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

FORM 8-K

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

Date of Report (Date of earliest event reported): June 30, 2021

NGM Biopharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

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

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

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

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

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

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

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

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

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

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

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

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

Emerging growth company ☒

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

Item 1.01 Entry into a Material Definitive Agreement.

Amended and Restated Research Collaboration, Product Development and License Agreement

On June 30, 2021, NGM Biopharmaceuticals, Inc. (the "Company") and Merck Sharp & Dohme Corp. ("Merck") entered into an Amended and Restated Research Collaboration, Product Development and License Agreement (the "Amended Agreement") that amends and restates their existing Research Collaboration, Product Development and License Agreement dated February 18, 2015, as previously amended (the "Original Agreement"). The Original Agreement covered 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 the Company with input from Merck. The Original Agreement contemplated an initial five-year research phase, and Merck was granted the unilateral right to extend the research phase of the collaboration for two additional two-year terms. In March 2019, Merck exercised its first option to extend the research phase of the collaboration for two additional years through March 16, 2022. Under the terms of the Amended Agreement, Merck and the Company agreed to extend the research phase of the collaboration generally until March 31, 2024 with a narrower scope than contemplated in the Original Agreement, which scope is focused on therapeutic areas of particular interest to Merck and is described in more detail below (the "Continuing Collaboration"). Accordingly, under the Amended Agreement, the Company now has the sole right, in its sole discretion, to independently research, develop and commercialize the product candidates known as NGM707, NGM120 and NGM438 and all other product candidates that the Company researched or developed under the Original Agreement that are not included within the scope of the Continuing Collaboration (collectively, the "NGM Product Candidates"). Product candidates that remain within the scope of the Continuing Collaboration under the Amended Agreement are referred to herein as the "Continuing Product Candidates." The parties' rights and obligations with respect to MK-3655 and related FGFR1c/KLB agonists for which Merck exercised its option in November 2018 remain the same under the Amended Agreement as under the Original Agreement. Merck remains a significant stockholder of the Company.

Under the terms of the Amended Agreement, the Continuing Collaboration will focus on the identification, research and development of product candidates directed to targets in the fields of ophthalmology and cardiovascular or metabolic ("CVM") disease, and will also include laboratory testing and other activities on molecules that are directed to one of up to two undisclosed targets outside of the fields of ophthalmology and CVM disease (each, a "Lab program"). As it did under the Original Agreement, Merck has an option to take an exclusive, worldwide license for each Continuing Product Candidate that is identified, researched and developed under the Amended Agreement and reaches the specified option exercise point, as well as to all other related compounds that are directed to the same target and that result in the same effect on such target (each such option, a "Merck Option" and each such Continuing Product Candidate and its related compounds, a "program"). In addition, under the terms of the Amended Agreement, new CVM-related programs to which Merck would have such an option may be added to the Continuing Collaboration if recommended by the Company and selected by Merck. Merck has a one-time right to exercise its option, during the research phase or a tail period following such research phase, as applicable, for any Continuing Product Candidate on a program-by-program basis when the Company or Merck achieves the specified option exercise point. The option exercise point for candidates under the Original Agreement was the completion of a human proof-of-concept trial. This generally continues to be the option exercise point under the Amended Agreement for Continuing Product Candidates that are directed to ophthalmology targets, including NGM621 and its related compounds and all of the compounds from two other ophthalmology programs directed against undisclosed ophthalmology targets and their related compounds (collectively, including NGM621 and its related compounds, the "Continuing Ophthalmology Product Candidates"). Upon the completion of the CATALINA clinical trial, a human proof-of-concept trial that the Company is currently conducting on NGM621, Merck will have an additional one-time option to obtain an exclusive, worldwide license to all of the Continuing Ophthalmology Product Candidates. If Merck does not exercise this one-time option for all Continuing Ophthalmology Product Candidates (the "Bundle Option"), it may nevertheless exercise its regular option with respect to NGM621 and its related compounds at such time, and it may also exercise its regular options for the Continuing Ophthalmology Product Candidates from each of the other two programs if a Continuing Ophthalmology Product Candidate from such program completes a human proof-of-concept trial. Unlike the Original Agreement, the option exercise point for a product candidate from the CVM-related programs or the Lab program will be the designation by Merck of such candidate as a research program development candidate that Merck intends to progress into preclinical development.

