1)	6,026	7,773
Accrued expenses	3,834	3,117
Total accrued liabilities	$ 33,638	$ 33,258

(1) As of December 31, 2022, the Company recorded an aggregate of $3.0 million for cancellation charges related to the Company's cancellation of its agreement with Lonza Ltd for the Phase 3 manufacturing of NGM621 following Merck's decision to not exercise its option to license NGM621 and the Company's decision not to proceed with further development of NGM621, of which $1.8 million was recorded in accrued manufacturing costs and $1.2 million was included in accounts payable. See Note 5 for additional information.

5. Research Collaboration and License Agreements

Merck

In 2015, the Company entered into a research collaboration, product development and license agreement with Merck, which, together with amendments made prior to June 30, 2021, is referred to as the Original Collaboration Agreement, covering the discovery, development and commercialization of novel therapies across a range of therapeutic areas, including a broad, multi-year drug discovery and early development program that was financially supported by Merck, and scientifically directed by the Company with input from Merck. The original research phase of the collaboration was for five years and was extended by Merck for an additional two years through March 2022. As part of that extension, Merck agreed to continue to fund up to $75.0 million of the Company's R&D efforts each year consistent with the initial five-year research term and, in lieu of a $20.0 million extension fee payable to the Company, Merck agreed to make additional payments totaling up to $20.0 million in support of the Company's R&D activities during 2021 through the first quarter of 2022.

On June 30, 2021, the Company entered into an amended and restated research collaboration, product development and license agreement with Merck, or the Amended Collaboration Agreement, replacing the Original Collaboration Agreement and extending the research phase of the collaboration generally through March 31, 2024, with possible extensions for each of the various programs to allow the Company or Merck to complete ongoing development, but with a narrower scope than in the Original Collaboration Agreement. Under the Amended Collaboration Agreement, the collaboration was focused primarily on the identification, research and development of collaboration compounds directed to targets of interest to Merck in the fields of ophthalmology and cardiovascular or metabolic, or CVM, disease, including heart failure. The collaboration scope also included certain laboratory testing

and other activities on compounds that are directed to one of up to two undisclosed targets outside of the fields of ophthalmology and CVM disease, or the Lab Programs.

Currently, the only ongoing research activities funded under the Amended Collaboration Agreement are certain CVM-related activities and remaining activities under the Lab Programs, or the Remaining Research Programs. The ophthalmology compounds in the collaboration under the Amended Collaboration Agreement initially included NGM621 (and its related compounds) and compounds directed against two other undisclosed ophthalmology targets (and their related compounds). Merck had a one-time option to license NGM621, its related compounds and the ophthalmology bundle upon completion of the Phase 2 CATALINA trial. In December 2022, Merck notified us that it would not exercise its option to license NGM621 and its related compounds, nor would Merck exercise the related ophthalmology bundle option; accordingly, these options expired unexercised in January 2023 and the programs are now wholly-owned by us. Further, Merck did not elect for us to continue to conduct R&D on any compounds from our other ophthalmology programs that were subject to the collaboration, which are preclinical and directed to undisclosed targets. Such an election would have resulted in an extended or tail period in which Merck would continue to fund our R&D of such ophthalmology compounds. Because Merck did not exercise its ophthalmology license options or make such a tail period election, we do not have any funding from Merck to pursue such ophthalmology programs.

Merck owned approximately 16% of the Company's outstanding shares as of December 31, 2022.

The Amended Collaboration Agreement

Pursuant to the Amended Collaboration Agreement, the prior two-year extension of the research phase under the Original Agreement was deemed to end on March 31, 2021, while a new three-year research phase commenced on April 1, 2021. Under the Original Collaboration Agreement, all of the Company’s R&D programs, both those existing at the time the Company entered into the Original Collaboration Agreement and those the Company worked on during the research phase of the collaboration, other than aldafermin, were included within the scope of the collaboration. Under the terms of the Original Collaboration Agreement, upon completion of a human proof-of-concept trial for a particular collaboration compound, regardless of the results of such trial, Merck had the one-time option to obtain an exclusive, worldwide license, on specified terms, to that collaboration compound, as well as to all other compounds that were directed against the same target and that result in the same effect on such target, or the related compounds, referred to as the Merck license option. Under the Amended Collaboration Agreement, the scope of the collaboration and the resulting programs for which Merck has the Merck license option was narrowed, but included NGM621 and its related compounds, and compounds directed against two other undisclosed ophthalmology targets and their related compounds and the CVM-related activities and the Lab Programs. Collaboration compounds that remained within the R&D scope of the continuing collaboration under the Amended Collaboration Agreement are referred to as continuing collaboration compounds. Given the narrowed research scope under the Amended Collaboration Agreement, the Company gained the right, in its sole discretion, to independently research, develop and commercialize the collaboration compounds known as NGM120, NGM707, NGM831 and NGM438, their related compounds and all other preclinical and research assets that the Company researched or developed under the Original Collaboration Agreement but that are not included within the R&D scope of the continuing collaboration, which are referred to as the released NGM compounds. Merck retained the right to receive royalties at low single-digit rates on the sales of any released NGM compounds that receive regulatory approval and, if the Company decides during a certain time period to engage in a formal partnering process for a released NGM compound or negotiations regarding a license or asset sale of a released NGM compound, the Company is obligated to notify Merck, provide Merck with certain information and engage in good faith, non-exclusive negotiations with respect to such released NGM compound with Merck at Merck’s request.

Under the Amended Collaboration Agreement, Merck continued to have a Merck license option, as it did under the Original Agreement, to each continuing collaboration compound that is identified, researched and developed under the Amended Collaboration Agreement and reaches the specified option exercise point for such continuing collaboration compound as described below, and to its related compounds (each such continuing collaboration compound and its related compounds are referred to generally as a continuing program). In addition, under the terms of the Amended Collaboration Agreement, new CVM-related programs may be added to the continuing collaboration if recommended by the Company and selected by Merck, and Merck would have a Merck license option to such CVM-related continuing program. We do not expect any new CVM-related programs to be added to the collaboration.

Merck had a one-time right to exercise its Merck license option, during the research phase or a tail period following such research phase, as applicable, for any continuing collaboration compound on a continuing program-by-continuing program basis when the Company or Merck achieves the specified Merck license option exercise

point. The Merck license option exercise point for all collaboration compounds under the Original Collaboration Agreement was the completion of a human proof-of-concept trial, exercisable within 60 days of Merck's receipt of an agreed-upon data package for the relevant program. This remained the Merck license option exercise point under the Amended Collaboration Agreement for the continuing collaboration compounds directed to ophthalmology targets, including NGM621 and its related compounds and the continuing collaboration compounds from two other ophthalmology programs directed against undisclosed ophthalmology targets and their related compounds (including NGM621 and its related compounds, collectively referred to as the continuing ophthalmology collaboration compounds). Merck also had an additional one-time option at the same license option exercise point to obtain an exclusive, worldwide license to all of the continuing ophthalmology collaboration compounds together, referred to as the ophthalmology bundle option. As described above, Merck's license option for NGM621 (and its related compounds) and compounds directed against two other undisclosed ophthalmology targets (and their related compounds) expired unexercised in January 2023.

