
**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): May 6, 2021

NGM Biopharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38853
(Commission File Number)

26-1679911
(IRS Employer
Identification No.)

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

94080
(Zip Code)

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

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

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

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

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

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

Item 2.02. Results of Operations and Financial Condition.

On May 6, 2021, NGM Biopharmaceuticals, Inc. provided business highlights and reported its financial results for the first quarter ended March 31, 2021. A copy of the press release titled “NGM Bio Provides Business Highlights and Reports First Quarter 2021 Financial Results,” is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated May 6, 2021, titled “NGM Bio Provides Business Highlights and Reports First Quarter 2021 Financial Results.”

The information in this report, including the exhibit hereto, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by NGM Biopharmaceuticals, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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.

Dated: May 6, 2021

NGM Biopharmaceuticals, Inc.

By: /s/ Siobhan Nolan Mangini

Siobhan Nolan Mangini

Chief Financial Officer



NGM Bio Provides Business Highlights and Reports First Quarter 2021 Financial Results

- Expect to report topline data from Phase 2b ALPINE 2/3 clinical trial of aldafermin in patients with NASH with F2 and F3 liver fibrosis in the second quarter
- Continued enrollment in Phase 2 CATALINA study of NGM621 in patients with geographic atrophy and expect to complete enrollment by mid-year
- Achieved key milestone in oncology portfolio with initiation in January of a Phase 2 placebo-controlled component of ongoing Phase 1/2 clinical trial of NGM120, testing NGM120 in combination in patients with metastatic pancreatic cancer
- Strengthened capital position with completion of public offering of NGM common stock in January, raising net proceeds of \$134.6 million
- \$412.7 million in cash, cash equivalents and marketable securities as of March 31, 2021

South San Francisco, CA, May 6, 2021 – NGM Biopharmaceuticals, Inc. (NGM) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today provided business highlights and reported financial results for the period ending March 31, 2021.

“In the first quarter of 2021, we achieved a key milestone in our oncology portfolio with the initiation of the randomized, placebo-controlled component of our NGM120 study in patients with metastatic pancreatic cancer,” said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM. “We also continued to make progress across our four other ongoing Phase 2 and Phase 2b programs. We remain on track to report topline data from our Phase 2b ALPINE 2/3 clinical study of aldafermin in patients with NASH in the second quarter and we expect to complete enrollment in our Phase 2 CATALINA clinical study of NGM621 in patients with geographic atrophy by mid-year. Our team continues to work diligently to advance our two lead immuno-oncology product candidates into the clinic later this year.”

Dr. Woodhouse continued, “We demonstrated strong pipeline and corporate execution despite the continued challenges presented by the COVID-19 pandemic and continue to focus on our mission to translate powerful biology with urgency and rigor to deliver life-changing medicines.”

Key First Quarter and Recent Highlights

Liver and metabolic diseases

- **Anticipate reporting topline data from the Phase 2b ALPINE 2/3 study of aldafermin in patients with NASH with liver fibrosis stage 2 or 3 (F2-F3) in the second quarter.** ALPINE 2/3 is a Phase 2b clinical study of aldafermin in patients with biopsy-confirmed NASH and liver fibrosis F2 or F3. The 24-week study will assess the efficacy, safety and tolerability of 0.3 mg, 1 mg and 3 mg doses of aldafermin compared to placebo. The primary objective of the ALPINE 2/3 study is to evaluate a dose response showing an improvement in liver fibrosis by ≥ 1 stage with no worsening of steatohepatitis at week 24.
- **Continued enrollment in Phase 2b ALPINE 4 study of aldafermin in patients with NASH with liver fibrosis stage 4 (F4) and compensated cirrhosis.** NGM continued enrollment in the Phase 2b ALPINE 4 clinical study of aldafermin in patients with biopsy-confirmed NASH with F4 liver fibrosis and compensated cirrhosis. The 48-week study is designed to enroll approximately 160 patients and will assess the efficacy, safety and tolerability of 0.3 mg, 1 mg and 3 mg doses of aldafermin compared to placebo. The primary

objective of ALPINE 4 is to evaluate a dose response showing an improvement in liver fibrosis by ≥ 1 stage with no worsening of steatohepatitis at week 48.

