

**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 1, 2022

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, CA
(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 1, 2022, NGM Biopharmaceuticals, Inc. provided business highlights and reported its financial results for the fourth quarter and full year ended December 31, 2021. A copy of the press release titled “NGM Bio Provides Business Highlights and Reports Fourth Quarter and Full Year 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated March 1, 2022, titled “NGM Bio Provides Business Highlights and Reports Fourth Quarter and Full Year 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.

Dated: March 1, 2022

NGM Biopharmaceuticals, Inc.

By: /s/ Siobhan Nolan Mangini

Siobhan Nolan Mangini

Chief Financial Officer



NGM Bio Provides Business Highlights and Reports Fourth Quarter and Full Year 2021 Financial Results

- Advanced programs across NGM Bio's pipeline in retinal diseases, oncology and liver and metabolic diseases during the fourth quarter and beginning of 2022:
 - Obtained Fast Track designation from the U.S. Food and Drug Administration (FDA) for NGM621, an anti-complement C3 antibody product candidate, for the treatment of patients with geographic atrophy (GA) secondary to age-related macular degeneration
 - Completed enrollment in the Phase 2b ALPINE 4 trial of aldafermin, an engineered FGF19 analog product candidate, in patients with compensated NASH cirrhosis (F4 NASH), with topline data expected in the first half of 2023
- \$366.3 million in cash, cash equivalents and marketable securities as of December 31, 2021

South San Francisco, CA, March 1, 2022 – NGM Biopharmaceuticals, Inc. (NGM Bio) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today provided business highlights and reported financial results for the full year and fourth quarter ending December 31, 2021.

"2021 was a meaningful year for NGM Bio. We made significant progress advancing our pipeline, which now includes five programs in the clinic, with four programs in Phase 2 trials," said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM Bio. "2022 is poised to be one of the most eventful years in NGM Bio's history with multiple milestones expected, including clinical data readouts from three of our programs, continued development across our pipeline and steady output from our research and discovery engine."

Key Fourth Quarter and Recent Highlights

Oncology

- Progressed the Phase 1/2 trial of NGM707, an ILT2/ITL4 dual antagonist antibody product candidate, in patients with advanced solid tumors through multiple dose cohorts in the Phase 1a monotherapy dose escalation. Initial data readout from the Phase 1a portion of the trial is expected in the second half of 2022.
- Continued to progress the Phase 1 portion of the PINNACLES trial of NGM120, an antagonist antibody product candidate that binds GFRAL and is designed to inhibit GDF15 signaling. The PINNACLES trial is evaluating NGM120 as a monotherapy in patients with advanced solid tumors and in combination with gemcitabine and Nab-paclitaxel in patients with metastatic pancreatic cancer. Additional clinical data from the Phase 1a and Phase 1b cohorts is expected in the second half of 2022.
- Continued enrollment in the placebo-controlled Phase 2 portion of the PINNACLES trial, evaluating NGM120 in combination with gemcitabine and Nab-paclitaxel as a first-line treatment in patients with metastatic pancreatic cancer.

Retinal disease

- Continued to advance the fully enrolled Phase 2 CATALINA trial of NGM621 in patients with GA. Topline data readout is expected in the fourth quarter of this year.
- The FDA granted Fast Track designation to NGM621 for the treatment of patients with GA secondary to age-related macular degeneration in February 2022.

Liver and metabolic diseases

- Completed enrollment in ALPINE 4, the Phase 2b trial of aldafermin in patients with compensated NASH cirrhosis (F4 NASH), in January 2022. Topline data readout is expected in the first half of 2023.
- Updated the design of the ALPINE 4 trial, elevating the Enhanced Liver Fibrosis (ELF) test, a reproducible, quantitative non-invasive liver prognostic test that evaluates liver fibrosis and correlates to liver-related outcomes to be the primary endpoint for the trial. The ELF test is a composite blood test measuring the presence of three biomarkers associated with liver matrix metabolism. Liver biopsy data will also be measured and reported as a secondary endpoint upon completion of the trial.
- Merck, known as MSD outside of the United States and Canada, continued to progress enrollment in a global Phase 2b trial of MK-3655 for the treatment of non-cirrhotic (F2/F3) NASH. MK-3655 is an agonistic antibody product candidate binding to fibroblast growth factor receptor 1c-beta-klotho that Merck licensed from NGM Bio.

