

**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 17, 2020

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 17, 2020, NGM Biopharmaceuticals, Inc. reported its financial results for the fourth quarter and full year ended December 31, 2019 and business highlights. A copy of the press release titled “NGM Bio Reports Fourth Quarter and Full Year 2019 Financial Results and Recent Highlights,” 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 17, 2020, titled “NGM Bio Reports Fourth Quarter and Full Year 2019 Financial Results and Recent Highlights.”

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 17, 2020

By: /s/ Valerie Pierce

Valerie Pierce

Senior Vice President and General Counsel



NGM Bio Reports Fourth Quarter and Full Year 2019 Financial Results and Recent Highlights

- Successfully completed 24-week Phase 2 study (Cohort 4) of aldafermin in non-alcoholic steatohepatitis (NASH) patients, and announced topline results demonstrating positive effect on all key liver histology and biomarker measures of disease –
- Commenced Phase 2b ALPINE 2/3 study of aldafermin in patients with F2-F3 liver fibrosis --
- Significant pipeline progress; four additional clinical programs now underway across cardio-metabolic and liver disease, ophthalmic disease and cancer –
- The Company maintains a strong balance sheet with \$344.5 million in cash, cash equivalents and marketable securities as of December 31, 2019 --

South San Francisco, CA, March 17, 2020 – NGM Biopharmaceuticals, Inc. (NGM or the Company) (Nasdaq: NGM), a biotechnology company focused on developing transformative therapeutics for patients, today reported financial results for the fourth quarter and year ended December 31, 2019 and business highlights.

“2019 was a year of significant growth and productivity for NGM. We completed a successful IPO and achieved several milestones furthering our goal to operate one of the most productive R&D engines in the biopharma industry and enabling strong momentum as we entered 2020,” said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM. “We now have multiple clinical programs underway across cardio-metabolic and liver disease, ophthalmic disease and cancer. Each of our programs tackles an area of significant unmet medical need and has the potential to deliver a transformative impact for patients while enhancing shareholder value.”

Dr. Woodhouse continued, “As we, along with our industry colleagues and our nation as a whole, navigate these uncertain times around the COVID-19 spread, we remain focused on delivering on our ambitious plans, while being mindful of the safety and well-being of our employees, patients and collaborators, and the broader community.”

Hsiao D. Lieu, M.D., Chief Medical Officer of NGM, commented, “Following last month’s data readout from the final cohort of our adaptive Phase 2 study of aldafermin in NASH patients, we are very excited about aldafermin’s potential as a potent monotherapy to help patients with advanced disease. The results of our clinical trials in NASH patients have demonstrated aldafermin’s meaningful effect on all key liver histology and biomarker measures of the disease, accompanied by a favorable tolerability profile. We look forward to the continued progress of our aldafermin Phase 2b development program, where we hope to gain important clinical experience with this drug across a broader number of NASH patients and in different stages of the disease.”

Key 2019 Accomplishments and Recent Highlights

Our Pipeline

Cardio-metabolic and liver disease

- **Reported positive preliminary topline liver histology and biomarker data from 24-week Phase 2 study of aldafermin 1 mg in patients with NASH (Cohort 4).** In February 2020, NGM announced positive preliminary topline results from a 24-week double-blind, randomized, placebo-controlled Phase 2 clinical study (Cohort 4) of aldafermin (formerly NGM282) in NASH patients with Stage 2 or 3 (F2-F3) fibrosis. Cohort 4 was powered to demonstrate the effect of aldafermin treatment versus placebo on the primary endpoint of change in absolute liver fat content (LFC), which achieved statistical significance. In addition, the study assessed secondary and exploratory endpoints of liver histology and biomarkers of disease activity. The histology results revealed that

treatment with aldafermin led to clinically meaningful improvements at 24 weeks versus placebo in fibrosis improvement of ≥ 1 stage with no worsening of NASH and in resolution of NASH with no worsening of liver fibrosis. In addition, the study demonstrated a statistically significant impact on the composite endpoint of both fibrosis improvement and resolution of NASH (22% in aldafermin-treated patients vs. 0% placebo). In the study, 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. NGM has exclusive worldwide commercial rights to aldafermin.

- **Initiated Phase 2b study of aldafermin in NASH patients with F2-F3 fibrosis.** In May 2019, NGM announced that it dosed the first patient in the Phase 2b ALPINE 2/3 clinical study evaluating aldafermin in patients with biopsy-confirmed NASH and F2-F3 liver fibrosis. This 24-week study is expected to enroll approximately 150 patients and will assess the efficacy, safety and tolerability of 0.3 mg, 1 mg and 3 mg of aldafermin compared to placebo. NGM expects to announce topline data from ALPINE 2/3 in the first half of 2021.
- **Initiated Phase 1 study of NGM395 in overweight healthy adults.** In March 2020, NGM dosed the first patient in a Phase 1 single ascending dose clinical study evaluating the safety, tolerability and pharmacokinetics of NGM395, a long acting GDF15 (growth differentiation factor 15) analog, in obese but otherwise healthy adults. NGM395 is wholly-owned by NGM.