- **Merck continued the Phase 2b study of MK-3655 in patients with NASH with F2-F3 liver fibrosis.** In November 2020, Merck initiated a global Phase 2b multicenter study of MK-3655 for the treatment of F2-F3 NASH. The 52-week randomized, double-blind study is designed to enroll approximately 320 patients and will assess the efficacy, safety and tolerability of 50 mg, 100 mg and 300 mg doses of MK-3655 compared to placebo. The primary objective of the Phase 2b study is NASH resolution without worsening of fibrosis after 52 weeks. Merck licensed MK-3655 following NGM's completion of a proof-of-concept study. NGM retains an option, at the initiation of the first Phase 3 clinical trial for MK-3655, to either receive milestone and royalty payments or to co-fund development and participate in a global cost and revenue sharing arrangement of up to 50% for MK-3655.

Retinal diseases

- **Expect to complete enrollment in the Phase 2 CATALINA study of NGM621 in patients with GA by mid-year.** NGM continues to enroll patients in the Phase 2 CATALINA study, a multi-center, randomized, double-masked, sham-controlled clinical trial to evaluate the safety and efficacy of intravitreal (IVT) injections of NGM621 every four weeks or every eight weeks in patients with geographic atrophy (GA) in one or both eyes secondary to age-related macular degeneration. NGM anticipates completing enrollment by mid-year. The primary endpoint is the rate of change in GA lesion area, as measured by fundus autofluorescence imaging, over 52 weeks of treatment.
- **Presented Phase 1 safety and pharmacokinetics (PK) data for NGM621 in patients with GA at the Angiogenesis, Exudation, and Degeneration 2021 - Virtual Edition.** Single and multiple IVT injections of NGM621 appeared safe and well tolerated in this first-in-human study, with no patients experiencing serious adverse events, drug-related adverse events, endophthalmitis, intraocular inflammation or choroidal neovascularization. The serum PK of NGM621 was linear and dose-proportional. Based on ocular PK/pharmacodynamics (PD) modeling, NGM believes NGM621 has the potential for up to an every eight-week dosing regimen.

Cancer

- **Initiated a Phase 2 placebo-controlled component of an ongoing Phase 1/2 study of NGM120 in January, testing NGM120 as a first-line treatment in combination with gemcitabine and Abraxane® (paclitaxel protein bound) in patients with metastatic pancreatic cancer.** NGM initiated a multi-center, randomized, single-blind (sponsor unblinded), placebo-controlled component of NGM120 in combination with gemcitabine and Abraxane as a first line treatment in patients with metastatic pancreatic cancer as part of its ongoing Phase 1/2 trial. This Phase 2 component of the Phase 1/2 study is designed to enroll approximately 60 patients and will assess the efficacy, safety and tolerability of NGM120 or placebo in combination with gemcitabine and Abraxane against both cancer and cancer-related cachexia endpoints. The Phase 1a/1b dose-finding portion of the study is still ongoing, and NGM expects to report interim results from that portion of the study in the second half of the year.
- **Continued to progress two new oncology clinical candidates, NGM707 and NGM438, toward the clinic.** These programs are part of NGM's strategy to treat cancer through myeloid reprogramming that reverses immune suppression in the tumor microenvironment. NGM707 is a dual antagonist antibody that inhibits Immunoglobulin-like transcript 2 (ILT2) and Immunoglobulin-like transcript 4 (ILT4). NGM438 is an antagonist antibody that inhibits Leukocyte-associated immunoglobulin-like receptor 1 (LAIR1). NGM expects to initiate a first-in-human Phase 1 trial for NGM707 in patients with advanced solid tumors in mid-2021 and for NGM438 in patients with advanced solid tumors during the fourth quarter.

Corporate

- **Completed a public offering of common stock.** In January, NGM completed an underwritten public offering of 5,324,074 shares of its common stock for net proceeds to NGM of \$134.6 million, which included the full exercise by the underwriters of their over-allotment option to purchase additional shares, at a price to the public of \$27.00 per share.