Corporate Highlights

- Entered into a clinical trial collaboration and supply agreement with Merck related to NGM Bio's ongoing Phase 1/2 trial of NGM707 in combination with Merck's KEYTRUDA® (pembrolizumab) in December 2021.

Fourth Quarter and Full Year 2021 Financial Results

- NGM Bio reported a net loss of \$27.2 million and \$120.3 million for the quarter and year ended December 31, 2021, respectively, compared to a net loss of \$28.0 million and \$102.5 million for the same periods in 2020.
- Related party revenue from our collaboration with Merck was \$21.0 million and \$77.9 million for the quarter and year ended December 31, 2021, respectively, compared to \$19.8 million and \$87.4 million for the same periods in 2020. Related party revenue decreased \$9.5 million in 2021 as compared to 2020 primarily due to the effects of amending and restating our collaboration agreement with Merck in June 2021.
- Research and development (R&D) expenses were \$38.7 million and \$161.7 million for the quarter and year ended December 31, 2021, respectively, compared to \$40.1 million and \$164.0 million for the same periods in 2020. R&D expenses decreased \$1.3 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. R&D expenses decreased \$2.3 million in 2021 as compared to 2020 primarily due to decreases in expenses for our manufacturing activities and our clinical trials of aldafermin partially offset by increases in personnel-related expenses and external expenses driven by our ongoing clinical trials of NGM621, NGM120 and NGM707 and our preclinical studies of NGM438 and NGM831.
- General and administrative expenses were \$9.5 million and \$36.9 million for the quarter and year ended December 31, 2021, respectively, compared to \$7.4 million and \$27.2 million for the same periods in 2020. The \$9.6 million increase in general and administrative expenses in 2021 was primarily attributable to increases in compensation-related expenses driven by higher headcount and an increase in expenses associated with being a public company.
- Cash, cash equivalents and short-term marketable securities were \$366.3 million as of December 31, 2021, compared to \$295.2 million as of December 31, 2020. NGM Bio believes its cash, cash equivalents and marketable securities will be sufficient to fund its planned operations into the first half of 2024.

About NGM Biopharmaceuticals, Inc.

NGM Bio is focused on discovering and developing novel, life-changing medicines for people whose health and lives have been disrupted by disease. The company's biology-centric drug discovery approach aims to seamlessly integrate interrogation of complex disease-associated biology and protein engineering expertise to unlock proprietary insights that are leveraged to generate promising product candidates and enable their rapid advancement into proof-of-concept studies. As explorers on the frontier of life-changing science, NGM Bio aspires to operate one of the most productive research and development engines in the biopharmaceutical industry. All therapeutic candidates in the NGM Bio pipeline have been generated by its in-house discovery engine, with a disease-agnostic mindset, always led by biology and motivated by unmet patient need. Today, the company has

seven disclosed programs, including four in Phase 2 or 2b studies, across three therapeutic areas: cancer, retinal diseases and liver and metabolic diseases. Visit us at www.ngmbio.com for more information.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

Abbreviations (in Alphabetical Order)

F2/F3/F4 = stage 2 or 3 or 4 liver fibrosis; GFRAL=Glial Cell-Derived Neurotrophic Factor Receptor Alpha-Like; GDF15 = Growth Differentiation Factor 15; ILT2=Immunoglobulin-Like Transcript 2; ILT4=Immunoglobulin-Like Transcript 4; NASH=non-alcoholic steatohepatitis

