

**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): November 12, 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 November 12, 2020, NGM Biopharmaceuticals, Inc. provided business highlights and reported its financial results for the quarter ended September 30, 2020. A copy of the press release titled “NGM Bio Provides Business Highlights and Reports Third Quarter 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	<u>Press release, dated November 12, 2020, titled “NGM Bio Provides Business Highlights and Reports Third Quarter 2020 Financial Results.”</u>

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: November 12, 2020

By: /s/ Siobhan Nolan Mangini

Siobhan Nolan Mangini

Chief Financial Officer



NGM Bio Provides Business Highlights and Reports Third Quarter 2020 Financial Results

- NGM continues to demonstrate the productivity of its research discovery engine and progress against its multi-therapeutic area pipeline:
 - Initiated a Phase 2 clinical trial of NGM621, an anti-complement C3 antibody, in patients with geographic atrophy (GA)
 - Announced expansion of oncology portfolio with first immuno-oncology candidate, NGM707, a novel dual antagonist antibody inhibiting ILT2 and ILT4
- NGM has \$287.9 million in cash, cash equivalents and marketable securities as of September 30, 2020
- NGM will present first-in-human results from Phase 1 study of NGM621 in patients with GA at the upcoming American Academy of Ophthalmology (AAO) Virtual Annual Meeting on November 13, 2020
- NGM will conduct an R&D Day showcasing its portfolio on December 9, 2020

South San Francisco, CA, November 12, 2020 – 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 quarter ended September 30, 2020.

“We made notable progress across our pipeline this past quarter, as we continue to pursue a portfolio of product candidates directed to biologically powerful targets,” said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM. “Since mid-July, we have initiated a Phase 2 clinical trial of NGM621, our anti-complement C3 antibody, designed to slow disease progression in people with geographic atrophy, and we have disclosed our first immuno-oncology development candidate, NGM707, a novel dual antagonist antibody inhibiting ILT2 and ILT4, designed to potentially improve patient immune responses to tumors.”

Dr. Woodhouse continued, “We look forward to our upcoming R&D Day on December 9th, where we will showcase not only our exciting portfolio of programs but also highlight the talented NGM scientists whose expertise, creativity and passion have enabled our track record of rapid innovation and sustained productivity.”

Key Third Quarter and Recent Highlights

Liver and metabolic diseases

- **Completed enrollment in Phase 2b ALPINE 2/3 study of aldafermin in NASH patients.** NGM completed enrollment in the Phase 2b ALPINE 2/3 clinical study of aldafermin in patients with biopsy-confirmed NASH and stage 2 or 3 (F2-F3) liver fibrosis. 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. NGM expects to report topline findings from the study in the second quarter of 2021.
- **Ongoing enrollment in Phase 2b ALPINE 4 study of aldafermin in NASH patients with compensated cirrhosis.** NGM continued enrollment in the Phase 2b ALPINE 4 study of aldafermin in patients with biopsy-confirmed compensated NASH cirrhosis (F4). The 48-week study is designed to enroll approximately 150 patients and will assess the efficacy, safety and tolerability of 0.3 mg, 1 mg and 3 mg doses of aldafermin compared to placebo.
- **Data from 24-week double-blind, randomized, placebo-controlled Phase 2 study (Cohort 4) of aldafermin in NASH patients presented at The Digital International Liver Congress™ 2020 and published in *Gastroenterology*.** Cohort 4 demonstrated statistically significant dual activity in both

reversing fibrosis and resolving NASH. 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, and the results observed in Cohort 4 were consistent with data from the three previous cohorts.

Retinal diseases

- **Initiated Phase 2 CATALINA study of NGM621 in patients with GA.** In July, NGM began 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 in patients with GA secondary to age-related macular degeneration. NGM anticipates enrolling 240 patients diagnosed with GA in one or both eyes.
- **NGM will present results from a Phase 1 study of NGM621 in patients with GA at the American Academy of Ophthalmology (AAO) Virtual Annual Meeting on November 13, 2020 at 10:00 a.m. ET.** NGM completed the Phase 1 study with single- and multiple-dose IVT injections of NGM621 in patients with GA. The AAO presentation will be the first-in-human data presented on NGM621 in GA.

Cancer

- **Expanded oncology portfolio with first immuno-oncology development candidate, NGM707, a dual antagonist antibody inhibiting ILT2 and ILT4.** These receptors represent key myeloid and lymphoid checkpoints, and may restrict anti-tumor immunity, enable tumors to evade immune detection and contribute to T cell checkpoint resistance. NGM plans to initiate first-in-human testing of NGM707 in mid-2021 in patients with advanced solid tumors.
- **Ongoing enrollment in Phase 1a/1b study of NGM120 in patients with cancer anorexia/cachexia syndrome (CACS) and cancer.** NGM continues to enroll patients 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 CACS and cancer. 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.