The Merck license option exercise point for a continuing collaboration compound from the CVM-related continuing programs or the Lab Programs will be the designation by Merck of such continuing collaboration compound as a research program development candidate that Merck intends to progress into preclinical development.

As was the case under the Original Collaboration Agreement, under the Amended Collaboration Agreement, if Merck exercises a Merck license option and obtains the relevant exclusive, worldwide license for a continuing collaboration compound and its related compounds, Merck will pay an option exercise fee to the Company and will be responsible, at its own cost, for any further development and commercialization activities for continuing collaboration compounds within that licensed continuing program. In such case, the Company will have the option to receive milestones and royalty payments or, in certain cases, to co-fund development and participate in a global cost and profit share arrangement of up to 50%, with an additional option to co-detail any such licensed continuing collaboration compound in the United States under the same terms as set forth in the Original Collaboration Agreement. If the Company elects to exercise its cost and profit share option for a particular continuing collaboration compound and its related compounds, Merck has agreed to advance to the Company and/or assume up to 25% of the Company’s share of the global development costs for such licensed compound, subject to an aggregate cap over the course of the collaboration. All such amounts advanced or assumed by Merck would accrue interest and be recouped by Merck in full out of the Company’s share of any profits resulting from sales of the licensed compound for which the Company elected to exercise its cost and profit share option before the Company was entitled to receive any of those profits.

Under the Amended Collaboration Agreement, if Merck exercises the Merck license option for a continuing collaboration compound from a CVM-related continuing program or the Lab Programs, Merck will pay the Company a $6.0 million option exercise fee at the time of selection to progress such licensed continuing collaboration compound or any of its related compounds into preclinical development and an additional $10.0 million milestone payment if such continuing collaboration compounds or one of its related compounds subsequently completes a human proof-of-concept trial.

Under the Amended Collaboration Agreement, the parties’ rights and obligations with respect to MK-3655 (NGM313) and related FGFR1c/KLB agonists for which Merck exercised its Merck license option in November 2018 did not change.

In March 2022, the Company and Merck entered into a letter agreement, or the Letter Agreement, regarding NGM621 manufacturing activities that the Company undertook with the intention of avoiding a significant delay between the completion of the CATALINA trial and the start of any Phase 3 clinical trial for NGM621.

Under the Amended Collaboration Agreement, Merck provided $86.0 million in research funding for the four calendar quarters that ended on March 31, 2022, which included the remaining $16.0 million of the up to $20.0 million in additional payments Merck agreed to pay as part of exercising its first option to extend the research phase of the collaboration under the Original Collaboration Agreement for two years through March 16, 2022. The Company was obligated to use commercially reasonable efforts to expend, and did spend, at least $35.0 million of such $86.0 million in funding during the same time frame on the ophthalmology and CVM-related programs and Lab Programs as required under the Amended Collaboration Agreement. The Company was permitted to use the remainder of the $86.0 million in research funding provided by Merck during such time frame to advance the released NGM compounds. During the remaining two years of the research phase after March 2022, Merck could provide up to a total of $20.0 million in research funding for the ophthalmology and CVM-related programs and the Lab Programs. Pursuant to the Letter Agreement, the Company also used part of this research funding to cover the costs of its personnel who provide support for the manufacturing activities that the Company undertook in preparation for a potential Phase 3 clinical trial for NGM621. Merck also funded certain R&D costs related to

NGM621 prior to Merck's decision to not exercise its license option with respect to NGM621 in December 2022. In accordance with the Letter Agreement, Merck agreed to reimburse the Company the maximum reimbursable amount for NGM621 third-party manufacturing costs of $4.75 million which is included in the related party receivable balance as of December 31, 2022. Merck continues to have license options for the CVM-related continuing programs and the Lab Programs.

The research phase for the CVM-related continuing programs will continue until March 31, 2024, unless the parties mutually agree to extend the research phase to March 31, 2026, in which case Merck would provide up to a total of $20.0 million in research funding during those additional two years. Although the research phase for the Lab Programs was scheduled to end no later than December 31, 2022, the Company is continuing to provide certain limited activities in 2023 to wrap up the Lab Programs.

In January 2023, the Company announced that Merck notified the Company of its decision to terminate the Phase 2b trial of MK-3655 in patients with nonalcoholic steatohepatitis, or NASH, and liver fibrosis stage 2 or 3, or F2/F3, and Merck subsequently provided the Company with the required 90-days' notice of partial termination of the Amended Collaboration Agreement as it relates to MK-3655 and its related compounds. As a result, in late April 2023, the license rights granted to Merck in 2018 with respect to MK-3655 will revert to the Company and the program will become wholly-owned by the Company.

As under the Original Collaboration Agreement, Merck has the right under the Amended Collaboration Agreement to review the then-ongoing continuing programs in the three-month period before the end of applicable research phase and to elect to designate one or more continuing programs for which R&D would continue to be conducted, until the applicable Merck license option exercise point is reached, for up to three years after the end of such research phase, with the possibility of extension if the Company is conducting ongoing ophthalmology clinical trials, if Merck is using commercially reasonable efforts to progress one or more ophthalmology continuing programs or if Merck determines to continue progressing a CVM-related continuing program or Lab Programs toward the nomination of a research program development candidate, and any such extension is referred to as an Amended Collaboration Agreement tail period. Under the Amended Collaboration Agreement, the Amended Collaboration Agreement tail period, if any, for the CVM-related continuing programs or any Lab Programs, Merck would be primarily responsible for performing all R&D activities, itself or through third-party contractors.

The Company concluded that the Amended Collaboration Agreement is a separate arrangement containing a three-year performance obligation to provide distinct R&D services in accordance with ASC 606. At December 31, 2022, the total transaction price under the Amended Collaboration Agreement is $120.3 million which includes $86.0 million in research funding for the four calendar quarters that ended on March 31, 2022, $15.7 million in research funding for the ophthalmology and CVM-related continuing programs and the Lab Programs during the remaining two years of the research phase after March 2022, $13.9 million in estimated NGM621 reimbursable expenses and costs during the remaining two years of the research phase after March 2022 and $4.75 million for reimbursable amounts paid to a third-party manufacturer in accordance with the terms of the Letter Agreement. The Company will continue to re-evaluate the transaction price as uncertain events are resolved or other changes in circumstances occur. The Company continues performing its R&D services in the area of both the continuing collaboration compounds and the released NGM compounds and has one performance obligation across all continuing programs. The Company will continue to use the cost-based input method to calculate the amount of revenue to recognize as services are being rendered from April 1, 2021 through March 31, 2024. For the period that started on January 1, 2023 and ends on March 31, 2024, the Company expects Merck will provide funding of approximately $13.0 million in the aggregate for the ongoing CVM-related activities, the remaining activities under the Lab Programs, and for certain costs and reimbursements related to the NGM621 program and this amount is included in the transaction price.