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,” “may,” “expected,” “anticipates,” “preliminary,” “enable,” “believed,” “designed,” “suggesting,” “suggest,” “look forward,” “potentially,” “potential,” “promise,” “goal,” “planned,” “plans,” “aspire,” “aim” 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 Bio’s product candidates, NGM Bio’s continued pipeline development and research and development output; the design of NGM Bio’s and Merck’s clinical trials of NGM Bio’s product candidates; the planned commencement of a Phase 1b cohort of the Phase 1/2 trial of NGM707 and the anticipated timing thereof; the availability and anticipated timing of the initial data readout from the Phase 1a monotherapy dose escalation cohort of the Phase 1/2 trial of NGM707; the availability and anticipated timing of additional clinical data readouts from the Phase 1a and Phase 1b cohorts of the Phase 1/2 PINNACLES trial of NGM120; the availability and anticipated timing of topline data from the Phase 2 CATALINA trial of NGM621; the availability and anticipated timing of the Phase 2b trial of aldafermin in patients with compensated NASH cirrhosis; the sufficiency of NGM Bio’s cash, cash equivalents and marketable securities to fund planned operations into the first half of 2024; and other statements that are not historical fact. Because such statements deal with future events and are based on NGM Bio’s current expectations, they are subject to various risks and uncertainties, and actual results, performance or achievements of NGM Bio 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 Bio’s product candidates may otherwise not be tolerable and effective treatments in their planned indications; NGM Bio’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 Bio would not obtain all of the anticipated financial and other benefits of the amended collaboration, and the development and/or commercialization of NGM Bio’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 Bio’s business and operations, including NGM Bio’s ability to timely supply, initiate, enroll and complete its ongoing and future clinical trials; the time-consuming and uncertain regulatory approval process; NGM Bio’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 Bio’s cash resources, including to fund its wholly-owned programs, and NGM Bio’s need for additional capital; and other risks and uncertainties affecting NGM Bio and its development programs, including those discussed in the section titled “Risk Factors” in NGM Bio’s quarterly report on Form 10-Q for the quarter ended September 30, 2021 filed with the United States Securities and Exchange Commission (SEC) on November 4, 2021 and future filings and reports that NGM Bio makes from time to time with the SEC. Except as required by law, NGM Bio 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,	
	2021	2020	2021	2020*
Related party revenue	\$ 20,959	\$ 19,767	\$ 77,882	\$ 87,368
Operating expenses:				
Research and development	38,729	40,060	161,712	163,972
General and administrative	9,454	7,380	36,865	27,229
Total operating expenses	48,183	47,440	198,577	191,201
Loss from operations	(27,224)	(27,673)	(120,695)	(103,833)
Interest income, net	85	116	420	1,939
Other expense, net	(95)	(434)	(60)	(593)
Net loss	\$ (27,234)	\$ (27,991)	\$ (120,335)	\$ (102,487)
Net loss per share, basic and diluted	\$ (0.35)	\$ (0.40)	\$ (1.56)	\$ (1.50)
Weighted average shares used to compute net loss per share, basic and diluted	77,779,419	69,370,960	77,085,405	68,475,378

* Derived from the audited consolidated financial statements.

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

	December 31, 2021	December 31, 2020*
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 151,795	\$ 147,017
Short-term marketable securities	214,458	148,139
Related party receivable from collaboration	4,945	333
Related party contract asset	—	6,100
Prepaid expenses and other current assets	8,082	6,837
Total current assets	379,280	308,426
Property and equipment, net	10,071	14,526
Operating lease right-of-use asset	4,045	—
Restricted cash	1,499	1,499
Other non-current assets	7,492	4,592
Total assets	<u>\$ 402,387</u>	<u>\$ 329,043</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 5,246	\$ 9,663
Accrued liabilities	33,258	29,945
Operating lease liability, current	5,077	—
Deferred rent, current	—	2,975
Contract liabilities	17,774	—
Total current liabilities	61,355	42,583
Operating lease liability, non-current	5,385	—
Deferred rent, non-current	—	6,417
Total liabilities	66,740	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	754,664	578,599
Accumulated other comprehensive (loss) income	(129)	4
Accumulated deficit	(418,966)	(298,631)
Total stockholders' equity	335,647	280,043
Total liabilities and stockholders' equity	<u>\$ 402,387</u>	<u>\$ 329,043</u>

* Derived from the audited consolidated financial statements.