Merck Collaboration

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 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 agreement also provides 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.

Third Quarter Financial Results

- For the quarter ended September 30, 2020, NGM reported a net loss of \$29.8 million, compared to a net loss of \$10.9 million for the corresponding period in 2019.
 - Related party revenue from our collaboration with Merck for the quarter ended September 30, 2020 was \$23.5 million, compared to \$21.6 million for the corresponding period in 2019.
 - Research and development expenses for the quarter ended September 30, 2020 were \$47.0 million, compared to \$29.0 million for the corresponding period in 2019. The increase in research and development expenses was mainly attributable to increases in external research and development expenses associated with the advancement of NGM's growing pipeline, primarily related to our aldafermin, NGM621, NGM120 and NGM707 programs, and personnel-related expenses driven by increased headcount.
 - General and administrative expenses for the quarter ended September 30, 2020 were \$6.5 million, compared to \$5.6 million for the corresponding period in 2019. The increase in general and administrative expenses 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 \$287.9 million as of September 30, 2020, compared to \$344.5 million as of December 31, 2019.
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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, with multiple programs in clinical development. 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 “will,” “planned,” “pursue,” “look forward,” “expects,” “designed to,” “anticipates,” “plans,” “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 intentions to present at future events; the productivity of NGM’s research and advancement of NGM’s clinical and preclinical pipeline; the continued progress of, and the timing of enrollment and results of, NGM’s clinical trials, including timing of topline results of the ALPINE 2/3 study and the presentation of data from the Phase 1 study of NGM621 in patients with GA; and the design, timing, enrollment, safety, tolerability and efficacy of, and continued development of, NGM’s product candidates, including aldafermin, NGM621, NGM707 and NGM120. 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 in humans may show that aldafermin is not a tolerable and effective treatment for NASH patients; the ongoing COVID-19 pandemic, which has adversely affected, and could materially and adversely affect in the future, our business and operations; 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, cash equivalents and short-term marketable securities 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 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors” in our quarterly report on Form 10-Q for the quarter ended June 30, 2020 and future filings and reports that NGM makes from time to time with the United States Securities and Exchange Commission. 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Related party revenue	\$ 23,482	\$ 21,568	\$ 67,601	\$ 72,461
Operating expenses:				
Research and development	46,979	28,953	123,912	87,299
General and administrative	6,460	5,612	19,849	17,208
Total operating expenses	53,439	34,565	143,761	104,507
Loss from operations	(29,957)	(12,997)	(76,160)	(32,046)
Interest income	260	1,984	1,823	5,138
Other expense, net	(68)	96	(159)	54
Net loss	\$ (29,765)	\$ (10,917)	\$ (74,496)	\$ (26,854)
Net loss per share, basic and diluted	\$ (0.43)	\$ (0.17)	\$ (1.09)	\$ (0.60)
Weighted average shares used to compute net loss per share, basic and diluted	68,815,696	65,948,207	68,174,654	44,828,596

- (1) In April 2019, the Company completed its initial public offering (IPO) and concurrent private placement with Merck Sharp & Dohme Corp., in which the Company issued an aggregate of 7,521,394 and 4,121,683 shares of common stock, respectively, and all of the then outstanding shares of convertible preferred stock were automatically converted into shares of common stock upon the closing of the IPO.

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

	September 30, 2020	December 31, 2019*
Assets		
Current assets:		
Cash and cash equivalents	\$ 253,976	\$ 245,598
Short-term marketable securities	33,973	98,913
Related party receivable from collaboration	7,215	5,206
Prepaid expenses and other current assets	7,076	5,531
Total current assets	302,240	355,248
Property and equipment, net	15,773	19,475
Restricted cash	1,499	1,874
Other non-current assets	6,570	3,806
Total assets	<u>\$ 326,082</u>	<u>\$ 380,403</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,613	\$ 9,026
Accrued liabilities	28,579	22,991
Deferred rent, current	2,938	2,829
Deferred revenue, current	4,586	4,872
Total current liabilities	37,716	39,718
Deferred rent, non-current	7,179	9,392
Other non-current liabilities	4,315	—
Early exercise stock option liability	169	574
Total liabilities	49,379	49,684
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value;	—	—
Common stock, \$0.001 par value;	69	67
Additional paid-in capital	547,259	526,771
Accumulated other comprehensive gain	15	25
Accumulated deficit	(270,640)	(196,144)
Total stockholders' equity	276,703	330,719
Total liabilities and stockholders' equity	<u>\$ 326,082</u>	<u>\$ 380,403</u>

*The Condensed Consolidated Balance Sheet as of December 31, 2019 has been derived from the audited financial statements as of that date.