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 4, 2021

NGM Biopharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-38853**	**26-1679911**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

333 Oyster Point Boulevard South San Francisco, CA	**94080**
(Address of Principal Executive Offices)	**(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 4, 2021, NGM Biopharmaceuticals, Inc. provided business highlights and reported its financial results for the third quarter ended September 30, 2021. A copy of the press release titled "NGM Bio Provides Business Highlights and Reports Third 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

Exhibit No.	Description
99.1	Press release, dated November 4, 2021, titled "NGM Bio Provides Business Highlights and Reports Third Quarter 2021 Financial Results."
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 4, 2021

By: /s/ Siobhan Nolan Mangini

Siobhan Nolan Mangini

Chief Financial Officer

Exhibit 99.1

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

- Presented preliminary Phase 1a/1b trial findings at ESMO 2021 for NGM120, a GFRAL antagonist antibody product candidate, that showed the drug was well tolerated in advanced solid tumors and provided encouraging initial signals of anti-cancer activity in patients with metastatic pancreatic cancer
- Initiated Phase 1/2 clinical study of NGM707, a dual ILT2/ILT4 antagonist antibody product candidate, as a monotherapy and in combination with KEYTRUDA® (pembrolizumab) in patients with advanced solid tumors; trial designed to enroll approximately 180 patients
- Disclosed NGM831, an ILT3 antagonist antibody product candidate, coinciding with a publication in *Cancer Immunology Research* revealing the discovery of one of ILT3's functional ligands, fibronectin; Phase 1 study in cancer patients planned to commence in 1H'22
- Announced completion of enrollment in 320-patient Phase 2 CATALINA study of NGM621, an anti-complement C3 antibody product candidate, being studied for the treatment of geographic atrophy; topline data expected in 2H'22

South San Francisco, CA, November 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 quarterly period ended September 30, 2021.

"This quarter we made notable progress advancing NGM's oncology portfolio, now four assets strong, all generated by our in-house discovery engine and wholly owned by NGM," said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM. "We reported the first preliminary human data from our NGM120 trial at ESMO 2021 and also unveiled our third myeloid reprogramming program, NGM831. Over the past 12 months, we have pulled back the curtain on the intensive discovery work in oncology that has been underway at NGM for several years. Leveraging integrated world-class target discovery research and protein engineering, we've created multiple oncology product candidates each with the potential to become next-generation treatment options to help patients mobilize their own immune systems to fight cancer more effectively. We strongly believe myeloid cell reprogramming can be an important additional approach to augment anti-tumor immunity and our portfolio of product candidates provide multiple opportunities to harness that biology."

Key Third Quarter and Recent Highlights

Cancer

- **Presented preliminary findings from ongoing Phase 1a/1b dose escalation study of NGM120, a first-in-class anti-GDNF family receptor alpha like (GFRAL) antagonist antibody, in patients with advanced solid tumors at the European Society for Medical Oncology (ESMO) Virtual Congress.** Preliminary results showed that treatment with the drug was well tolerated with no dose-limiting toxicities. All six evaluable metastatic pancreatic cancer patients in the Phase 1b combination cohort (NGM120 in combination with gemcitabine + Nab-paclitaxel) demonstrated disease control at 16 weeks, with three partial responses (PR) and three stable disease (SD). Four metastatic pancreatic cancer patients in the Phase 1b cohort continued to exhibit PR/SD beyond 36 weeks at the July 26 data cut-off, compared to the historic median progression-free survival in metastatic pancreatic cancer of 22 weeks[1]. As of September 16, 2021, three of those four patients remained on drug, with two patients exhibiting PR and one patient exhibiting SD beyond 44 weeks.

- **Continued enrollment in a Phase 2 placebo-controlled component of the ongoing Phase 1/2 PINNACLES study, with the Phase 2 component testing NGM120 as a first-line treatment in combination with gemcitabine and Nab-paclitaxel in patients with metastatic pancreatic cancer.** In March 2021, NGM initiated a multi-center, randomized, single-blind (sponsor unblinded), placebo-controlled component of NGM120 in combination with gemcitabine and Nab-paclitaxel as a first-line treatment in patients with metastatic pancreatic cancer as part of the ongoing Phase 1/2 trial. The Phase 2 component of the 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 Nab-paclitaxel against both cancer and cancer-related cachexia endpoints.

