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 24, 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, 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 8.01 Other Events.

On May 24, 2021, NGM Biopharmaceuticals, Inc. issued a press release announcing topline results from the 24-week Phase 2b ALPINE 2/3 study evaluating aldafermin in 171 patients with biopsy-confirmed non-alcoholic steatohepatitis with stage 2 or 3 liver fibrosis. A copy of the press release titled "NGM Bio Reports Topline Results from 24-Week Phase 2b ALPINE 2/3 Study of Aldafermin in NASH" is filed as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Press release, dated May 24, 2021, titled "NGM Bio Reports Topline Results from 24-Week Phase 2b ALPINE 2/3 Study of Aldafermin in NASH."
104	Cover Page Interactive Data File (formatted in Inline XBRL)

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: May 24, 2021

By: /s/ David J. Woodhouse
David J. Woodhouse, Ph.D.
Chief Executive Officer and Director

Exhibit 99.1

NGM Bio Reports Topline Results from 24-Week Phase 2b ALPINE 2/3 Study of Aldafermin in NASH

- Study did not meet primary endpoint of fibrosis improvement by ≥1 stage with no worsening of NASH versus placebo
- Statistical significance achieved versus placebo on certain secondary endpoints, including NASH resolution (at the 3 mg dose) and multiple non-invasive measures of NASH, including liver fat content reduction by MRI-PDFF, ALT, AST and Pro-C3 (at the 1 mg and 3 mg doses)
- Aldafermin was generally well tolerated with an overall safety profile similar to placebo
- NGM plans not to pursue Phase 3 clinical development of aldafermin in F2/F3 NASH; will focus on its growing ophthalmology and oncology portfolio
- Company to host conference call and webcast today at 8:30 a.m. ET (5:30 a.m. PT)

SOUTH SAN FRANCISCO, Calif., May 24, 2021 (GLOBE NEWSWIRE) — NGM Biopharmaceuticals, Inc. (NGM) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today reported results from the 24-week Phase 2b ALPINE 2/3 study evaluating aldafermin in 171 patients with biopsy-confirmed non-alcoholic steatohepatitis (NASH) with stage 2 or 3 liver fibrosis (F2/F3). The trial was an equally randomized, double-blind, placebo-controlled study that assessed the efficacy, safety and tolerability of 0.3 mg, 1 mg and 3 mg doses of aldafermin once-daily subcutaneous injections compared to placebo. The study did not meet its primary endpoint evaluating a dose response showing improvement in liver fibrosis by ≥1 stage with no worsening of NASH at week 24 (p=0.55), analyzed using a dose response-driven statistical analysis plan (Multiple Comparison Procedure Modeling, or MCP-Mod). The study did achieve statistical significance versus placebo on certain secondary endpoints, including NASH resolution (at the 3 mg dose) and multiple non-invasive measures of NASH, including liver fat content reduction by MRI-PDFF, ALT, AST and Pro-C3 (at the 1 mg and 3 mg doses).

“These results are certainly disappointing, particularly given the dire unmet need in this patient population. The lack of significant fibrosis improvement was unexpected given the consistency of histology findings previously seen with aldafermin in our adaptive four-cohort Phase 2 study,” said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM. “However, in line with the data from that study, ALPINE 2/3 achieved statistical significance on multiple non-invasive measures of NASH at the two higher doses. That said, given the failure to meet the primary endpoint, we have decided to shift resources that had previously been reserved for a Phase 3 F2/F3 NASH development program toward advancing our other programs.”

Dr. Woodhouse further commented, “NGM is a markedly different company than when we initiated ALPINE 2/3 in May 2019, when our clinical-stage pipeline consisted primarily of liver and metabolic programs. Over the past two years, we have steadily expanded that pipeline with programs generated from our productive in-house discovery engine, and today we are also an ophthalmology and oncology company with four Phase 2 programs underway. We look forward to advancing our clinical programs and moving additional programs into the clinic, supported by our cash balance that was in excess of $400 million at the end of the first quarter.”

NGM's disclosed pipeline includes: NGM621, an anti-complement C3 antibody, currently in Phase 2 development for the treatment of geographic atrophy; NGM120, a GFRAL antagonistic antibody in Phase 2 development for the treatment of metastatic pancreatic cancer and cancer-related cachexia; and NGM707 and NGM438, anti-ILT2/ILT4 and LAIR1 myeloid checkpoint candidates, respectively, both of which are anticipated to begin Phase 1 studies for the treatment of advanced solid tumors this year. Additionally, Merck continues to progress a global Phase 2b study of MK-3655, an FGFR1c/KLB agonistic antibody for the treatment of NASH, which was discovered by NGM under its collaboration with Merck.