The Company considered whether the Merck license option and the ophthalmology bundle option created material rights in the contract and concluded that the fee attached to the exercise of such options approximated the SSP of the promised goods or services included in the options. Therefore, the Company concluded that such options did not give rise to material rights, were not performance obligations in the Amended Collaboration Agreement and, if and when exercised, would be accounted for as separate arrangements under ASC 606.

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

	First Indication	Second Indication	Third Indication
Upon administration of an applicable product to the first patient in the first Phase 3 clinical trial for such product for the given indication	$ 35,000	$ 25,250	$ 17,500
Upon first completion of a proof-of-concept trial for a CVM-related research program development candidate	$ 10,000	$ —	$ —
Upon first completion of a proof-of-concept trial for a certain research development candidate for a lab program	$ 10,000	$ —	$ —

A breakout of the aggregate milestone payments in connection with the potential achievement of both acceptance of an application for and receipt of regulatory approval for each of the first three indications, for each of the three geographic areas, is as follows (in thousands):

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

Summary of Related Party Revenue

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

	Year Ended December 31,		
	2022	2021	2020
Related party revenue	$ 55,333	$ 77,882	$ 87,368

For the year ended December 31, 2022, the Company recognized collaboration and license revenue of $55.3 million primarily related to reimbursable R&D activities associated with the performance obligation under the Amended Collaboration Agreement under which Merck is providing significantly less annual R&D funding than it had provided through March 31, 2022. Revenue recognized related to the reimbursable R&D activities was recognized using the cost-based input model related to R&D activities.

For the year ended December 31, 2021, the Company recognized collaboration and license revenue of $77.9 million primarily related to reimbursable R&D activities associated with the performance obligation for the two-year extension period through March 31, 2021 under the Original Collaboration Agreement and from April 1, 2021 through December 31, 2021 under the Amended Collaboration Agreement, all of which were recognized using the cost-based input model.

For the year ended December 31, 2020, the Company recognized collaboration and license revenue under the Original Collaboration Agreement of $87.4 million primarily related to reimbursable R&D activities, including $61.8 million associated with the performance obligation for the prior two-year extension period under the Original Collaboration Agreement, and $4.9 million related to collaboration and license revenue earned under the initial five-year term that ended in March 2020. Revenue related to reimbursable R&D activities was recognized using the cost-based input model.

Related Party Contract Assets and Liabilities

Amounts recognized as revenue prior to the Company having an unconditional right (or a right that is conditioned only on the passage of time) to receipt are recorded as contract assets in the Company's consolidated balance sheets. If the Company expects to have an unconditional right to receive the consideration in the next twelve months, the contract asset will be classified in current assets. As of December 31, 2022 and 2021, the Company did not have a related party contract asset.

Amounts received prior to satisfying the revenue recognition criteria are recorded as contract liabilities in the Company’s consolidated balance sheets. If the related performance obligation is expected to be satisfied within

the next twelve months, the contract liability will be classified in current liabilities. As of December 31, 2022 and December 31, 2021, the Company recorded contract liabilities of $0.4 million and $17.8 million, respectively.

6. Commitments and Contingencies

Operating Leases and Lease Guarantee

In December 2015, the Company entered into an operating lease agreement, or the 333 Oyster Point lease agreement, for its corporate office space and facilities at 333 Oyster Point Blvd., South San Francisco, California, or the 333 Oyster Point facility, for approximately 122,000 square feet that expires in December 2023. The 333 Oyster Point lease agreement provided a tenant improvement allowance of $15.2 million that the Company used in 2016 towards $22.3 million in total leasehold improvements that are amortized over the lease term of seven years. As of December 31, 2022, restricted cash on the Company's consolidated balance sheets included a letter of credit in the amount of $1.5 million required under the 333 Oyster Point lease agreement.

As of December 31, 2022, the weighted-average remaining lease term for the 333 Oyster Point lease agreement was 1 year and the weighted-average discount rate used to determine the Company's operating lease liability was 2.85%. Cash paid for amounts included in the measurement of the lease liabilities were $5.3 million and $5.1 million for the years ended December 31, 2022 and December 31, 2021, respectively.

During the year ended December 31, 2022, the components of lease costs, which were included in general and administrative expenses on the Company's consolidated statements of operations, were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Operating lease costs	$ 2,166	$ 2,166
Variable lease costs (1)	1,286	1,235
Total lease costs	$ 3,452	$ 3,401

(1) Variable lease costs include certain additional charges for operating costs, including insurance, maintenance, taxes and other costs incurred, which are billed based on both usage and as a percentage of the Company's share of total square footage.

As of December 31, 2022, the maturities of the Company's operating lease liabilities and future minimum lease payments were as follows (in thousands):

Total undiscounted lease payments for the year ending December 31, 2023	5,455
Less: present value adjustment	(70)
Present value of lease liabilities	$ 5,385

In July 2022, the Company entered into an operating lease agreement, or the 2024 Lease Agreement, for its corporate office space and facilities at 333 Oyster Point Blvd., South San Francisco, California, which the Company currently occupies pursuant to a sublease agreement that is scheduled to expire on December 31, 2023. Pursuant to the 2024 Lease Agreement, the lease term with the new landlord begins on January 1, 2024 and expires on December 31, 2033, and the Company will pay an initial monthly base rent of approximately $0.9 million for the first year, which is subject to increase at an annual rate of 3.5% each year thereafter, plus certain operating and tax expenses. Base rent during the initial ten-year term of the 2024 Lease Agreement will total $124.1 million. The 2024 Lease Agreement provides a tenant improvement allowance of approximately $4.9 million. The Company has an option to extend the 2024 Lease Agreement for a period of either eight or ten years after the initial term. In July 2022, pursuant to the 2024 Lease Agreement, the Company provided the landlord with a letter of credit in the amount of $2.5 million, which the landlord may draw from upon the occurrence of certain events provided in the lease.

Indemnification

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

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

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

7. Stockholders' Equity

Preferred Stock

The Company has 10.0 million shares of preferred stock authorized, which may be issued at the discretion of the Company's board of directors. The board of directors may issue shares of preferred stock in one or more series and may fix the number, rights, preferences, privileges and restrictions on such shares. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and sinking fund terms. As of December 31, 2022, the Company does not have any shares of preferred stock issued or outstanding.

Common Stock

Public Offering of Common Stock

In January 2021, the Company sold 5.3 million shares of its common stock through an underwritten public offering at a price to the public of $27.00 per share for aggregate net proceeds to the Company of $134.6 million, after deducting underwriting discounts and commissions and other offering expenses paid by the Company. The offering closed on January 8, 2021.