Ophthalmic disease

- **Initiated Phase 1 study of NGM621 for the potential treatment of geographic atrophy, an advanced dry form of age-related macular degeneration (AMD).** In August 2019, NGM announced that it dosed the first patient in a Phase 1 clinical study to evaluate the safety, tolerability and pharmacokinetics of up to two intravitreal doses of NGM621 in patients with geographic atrophy. NGM621 is an inhibitory antibody binding complement C3, a key node of all three complement pathways.

Cancer

- **Initiated Phase 1a/1b study of NGM120 for the potential treatment of cancer and cancer anorexia/cachexia syndrome (CACS).** In February 2020, NGM announced that it dosed the first patient in a Phase 1a/1b clinical study to evaluate NGM120, a first-in-class antagonistic antibody that binds glial cell-derived neurotrophic factor receptor alpha-like (GFRAL) and inhibits GDF15 signaling, for the potential treatment of cancer and CACS. CACS is the uncontrolled wasting of both skeletal muscle and fat that is a common co-morbidity of cancer and is associated with shortened survival in cancer patients. The Phase 1a/1b study initiation followed the successful completion of a Phase 1 safety, tolerability and pharmacokinetics study of NGM120 in healthy adult subjects in 2019.

Merck has a one-time option to license NGM pipeline programs, other than aldafermin and NGM395, following human proof-of-concept trials, under the terms of the companies' ongoing strategic collaboration. Upon exercising any such options, 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, in certain cases, to co-fund development and participate in a global cost and revenue share arrangement of up to 50%. The agreement also provides NGM with the option to participate in the co-promotion of any co-funded program in the United States.

Corporate

- **Raised \$173.7 million in net cash proceeds from initial public offering (IPO) and concurrent private placement with Merck.** Commenced trading on the Nasdaq Global Select Market under the ticker symbol "NGM" on April 4, 2019.
 - **Extended strategic collaboration with Merck to 2022.** In March 2019, NGM and Merck announced that Merck exercised its option, under the terms of its original agreement with NGM, to extend the initial five-year research and early development phase of the collaboration for an additional two-year period from March 2020 to March 2022. The collaboration, originally announced in February 2015, is focused on discovering, developing and commercializing novel biologic therapeutics across a wide range of therapeutic areas. During the two-year extension period, Merck will continue to fund NGM's research and development efforts at levels similar to those funded under the original collaboration terms and will make additional payments totaling up to \$20 million in support of NGM's research and development activities in 2021 and 2022. Merck retains one additional two-year extension option that is exercisable in March 2021, which would extend the collaboration from March 2022 to March 2024.
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- **Expanded leadership with key management team and board appointments.** NGM announced the appointment of two new executive leadership team members in 2019, Hsiao D. Lieu, M.D., as Senior Vice President, Chief Medical Officer and Valerie Pierce as Senior Vice President, General Counsel and Chief Compliance Officer. Last year, NGM also announced the appointment of Shelly Guyer to its Board of Directors. Ms. Guyer currently serves as Chief Financial Officer of Invitae Corporation.

Fourth Quarter and Full Year 2019 Financial Results

- For the quarter ended December 31, 2019, NGM reported a net loss of \$15.9 million compared with net income of \$14.2 million for the corresponding period in 2018. For the year ended December 31, 2019, net loss was \$42.8 million compared with a net loss of \$0.5 million for the year ended December 31, 2018.
- Related party revenue from our collaboration with Merck for the quarter and year ended December 31, 2019 was \$31.1 million and \$103.5 million compared to \$47.1 million and \$108.7 million for the quarter and year ended December 31, 2018. The decrease in related party revenue was primarily attributable to a one-time license fee received from Merck in the fourth quarter of 2018, partially offset by year-over-year increases in reimbursable research and development expenses for ongoing clinical activities and clinical material purchases, as well as additional upfront revenue recognized as a result of the adoption of ASU 2014-09, Revenue from Contracts with Customers (Topic 606) which was effective January 1, 2019.
- Research and development expenses for the quarter and year ended December 31, 2019 were \$42.0 million and \$129.3 compared to \$28.9 million and \$95.7 million for the quarter and year ended December 31, 2018. The increase in research and development expenses was primarily attributable to increases in personnel-related expenses, including stock-based compensation expense driven by increased headcount and the commencement of the 2019 Employee Stock Purchase Plan (the "2019 ESPP"), clinical trial material purchases and external research and development expenses associated with the advancement of NGM's growing pipeline and aldafermin program expenses for ongoing Phase 2b clinical trials.
- General and administrative expenses for the quarter and year ended December 31, 2019 were \$6.4 million and \$23.6 million compared to \$5.1 million and \$17.3 million for the quarter and year ended December 31, 2018. The increase in general and administrative expenses was primarily attributable to increases in personnel-related expenses, including stock-based compensation expense driven by increased headcount and the commencement of the 2019 ESPP, insurance expenses, legal expenses associated with maintaining our intellectual property rights and other professional service expenses required to support NGM's operations as a public company.
- Cash, cash equivalents and short-term marketable securities were \$344.5 million as of December 31, 2019, compared to \$206.6 million as of December 31, 2018. The increase of \$137.9 million was primarily attributable to net cash proceeds of \$173.7 million from the Company's IPO and concurrent private placement, related party revenue from Merck, partially offset by cash used in operations during the period.

