

**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): May 4, 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 94080**  
(Address of Principal Executive Offices, Including 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 May 4, 2023, NGM Biopharmaceuticals, Inc. reported its financial results for the first quarter ended March 31, 2023 and provided business highlights, including topline ALPINE 4 data. A copy of the press release titled “NGM Bio Reports First Quarter 2023 Financial Results and Provides Business Highlights, Including Topline ALPINE 4 Data,” 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	<a href="#">Press release, dated May 4, 2023, titled “NGM Bio Reports First Quarter 2023 Financial Results and Provides Business Highlights, Including Topline ALPINE 4 Data.”</a>
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.

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## 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: May 4, 2023

**NGM Biopharmaceuticals, Inc.**

By: /s/ Siobhan Nolan Mangini

Siobhan Nolan Mangini

***President and Chief Financial Officer***



## **NGM Bio Reports First Quarter 2023 Financial Results and Provides Business Highlights, Including Topline ALPINE 4 Data**

- Phase 2b ALPINE 4 trial met its primary endpoint, demonstrating a statistically significant improvement in Enhanced Liver Fibrosis (ELF) score at 48 weeks versus baseline in patients with compensated cirrhosis (F4) due to NASH treated with 3 mg of aldafermin, an engineered FGF19 analog product candidate, compared to patients treated with placebo
- Initiated the first two Phase 2b expansion cohorts in the Phase 1/2 trial evaluating NGM707, an ILT2/ILT4 antagonist antibody product candidate, in combination with KEYTRUDA® (pembrolizumab)
- Announced the appointment of Dan Kaplan, Ph.D. to Chief Scientific Officer
- Extended expected cash runway into the second quarter of 2025 following a restructuring of NGM Bio's workforce that reduced headcount by approximately 33%

**South San Francisco, CA**, May 4, 2023 – NGM Biopharmaceuticals, Inc. (NGM Bio) (Nasdaq: NGM), a clinical-stage biotechnology company focused on discovering and developing transformative therapeutics for patients, today reported financial results for the quarterly period ended March 31, 2023 and provided business highlights.

"We are pleased with the results of the ALPINE 4 trial supporting the therapeutic potential of aldafermin in patients with advanced NASH. We continue to make progress on our corporate strategy with the initiation of Phase 2 expansion cohorts in our proof-of-concept trial of NGM707 and the extension of our expected cash runway. With these activities, we are optimizing our resource allocation strategy towards advancing our solid tumor oncology portfolio in the clinic, while our discovery engine continues to generate new product candidates," said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM Bio. "I would like to extend my sincere gratitude and thanks to NGM Bio's departing staff impacted by our recent restructuring for their significant contributions and unwavering commitment to discovering and developing novel, life-changing medicines for people whose health and lives are disrupted by disease."

### **Key First Quarter and Recent Highlights**

#### **Corporate Updates**

- Announced the appointment of Dan Kaplan, Ph.D. to Chief Scientific Officer. Dr Kaplan has been a member of NGM Bio's Research and Development organization for fourteen years, most recently as Vice President, Immuno-oncology. Jin-Long Chen, Ph.D., who founded NGM Bio and served as Chief Scientific Officer and as a member of NGM Bio's Board of Directors, resigned from NGM Bio effective April 4, 2023.
- Announced a restructuring resulting in a reduction of NGM Bio's workforce by 75 people, or approximately 33% of the pre-restructuring headcount. NGM Bio expects to incur approximately \$5.0 million in charges in connection with the restructuring, the majority to be incurred in the second quarter. The execution of the restructuring, including cash payments, will be substantially complete by the end of the second quarter.

#### **Solid Tumor Oncology**

- Initiated the first two Phase 2b cohorts in the Phase 1/2 trial evaluating NGM707 in combination with pembrolizumab.
- Continued enrollment in the Phase 1/1b trial evaluating NGM438, a LAIR1 antagonist antibody product candidate, as a monotherapy and in combination with pembrolizumab for the treatment of patients with advanced or metastatic solid tumors.

- Continued enrollment in the Phase 1/1b trial evaluating NGM831, an ILT3 antagonist antibody product candidate, as a monotherapy and in combination with pembrolizumab for the treatment of patients with advanced or metastatic solid tumors.

#### **Phase 2b ALPINE 4 Trial Topline Results**

- Today NGM Bio is reporting topline data from the Phase 2b ALPINE 4 trial of aldafermin in 160 patients with compensated cirrhosis due to NASH (liver fibrosis stage 4, or, F4). The 48-week trial assessed the efficacy, safety and tolerability of 1 mg and 3 mg doses of aldafermin compared to placebo<sup>1</sup>.
- The study met its primary endpoint with a statistically significant reduction in ELF score from baseline to week 48 in patients treated with 3 mg of aldafermin versus patients receiving placebo. Patients receiving 3 mg of aldafermin had a 0.5 point greater reduction in ELF at week 48 compared to patients receiving placebo (p-value = 0.0003). The ELF score is a reproducible, quantitative non-invasive liver prognostic test that evaluates liver fibrosis and correlates to liver-related outcomes.
- On the secondary endpoint of fibrosis improvement of  $\geq 1$  stage (for which the trial was not statistically powered) 21% (p-value=0.39) and 23% (p-value=0.36) of patients in the 1 mg and 3 mg cohorts, respectively, achieved fibrosis improvement versus 15% in the placebo cohort.
- Aldafermin was generally well tolerated with no treatment-related serious adverse events and a safety and tolerability profile generally consistent with prior trials of aldafermin, including higher levels of gastrointestinal events in patients treated with aldafermin as compared to patients treated with placebo.