- **Initiated the Phase 1 component of a Phase 1/2 Study of NGM707, a novel dual antagonist antibody that inhibits the Immunoglobulin-like Transcript 2 (ILT2) and Immunoglobulin-like Transcript 4 (ILT4) receptors, for the treatment of patients with advanced solid tumors.** The Phase 1 portion (n≅60) of the study includes a monotherapy dose escalation arm (Part 1a) and a dose-finding arm in combination with KEYTRUDA® (pembrolizumab) (Part 1b). The Phase 2 portion (n≅120) of the study will employ a basket design that will include expansion cohorts of patients treated with NGM707 monotherapy (Part 2a) or NGM707 in combination with KEYTRUDA (Part 2b) in a variety of selected solid tumor types.

- **Disclosed fourth oncology development candidate, NGM831, coinciding with a publication on the ILT3-fibronectin pathway in *Cancer Immunology Research*.** In August 2021, NGM disclosed its fourth oncology development candidate, NGM831, an antagonist antibody designed to block the interaction of Immunoglobulin-like transcript 3 (ILT3) with fibronectin, a key component of tumor stroma, as well as with other ligands. ILT3-fibronectin interactions within the tumor microenvironment may form a stromal checkpoint that actively suppresses myeloid cell function and inhibits tumor activity. NGM plans to advance NGM831 into a Phase 1 study in the first half of 2022. NGM831 joins NGM438 to become the second program in the Company's oncology portfolio being studied for the potential to impact the tumor microenvironment by releasing stromal checkpoints.

Retinal disease

- **Completed enrollment in the Phase 2 CATALINA study of NGM621 in patients with geographic atrophy.** NGM completed enrollment in the Phase 2 CATALINA study, a multi-center, randomized, double-masked, sham-controlled clinical trial to evaluate the safety and efficacy of intravitreal, or IVT, injections of NGM621 every four weeks or every eight weeks in 320 patients with geographic atrophy in one or both eyes secondary to age-related macular degeneration. The primary efficacy endpoint is the rate of change in geographic atrophy lesion area, as measured by fundus autofluorescence imaging over 52 weeks of treatment. NGM anticipates reporting topline data from the CATALINA study in the second half of 2022. Upon completion of a proof-of-concept study in humans, Merck has a one-time option to license NGM621 and its related molecules or to license NGM621 and its related molecules together with all other ophthalmology compounds included within the scope of our ongoing collaboration with Merck.

Liver and metabolic diseases

- **Continued enrollment in Phase 2b ALPINE 4 study of aldafermin in patients with compensated non-alcoholic steatohepatitis (NASH) cirrhosis (liver fibrosis stage 4, or F4).** The 48-week study is designed to assess the efficacy, safety and tolerability of 0.3 mg, 1 mg and 3 mg doses of aldafermin compared to placebo.
- **Merck continued enrollment in its Phase 2b study of MK-3655 in patients with NASH and liver fibrosis stage 2 or 3 (F2 or F3).** In November 2020, Merck initiated a global Phase 2b multicenter study of MK-3655 for the treatment of patients with F2 or 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 once monthly 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%.

Third Quarter 2021 Financial Results

- NGM reported a net loss of $28.9 million for the quarter ended September 30, 2021, compared to a net loss of $29.8 million for the same period in 2020.
- Related party revenue from our collaboration with Merck was $18.6 million for the quarter ended September 30, 2021, compared to $23.5 million for the same period in 2020. Related party revenue decreased $4.9 million in the quarter ended September 30, 2021 as compared to the prior year period, primarily due to a decrease in research and development revenue.
- R&D expenses were $38.7 million for the quarter ended September 30, 2021, compared to $47.0 million for the same period in 2020. R&D expenses decreased $8.3 million in the quarter as compared to the prior year period, primarily due to decreases in expenses for our manufacturing activities and our clinical trials of aldafermin.
- General and administrative expenses were $8.9 million for the quarter ended September 30, 2021, compared to $6.5 million for the same period in 2020. The $2.4 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.
- Cash, cash equivalents and short-term marketable securities were $383.4 million as of September 30, 2021, compared to $295.2 million as of December 31, 2020.