As of December 31, 2022 and 2021, the Company had 81.9 million and 78.0 million shares of common stock outstanding, respectively.

The Company had reserved the following shares of common stock for issuance as follows (in thousands):

	December 31,	
	2022	2021
Reserve balance for Sales Agreement	10,937	14,183
Common stock options outstanding	14,215	10,485
Common stock options available for grant	5,661	6,698
ESPP shares available for purchase	264	507
401(k) matching plan	192	18
Total	31,269	31,891

Open Market Sale Agreement

In June 2020, the Company entered into the Sales Agreement with Jefferies relating to the sale of shares of its common stock. In accordance with the terms of the Sales Agreement, the Company may offer and sell shares of its common stock having an aggregate offering price of up to $150.0 million from time to time through Jefferies acting as its sales agent. During the year ended December 31, 2022, approximately 3.2 million shares were sold pursuant to the Sales Agreement for net proceeds to the Company of $49.4 million, after deducting issuance costs. As of December 31, 2022, $76.2 million of the Company's common stock remained available to be sold under the Sales Agreement, subject to conditions specified in the Sales Agreement.

Equity Incentive Plan

In 2018, the Company adopted the 2018 Equity Incentive Plan, or the 2018 Plan, for eligible employees, officers, directors, advisors and consultants, which provides for the grant of incentive and non-statutory stock options, restricted stock awards and stock appreciation rights. The terms of the stock option agreements, including vesting requirements, are determined by the board of directors, subject to the provisions of the 2018 Plan. Options

granted by the Company generally vest within four years and are exercisable from the grant date until ten years after the date of grant. Vesting of certain employee options may be accelerated in the event of a change in control of the Company. Pursuant to the terms of the 2018 Plan, the number of shares reserved and available to issue will automatically increase on January 1st of each year in an amount equal to 4% of the total number of common shares outstanding on the December 31st immediately preceding calendar year, unless the board of directors elects to forego or reduce such increase. As of December 31, 2022, 19.9 million shares of common stock had been authorized for issuance under the 2018 Plan and the Company's 2008 Equity Incentive Plan which expired in 2018.

Stock options are governed by stock option agreements between the Company and recipients of stock options. The exercise price of each option may not be less than 100% of the fair market value of the common stock subject to the option on the date the option is granted. A 10% or greater stockholder may not be granted an incentive stock option unless the exercise price of such option is at least 110% of the fair value of the common stock on the date of grant and the option is not exercisable after the expiration of five years from the grant date. Options become exercisable and expire as determined by the Compensation Committee of the Company's board of directors, provided that the term of incentive stock options may not exceed ten years from the date of grant for options granted to those other than 10% stockholders.

Early Exercise of Stock Options

The 2018 Plan allows for the granting of options that may be exercised before the options have vested. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment or services, at the price paid by the purchaser, and are not deemed to be issued for accounting purposes until those related shares vest. The amounts received in exchange for these shares have been recorded as a liability on the consolidated balance sheets and will be reclassified into Company common stock and additional paid-in-capital as the shares vest. The Company's right to repurchase these shares generally lapses in equal installments over four years beginning from the original vesting commencement date. Since the beginning of March 2021, the Company has not granted any options under the 2018 Plan that can be early exercised prior to vesting.

2019 Employee Stock Purchase Plan

In March 2019, the Company adopted the ESPP. The Company reserved 1,000,000 shares of common stock pursuant to purchase rights granted to the Company's employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase on January 1 of each calendar year, beginning January 1, 2020, by the lesser of (1) 1.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, (2) 1,000,000 shares or (3) a number determined by the Company's board of directors that is less than (1) and (2). Under the ESPP, eligible employees are granted the right to purchase shares of the Company's common stock through payroll deductions that cannot exceed 15.0% of each employee's salary. The ESPP provides for a 24-month offering period, which includes four six-month purchase periods. At the end of each purchase period, eligible employees are permitted to purchase shares of common stock at the lower of 85% of fair market value at the beginning of the offering period or fair market value at the end of the purchase period. The ESPP is considered a compensatory plan. As of December 31, 2022, 736,170 shares of common stock had been purchased under the ESPP.

Stock Option Activity

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

	Outstanding Options			
	Number of Options (in Thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In Years)	Aggregate Intrinsic Value (In Thousands)
Balances at December 31, 2021	10,485	$ 15.79	6.68	$ 52,349
Options granted	4,925	12.82		
Options exercised	(426)	7.01		
Options forfeited	(552)			
Options expired	(217)	20.98		
Balances at December 31, 2022	14,215	$ 14.74	6.89	$ 1,749
Vested and expected to vest at December 31, 2022	13,646	$ 14.78	6.79	$ 1,749
Exercisable at December 31, 2022	9,087	$ 13.99	5.63	$ 1,749

The aggregate intrinsic values of options outstanding, vested and expected to vest, and exercisable were calculated as the difference between the exercise price of the options and the estimated fair value of the Company's common stock.

Stock-Based Compensation Expense

Stock-based compensation expense for stock options was calculated based on awards previously granted to employees, directors and non-employees that are ultimately expected to vest and has been reduced for estimated forfeitures.

Stock-based compensation expense was allocated as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Research and development	$ 17,875	$ 14,271	$ 8,339
General and administrative	14,508	11,971	7,312
Total stock-based compensation expense	$ 32,383	$ 26,242	$ 15,651

Stock-based compensation expense included expense related to the ESPP of $2.9 million, $1.6 million and $1.2 million for the years ended December 31, 2022, 2021 and 2020, respectively.

Valuation Assumptions

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

The expected volatility is based on the historical volatility of the Company's stock and the stock of similar entities within the Company's industry over periods commensurate with the Company's expected term assumption. The expected term of stock option grants represents the weighted-average period the options are expected to remain outstanding and is based on the "simplified" method where the expected term is the midpoint between the vesting date and the end of the contractual term for each option. The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term. In reference to the expected dividend yield assumption, the Company has not historically paid, and does not expect for the foreseeable future to pay, a dividend.

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2022, 2021 and 2020 was $8.63, $18.57 and $10.86 per share, respectively. The intrinsic value of stock options

exercised was $3.2 million, $34.2 million and $40.9 million for the years ended December 31, 2022, 2021 and 2020, respectively. Due to the Company's net operating losses, the Company did not realize any tax benefits from stock-based payment arrangements for the years ended December 31, 2022, 2021 and 2020.

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

	Year Ended December 31,		
	2022	2021	2020
Volatility	78 %	72 %	68 %
Expected term (years)	5.93	5.98	6.23
Risk-free interest rate	2.52 %	0.95 %	1.04 %
Expected dividend yield	—	—	—

As of December 31, 2022, total compensation cost not yet recognized related to unvested stock options granted to employees and directors was $54.3 million, which is expected to be recognized over a weighted-average period of 2.6 years.