- **Nomination of Roger M. Perlmutter for election to Board of Directors.** On April 28, 2021, NGM announced that the company has nominated Roger M. Perlmutter, M.D., Ph.D. to stand for election to the company's board of directors at its June 8, 2021 annual meeting of stockholders. Dr. Perlmutter brings decades of expertise and renowned leadership in drug discovery and development with global healthcare companies including Merck and Amgen.
- **Extended deadline for Merck collaboration extension notice.** Merck has a unilateral option to extend the research and early development phase of its ongoing strategic collaboration with NGM, which would, if exercised by Merck, extend the research phase of the collaboration for an additional two-year period from March 2022 to March 2024. Merck was required to notify NGM of its unilateral decision whether to exercise its option in March 2021, but in order to allow the parties to negotiate potential modifications to the terms of the collaboration agreement, on March 12, 2021, Merck and NGM agreed to extend the deadline for Merck's decision until June 30, 2021. NGM expects that any modified collaboration would result in a level of annual research support from Merck during any extension of the current research phase after March 2022 that is meaningfully lower than the annual research support Merck provided NGM during the initial five-year term and the first extension period. NGM also expects that if Merck and NGM are unable to reach agreement on modified terms, Merck will not elect to extend the research phase of the collaboration and that NGM's obligation to fund its own research and development efforts will substantially increase after March 2022.

First Quarter 2021 Financial Results

- NGM reported a net loss of \$27.5 million for the quarter ended March 31, 2021, compared to a net loss of \$19.1 million for the same period in 2020.
- Related party revenue from our collaboration with Merck was \$21.6 million for the quarter ended March 31, 2021, compared to \$24.4 million for the same period in 2020. The decrease in related party revenue of \$2.8 million in 2021 was primarily attributable to a decrease in the recognition of the initial upfront payment received from Merck in 2015 that was included in the transaction price and fully recognized by March 2020.
- Research and development, or R&D, expenses were \$40.7 million for the quarter ended March 31, 2021, compared to \$38.4 million for the same period in 2020. R&D expenses increased \$2.3 million in 2021, primarily due to a \$3.5 million increase in personnel-related expenses and an increase in external expenses driven by our ongoing clinical and pre-clinical studies of NGM621, NGM438 and NGM707. These increases were partially offset by a decrease of \$4.6 million in our manufacturing activities and ongoing clinical trials of aldafermin and \$1.2 million in external expenses related to our other development programs.
- General and administrative expenses were \$8.7 million for the quarter ended March 31, 2021, compared to \$6.6 million for the same period in 2020. The \$2.1 million increase in general and administrative expenses in 2021 was primarily attributable to increases in personnel-related expenses driven by increased headcount, as well as external expenses to support our operations as a public company.
- Cash, cash equivalents and short-term marketable securities were \$412.7 million as of March 31, 2021, compared to \$295.2 million as of December 31, 2020.

Merck Collaboration

Under the current terms of NGM's collaboration with Merck, Merck has a one-time option to license NGM pipeline programs – other than aldafermin, NGM386 and NGM395 – following human proof-of-concept trials under the terms of the companies' ongoing strategic collaboration. Upon exercising any such option, Merck would lead global product development and commercialization for the resulting products, if approved. Prior to Merck initiating a Phase 3 study for a licensed program, NGM may elect to either receive milestone and royalty payments or to co-fund development and participate in a global cost and revenue share arrangement of up to 50%. The current terms of the collaboration also provide NGM with the option to participate in the co-promotion of any co-funded program in the United States. In January 2019, Merck exercised its first option under the collaboration to license MK-3655, previously referred to as NGM313. As described above, the parties continue to negotiate potential modifications to the terms of the collaboration.

About NGM Biopharmaceuticals, Inc.

NGM is a biopharmaceutical company focused on discovering and developing novel therapeutics based on scientific understanding of key biological pathways underlying liver and metabolic diseases, retinal diseases and cancer. We leverage our biology-centric drug discovery approach to uncover novel mechanisms of action and generate proprietary insights that enable us to move rapidly into proof-of-concept studies and deliver potential first-in-class medicines to patients. At NGM, we aspire to operate one of the most productive research and development engines in the biopharmaceutical industry. Visit us at www.ngmbio.com for more information.