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 retinal diseases, cancer and liver and metabolic diseases. 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. All of our therapeutics have been generated by our in-house discovery engine; today, we have seven disclosed programs, including four in Phase 2 or 2b studies, across three therapeutics areas. 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 "focused," "anticipates," "believe," "will," "designed to," "preliminary," "encouraging," "enable," "expected," "potential," "aspire," "opportunities," "planned," "plans" 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: the therapeutic potential of NGM's product candidates, including the potential of NGM's oncology product candidates to become next-generation treatment options; NGM's belief that myeloid cell reprogramming can be an important additional approach to augment anti-tumor immunity and that its portfolio of product candidates provide multiple opportunities to harness that biology; the design of NGM's and Merck's clinical trials of NGM's product candidates; the preliminary findings in the Phase 1a/1b study of NGM120 providing encouraging initial signals of anti-cancer activity; the planned commencement of a Phase 1 clinical trial of NGM831 and the anticipated timing thereof; the availability and anticipated timing of topline data from Phase 2 CATALINA study of NGM621 in patients with geographic atrophy; potential activities under NGM's amended collaboration with Merck and the potential receipt of milestone and royalty payments by NGM under the amended collaboration with Merck; 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 initiating, enrolling, reporting data from or completing clinical studies, as well as the risks that results obtained in clinical trials to date

may not be indicative of results obtained in ongoing or future trials and that NGM's product candidates may otherwise not be tolerable and effective treatments in their planned indications; NGM's ability to maintain its amended collaboration with Merck, including the risk that if Merck were to breach or terminate the amended collaboration or Merck's development funding obligations, NGM would not obtain all of the anticipated financial and other benefits of the amended collaboration, and the development and/or commercialization of NGM's product candidates within the scope of the amended collaboration could be delayed, perhaps substantially; 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 ability to timely supply, initiate, enroll and complete its ongoing and future clinical trials; the time-consuming and uncertain regulatory approval process; NGM's reliance on third-party manufacturers for aldafermin, NGM120, NGM707, NGM831, NGM621 and its other product candidates and the risks inherent in manufacturing and testing pharmaceutical products; the sufficiency of NGM's cash resources, including to fund its wholly-owned programs, and NGM's 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 quarterly report on Form 10-Q for the quarter ended June 30, 2021 filed with the United States Securities and Exchange Commission (SEC) on August 5, 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.

[1]Von Hoff DD, et al. N Engl J Med. 2013

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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,	
	2021	2020	2021	2020
Related party revenue	$ 18,575	$ 23,482	$ 56,923	$ 67,601
Operating expenses:				
Research and development	38,714	46,979	122,983	123,912
General and administrative	8,867	6,460	27,411	19,849
Total operating expenses	47,581	53,439	150,394	143,761
Loss from operations	(29,006)	(29,957)	(93,471)	(76,160)
Interest income, net	106	260	335	1,823
Other income (expense), net	35	(68)	35	(159)
Net loss	$ (28,865)	$ (29,765)	$ (93,101)	$ (74,496)
Net loss per share, basic and diluted	$ (0.37)	$ (0.43)	$ (1.21)	$ (1.09)
Weighted average shares used to compute net loss per share, basic and diluted	77,408,893	68,815,696	76,851,508	68,174,654

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

	September 30, 2021	December 31, 2020*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 145,826	$ 147,017
Short-term marketable securities	237,603	148,139
Related party receivable from collaboration	4,400	333
Related party contract asset	—	6,100
Prepaid expenses and other current assets	8,054	6,837
Total current assets	395,883	308,426
Property and equipment, net	11,452	14,526
Restricted cash	1,499	1,499
Other non-current assets	7,024	4,592
Total assets	$ 415,858	$ 329,043
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,632	$ 9,663
Accrued liabilities	34,720	29,945
Deferred rent, current	3,088	2,975
Contract liabilities	12,288	—
Total current liabilities	57,728	42,583
Deferred rent, non-current	4,091	6,417
Total liabilities	61,819	49,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value;	—	—
Common stock, $0.001 par value;	78	71
Additional paid-in capital	745,704	578,599
Accumulated other comprehensive (loss) income	(11)	4
Accumulated deficit	(391,732)	(298,631)
Total stockholders' equity	354,039	280,043
Total liabilities and stockholders' equity	$ 415,858	$ 329,043

* Derived from the audited consolidated financial statements.