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

	Year Ended December 31,		
	2022	2021	2020
Volatility	110 %	72 %	74 %
Expected term (years)	1.63	1.27	1.17
Risk-free interest rate	3.76 %	0.27 %	0.15 %
Expected dividend yield	—	—	—

8. Employee Benefit Plan

The Company sponsors a 401(k) defined contribution plan for its employees. Employee contributions are voluntary. In December 2011, the Company adopted the 401(k) Matching Plan, under which the Company makes matching contributions in the form of common stock at a rate of $1.00 for each $2.00 of employee contributions up to a maximum of $3,500 of common stock per employee per year beginning in 2022 and $750 prior to 2022. As of December 31, 2022 and 2021, the Company had reserved 192,385 and 17,813 shares of common stock for issuance pursuant to the 401(k) Matching Plan, respectively. Matching contributions of 7,615, 4,117 and 6,344 shares, or $137,000, $125,000 and $119,000 were issued for the years ended December 31, 2022, 2021 and 2020, respectively.

9. Income Taxes

The Company has reported pre-tax operating losses for all periods presented. The Company has not reflected any benefit for corresponding tax net operating loss carryforwards in the accompanying consolidated financial statements. The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

The components of the Company's losses before income taxes were as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Domestic	$ (161,813)	$ (120,858)	$ (102,209)
Foreign	(854)	523	(278)
Total	$ (162,667)	$ (120,335)	$ (102,487)

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

	Year Ended December 31,		
	2022	2021	2020
U.S. federal tax at statutory rate	21.0 %	21.0 %	21.0 %
Foreign tax rate differential	0.1	—	—
State, net of federal benefit	—	—	(0.1)
Stock-based compensation (recovery)	(1.3)	1.3	3.8
Change in valuation allowance	(19.9)	(21.8)	(25.0)
Other	0.1	(0.5)	0.3
Total	— %	— %	— %

The components of the net deferred tax assets are as follows (in thousands):

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 77,563	$ 83,322
Capitalized R&D Section 174	31,964	—
Stock-based compensation	4,739	7,579
Research and development credit	2,918	2,918
Lease liability	1,132	2,198
Other temporary differences	435	514
Total gross deferred tax assets	118,751	96,531
Deferred tax liabilities:		
Depreciation and amortization	(779)	(997)
ROU asset	(440)	(850)
Non-qualified stock options with 83(b) election	(15)	(15)
Total gross deferred tax liabilities	(1,234)	(1,862)
Net deferred tax assets before valuation allowance	117,517	94,669
Deferred tax asset valuation allowance	(117,517)	(94,669)
Net deferred tax assets	$ —	$ —

ASC 740 requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's recent history of operating losses, management believes that recognition of the deferred tax assets arising from the above-mentioned future tax benefits is currently not more-likely-than-not to be realized and, accordingly, has provided a valuation allowance.

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately $22.8 million and $24.6 million during the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, the Company had approximately $345.4 million in federal net operating loss carryforwards to reduce future taxable income. Of this amount, $285.6 million was generated after December 31, 2017 and can be carried forward indefinitely. The federal net operating loss carryforwards generated prior to January 1, 2018 are subject to a 20-year carryforward period and will begin to expire after 2032. The utilization of the federal net operating loss carryforwards generated in fiscal year 2020 and onwards is limited to 80% of the federal taxable income. The Company also had approximately $466.6 million in state net operating loss carryforwards to reduce future taxable income, which will begin to expire after 2028, if not utilized.

In accordance with the 2017 Tax Act, research and experimental, or R&E, expenses under Internal Revenue Code Section 174 are required to be capitalized beginning in 2022. R&E expenses are required to be amortized over a period of five years for domestic expenses and 15 years for foreign expenses.

The Company had approximately $3.1 million in federal R&D tax credits for each of the years ended December 31, 2022 and 2021. In addition, the Company had approximately $4.0 million in state R&D tax credits for each of the years ended December 31, 2022 and 2021. The federal research credits will begin to expire in the years 2028 through 2035, if not utilized. The state R&D credits have no expiration date and can be carried forward indefinitely.

As of December 31, 2022, the Company had no foreign net operating loss carryforwards. As of December 31, 2021, the Company had foreign net operating loss carryforwards of approximately $21.3 million which had no expiration date.

Utilization of the Company's net operating losses and R&D tax credits may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and R&D tax credits before utilization.

A reconciliation of the Company's unrecognized tax benefits is as follows (in thousands):

	December 31,		
	2022	2021	2020
Balance at beginning of year	$ 25,870	$ 10,346	$ 3,819
Additions based on tax positions related to prior year	49	4,447	314
Additions based on tax positions related to current year	12,778	11,077	6,213
Balance at end of year	$ 38,697	$ 25,870	$ 10,346

The entire amount of the unrecognized tax benefits would not impact the Company's effective tax rate if recognized. The Company has elected to include interest and penalties as a component of tax expense. During the years ended December 31, 2022 and 2021, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease during the next 12 months.

The Company files U.S. federal, state and foreign income tax returns with varying statutes of limitations. The tax years from inception in 2008 to December 31, 2022 remain subject to examination.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of December 31, 2022, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2022, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(f) and 15d-15(f) of the Exchange Act that occurred during the quarter ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act).

Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in "Internal Control—Integrated Framework" (2013). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Our independent registered public accounting firm, Ernst & Young LLP, has audited our Consolidated Financial Statements included in Item 8 of this Annual Report on Form 10-K and have issued an audit report on our internal control over financial reporting as of December 31, 2022 which appears below.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of NGM Biopharmaceuticals, Inc.

Opinion on Internal Control over Financial Reporting

We have audited NGM Biopharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, NGM Biopharmaceuticals, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2022, and the related notes and our report dated February 28, 2023 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable

assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Mateo, California
February 28, 2023

Item 9B. Other Information.

On February 27, 2023, the Compensation Committee of our Board of Directors approved an addendum, or the Addendum, to the offer letter agreement between us and Hsiao D. Lieu, M.D., dated January 16, 2019. Pursuant to the Addendum, in the event of a termination without cause (and other than as a result of death or disability) or resignation for good reason, in either case on or within 18 months after the effective date of a change in control of the Company, and contingent on execution of an effective release of claims against us and satisfaction of certain other conditions, Dr. Lieu will be entitled to (i) continued payment of his base salary for six months; (ii) payment or reimbursement of COBRA premiums for him and his eligible dependents for up to six months; and (iii) full vesting of any unvested equity awards held by Dr. Lieu.

The foregoing description of the Addendum does not purport to be complete and is qualified in its entirety by reference to the full text of the Addendum, which is filed herewith as Exhibit 10.14.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item regarding directors and director nominees, executive officers, the board of directors and its committees, and certain corporate governance matters is incorporated by reference to the information set forth under the captions "Proposal No. 1—Election of Directors," "Corporate Governance and Board Matters" and "Executive Officers" to be included in our Proxy Statement for our 2023 Annual Meeting of Stockholders, or the 2023 Proxy Statement. If required, information required by this item regarding compliance with Section 16(a) of the Exchange Act is incorporated by reference to the information set forth under the caption "Delinquent Section 16(a) Reports" to be included in our 2023 Proxy Statement. The 2023 Proxy Statement will be filed with the SEC no later than 120 days after December 31, 2022.