Forward Looking Statements

Statements contained in this press release 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 “anticipates,” “will,” “build,” “vision,” “designed to,” “potential,” “aspire,” “continue,” “expect,” “plan” 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 NGM’s mission to build a biologic therapeutics company that delivers lifechanging medicines for patients; the availability and anticipated timing of topline data from Phase 2b ALPINE 2/3 clinical trial of aldafermin and interim results from the Phase 1a/1b dose-finding portion of the Phase 1/2 clinical trial of NGM120; the timing of initiation of Phase 1 clinical trials for NGM707 and NGM438 and NGM’s strategy to treat cancer through myeloid reprogramming; the timing of completion of enrollment in the Phase 2 CATALINA study of NGM621; the therapeutic potential of NGM’s product candidates, including the potential for every eight-week dosing for NGM621; NGM and Merck potentially reaching agreement on the terms of a modified collaboration and NGM’s expectations that any modified collaboration would result in a meaningfully lower level of annual research support from Merck during any extension of the current research phase, if any, and that if Merck and NGM are unable to reach agreement on modified terms, Merck will not elect to extend the research phase of the collaboration and NGM’s obligation to fund its own research and development efforts will substantially increase after March 2022; Dr. Perlmutter’s potential election to NGM’s board of directors; and other statements that are not historical fact. Because such statements deal with future events and are based on NGM’s current expectations, they are subject to various risks and uncertainties, and actual results, performance or achievements of NGM could differ materially from those described in or implied by the statements in this press release. These forward-looking statements are subject to risks and uncertainties, including, without limitation, risks and uncertainties associated with the costly and time-consuming pharmaceutical product development process and the uncertainty of clinical success, including risks related to failure or delays in successfully enrolling or completing clinical studies, the risk that the results obtained to date in NGM’s clinical trials may not be indicative of results obtained in subsequent pivotal or other late-stage trials and the risk that NGM’s ongoing or future clinical studies may show that aldafermin, or Merck’s ongoing or future clinical studies of MK-3655, are not tolerable and effective treatments for patients with NASH and the risk that its other product candidates may also not be tolerable and effective treatments in their planned indications; the risks that Merck may elect not to extend the research phase of the collaboration and NGM may otherwise be unable to reach agreement with Merck on the terms of a modified collaboration and, regardless of whether NGM and Merck reach agreement on the terms of a modified collaboration, NGM expects that Merck will not provide research funding for certain of NGM’s product candidates and the NGM’s collaboration with Merck otherwise involves numerous other risks, any of which could materially and adversely affect NGM’s business and financial condition; the ongoing COVID-19 pandemic, which has adversely affected, and could materially and adversely affect in the future, NGM’s business and operations, including NGM’s clinical trials; the time-consuming and uncertain regulatory approval process; NGM’s reliance on third-party manufacturers for aldafermin and its other product candidates; the sufficiency of NGM’s cash resources and need for additional capital; and other risks and uncertainties affecting NGM and its development programs, including those discussed in the section titled “Risk Factors” in NGM’s annual report on Form 10-K for the year ended December 31, 2020 filed with the United States Securities and Exchange Commission (SEC) on March 15, 2021 and future filings and reports that NGM makes from time to time with the SEC. Except as required by law, NGM 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.

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

	Three Months Ended March 31,	
	2021	2020
Related party revenue	\$ 21,575	\$ 24,364
Operating expenses:		
Research and development	40,699	38,439
General and administrative	8,721	6,595
Total operating expenses	<u>49,420</u>	<u>45,034</u>
Loss from operations	(27,845)	(20,670)
Interest income, net	114	1,175
Other income, net	187	380
Net loss	<u>\$ (27,544)</u>	<u>\$ (19,115)</u>
Net loss per share, basic and diluted	<u>\$ (0.36)</u>	<u>\$ (0.28)</u>
Weighted average shares used to compute net loss per share, basic and diluted	<u>76,034,145</u>	<u>67,396,229</u>

NGM BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	March 31, 2021	December 31, 2020*
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 148,113	\$ 147,017
Short-term marketable securities	264,543	148,139
Related party receivable from collaboration	325	333
Related party contract asset	4,600	6,100
Prepaid expenses and other current assets	8,268	6,837
Total current assets	425,849	308,426
Property and equipment, net	13,733	14,526
Restricted cash	1,499	1,499
Other non-current assets	4,460	4,592
Total assets	\$ 445,541	\$ 329,043
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 7,535	\$ 9,663
Accrued liabilities	29,763	29,945
Deferred rent, current	3,011	2,975
Total current liabilities	40,309	42,583
Deferred rent, non-current	5,655	6,417
Total liabilities	45,964	49,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value;	—	—
Common stock, \$0.001 par value;	77	71
Additional paid-in capital	725,693	578,599
Accumulated other comprehensive income (loss)	(18)	4
Accumulated deficit	(326,175)	(298,631)
Total stockholders' equity	399,577	280,043
Total liabilities and stockholders' equity	\$ 445,541	\$ 329,043

* Derived from the audited consolidated financial statements.