

**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): March 4, 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 March 4, 2021, NGM Biopharmaceuticals, Inc. provided business highlights and reported its financial results for the fourth quarter and full year ended December 31, 2020. A copy of the press release titled “NGM Bio Provides Business Highlights and Reports Fourth Quarter and Full Year 2020 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 March 4, 2021, titled “NGM Bio Provides Business Highlights and Reports Fourth Quarter and Full Year 2020 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.

NGM Biopharmaceuticals, Inc.

Dated: March 4, 2021

By: /s/ Siobhan Nolan Mangini

Siobhan Nolan Mangini

Chief Financial Officer



NGM Bio Provides Business Highlights and Reports Fourth Quarter and Full Year 2020 Financial Results

- Significant progress made across liver and metabolic diseases, retinal diseases and cancer during fourth quarter 2020:
 - Presented first-in-human results from Phase 1 clinical trial of NGM621 in patients with geographic atrophy (GA) at the American Academy of Ophthalmology (AAO) 2020 Virtual
 - Merck advanced collaboration compound MK-3655 into a global Phase 2b clinical trial in patients with non-alcoholic steatohepatitis (NASH)
 - Announced expansion of NGM's oncology portfolio with addition of two product candidates, NGM707, a dual antagonist antibody inhibiting ILT2 and ILT4, and NGM438, an antagonist antibody inhibiting LAIR1
- Recently initiated placebo-controlled expansion of Phase 1b clinical trial of NGM120 in patients with metastatic pancreatic cancer
- NGM anticipates reporting topline data from Phase 2b ALPINE 2/3 clinical trial in second quarter 2021
- \$295.2 million in cash, cash equivalents and marketable securities as of December 31, 2020, which amount does not include net proceeds of approximately \$134.7 million from the public offering of NGM common stock completed in January 2021

South San Francisco, CA, March 4, 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 periods ending December 31, 2020.

“Our vision at NGM is to build an iconic biologic therapeutics company that delivers transformative medicines for patients. Our team made notable progress across multiple fronts in 2020: presenting aldafermin Cohort 4 data and NGM621 first-in-human data at major medical conferences, advancing multiple programs into Phase 2 clinical testing and announcing the expansion of our oncology portfolio including the nomination of two immuno-oncology candidates,” said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM. “Behind every disease name and statistic, whether it is NASH, cancer-related cachexia, geographic atrophy or solid tumor cancers, are countless individuals who are hoping for better treatment options, all of whom fuel our motivation and mission to improve human health.”

Key Fourth 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 in second quarter 2021.** ALPINE 2/3 is a Phase 2b clinical study of aldafermin in patients with biopsy-confirmed NASH and liver fibrosis stage 2 or 3 (F2-F3). The 24-week study is assessing 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 well-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 well-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.
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- **Presented data from 24-week double-blind, randomized, placebo-controlled Phase 2 study (Cohort 4) of aldafermin in NASH patients at AASLD The Liver Meeting®.** Cohort 4 demonstrated statistically significant dual activity in fibrosis improvement and NASH resolution in patients with F2 and F3 liver fibrosis. Analysis of Cohort 4 data at AASLD also showed that 30% of patients with more advanced F3 liver fibrosis treated with aldafermin 1 mg achieved fibrosis improvement ≥ 1 stage without worsening of NASH compared to 0% in the placebo arm. In Cohort 4, aldafermin continued to demonstrate a favorable tolerability profile. Cohort 4 was the final reported cohort from NGM's adaptive Phase 2 clinical study of aldafermin in NASH and the results observed in Cohort 4 were consistent with data from the three previous cohorts.
- **Merck initiated Phase 2b study of MK-3655 (formerly NGM313) in patients with NASH with F2-F3 liver fibrosis.** In November, Merck initiated a global Phase 2b multicenter, randomized, double-blind study of MK-3655 in patients with biopsy-confirmed NASH. The 52-week 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 administered every 4 weeks compared to placebo in patients with biopsy-confirmed NASH and F2-F3 liver fibrosis. 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.

Retinal diseases

- **Continued enrollment in Phase 2 CATALINA study of NGM621 in patients with Geographic Atrophy (GA).** NGM continued enrollment in the Phase 2 CATALINA study, a multicenter, 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 GA secondary to age-related macular degeneration. 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 data for NGM621 in patients with GA at the American Academy of Ophthalmology 2020 Virtual.** 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 AEs, endophthalmitis, intraocular inflammation or choroidal neovascularization. The serum PK of NGM621 was linear and dose-proportional.