Our written code of business conduct and ethics, the Code of Conduct, applies to all of our employees, officers and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The Code of Conduct is available on our corporate website at https://www.ngmbio.com/ in the Investors & Media section under "Corporate Governance." We intend to promptly disclose on our website or in a Current Report on Form 8-K in the future (i) the date and nature of any amendment (other than technical, administrative or other non-substantive amendments) to the Code of Conduct that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and relates to any element of the code of ethics definition enumerated in Item 406(b) of Regulation S-K and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Conduct that is granted to one of these specified individuals that relates to one or more of the elements of the code of ethics definition enumerated in Item 406(b) of Regulation S-K, the name of such person who is granted the waiver and the date of the waiver.

Item 11. Executive Compensation.

Information required by this item regarding executive compensation is incorporated by reference to the information set forth under the captions “Compensation Discussion and Analysis,” “Executive Compensation,” “CEO Pay Ratio” and “Director Compensation” in the 2023 Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item regarding security ownership of certain beneficial owners and management is incorporated by reference to the information set forth under the caption “Security Ownership of Certain Beneficial Owners and Management” and “Equity Compensation Plans at December 31, 2022” in the 2023 Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item regarding certain relationships, related transactions and director independence is incorporated by reference to the information set forth under the caption “Transactions with Related Persons and Indemnification” and “Corporate Governance and Board Matters” in the 2023 Proxy Statement.

Item 14. Principal Accounting Fees and Services.

Information required by this item regarding principal accounting fees and services is incorporated by reference to the information set forth under the caption “Proposal No. 3—Ratification of Selection of Independent Registered Public Accounting Firm” in the 2023 Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

1. *Financial Statements.* See Index to Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.
2. *Financial Statement Schedules*. None. All financial statement schedules are omitted because they are not applicable, not required under the instructions, or the requested information is included in the consolidated financial statements or notes thereto.
3. *Exhibits*. The following is a list of exhibits filed with this Annual Report or incorporated herein by reference:

		Incorporated by Reference				
Exhibit Number	**Exhibit Description**	**Form**	**File No.**	**Exhibit**	**Filing Date**	**Filed Herewith**
3.1	Amended and Restated Certificate of Incorporation	8-K	001-38853	3.1	4/8/19	
3.2	Amended and Restated Bylaws	S-1	333-227608	3.4	9/28/18	
4.1	Amended and Restated Investors’ Rights Agreement among the Registrant and certain of its stockholders, dated March 20, 2015.	S-1	333-227608	4.1	9/28/2019	
4.2	Form of Common Stock Certificate.	S-1	333-227608	4.2	4/1/2019	
4.3	Description of Capital Stock.	10-K	001-38853	4.3	3/17/2020	
10.1*	2008 Equity Incentive Plan, as amended.	S-1	333-227608	10.1	9/28/2018	
10.2*	Form of Stock Option Agreement and Stock Option Grant Notice under the 2008 Equity Incentive Plan.	S-1	333-227608	10.2	9/28/2018	
10.3*	Amended and Restated 2018 Equity Incentive Plan.	S-1	333-227608	10.3	3/25/2019	

10.4*	Forms of Stock Option Agreement and Notice of Grant of Stock Option under the Amended and Restated 2018 Equity Incentive Plan.	S-1	333-227608	10.4	3/25/2019	
10.5*	Forms of Restricted Stock Unit Agreement and Notice of Grant of Restricted Stock Unit under the Amended and Restated 2018 Equity Incentive Plan.	S-1	333-227608	10.5	3/25/2019	
10.6*	2019 Employee Stock Purchase Plan.	S-1	333-227608	10.6	3/25/2019	
10.7*	Form of Indemnification Agreement, by and between NGM Biopharmaceuticals, Inc. and each of its directors and executive officers.	S-1	333-227608	10.7	9/28/2018	
10.8*	NGM Biopharmaceuticals, Inc. Non-Employee Director Compensation Policy.	S-1	333-227608	10.8	3/25/2019	
10.9*	Amended and Restated Non-Employee Director Executive Compensation Policy					X
10.10*	Forms of Stock Option Agreement and Notice of Grant of Stock Option for Non-employee Directors Under the Amended and Restated 2018 Equity Incentive Plan.	10-Q	001-38853	10.2	8/5/2021	
10.11	Sublease Agreement, by and between NGM Biopharmaceuticals, Inc. and AMGEN Inc., dated December 11, 2015.	S-1	333-227608	10.9	9/28/2018	
10.12*	Executive Employment Offer Letter, by and between NGM Biopharmaceuticals, Inc. and Jin-Long Chen, Ph.D.	S-1	333-227608	10.11	9/28/2018	
10.13*	Executive Employment Agreement, by and between NGM Biopharmaceuticals, Inc. and David Woodhouse, Ph.D.	S-1	333-227608	10.13	3/25/2019	
10.14*	Offer Letter Agreement, by and between the Registrant and Hsiao D. Lieu, M.D., dated as of January 16, 2019.					X
10.15*	Offer Letter Agreement, by and between the Registrant and Valerie L. Pierce, dated as of August 6, 2019, and related information.	10-Q	001-38853	10.3	5/6/2021	
10.16*	Offer Letter Agreement, by and between the Registrant and Siobhan Nolan Mangini, dated as of May 20, 2020.	10-Q	001-38853	10.12	8/12/2020	
10.17#	Research Collaboration, Product Development and License Agreement by and between NGM Biopharmaceuticals, Inc. and Merck Sharp & Dohme Corp., dated as of February 18, 2015.	S-1	333-227608	10.15	9/28/2018	
10.18	Letter Agreement, by and between NGM Biopharmaceuticals, Inc. and Merck Sharp & Dohme Corp., dated as of March 20, 2015.	S-1	333-227608	10.17	9/28/2018	
10.19**	Amended and Restated Research Collaboration, Product Development and License Agreement, made effective as of June 30, 2021, by and between NGM Biopharmaceuticals, Inc. and Merck Sharp & Dohme Corp.	10-Q	001-38853	10.1	8/5/2021	