The Company is primarily responsible under the Amended Agreement for all research and development for the ophthalmology programs prior to the relevant option exercise point and for the CVM-related programs prior to the expiration of the research phase for the CVM-related programs as described below. For the Lab program, the Company will be solely responsible for conducting or overseeing certain pre-specified research that is expected to be completed in early 2022, at which time Merck will decide whether to take sole responsibility for all subsequent research on compounds resulting from the Lab program prior to the option exercise point or to grant the Company the sole right, in its sole discretion, to independently research, develop and commercialize such Lab program compounds. As was the case under the Original Agreement, if Merck exercises a Merck Option and obtains the relevant exclusive, worldwide license for a Continuing Product Candidate 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 compounds within that licensed program. In such case, the Company will have the option to receive milestones and royalty payments or participate in the adjusted net sales in exchange for co-funding a share of the development costs and allowable expenses for any compound within that licensed program and an option to co-detail any such compound in the United States. Except for the Bundle Option, the amount of the option exercise fees for Continuing Ophthalmology Product Candidates upon completion of a human proof-of-concept trial remains the same as under the Original Agreement. If Merck exercises the Bundle Option, it will pay the Company either $40.0 million or $45.0 million as the option exercise fee, depending upon the stage of development of one of the two earlier stage ophthalmology programs that is included in the Bundle Option. Under the Amended Agreement, if Merck exercises the Merck Option for a candidate from a CVM-related program or the Lab program, Merck will pay the Company a $6.0 million option exercise fee and an additional $10.0 million milestone payment if such candidate or one of its related compounds subsequently completes a human proof-of-concept trial.

Merck remains committed under the Amended Agreement to provide up to $86.0 million in research funding for the four calendar quarters ending March 31, 2022, which includes 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 Agreement for two years through March 16, 2022. The Company is obligated to use commercially reasonable efforts to expend $35.0 million of such funding during such time frame on the ophthalmology- and CVM-related programs, as well as the Lab program. The Company is permitted to use the remaining research funding provided by Merck during such time frame to advance the NGM Product Candidates, for which Merck no longer has option rights under the Amended Agreement. During the remaining two years of the research phase after March 2022, Merck will provide up to a total of $20.0 million in research funding for the ophthalmology- and CVM-related programs and Merck will also fund the research and development costs related to NGM621, including the Company’s CATALINA clinical trial, subject to certain limitations. After March 2022, the Company will use its own funding to complete the work needed to be ready to submit an investigational new drug application, or IND, for a specific product candidate included in one of the two earlier stage ophthalmology programs and it will use commercially reasonable efforts to complete such work by March 31, 2023. If Merck exercises its regular option for NGM621 or the Bundle Option for all of the Continuing Ophthalmology Product Candidates upon completion of the CATALINA clinical trial and pays the applicable option exercise fee to the Company, then the Company will be obligated to reinvest $5.0 million or $15.0 million, respectively, of such option fee to fund research on the ophthalmology- and CVM-related programs.

The research phase for the ophthalmology-related programs will end no later than March 31, 2024. The research phase for the CVM-related 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 will provide up to a total of $20 million in research funding during those additional two years. The research phase for the Lab program will end no later than March 31, 2022.

As it did under the Original Agreement, Merck has the right under the Amended Agreement to review the then-ongoing research programs in the three-month period before the end of applicable research phase and to elect to designate one or more programs for which research and development would continue to be conducted, until the applicable option exercise point is reached, for up to three years after the end of such research phase, with the possibility of extension if ophthalmology clinical studies are then ongoing or if Merck determines to continue progressing a CVM-related program or Lab program toward the nomination of a research program development candidate (the “Tail Period”). The principal Tail Period-related changes in the Amended Agreement are that the Tail

Period, if any, for the ophthalmology-related programs would be separate from the Tail Period, if any, for the CVM-related programs and the Lab program and that Merck would be primarily responsible for performing all research and development activities, itself or through third party contractors, during the Tail Period, if any, for the CVM-related programs and the Lab program.

