# NGM Bio Provides Business Update and Reports First Quarter 2020 Financial Results

May 13, 2020

*-- Initiated Phase 2b ALPINE 4 clinical study of aldafermin (formerly NGM282) in non-alcoholic steatohepatitis (NASH) patients with compensated cirrhosis (F4 fibrosis) --*

*-- Continuing enrollment in Phase 2b ALPINE 2/3 clinical study of aldafermin in NASH patients with F2-F3 fibrosis; topline data readout still targeted for first half of 2021 --*

*-- Sustaining progress across broad pipeline, which includes six clinical-stage products targeting cardio-metabolic and liver disease, ophthalmic disease and cancer --*

*-- Maintained strong balance sheet, with $328.5 million in cash, cash equivalents and marketable securities as of March 31, 2020 --*

SOUTH SAN FRANCISCO, Calif., May 13, 2020 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM) (Nasdaq: NGM), a biotechnology company focused on developing transformative therapeutics for patients, today provided a business update and reported financial results for the period ending March 31, 2020.

“In the first quarter of 2020, we demonstrated strong execution across our broad pipeline in multiple therapeutic areas. As we continue to navigate the ever-evolving COVID-19 situation, we have been fortunate to continue to move forward with our programs, most notably with the initiation of our Phase 2b ALPINE 4 study of aldafermin in patients with compensated cirrhosis due to NASH, a very sick patient population for which there is no currently available treatment other than liver transplant,” said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM. “As previously announced, in the first quarter of 2020, we also initiated a Phase 1a/1b clinical study for NGM120 as a potential treatment for cancer and cancer anorexia/cachexia syndrome, or CACS, and a Phase 1 clinical study for NGM395 as a potential treatment for metabolic disease, bringing us to a total of six product candidates now in clinical development. As we advance our clinical programs during these uncertain and unsettling times, the safety and well-being of patients, healthcare workers and our employees remain our top priority. We are closely monitoring the impact of COVID-19 on our organization and business operations and, like others in our industry, are managing multiple challenges to mitigate disruptions in our ongoing and planned trials in order to remain on track with our development timelines. The high unmet medical needs targeted by each of our development programs provide strong motivation for us to remain focused on execution across our pipeline.”

Throughout the unfolding COVID-19 situation, NGM has worked proactively to establish policies that are designed to enable the company to operate safely, efficiently and productively, preserving mission-critical functions necessary to advance key research and development activities while safeguarding the well-being of patients, study investigators, clinical research staff and NGM employees. For patients already enrolled in NGM clinical trials, the company is working closely with investigators and site staff to continue treatment in compliance with study protocols and to uphold trial integrity, while observing government and institutional guidelines. NGM is continuing to evaluate site initiations and patient enrollment on a case-by-case and patient-by-patient basis in close coordination with investigators and site staff. Some sites, both within and outside of the United States, continue to screen patients for studies, and new patients are being enrolled when appropriate. These internal and external efforts have allowed NGM to continue progress across its clinical development programs. While NGM has experienced a slower pace of site initiation and trial enrollment than originally anticipated in certain of its clinical studies, the impact of the COVID-19 pandemic, to date, has not resulted in a significant impact to the company’s development timelines.

“At this time, we remain on track with all previously provided clinical trial timing guidance and will continue to monitor screening, enrollment and site initiations across our pipeline to understand any potential future impact on timing,” said Dr. Woodhouse. “I admire and am extremely grateful for the dedication and agility of our team, the ongoing commitment of study investigators and clinical study site staff, and the broader ecosystem that is enabling important research and development work to continue at NGM and across our industry.”

**Key First Quarter and Recent Highlights**

*Cardio-metabolic and liver disease*

- **Initiated Phase 2b ALPINE 4 study of aldafermin in compensated NASH cirrhosis (F4)**. In March 2020, NGM dosed the first patient in the dose-ranging ALPINE 4 study to evaluate the safety and efficacy of aldafermin versus placebo in patients with biopsy-confirmed NASH cirrhosis. The primary efficacy objective is to evaluate the treatment effect on histology, defined as fibrosis regression of at least one stage without worsening of NASH. This global, multi-center study is expected to enroll approximately 150 patients who will be dosed with 0.3 mg, 1 mg, 3 mg of aldafermin or placebo for 48 weeks. Aldafermin is wholly-owned by NGM.

  “We are pleased to have initiated our Phase 2b ALPINE 4 clinical study and thrilled we have achieved this significant milestone, marking our first study in F4 NASH patients with well-compensated cirrhosis,” said Hsiao D. Lieu, M.D., Chief Medical Officer at NGM. “We anticipate that the COVID-19 pandemic will impact activation of additional trial sites, and we plan to work closely with our target sites to navigate their processes and needs in an effort to mitigate delays. Reversing

fibrosis and bringing advanced stage NASH patients back from the brink of liver transplant could have a profound, potentially life-saving impact. Based on the rapid, robust anti-fibrotic treatment effect we have seen with aldafermin to date in F2 and F3 NASH patients, we are encouraged by the potential to see activity in a patient population facing a particularly critical need for effective therapeutic solutions."