ALPINE 2/3 Topline Findings – Secondary Analyses of Key Histology Measures

Summary of ALPINE 2/3 Histology Data (pairwise) ±

	Placebo (n=36)	Aldafermin 0.3 mg (n=36)	Aldafermin 1 mg (n=34)	Aldafermin 3 mg (n=37)
Fibrosis Improvement ³1 Stage with No Worsening of NASH[1]	19%	31%	15%	30%
NASH Resolution with No Worsening of Fibrosis[2]	6%	11%	18%	22%*
Fibrosis Improvement and NASH Resolution[3]	3%	11%	9%	14%

* $p \leq 0.05$

± Analyzed using a pre-specified, pairwise statistical analysis plan; per protocol includes only those patients who completed both baseline and week 24 biopsies (n=143)

1 Defined as patients who have an improvement in liver fibrosis by ³1 stage with no worsening of NASH (no worsening of steatosis, lobular inflammation or hepatocyte ballooning grade) from baseline to W24.

2 Defined as patients having a NAS score of 0 or 1 for inflammation and 0 for ballooning, with no worsening of fibrosis (no progression of NASH CRN fibrosis stage) from baseline to W24; NAS refers to the non-alcoholic fatty liver disease (NAFLD) activity score, which is comprised of three components: steatosis, lobular inflammation and hepatocellular ballooning.

3 Defined as patients who have an improvement in liver fibrosis by ³1 stage AND have a NAS score of 0 or 1 for inflammation and 0 for ballooning and no worsening of steatosis at W24.

"We want to thank our clinical development team, all of the clinical trial investigators, clinical site staff and, most importantly, the patients who participated in ALPINE 2/3. Clearly, NASH continues to be an area of high unmet need, while proving to be a difficult area for clinical development," said Hsiao D. Lieu, M.D., Chief Medical Officer at NGM. "We are obviously disappointed by the outcome on fibrosis improvement in ALPINE 2/3. We plan to continue enrollment in our ongoing 48-week Phase 2b ALPINE 4 study to understand the profile of aldafermin in patients with F4 NASH and compensated cirrhosis, which is a disease with a particularly acute unmet need."

ALPINE 2/3 Topline Non-Invasive Biomarker Findings

Summary of ALPINE 2/3 Non-Invasive Biomarker Data±

Relative Change from Baseline in Patients':	Placebo (n=43)	Aldafermin 0.3 mg (n=43)	Aldafermin 1 mg (n=42)	Aldafermin 3 mg (n=43)
Liver Fat Content (LFC) by MRI-PDFF	-15%	-25%	-38%***	-59%***
Alanine Aminotransferase (ALT)	-8%	-25%	-40%***	-51%***
Aspartate Aminotransferase (AST)	-6%	-18%	-30%**	-39%***
Pro-C3	+4%	-7%*	-9%*	-26%***

* $p \leq 0.05$; ** $p \leq 0.01$; *** $p \leq 0.001$

± Analyzed using a pre-specified pairwise statistical analysis plan; intent-to-treat (ITT) population (n=171)

ALPINE 2/3 Safety and Tolerability Findings

In the 24-week study (n=171), the overall safety profile of aldafermin was consistent with prior studies and similar to that of placebo. Patients treated with aldafermin at all three doses studied in the trial demonstrated a comparable frequency of adverse events versus placebo:

- any treatment-emergent adverse events (TEAEs) for placebo, 0.3 mg, 1 mg and 3 mg aldafermin were 84%, 70%, 83% and 88%, respectively;
- serious adverse events (SAEs) for placebo, 0.3 mg, 1 mg and 3 mg aldafermin were 7%, 2%, 10% and 2%, respectively. None of the reported SAEs were deemed related to treatment by the site investigator;
- drug-related TEAEs leading to discontinuation for placebo, 0.3 mg, 1 mg and 3 mg aldafermin were 5%, 2%, 2% and 2%, respectively; and
- there was one fatal adverse event in the 1 mg aldafermin arm, which occurred 30 days after the last confirmed aldafermin dose and was determined unrelated to treatment by the site investigator.

As expected, given aldafermin's mechanism of action as a potent inhibitor of the classical bile acid synthesis pathway, a mean LDL-cholesterol increase was observed, which was fully mitigated by concomitant statin use.

Conference Call / Webcast Details

NGM will host a conference call and webcast with slide presentation at 8:30 a.m. ET (5:30 a.m. PT) today. The live conference call details are as follows: domestic (844) 873-0551; international (602) 563-8472; and Passcode: 9393531. To access the live webcast and slides, please visit the "Investors & Media" section of NGM's website at https://ir.ngmbio.com/. The webcast will be archived for 30 days. Archived conference call details are as follows: domestic (855) 859-2056; international (404) 537-3406; and Passcode: 9393531. The archived conference call will be available for 30 days.