Similar to the Original Agreement, during the research phase and any applicable Tail Period of the Continuing Collaboration, the Company may not directly or indirectly research, develop, manufacture or commercialize, outside of the Continuing Collaboration, any product with specified activity against any target that is being researched or developed under the Continuing Collaboration and, if Merck exercises its option for a program, the Company may not directly or indirectly research, develop, manufacture or commercialize any product with specified activity against the target that is the subject of that program for so long as Merck's license to it remains in effect. In addition, under the Amended Agreement, the Company is prohibited from, direct or indirectly, researching, developing or commercializing any product for the treatment of heart failure with preserved ejection fraction (HFpEF) during the research phase for the CVM-related programs.

Upon the signing of the Amended Agreement, Merck's options to the NGM Product Candidates were extinguished and the Company gained the right to research, develop and commercialize all NGM Product Candidates, in its sole discretion and at its expense, without any obligations to Merck other than to pay royalties to Merck at low single digit rates on the sales of any NGM Product Candidates that receive regulatory approval and, if the Company decides during a certain time period to engage in a formal partnering process for an NGM Product Candidate or negotiations regarding a license or asset acquisition for an NGM Product Candidate, to notify Merck, provide Merck with certain information and engage in good faith, non-exclusive negotiations with respect to such NGM Product Candidate with Merck at Merck's request.

The foregoing description of the Amended Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Amended Agreement, a redacted copy of which will be filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2021. Refer to the Company's annual report on Form 10-K, filed with the Securities and Exchange Commission ("SEC") on March 15, 2021, for additional information regarding the Company's collaboration with Merck.

Forward-Looking Statements

Statements contained in this current report on Form 8-K regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "expected," "will," "may," "continue" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These statements include those related to anticipated activities by Merck and the Company under the Amended Agreement; the amount of development funding under, and potential option exercise fee payments to the Company under, the Amended Agreement; possible extensions and option exercises under the Amended Agreement; the potential receipt of milestone and royalty payments by the Company under the Amended Agreement; the Company funding the research, development and commercialization of NGM Product Candidates; the completion of the CATALINA clinical trial; and other statements that are not historical fact. Because such statements deal with future events and are based on the Company's current expectations, they are subject to various risks and uncertainties, and actual results, performance or achievements of the Company could differ materially from those described in or implied by the statements in this current report on Form 8-K. These forward-looking statements are subject to risks and uncertainties, including, without limitation, risks and uncertainties associated with the costly and time-consuming biopharmaceutical product development process and the uncertainty of clinical success, including risks related to failure or delays in successfully initiating, enrolling or completing clinical studies, as well as the risk that results obtained in clinical trials to date may not be indicative of results obtained in ongoing or future trials; the Company's ability to maintain the Continuing Collaboration with Merck, including the risk that if Merck were to breach or terminate the Amended Agreement or Merck's development funding obligations thereunder, the Company would not obtain all of the anticipated financial and other benefits of the Amended Agreement, and the development and/or commercialization of the Company's product candidates within the scope of the Continuing Collaboration could be delayed, perhaps substantially; the time-consuming and uncertain regulatory approval process; the Company's reliance on third-party manufacturers for its product candidates; the sufficiency of the Company's cash resources, including to fund programs that fall outside of the narrower scope of the Continuing Collaboration, and the Company's need for additional capital; the ongoing COVID-19 pandemic, which has adversely affected, and could materially and adversely affect in the future, the

Company’s business and operations, including the Company’s clinical trials; and other risks and uncertainties affecting the Company and its development programs, including those discussed in the section titled “Risk Factors” in the Company’s quarterly report on Form 10-Q for the quarter ended March 31, 2021 filed with the SEC on May 6, 2021 and future filings and reports that the Company makes from time to time with the SEC. Except as required by law, the Company assumes no obligation to update these forward-looking statements, or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

SIGNATURES

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

NGM Biopharmaceuticals, Inc.

Dated: June 30, 2021

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