- **Continued enrollment in Phase 2b study of aldafermin in NASH patients with Stage 2 or 3 (F2-F3) fibrosis.** NGM has continued to enroll patients in the Phase 2b ALPINE 2/3 clinical study in patients with biopsy-confirmed NASH and F2-F3 liver fibrosis. The 24-week study is designed to enroll approximately 150 patients and will assess the efficacy, safety and tolerability of 0.3 mg, 1 mg and 3 mg doses of aldafermin compared to placebo. Despite a lower-than-anticipated pace of enrollment as a result of COVID-19, NGM expects to announce topline data from the study in the first half of 2021, as previously guided. However, the extended impact of COVID-19 on our timeline is difficult to predict.

- **Announced positive preliminary topline liver histology and biomarker data from 24-week Phase 2 study of aldafermin 1 mg in patients with NASH (Cohort 4).** In February 2020, NGM announced positive preliminary topline results from a 24-week double-blind, randomized, placebo-controlled Phase 2 clinical study (Cohort 4) of aldafermin in NASH patients with F2-F3 fibrosis. Cohort 4 was the final reported cohort from NGM's adaptive Phase 2 clinical study of aldafermin in NASH. Cohort 4 was powered to demonstrate the effect of 1 mg aldafermin treatment versus placebo on the primary endpoint of change in absolute liver fat content, which achieved statistical significance. In addition, the study assessed secondary and exploratory endpoints of liver histology and biomarkers of disease activity. The histology results revealed that treatment with aldafermin led to clinically meaningful improvements at 24 weeks versus placebo in fibrosis improvement of ≥1 stage with no worsening of NASH (38% of aldafermin-treated patients vs. 18% placebo) and in resolution of NASH with no worsening of liver fibrosis (24% of aldafermin-treated patients vs. 9% placebo). The study also demonstrated a statistically significant impact on the composite endpoint of both fibrosis improvement and resolution of NASH (22% in aldafermin-treated patients vs. 0% placebo). In the study, aldafermin continued to demonstrate a favorable tolerability profile.

- **Initiated Phase 1 study of NGM395 in overweight and obese healthy adults.** As announced in March 2020, NGM initiated a Phase 1 single ascending dose clinical study evaluating the safety, tolerability and pharmacokinetics of NGM395, a long-acting growth differentiation factor 15 (GDF15) analog, in overweight and obese but otherwise healthy adults. NGM395 is wholly-owned by NGM.

*Ophthalmic disease*

- **Completed enrollment in Phase 1 study of NGM621 for the potential treatment of geographic atrophy (GA), an advanced dry form of age-related macular degeneration (AMD).** The Phase 1 clinical study is designed to evaluate the safety, tolerability and pharmacokinetics of up to two intravitreal doses of NGM621 in patients with GA. NGM621 is an inhibitory antibody binding complement C3, a key node of all three complement pathways. NGM plans to present the Phase 1 results at a future scientific congress and to initiate a Phase 2 study in the second half of this year.

*Cancer*

- **Initiated Phase 1a/1b study of NGM120 for the potential treatment of CACS and cancer.** As announced in February 2020, NGM initiated a Phase 1a/1b clinical study to evaluate NGM120, a first-in-class antagonistic antibody that binds glial cell-derived neurotrophic factor receptor alpha-like, or GFRAL, and inhibits GDF15 signaling, for the potential treatment of CACS and cancer. CACS is the uncontrolled wasting of both skeletal muscle and fat that is a common co-morbidity of cancer and is associated with shortened survival in cancer patients.

**Merck Collaboration**

Merck has a one-time option to license NGM pipeline programs, other than aldafermin and NGM395, following human proof-of-concept trials, under the terms of the companies' ongoing strategic collaboration. Upon exercising any such options, Merck would lead global product development and commercialization for the resulting products, if approved. Prior to Merck initiating a Phase 3 study for a licensed program, NGM may elect to either receive milestone and royalty payments or, in certain cases, to co-fund development and participate in a global cost and revenue share arrangement of up to 50%. The agreement also provides NGM with the option to participate in the co-promotion of any co-funded program in the United States.

**First Quarter Financial Results**

- For the quarter ended March 31, 2020, NGM reported a net loss of $19.1 million compared to a net loss of $8.3 million for the corresponding period in 2019.

- Related party revenue from our collaboration with Merck for the quarter ended March 31, 2020 was $24.4 million compared to $25.6 million for the corresponding period in 2019.