“On behalf of the entire NGM Bio team, I’d like to thank the ALPINE 4 investigators and clinical trial staff, our employees who contributed to this effort and, most importantly, the patients who participated in the study,” said Hsiao D. Lieu, M.D., Chief Medical Officer at NGM Bio. “We are encouraged that we continue to see evidence of the potential therapeutic activity of aldafermin, including on the ELF biomarker that has been correlated to patient outcomes, and we look forward to having conversations with potential partners to determine further development of the program.”

#### **First Quarter 2023 Financial Results**

- NGM Bio reported a net loss of \$47.6 million for the quarter ended March 31, 2023, compared to a net loss of \$32.5 million for the same period in 2022.
- Related party revenue from our collaboration with Merck Sharp & Dohme LLC, or Merck, was \$2.2 million for the quarter ended March 31, 2023, compared to \$20.9 million for the same period in 2022. Our related party revenue from Merck decreased substantially after March 2022 and is expected to continue to decrease in 2023.
- R&D expenses were \$40.9 million for the quarter ended March 31, 2023, compared to \$42.8 million for the same period in 2022.
- General and administrative expenses were \$11.6 million for the quarter ended March 31, 2023, compared to \$10.7 million for the same period in 2022.
- Cash, cash equivalents and short-term marketable securities were \$231.0 million as of March 31, 2023, compared to \$271.5 million as of December 31, 2022. NGM Bio expects its cash, cash equivalents and marketable securities will be sufficient to fund its planned operations into the second quarter of 2025. NGM Bio has based this estimate on plans and assumptions that may prove to be insufficient or inaccurate (for example, with respect to anticipated costs, timing or success of certain activities), and the company could utilize its available financial resources sooner than it currently expects.

#### **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](http://www.ngmbio.com) for more information.

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

<sup>1</sup> A 0.3 mg aldafermin cohort was part of the original design of the trial and enrolled 7 patients prior to being discontinued in favor of enrolling more patients in the 1 mg and 3 mg arms of the trial. Patients in the 0.3 mg arm were primarily evaluated for safety.

### **Abbreviations (in Alphabetical Order)**

F4=Stage 4 Liver Fibrosis; 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,” “could,” “expect,” “expected,” “potential,” “promising,” “aspires,” “aims,” “look forward 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: 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 business development arrangements (“BD Arrangements”) to determine further development of aldafermin, and research and development and discovery engine output; NGM Bio’s expectation of continued decreasing revenue from Merck; the costs, timing and financial impact of the restructuring; NGM Bio extending its expected cash runway and the timing thereof; 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 expected cash runway, including the risk that NGM Bio could utilize its available capital resources sooner than it currently expects and its need for additional capital; macroeconomic conditions (such as the impacts of the ongoing COVID-19 pandemic and the conflict between Russia and Ukraine, global economic slowdown, increased inflation, rising interest rates and recent and potential future bank failures); 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 Annual Report on Form 10-K for the year ended December 31, 2022 filed with the United States Securities and Exchange Commission (“SEC”) on February 28, 2023 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 March 31,	
	2023	2022
Related party revenue	\$ 2,247	\$ 20,948
Operating expenses:		
Research and development	40,857	42,806
General and administrative	11,584	10,723
Total operating expenses	52,441	53,529
Loss from operations	(50,194)	(32,581)
Interest income, net	2,584	176
Other expense, net	(37)	(45)
Net loss	\$ (47,647)	\$ (32,450)
Net loss per share, basic and diluted	\$ (0.58)	\$ (0.42)
Weighted average shares used to compute net loss per share, basic and diluted	82,008	78,023

**NGM BIOPHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(In thousands, except per share amounts)  
(Unaudited)

	March 31, 2023	December 31, 2022*
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 67,549	\$ 73,456
Short-term marketable securities	163,455	198,036
Related party receivable from collaboration	1,257	7,580
Prepaid expenses and other current assets	8,769	9,787
Restricted cash	1,499	—
Total current assets	242,529	288,859
Property and equipment, net	7,966	8,496
Operating lease right-of-use asset	1,586	2,096
Restricted cash	2,455	3,954
Other non-current assets	4,301	3,997
Total assets	<u>\$ 258,837</u>	<u>\$ 307,402</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 13,293	\$ 8,453
Accrued liabilities	20,161	33,638
Operating lease liability, current	4,073	5,385
Contract liabilities	376	366
Total current liabilities	37,903	47,842
Total liabilities	<u>37,903</u>	<u>47,842</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value	—	—
Common stock, \$0.001 par value	82	82
Additional paid-in capital	850,229	841,413
Accumulated other comprehensive loss	(97)	(302)
Accumulated deficit	(629,280)	(581,633)
Total stockholders' equity	<u>220,934</u>	<u>259,560</u>
Total liabilities and stockholders' equity	<u>\$ 258,837</u>	<u>\$ 307,402</u>

\* Derived from the audited consolidated financial statements.