

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): February 28, 2023

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 February 28, 2023, NGM Biopharmaceuticals, Inc. provided business highlights and reported its financial results for the fourth quarter and full year ended December 31, 2022. A copy of the press release titled “NGM Bio Provides Business Highlights and Reports Fourth Quarter and Full Year 2022 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 February 28, 2023, titled “NGM Bio Provides Business Highlights and Reports Fourth Quarter and Full Year 2022 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: February 28, 2023

NGM Biopharmaceuticals, Inc.

By: /s/ Siobhan Nolan Mangini

Siobhan Nolan Mangini

President and Chief Financial Officer



NGM Bio Provides Business Highlights and Reports Fourth Quarter and Full Year 2022 Financial Results

- Presented preliminary findings from the Phase 1a monotherapy dose escalation portion of the ongoing Phase 1/2 trial of NGM707 in patients with advanced or metastatic solid tumors at the ESMO I-O Annual Congress
- Initiated a Phase 1b cohort of the ongoing Phase 1/1b trial evaluating NGM438 in combination with KEYTRUDA® (pembrolizumab) for the treatment of patients with advanced or metastatic solid tumors

South San Francisco, CA, February 28, 2023 – 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 fourth quarter and full year ended December 31, 2022.

“In 2022, NGM Bio further focused our clinical development efforts on our portfolio of clinical-stage solid tumor oncology programs, while continuing the efforts of our prolific drug discovery engine to produce potential next-generation biologic therapeutics.” said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM Bio. “At year end, we reported promising preliminary data from our first myeloid checkpoint inhibitor program, NGM707, at the ESMO Immuno-Oncology Congress and advanced our other myeloid checkpoint inhibitor programs, NGM438 and NGM831, in their ongoing Phase 1/1b trials in patients with advanced solid tumors.”

Key Fourth Quarter and Recent Highlights

Solid Tumor Oncology

- Presented preliminary findings from the Phase 1a monotherapy dose escalation arm of the ongoing Phase 1/2 trial of NGM707, an ILT2/ILT4 antagonist antibody product candidate for the treatment of patients with advanced or metastatic solid tumors, at the 2022 European Society of Medical Oncologists Immuno-Oncology (ESMO I-O) Congress. Preliminary findings indicated that NGM707 was generally well tolerated across all dose levels and demonstrated early signals of anti-tumor activity across multiple tumor types.
- Initiated a Phase 1b cohort of the Phase 1/1b trial evaluating NGM438, a LAIR1 antagonist antibody product candidate, in combination with pembrolizumab for the treatment of patients with advanced or metastatic solid tumors.

Other Programs

- Remained on track for topline data readout of ALPINE 4, the Phase 2b trial of aldafermin, an engineered FGF19 analog product candidate, in patients with compensated NASH cirrhosis (F4 NASH) in the second quarter of 2023.
- Announced that our Phase 2 CATALINA trial evaluating NGM621, a monoclonal antibody engineered to potently inhibit complement C3, in patients with geographic atrophy (GA) secondary to advanced macular degeneration did not meet its primary endpoint. Merck Sharp & Dohme LLC's, or Merck's, option to license NGM621 and its related compounds under our amended and restated research collaboration, product development and license agreement, or the Amended Collaboration Agreement, expired unexercised in January 2023 and the program is now wholly owned by us.
- Presented characterization of our first disclosed preclinical bispecific program, NGM936, a bispecific T cell engager therapeutic candidate for the treatment of hematologic malignancies that targets ILT3 and CD3, at the American Society of Hematology (ASH) Annual Meeting.
- Received notification from Merck of its decision to terminate the Phase 2b trial of MK-3655 (NGM313), an agonistic antibody that selectively activates fibroblast growth factor receptor 1c-beta-klotho, for the treatment of patients with NASH and liver fibrosis stage 2 or 3 and our amended and restated research collaboration, product development and license agreement as it relates to the MK-3655 (NGM313) and its

related compounds. Merck's decision to discontinue the trial was based on its interim analysis of reduction in liver fat at Week 24 and was not related to safety concerns. As a result, in late April 2023, the license rights granted to Merck in 2018 with respect to MK-3655 (NGM313) and its related compounds will revert to us and we will wholly own the program.

- Due to the need to conserve capital and prioritize focused execution, we are actively seeking, or intend to seek, collaboration, out licensing, partnering or other business development arrangements with third-party partners with sufficient resources and relevant domain expertise in the relevant therapeutic area in order to further clinical development of the following programs:
 - NGM621, a product candidate designed for the treatment of patients with GA secondary to advanced macular degeneration;
 - Aldafermin, a product candidate designed for the treatment of patients with NASH and/or diseases related to bile acid dysregulation;
 - MK-3655 (NGM313), a product candidate designed as an insulin sensitizer for the treatment of patients with NASH, once termination of Merck's license is effective; and
 - NGM936, a product candidate designed for the treatment of patients with AML and multiple myeloma.