Cancer

- **Completed enrollment in the Phase 1a/1b dose-finding study of NGM120 in patients with cancer in November 2020.** NGM completed enrollment in the Phase 1a/1b dose-finding trial to assess NGM120's effect on cancer-related cachexia and cancer. This Phase 1a/1b study was conducted in two cohorts: a Phase 1a cohort evaluating NGM120 as a monotherapy in patients with select advanced solid tumors and a Phase 1b cohort evaluating NGM120 in combination with gemcitabine and Abraxane® (paclitaxel protein bound) in patients with metastatic pancreatic cancer.
- **Initiated placebo-controlled, proof-of-concept expansion of Phase 1b dose-finding study of NGM120 as a first-line treatment in patients with metastatic pancreatic cancer in January 2021.** NGM initiated a multi-center, randomized, single-blind (sponsor unblinded), placebo-controlled expansion of the ongoing Phase 1a/1b study to evaluate NGM120 in combination with gemcitabine and Abraxane as a first-line treatment in patients with metastatic pancreatic cancer.
- **Announced two new oncology clinical candidates, NGM707 and NGM438, in fourth quarter 2020.** 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).

Fourth Quarter and Full Year 2020 Financial Results

- NGM reported a net loss of \$28.0 million and \$102.5 million for the quarter and year ended December 31, 2020, respectively, compared to a net loss of \$15.9 million and \$42.8 million for the corresponding periods in 2019.
 - Related party revenue from our collaboration with Merck was \$19.8 million and \$87.4 million for the quarter and year ended December 31, 2020, respectively, compared to \$31.1 million and \$103.5 million for the corresponding periods in 2019. The decrease in related party revenue of \$16.1 million in 2020 was
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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 \$40.1 million and \$164.0 million for the quarter and year ended December 31, 2020, respectively, compared to \$42.0 million and \$129.3 million for the corresponding periods in 2019. R&D expenses increased \$34.7 million in 2020, primarily due to an increase in external expenses driven by our manufacturing activities and ongoing clinical trials of aldafermin, NGM621, NGM120 and NGM395 and an increase in costs associated with pre-clinical IND-enabling studies for NGM707 and NGM438. The increase in R&D expenses in 2020 also included an increase in personnel-related expenses partially offset by a decrease in unallocated R&D expenses related to multiple R&D programs.
- General and administrative expenses were \$7.4 million and \$27.2 million for the quarter and year ended December 31, 2020, respectively, compared to \$6.4 million and \$23.6 million for the corresponding periods in 2019. The \$3.6 million increase in general and administrative expenses in 2020 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 \$295.2 million as of December 31, 2020, compared to \$344.5 million as of December 31, 2019.

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,” “iconic”, “designed to,” “potential,” “aspire” 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 vision to build an iconic biologic therapeutics company that delivers transformative medicines for patients; the availability and anticipated timing of topline data from Phase 2b ALPINE 2/3 clinical trial of aldafermin; the therapeutic potential of NGM’s product candidates; 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; 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 Exhibit 99.1 to NGM’s current report on Form 8-K filed with the United States Securities and Exchange Commission (SEC) on January 6, 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 December 31,		Year Ended December 31,	
	2020	2019	2020	2019 ⁽¹⁾
Related party revenue	\$ 19,767	\$ 31,083	\$ 87,368	\$ 103,544
Operating expenses:				
Research and development	40,060	41,954	163,972	129,253
General and administrative	7,380	6,423	27,229	23,631
Total operating expenses	<u>47,440</u>	<u>48,377</u>	<u>191,201</u>	<u>152,884</u>
Loss from operations	(27,673)	(17,294)	(103,833)	(49,340)
Interest income	116	1,554	1,939	6,692
Other expense, net	(434)	(201)	(593)	(147)
Net loss	<u>\$ (27,991)</u>	<u>\$ (15,941)</u>	<u>\$ (102,487)</u>	<u>\$ (42,795)</u>
Net loss per share, basic and diluted	<u>\$ (0.40)</u>	<u>\$ (0.24)</u>	<u>\$ (1.50)</u>	<u>\$ (0.85)</u>
Weighted average shares used to compute net loss per share, basic and diluted	<u>69,370,960</u>	<u>66,532,038</u>	<u>68,475,378</u>	<u>50,297,524</u>

(1) Derived from the audited consolidated financial statements.

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

	December 31, 2020 (unaudited)	December 31, 2019 ⁽¹⁾
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 147,017	\$ 245,598
Short-term marketable securities	148,139	98,913
Related party receivable from collaboration	333	5,206
Related party contract asset	6,100	-
Prepaid expenses and other current assets	6,837	5,531
Total current assets	308,426	355,248
Property and equipment, net	14,526	19,475
Restricted cash	1,499	1,874
Other non-current assets	4,592	3,806
Total assets	<u>\$ 329,043</u>	<u>\$ 380,403</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 9,663	\$ 9,026
Accrued liabilities	29,945	22,991
Deferred rent, current	2,975	2,829
Contract liabilities	-	4,872
Total current liabilities	42,583	39,718
Deferred rent, non-current	6,417	9,392
Early exercise stock option liability	-	574
Total liabilities	49,000	49,684
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value;	—	—
Common stock, \$0.001 par value;	71	67
Additional paid-in capital	578,599	526,771
Accumulated other comprehensive gain	4	25
Accumulated deficit	(298,631)	(196,144)
Total stockholders' equity	280,043	330,719
Total liabilities and stockholders' equity	<u>\$ 329,043</u>	<u>\$ 380,403</u>

(1) Derived from the audited consolidated financial statements.