

**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, 2019

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, 2019, NGM Biopharmaceuticals, Inc. reported its financial results for the quarter ended September 30, 2019. A copy of the press release titled “NGM Reports Recent Highlights and Third Quarter 2019 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>
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99.1	<u>Press release, dated November 12, 2019, titled “NGM Reports Recent Highlights and Third Quarter 2019 Financial Results.”</u>
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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, 2019

By: /s/ Aetna Wun Trombley

Aetna Wun Trombley

President and Chief Operating Officer



NGM Reports Business Highlights and Third Quarter 2019 Financial Results

- Announced positive interim results from ongoing 24-week Phase 2 study evaluating 1 mg aldafermin (formerly NGM282) (Cohort 4) in non-alcoholic steatohepatitis (NASH) patients -

- Anticipates full Cohort 4 data, including biopsy assessments in Q1 2020 -

- Disclosed complement C3 as the target for NGM621, an inhibitory antibody intended to treat patients with dry age-related macular degeneration (AMD) -

South San Francisco, CA, November 12, 2019 – NGM Biopharmaceuticals, Inc. (NGM or the Company) (Nasdaq: NGM), a clinical stage biotechnology company focused on developing transformative therapeutics for patients, today reported business highlights and third quarter 2019 financial results for the period ending September 30, 2019.

“We continue to build momentum across our three therapeutic focus areas: metabolic disease, oncology and ophthalmic disease,” said David J. Woodhouse, Ph.D., chief executive officer of NGM. “We’re very encouraged by the interim results we reported last month from the 24-week cohort in our aldafermin Phase 2 study. Consistent with our prior Phase 2 readouts, these data reinforce that aldafermin rapidly returns patients to near normal levels of liver fat and other key inflammatory and fibrotic biomarker measures by 12 weeks, and that these clinically meaningful reductions are sustained through a 24-week period. We look forward to learning early next year whether extending the duration of improved liver health from 12 to 24 weeks will translate to histological benefit. With our ongoing Phase 2b ALPINE 2/3 study of aldafermin, we are working to build a strong clinical case for the efficacy and tolerability of aldafermin in treating NASH patients.”

Dr. Woodhouse continued, “We are also advancing a Phase 1 study of NGM621 in patients with dry AMD and are preparing to initiate a Phase 1a/1b study of NGM120 in patients with solid tumors, some of whom are afflicted with cancer anorexia-cachexia syndrome (CACS). Like NASH, dry AMD and CACS are diseases characterized by large unmet medical needs. We are working diligently to develop transformative medicines for those patients. These programs are part of our strategic collaboration with Merck, which has enabled us to broaden our pipeline into areas such as oncology and ophthalmology. We are also advancing another wholly-owned program, NGM395, a long-acting GDF15 receptor agonist, into a Phase 1 safety and tolerability study.”

Third Quarter 2019 and Recent Highlights

- **Reported preliminary topline results from interim analysis of Cohort 4 in the Phase 2 clinical study of aldafermin (NGM282) in NASH patients with Stage 2 or 3 (F2-F3) fibrosis.** The protocol for this cohort, which includes 78 patients with biopsy-confirmed NASH and F2-F3 liver fibrosis, consists of an assessment of the efficacy, safety and tolerability of a 1 mg daily dose of aldafermin compared to placebo over 24 weeks. A pre-specified interim analysis conducted in approximately half the patients revealed that 24 weeks of treatment with aldafermin was well-tolerated and resulted in statistically significant reductions compared to placebo in absolute and relative liver fat, alanine aminotransferase (ALT) and PRO-C3. See link [here](#) to view a summary of the Cohort 4 interim analysis findings.

Topline results of the full Cohort 4, which will include an assessment of the effect of 24 weeks of treatment on liver histology, are anticipated in the first quarter of 2020. NGM plans to report preliminary results on ALPINE 2/3, an ongoing Phase 2b study of aldafermin in NASH patients with F2-F3 fibrosis, by the end of 2020.

- **Disclosed complement C3 as the target for NGM621, an antibody intended to slow progression of vision loss in patients with dry AMD.** NGM621 is an inhibitory antibody binding complement C3, a key node of all three complement pathways. Human genetics data suggest that inhibition of complement can effectively slow the progression of AMD. A Phase 1 study is currently underway to evaluate the safety, tolerability and pharmacokinetics of up to two intravitreal doses of NGM621 in patients with geographic atrophy, the dry form of advanced AMD. Currently, there are no approved therapies to treat geographic atrophy, a disease that is prevalent in approximately one million adults in the United States and progresses to permanent loss of central vision.
 - **Announced addition of Valerie Pierce as Senior Vice President, General Counsel and Chief Compliance Officer.** NGM continued to expand its leadership team with the addition of Ms. Pierce to provide legal oversight to the Company. Prior to joining NGM in September 2019, Ms. Pierce served as Senior Vice President, Associate General Counsel at Jazz Pharmaceuticals, Inc. (Jazz). She brings to NGM over 25 years of experience providing legal counsel to public pharmaceutical and biotechnology companies, including Jazz, Amyris, Inc., Sunesis Pharmaceuticals, Inc., Tularik Inc. (acquired by Amgen, Inc.) and ALZA Corporation (acquired by Johnson & Johnson). Ms. Pierce received a B.A. from Yale University and a J.D. from the Yale Law School.
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Third Quarter Financial Results