10.20#	Multi-Product Licence Agreement by and between NGM Biopharmaceuticals, Inc. and Lonza Sales AG, dated as of October 31, 2014, as amended by Amendment No. 1 on July 28, 2015, Amendment No. 2 on October 7, 2015, Amendment No. 3 on April 26, 2016, Amendment No. 4 on October 3, 2017, Amendment No. 5 on March 16, 2018 and Amendment No. 6 on February 6, 2019.	S-1	333-227608	10.17	4/1/2019	
10.21**	Amendment No. 7 on December 22, 2020 to Multi-Product Licence Agreement by and between NGM Biopharmaceuticals, Inc. and Lonza Sales AG, dated as of October 31, 2014.	10-K	001-38853	10.17	3/15/2020	
10.22**	Amendment No. 8 on February 10, 2021 to Multi-Product Licence Agreement by and between NGM Biopharmaceuticals, Inc. and Lonza Sales AG, dated as of October 31, 2014.	10-K	001-38853	10.18	3/15/2020	
10.23**	Amendment No. 9 on November 3, 2021 to Multi-Product Licence Agreement by and between NGM Biopharmaceuticals, Inc. and Lonza Sales AG, dated as of October 31, 2014.	10-K	001-38853	10.23	3/1/2022	
10.24	Letter Agreement, by and between NGM Biopharmaceuticals, Inc. and Merck Sharp & Dohme Corp., dated as of March 15, 2019.	S-1	333-227608	10.18	3/25/2019	
10.25	Letter Agreement, by and between NGM Biopharmaceuticals, Inc. and Merck Sharp & Dohme Corp., dated as of March 30, 2022.	10-Q	001-38853	10.1	5/5/2022	
10.26	Lease agreement, by and between NGM Biopharmaceuticals, Inc. and HCP BTC, LLC, dated as of July 7, 2022.	10-Q	001-38853	10.1	8/4/2022	
21.1	Subsidiaries of NGM Biopharmaceuticals, Inc.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (included on signature page).					X
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1†	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X

101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	X

* Indicates management contract or compensatory plan or arrangement.

** Certain confidential information contained in this exhibit has been omitted because it is both not material and is of the type that the Registrant treats as private or confidential.

Confidential treatment has been granted for a portion of this exhibit.

† The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K are not deemed filed with the SEC and are not to be incorporated by reference into any filing of NGM Biopharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

The agreements and other documents filed as exhibits to this Annual Report on Form 10-K are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by us in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NGM Biopharmaceuticals, Inc.

Date: February 28, 2023

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

Date: February 28, 2023

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David J. Woodhouse, Siobhan Nolan Mangini and Valerie Pierce, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution for him or her, and in his or her name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and either of them, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ David J. Woodhouse David J. Woodhouse, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	February 28, 2023
/s/ Siobhan Nolan Mangini Siobhan Nolan Mangini	President and Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 28, 2023
/s/ Bill Rieflin William J. Rieflin	Chairman and Director	February 28, 2023
/s/ Jin-Long Chen Jin-Long Chen, Ph.D.	Chief Scientific Officer and Director	February 28, 2023
/s/ David V. Goeddel, Ph.D. David V. Goeddel, Ph.D.	Director	February 28, 2023
/s/ Shelly D. Guyer Shelly D. Guyer	Director	February 28, 2023
/s/ Carole Ho Carole Ho, M.D.	Director	February 28, 2023
/s/ Suzanne Sawochka Hooper Suzanne Sawochka Hooper	Director	February 28, 2023
/s/ Roger M. Perlmutter, M.D. Roger M. Perlmutter, M.D.	Director	February 28, 2023

Exhibit 10.9

Amended Non-Employee Director Compensation Policy

NGM BIOPHARMACEUTICALS, INC.
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Approved by the Board of Directors: June 29, 2022

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of NGM Biopharmaceuticals, Inc. ("***NGM***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (the "***Director Compensation Policy***") for his or her Board service following the closing of the initial public offering of the common stock of NGM (the "***IPO***").

The Director Compensation Policy will be effective upon the date of the underwriting agreement between NGM and the underwriters managing the IPO (the "***Effective Date***"). The Director Compensation Policy may be amended at any time in the sole discretion of the Board. Capitalized terms not explicitly defined in this Director Compensation Policy but defined in the Plan (as defined below) will have the same definitions as in the Plan.

An Eligible Director may decline all or any portion of his or her compensation by giving notice to NGM prior to the date cash is to be paid or equity awards are to be granted, as the case may be.

Annual Cash Compensation

Commencing at the IPO, each Eligible Director shall receive the cash compensation described below. The annual cash compensation amount set forth below is payable in equal quarterly installments in arrears within 30 days following each fiscal quarter in which the service occurred. The first installment following the IPO will be pro-rated for the number of days remaining in the calendar quarter. If an Eligible Director joins the Board or a committee of the Board ("***Committee***") at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash retainer fees are vested upon payment.

1. Annual Board Service Retainer:
   a. Eligible Directors other than the Lead Independent Director or Non-Executive Chairperson, as applicable: $40,000
   b. Lead Independent Director: $65,000
   c. Non-Executive Chairperson: $75,000

2. Annual Committee Chair Service Retainer:
   a. Chairperson of the Audit Committee: $30,000
   b. Chairperson of the Compensation Committee: $15,000
   c. Chairperson of the Nominating & Corporate Governance Committee: $10,000

3. Annual Committee Member Service Retainer (excludes Committee Chairs):
   a. Member of the Audit Committee: $10,000
   b. Member of the Compensation Committee: $6,000
   c. Member of the Nominating & Corporate Governance Committee: $5,000

Equity Compensation

The equity compensation set forth below (including pursuant to an Annual Election, as defined below) will be granted under the Company's 2018 Equity Incentive Plan, as amended and restated from time to time, or any successor equity incentive plan adopted by NGM (the "***Plan***"), and will be documented on the applicable form of equity award agreement most recently approved for use by the Board (or a duly authorized committee thereof) for Eligible Directors. All stock options granted under the Director Compensation Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of Continuous Service or a Corporate Transaction as provided in the Plan). Upon a termination of Continuous Service other than for death, Disability or Cause, the post-termination exercise period of a stock option will be 12 months from the date of termination.

1. Initial Option Grant. On the date of the Eligible Director's initial election to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director automatically, and without further action by the Board or Compensation Committee of the Board, will be granted a stock option to purchase shares of Common Stock having a Grant Date Value (defined below) of $500,000 (the "***Initial Option Grant***"). The Initial Option Grant will vest one-third after the first year, with the remaining shares vesting quarterly in years two and three following the grant date, such that the Initial Option Grant will be fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service on each applicable vesting date.

2. Annual Option Grant. On the date of each NGM annual stockholder meeting held after the effective date of the IPO (an "***Annual Meeting***"), each Eligible Director automatically, and without further action by the Board or Compensation Committee of the Board, will be granted a stock option to purchase Common Stock having an Grant Date Value of $200,000 (the "***Annual Option Grant***"). The Annual Option Grant will vest in four approximately equal quarterly tranches, with the final tranche vesting on the earlier of (x) first anniversary of the date of grant, and (y) the day prior to the next Annual Meeting,

subject to the Eligible Director's Continuous Service on each applicable vesting date.

3. Calculation of Grant Date Value. The "***Grant Date Value***" of an equity award granted under this Director Compensation Policy will be determined using the same method the Company uses to calculate the grant date fair value of stock-based compensation for its financial statements (e.g., applying a Black-Scholes option pricing model in the case of stock options).