Fourth Quarter and Full Year 2022 Financial Results

- NGM Bio reported a net loss of \$36.4 million and \$162.7 million for the quarter and year ended December 31, 2022, respectively, compared to a net loss of \$27.2 million and \$120.3 million for the same periods in 2021.
- Related party revenue from our collaboration with Merck under the Amended Collaboration Agreement was \$18.2 million and \$55.3 million for the quarter and year ended December 31, 2022, respectively, compared to \$21.0 million and \$77.9 million for the same periods in 2021. Our related party revenue from Merck decreased substantially in 2022 and is expected to be significantly lower from January 1, 2023 through March 31, 2024.
- Research and development (R&D) expenses were \$46.7 million and \$181.1 million for the quarter and year ended December 31, 2022, respectively, compared to \$38.7 million and \$161.7 million for the same periods in 2021. R&D expenses increased \$8.0 million in the quarter ended December 31, 2022 as compared to the prior year period and \$19.4 million in 2022 as compared to 2021 primarily due to costs related to our ongoing clinical trials of NGM707, NGM438, NGM831 and NGM120, our completed Phase 2 trial of NGM621, and personnel-related expenses, partially offset by decreased expenses for our manufacturing activities and our clinical trials of aldafermin.
- General and administrative expenses were \$9.8 million and \$40.5 million for the quarter and year ended December 31, 2022, respectively, compared to \$9.5 million and \$36.9 million for the same periods in 2021.
- Cash, cash equivalents and short-term marketable securities were \$271.5 million as of December 31, 2022, compared to \$366.3 million as of December 31, 2021.

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, always led by biology and motivated by unmet patient need. Today, the company has four solid tumor oncology programs in clinical development. 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)

AML=acute myeloid leukemia; CD3=cluster of differentiation 3; F4=stage 4 liver fibrosis; FGF19=fibroblast growth factor 19; ILT2=Immunoglobulin-Like Transcript 2; ILT3=Immunoglobulin-Like Transcript 3; ILT4=Immunoglobulin-Like Transcript 4; LAIR1=Leukocyte-Associated Immunoglobulin-Like Receptor 1; 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,” “expect,” “potentially,” “promising,” “aspires,” “aims” 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, including identification and engagement of third-party partners for potential future collaboration, out licensing, partnering or other business development arrangements (“BD Arrangements”) with respect to NGM621, aldafermin, NGM936 and, once termination of Merck’s license is effective, MK-3655 (NGM313), and research and development and discovery engine output; NGM Bio’s expectation of providing updates and meeting multiple milestones, including the availability and anticipated timing of clinical data readouts from the Phase 2b trial of aldafermin in patients with F4 NASH in the second quarter of 2023; expectation of significantly lower revenue from Merck; 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; 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 preclinical or clinical trials to date may not be indicative of results obtained in future trials; NGM Bio’s reliance on its amended collaboration with Merck; NGM Bio’s ability to identify and engage third-party partners for BD Arrangements, if any, and its ability to attract such partners; the time-consuming and uncertain regulatory approval process; NGM Bio’s reliance on third-party manufacturers for its product candidates and the risks inherent in manufacturing and testing pharmaceutical products; the sufficiency of NGM Bio’s cash resources and NGM Bio’s need for additional capital, particularly in light of NGM Bio’s expectation that Merck will provide significantly lower funding through March 31, 2024 and macroeconomic conditions (such as the impacts of the ongoing COVID-19 pandemic and the conflict between Russia and Ukraine, global economic slowdown, increased inflation and rising interest rates); 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, 2022 filed with the United States Securities and Exchange Commission (SEC) on November 3, 2022 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 per share amounts)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021*
Related party revenue	\$ 18,181	\$ 20,959	\$ 55,333	\$ 77,882
Operating expenses:				
Research and development	46,722	38,729	181,067	161,712
General and administrative	9,756	9,454	40,515	36,865
Total operating expenses	56,478	48,183	221,582	198,577
Loss from operations	(38,297)	(27,224)	(166,249)	(120,695)
Interest income, net	2,030	85	3,714	420
Other expense, net	(170)	(95)	(132)	(60)
Net loss	\$ (36,437)	\$ (27,234)	\$ (162,667)	\$ (120,335)
Net loss per share, basic and diluted	\$ (0.45)	\$ (0.35)	\$ (2.03)	\$ (1.56)
Weighted average shares used to compute net loss per share, basic and diluted	81,787	77,779	79,950	77,085

* Derived from the audited consolidated financial statements.

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

	December 31, 2022	December 31, 2021*
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 73,456	\$ 151,795
Short-term marketable securities	198,036	214,458
Related party receivable from collaboration	7,580	4,945
Prepaid expenses and other current assets	9,787	8,082
Total current assets	288,859	379,280
Property and equipment, net	8,496	10,071
Operating lease right-of-use asset	2,096	4,045
Restricted cash	3,954	1,499
Other non-current assets	3,997	7,492
Total assets	\$ 307,402	\$ 402,387
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 8,453	\$ 5,246
Accrued liabilities	33,638	33,258
Operating lease liability, current	5,385	5,077
Contract liabilities	366	17,774
Total current liabilities	47,842	61,355
Operating lease liability, non-current	—	5,385
Total liabilities	47,842	66,740
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value	—	—
Common stock, \$0.001 par value	82	78
Additional paid-in capital	841,413	754,664
Accumulated other comprehensive loss	(302)	(129)
Accumulated deficit	(581,633)	(418,966)
Total stockholders' equity	259,560	335,647
Total liabilities and stockholders' equity	\$ 307,402	\$ 402,387

* Derived from the audited consolidated financial statements.