- Related party revenue for the third quarter of 2019 was \$21.6 million, compared to \$20.8 million for the same period in 2018.
- Research and development expenses for the third quarter of 2019 were \$29.0 million, compared to \$24.5 million for the same period in 2018. The increase in research and development expenses was primarily attributable to increases in unallocated research and development expenses associated with personnel-related expenses, external research and development expenses associated with the advancement of NGM's growing pipeline and aldafermin program expenses for ongoing Phase 2 and Phase 2b clinical trials.
- General and administrative expenses for the third quarter of 2019 were \$5.6 million, compared to \$4.8 million for the same period in 2018. The increase in general and administrative expenses was primarily attributable to personnel-related expenses and an increase in legal and other professional service expenses required to support NGM's operations as a public company.
- For the third quarter of 2019, NGM reported a net loss of \$10.9 million, compared to a net loss of \$7.5 million for the same period in 2018.
- Cash, cash equivalents and short-term marketable securities were \$356.6 million as of September 30, 2019, compared to \$206.6 million as of December 31, 2018. The increase of \$150.0 million was primarily attributable to net cash proceeds of \$173.7 million from the Company's initial public offering and concurrent private placement, offset by cash used in operations over the period.

About NGM Biopharmaceuticals, Inc.

NGM is a clinical stage 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 "plans," "will," "anticipate," "intended," "continue," "look forward to," "working to," "preparing 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 timing, enrollment and results of NGM's clinical trials, including the announcement of Cohort 4 topline results of the Phase 2 clinical study of aldafermin (NGM282) in patients with NASH and preliminary results of ALPINE 2/3; the safety, tolerability and efficacy of NGM's product candidates; continued development of additional product candidates, including NGM621 in patients with dry AMD, 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 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 June 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 quarterly report on Form 10-Q for the quarter ended September 30, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Related party revenue	\$ 21,568	\$ 20,815	\$ 72,461	\$ 61,546
Operating expenses:				
Research and development	28,953	24,473	87,299	66,773
General and administrative	5,612	4,811	17,208	12,143
Total operating expenses	34,565	29,284	104,507	78,916
Loss from operations	(12,997)	(8,469)	(32,046)	(17,370)
Interest income	1,984	966	5,138	2,609
Other income (expense), net	96	(14)	54	103
Net loss	\$ (10,917)	\$ (7,517)	\$ (26,854)	\$ (14,658)
Net loss per common share, basic and diluted	\$ (0.17)	\$ (1.15)	\$ (0.60)	\$ (2.33)
Weighted average shares used to compute net loss per common share, basic and diluted	65,948,207	6,525,660	44,828,596	6,285,905

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

	September 30, 2019	December 31, 2018*
Assets		
Current assets:		
Cash and cash equivalents	\$ 303,016	\$ 56,923
Short-term marketable securities	53,557	149,710
Related party receivable from collaboration	—	3,669
Prepaid expenses and other current assets	7,747	4,255
Total current assets	364,320	214,557
Property and equipment, net	20,485	23,893
Restricted cash	1,874	2,249
Deferred IPO costs	—	2,292
Other non-current assets	3,936	3,094
Total assets	<u>\$ 390,615</u>	<u>\$ 246,085</u>
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 4,457	\$ 5,775
Accrued liabilities	18,605	14,003
Deferred rent, current	2,792	2,683
Deferred revenue, current	14,624	19,025
Total current liabilities	40,478	41,486
Deferred rent, non-current	10,118	12,221
Deferred revenue, non-current	—	3,942
Early exercise stock option liability	833	1,559
Convertible preferred stock warrant liability	—	198
Total liabilities	51,429	59,406
Commitments and contingencies		
Convertible preferred stock, \$0.001 par value;	—	294,874
Stockholders' equity (deficit):		
Common stock, \$0.001 par value;	66	7
Additional paid-in capital	519,224	39,258
Accumulated other comprehensive gain (loss)	99	(267)
Accumulated deficit	(180,203)	(147,193)
Total equity (deficit)	339,186	(108,195)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 390,615</u>	<u>\$ 246,085</u>

*The Condensed Consolidated Balance Sheet as of December 31, 2018 has been derived from the audited financial statements as of that date.