About NGM Biopharmaceuticals, Inc.

NGM is a biopharmaceutical company focused on developing novel therapeutics based on scientific understanding of key biological pathways underlying cardio-metabolic, liver, oncologic and ophthalmic diseases. The company leverages its biology-centric drug discovery approach to uncover novel mechanisms of action and generate proprietary insights that enable it to move rapidly into proof-of-concept studies and deliver potential first-in-class medicines to patients. NGM aspires to operate one of the most productive research and development engines in the biopharmaceutical industry, with multiple programs in clinical development. Visit <http://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 “plan,” “will,” “initiate,” “anticipate,” “continue,” “look forward to” 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 R&D engine and ability to build a robust pipeline of product candidates; the advancement of its clinical and preclinical pipeline; the enrollment and results of NGM’s clinical trials; the safety, tolerability and efficacy of NGM’s product candidates; continued development of additional product candidates, including NGM120 in patients with solid tumors and NGM395; NGM’s ability to fund its clinical programs and NGM’s financial outlook. 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 pivotal or other late-stage trials, and the risk that NGM’s ongoing or future clinical studies in humans may show that aldafermin is not a tolerable and effective treatment for NASH patients; the COVID-19 pandemic, which may significantly impact (i) our business and operations, including out of our headquarters in the San Francisco Bay Area and our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations or other third parties with whom we conduct business, (ii) our ability to access capital, and (iii) the value of our common stock; 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, as well as those discussed in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our quarterly report on Form 10-Q for the quarter ended September 30, 2019 and future filings and reports that NGM makes from time to time with the United States Securities and Exchange Commission, including NGM’s annual report on Form 10-K for the year ended December 31, 2019. 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.

Investor Contact:

Sylvia Wheeler and Alex Santos
swheeler@wheelhouselsa.com
asantos@wheelhouselsa.com
ir@ngmbio.com

Media Contact:

Liz Melone
media@ngmbio.com

NGM Biopharmaceuticals, Inc.
Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018 ⁽¹⁾
Related party revenue	\$ 31,083	\$ 47,119	\$ 103,544	\$ 108,665
Operating expenses:				
Research and development	41,954	28,941	129,253	95,714
General and administrative	6,423	5,122	23,631	17,265
Total operating expenses	<u>48,377</u>	<u>34,063</u>	<u>152,884</u>	<u>112,979</u>
Income (loss) from operations	(17,294)	13,056	(49,340)	(4,314)
Interest income	1,554	1,013	6,692	3,622
Other income (expense), net	(201)	96	(147)	199
Net income (loss)	<u>\$ (15,941)</u>	<u>\$ 14,165</u>	<u>\$ (42,795)</u>	<u>\$ (493)</u>
Net loss per share, basic and diluted	<u>\$ (0.24)</u>	<u>\$ —⁽²⁾</u>	<u>\$ (0.85)</u>	<u>\$ (0.08)</u>
Weighted average shares used to compute net loss per share, basic and diluted	<u>66,532,038</u>	<u>6,674,091</u>	<u>50,297,524</u>	<u>6,383,751</u>

(1) Derived from the audited consolidated financial statements.

(2) Through the application of the two-class method, all undistributed earnings were allocated to then outstanding convertible preferred stock.

NGM Biopharmaceuticals, Inc.
Consolidated Balance Sheets
(In thousands)

	December 31, 2019	December 31, 2018(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 245,598	\$ 56,923
Short-term marketable securities	98,913	149,710
Related party receivable from collaboration	5,206	3,669
Prepaid expenses and other current assets	5,531	4,255
Total current assets	355,248	214,557
Property and equipment, net	19,475	23,893
Restricted cash	1,874	2,249
Deferred IPO costs	—	2,292
Other non-current assets	3,806	3,094
Total assets	<u>\$ 380,403</u>	<u>\$ 246,085</u>
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 9,026	\$ 5,775
Accrued liabilities	22,991	14,003
Deferred rent, current	2,829	2,683
Deferred revenue, current	4,872	19,025
Total current liabilities	39,718	41,486
Deferred rent, non-current	9,392	12,221
Deferred revenue, non-current	—	3,942
Early exercise stock option liability	574	1,559
Convertible preferred stock warrant liability	—	198
Total liabilities	49,684	59,406
Commitments and contingencies		
Convertible preferred stock, \$0.001 par value;	—	294,874
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value;	—	—
Common stock, \$0.001 par value;	67	7
Additional paid-in capital	526,771	39,258
Accumulated other comprehensive gain (loss)	25	(267)
Accumulated deficit	(196,144)	(147,193)
Total stockholders' equity (deficit)	330,719	(108,195)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 380,403</u>	<u>\$ 246,085</u>

(1) Derived from the audited consolidated financial statements.