- Research and development expenses for the quarter ended March 31, 2020 were $38.4 million compared to $29.5 million for the corresponding period in 2019. The increase in research and development expenses was primarily attributable to increases in external research and development expenses associated with the advancement of NGM's growing pipeline, including aldafermin program expenses for Phase 2b clinical trials, and personnel-related expenses driven by increased headcount.

- General and administrative expenses for the quarter ended March 31, 2020 were $6.6 million compared to $5.4 million for the corresponding period in 2019. The increase in general and administrative expenses was primarily attributable to increases in personnel-related expenses driven by increased headcount, insurance expenses, consulting expenses and other professional service expenses required to support NGM's operations as a public company.

- Cash, cash equivalents and short-term marketable securities were $328.5 million as of March 31, 2020, compared to $344.5 million as of December 31, 2019.

**About NGM Biopharmaceuticals, Inc.**

NGM is a biopharmaceutical company focused on developing novel therapeutics based on scientific understanding of key biological pathways underlying cardio-metabolic, liver, oncologic and ophthalmic 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, with multiple programs in clinical development. 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 "continue," "move forward," "advance," "anticipates," "expect," "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 advancement of NGM's clinical and preclinical pipeline; the impact of the COVID-19 pandemic on clinical trial plans and timelines, including enrollment, activation and initiation of additional trial sites and results of NGM's clinical trials; the continued progress of, and the timing of enrollment and results of, NGM's clinical trials, including timing of preliminary results of the ALPINE 2/3 study, the presentation of results of the Phase 1 study of NGM621 for the potential treatment of geographic atrophy and the initiation of the related Phase 2 study; the safety, tolerability and efficacy of NGM's product candidates; and continued development of additional product candidates, including NGM621 in patients with GA, NGM120 in patients with CACS and cancer and NGM395. 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 those discussed in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our annual report on Form 10-K for the year ended December 31, 2019 and future filings and reports that NGM makes from time to time with the United States Securities and Exchange Commission. 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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**NGM BIOPHARMACEUTICALS, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
*(In thousands, except share and per share amounts)*
*(Unaudited)*

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019[1]** |
| Related party revenue | $ 24,364 | $ 25,552 |
| Operating expenses: | | |
| Research and development | 38,439 | 29,527 |
| General and administrative | 6,595 | 5,367 |
| Total operating expenses | 45,034 | 34,894 |
| Loss from operations | (20,670) | (9,342) |
| Interest income | 1,175 | 1,110 |
| Other income (expense), net | 380 | (36) |
| Net loss | $ (19,115) | $ (8,268) |
| Net loss per share, basic and diluted | $ (0.28) | $ (1.21) |

| | | |
|---|---|---|
| Weighted average shares used to compute net loss per share, basic and diluted | 67,396,229 | 6,812,129 |

(1) In April 2019, the Company completed its initial public offering (IPO) and concurrent private placement with Merck Sharp & Dohme Corp., in which the Company issued an aggregate of 7,521,394 and 4,121,683 shares of common stock, respectively. All of the then outstanding shares of convertible preferred stock were automatically converted into shares of common stock upon the closing of the IPO.

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

| | March 31, 2020 | December 31, 2019* |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 256,952 | $ 245,598 |
| Short-term marketable securities | 71,517 | 98,913 |
| Related party receivable from collaboration | 742 | 5,206 |
| Prepaid expenses and other current assets | 9,096 | 5,531 |
| Total current assets | 338,307 | 355,248 |
| Property and equipment, net | 18,274 | 19,475 |
| Restricted cash | 1,874 | 1,874 |
| Other non-current assets | 2,246 | 3,806 |
| Total assets | $ 360,701 | $ 380,403 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,648 | $ 9,026 |
| Accrued liabilities | 21,949 | 22,991 |
| Deferred rent, current | 2,865 | 2,829 |
| Deferred revenue, current | — | 4,872 |
| Total current liabilities | 28,462 | 39,718 |
| Deferred rent, non-current | 8,667 | 9,392 |
| Other non-current liabilities | 4,188 | — |
| Early exercise stock option liability | 412 | 574 |
| Total liabilities | 41,729 | 49,684 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value; | — | — |
| Common stock, $0.001 par value; | 68 | 67 |
| Additional paid-in capital | 534,218 | 526,771 |
| Accumulated other comprehensive gain (loss) | (55) | 25 |
| Accumulated deficit | (215,259) | (196,144) |
| Total stockholders' equity | 318,972 | 330,719 |
| Total liabilities and stockholders' equity | $ 360,701 | $ 380,403 |

*The Condensed Consolidated Balance Sheet as of December 31, 2019 has been derived from the audited financial statements as of that date.