Design of Phase 2b ALPINE 2/3 Study

ALPINE 2/3 was a multi-center, double-blind, randomized, placebo-controlled Phase 2b study that evaluated the efficacy, safety and tolerability of 0.3 mg, 1 mg and 3 mg once-daily subcutaneous injections of aldafermin over 24 weeks of treatment. The study enrolled 171 patients with biopsy-confirmed NASH with F2-F3 liver fibrosis who were randomized 1:1:1:1 to receive aldafermin 0.3 mg (n=43), aldafermin 1 mg (n=42), aldafermin 3 mg (n=43) or placebo (n=43). The primary objective of the

study was to evaluate a dose-response showing fibrosis improvement ≥1 stage with no worsening of NASH at week 24. Secondary endpoints included NASH resolution, fibrosis improvement and NASH resolution, and relative changes in LFC, ALT, AST and biomarkers of fibrosis at week 24. Patients were also evaluated at week 30 following six weeks off treatment for safety and non-invasive measures.

The primary endpoint, improvement in liver fibrosis ³1 stage and no worsening of steatohepatitis at week 24, was evaluated using the MCP-Mod (Multiple Comparison Procedure-Modeling) approach to assess the dose response relationship in the ITT population. All remaining analyses of the primary endpoint and of all secondary endpoints were evaluated using a pre-specified pairwise approach and used the Cochran-Mantel-Haenszel test. Continuous efficacy endpoints were analyzed using analysis of covariance. Per protocol, patient liver biopsies were performed at baseline screening and after 24 weeks of treatment (n=143) and were read using the NASH CRN criteria by one central, independent hepatopathologist who was blinded to patient and treatment assignment.

Design of Ongoing Phase 2b ALPINE 4 Study

ALPINE 4 is a multi-center, double-blind, randomized, placebo-controlled Phase 2b study evaluating the efficacy, safety and tolerability of 0.3 mg, 1 mg and 3 mg once-daily subcutaneous injections of aldafermin over 48 weeks of treatment. The study is designed to enroll 160 patients with biopsy-confirmed NASH with F4 liver fibrosis and compensated cirrhosis. The primary endpoint is to evaluate a dose-response showing fibrosis improvement >1 stage with no worsening of NASH at week 48. Secondary endpoints include relative changes in ALT, AST, biomarkers of fibrosis and Liver Stiffness Measure at week 48. Patients will also be evaluated at week 54 following six weeks off treatment for safety and non-invasive measures.

About Aldafermin

Aldafermin is an engineered analog of the human hormone FGF19 that is dosed once daily as a subcutaneous injection. NGM has evaluated this wholly-owned therapeutic in over 650 healthy volunteers and patients across multiple liver and metabolic diseases, including more than 375 patients with NASH.

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 liver and metabolic diseases, ocular diseases and cancer. 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 six active clinical-stage 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 “plans,” “will,” “toward,” “look forward,” “continuing,” “anticipated,” “designed to,” “potential,” “aspire,” “continue,” 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 advancing its other ongoing clinical programs and moving additional programs into the clinic; the therapeutic potential of NGM621, NGM120, NGM707, NGM438 and MK-3655, and of aldafermin in F4 NASH patients; the anticipated initiation this year of Phase 1 studies for NGM707 and NGM438 for the treatment of advanced solid tumors; the continuation by Merck of the Phase 2b study of MK-3655; NGM’s plan to continue enrollment in its Phase 2b ALPINE 4 study of aldafermin and the design of the ALPINE 4 study; NGM’s aspiration to operate one of the most productive R&D engines in the biopharmaceutical industry and to deliver first-in-class medicines to patients; 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 biopharmaceutical product development process and the uncertainty of clinical success, including risks related to failure or delays in successfully initiating, enrolling or completing clinical studies; the risks that results obtained in clinical trials to date may not be inductive of results obtained in ongoing or future trials, including the risk that NGM’s ALPINE 4 study of aldafermin, or Merck’s ongoing or future clinical studies of MK-3655, may show that aldafermin and/or MK-3655 are not tolerable and effective treatments for patients with NASH, particularly in light of the failure to achieve the primary endpoint in the ALPINE 2/3 study of aldafermin, and the risk that NGM’s other product candidates may also not be tolerable and effective treatments in their planned indications; the risks that Merck may elect not to extend the research phase of NGM’s collaboration with Merck, and may otherwise be unable to reach agreement with Merck on the terms of a modified collaboration and, regardless of whether NGM and Merck reach agreement on the terms of a modified collaboration, Merck will not provide research funding for certain of NGM’s product candidates, and NGM’s collaboration with Merck otherwise involves numerous other risks, any of which could materially and adversely affect NGM’s business and financial condition; 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 clinical trials; the time-consuming and uncertain regulatory approval process; NGM’s reliance on third-party manufacturers for its product candidates; the sufficiency of NGM’s cash resources and 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 March 31, 2021 filed with the United States Securities and Exchange Commission (SEC) on May 6, 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.

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