4. Treatment on a Change in Control. In the event of a Change in Control, any then-unvested equity award will fully vest (and become exercisable, in the case of an option) as of immediately prior to the effective time of such transaction, subject to the Eligible Director's Continuous Service on the effective date of such transaction. For clarity, such accelerated vesting will not accelerate the settlement of any equity award subject to a deferral election in accordance with Section 409A of the Internal Revenue Code.

5. Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board shall appropriately and proportionately adjust the number of shares provided above to be subject to any Initial Option Grant and Annual Option Grant made after the date of such Capitalization Adjustment.

Election to Receive Annual Cash Compensation in the Form of Stock Options

Following the IPO, each Eligible Director may elect in writing (an "***Annual Election***") to receive his or her annual cash compensation in the form of a stock option (an "***Annual Election Option***"). Such Annual Election would apply to all annual cash compensation payable during the subsequent year of service, measured from the date of the Annual Meeting.

Except as provided below, any Annual Election must be submitted in January of each calendar year, or in the case of an individual who first becomes an Eligible Director in any calendar year, within 30 days following the date on which he or she first becomes an Eligible Director (and no later than 30 days prior to the date of the Annual Meeting). An Annual Election will be irrevocable once submitted. All Annual Elections must also be submitted during an "open window period" in accordance with the Company's then-effective Insider Trading and Trading Window Policy (or any other policy on trading in Company securities), and when the Eligible Director submitting the Annual Election is not otherwise aware of any material, nonpublic information with respect to the Company or any of its securities (collectively, an "***Open Window***"). If there were no Open Windows within the applicable timeframe above during which an Annual Election could be submitted, then the Annual Election for that calendar year will be due no later than the tenth business day following the commencement of the next Open Window.

An Annual Election Grant will be granted on the date of the next Annual Meeting, with a Grant Date Value equal to the aggregate amount of cash retainers that such Eligible Director would otherwise have been eligible to receive over the four fiscal quarters following such Annual Meeting, and will vest in quarterly tranches, with the final tranche vesting on the earlier of (x) the first anniversary of the date of grant, and (y) the day prior to the next Annual Meeting.

Expenses

The Company will reimburse Eligible Directors for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and/or Committee meetings; *provided*, that Eligible Directors timely submit to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

Philosophy

The Director Compensation Policy is designed to attract and retain experienced, talented individuals to serve on the Board. The Board anticipates that the Board, or a duly authorized committee thereof, will generally review Eligible Director compensation on an annual basis following the IPO. The Director Compensation Policy, as amended from time to time, may take into account the time commitment expected of Eligible Directors, best practices and market rates in director compensation, the economic position of NGM, broader economic conditions, historical compensation structure, the advice of the compensation consultant that the Compensation Committee or the Board may retain from time to time, and the potential dilutive effect of equity awards on our stockholders.

Under the Director Compensation Policy, Eligible Directors receive cash compensation in the form of retainers to recognize their level of responsibility as well as the necessary time commitment involved in serving in a leadership role and/or on Committees. Eligible Directors also receive equity compensation because we believe that stock ownership provides an incentive to act in ways that maximize long-term stockholder value. Further, we believe that stock-based awards are essential to attracting and retaining talented Board members. When stock options are granted, these stock options will have an exercise price at least equal to the Fair Market Value of Common Stock on the date of grant, so that stock options provide a return only if the Fair Market Value appreciates over the period in which the stock option vests and remains exercisable. We believe that the vesting acceleration provided in the case of a Change in Control is consistent with market practices and is critical to attracting and retaining high quality directors.

To the extent this Director Compensation Policy would otherwise provide for compensation to any Eligible Director that would exceed any separate stockholder approved limit set forth in the Plan, the benefits provided under this Director Compensation Policy will automatically be reduced to fall within such limits (or if previously paid, are subject to recoupment).

Exhibit 10.14

January 16, 2019

Hsiao D. Lieu, M.D.

Dear Hsiao,

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

/s/ David J. Woodhouse

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

Exhibit A — Employee Proprietary Information and Inventions Agreement

Understood and Accepted

/s/ Hsiao D. Lieu
Hsiao D. Lieu, M.D.

1/22/2019
Date

ADDITIONAL INFORMATION REGARDING SEVERANCE AND CHANGE IN CONTROL ARRANGEMENTS

In addition to the employment offer letter with Dr. Lieu entered into on January 16, 2019, in February 2023, the Compensation Committee of the NGM Biopharmaceuticals, Inc. Board of Directors determined that, in the event of a termination without cause (and other than as a result of death or disability) or resignation for good reason, in either case on or within 18 months after the effective date of a change in control of the Company, and contingent on execution of an effective release of claims against us and satisfaction of certain other conditions, Dr. Lieu will be entitled to (i) continued payment of his base salary for 6 months; (ii) payment or reimbursement of COBRA premiums for him and his eligible dependents for up to 6 months; and (iii) full vesting of any unvested equity awards held by Dr. Lieu. The complete details of the foregoing benefits will be set forth in a written document provided to Dr. Lieu by the Company.

Exhibit 21.1

SUBSIDIARIES

Subsidiary Name	Jurisdiction of Incorporation or Organization
NGM Biopharmaceuticals Australia Pty Ltd.	Australia

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-8 No. 333-230725) pertaining to NGM Biopharmaceuticals, Inc. Amended and Restated 2018 Equity Incentive Plan and NGM Biopharmaceuticals, Inc. 2019 Employee Stock Purchase Plan;
2. Registration Statements (Form S-8 Nos. 333-237243, 333-254295 and 333-263155) pertaining to NGM Biopharmaceuticals, Inc. Amended and Restated 2018 Equity Incentive Plan; and
3. Registration Statement (Form S-3 No. 333-238991) and related prospectus and prospectus supplements of NGM Biopharmaceuticals, Inc.;

of our reports dated February 28, 2023, with respect to the consolidated financial statements of NGM Biopharmaceuticals, Inc., and the effectiveness of internal control over financial reporting of NGM Biopharmaceuticals, Inc., included in this Annual Report (Form 10-K) of NGM Biopharmaceuticals, Inc. for the year ended December 31, 2022.

/s/ Ernst & Young LLP

San Mateo, California
February 28, 2023

Exhibit 31.1

CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David J. Woodhouse, certify that:

1. I have reviewed this Annual Report on Form 10-K of NGM Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2023

By: /s/ David J. Woodhouse, Ph.D.

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

Exhibit 31.2

CERTIFICATION BY THE CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Siobhan Nolan Mangini, certify that:

1. I have reviewed this Annual Report on Form 10-K of NGM Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our 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;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2023

By: /s/ Siobhan Nolan Mangini

Siobhan Nolan Mangini

President and Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

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

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

1. The Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Date: February 28, 2023

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

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

This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of NGM Biopharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.