NGM Bio Outlines 2021 Strategic Priorities Across Its Three Therapeutic Area Portfolios, Including Liver and Metabolic Diseases, Retinal Diseases and Oncology

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- NGM advances its vision to build the next iconic biologics company, fueled by its in-house discovery engine
- Significant progress made across all three therapeutic area portfolios in 2020
- Phase 2b or Phase 3-enabling studies currently underway for three product candidates
- Recently completed upsized underwritten public offering of common stock, which included the full exercise by the underwriters of their option to purchase additional shares, resulting in gross proceeds of approximately $143.7 million
- Key 2021 milestones include:
  • Planned initiation of Phase 1 studies for recently disclosed oncology candidates NGM707 and NGM438 expected in mid-2021 and fourth quarter 2021, respectively
  • Topline data readout for Phase 2b ALPINE 2/3 study of aldafermin in patients with NASH expected in second quarter 2021
  • Topline data readout for the dose-finding portion of the Phase 1a/1b study of NGM120 for the treatment of cancer anorexia/cachexia syndrome and cancer expected in the second half of 2021

SOUTH SAN FRANCISCO, Calif., Jan. 12, 2021 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today outlined its key achievements in 2020 and its strategic priorities for 2021.

“2020 was a year of significant progress and growth for NGM across our pipeline, now comprising three therapeutic area portfolios – liver and metabolic diseases, retinal diseases and oncology. We have clinical programs underway across all of these therapeutic areas, including three programs in Phase 2b or Phase 3-enabling studies. We are also pleased to be heading into 2021 with approximately $425 million in cash, cash equivalents and short-term marketable securities, inclusive of the proceeds of our recent equity offering, to fuel our growing pipeline,” said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM.

Dr. Woodhouse further commented, “Our vision is to build the next iconic biologics company, ultimately self-sustaining with multiple products on the market and a diverse pipeline of development candidates, all fueled by our in-house discovery engine and talented team. In 2021 we expect to make meaningful progress toward realizing that vision. We anticipate reporting topline data from our Phase 2b ALPINE 2/3 study of aldafermin in NASH patients in the second quarter and continue to aggressively plan for Phase 3 development. We also anticipate moving our two recently announced oncology clinical candidates, NGM707 and NGM438, into the clinic this year. Our inspiration to make progress and advance our pipeline are the many patients waiting for effective treatments.”

2020 Highlights

NGM’s key achievements and milestones across its pipeline in 2020 included:

Liver and metabolic diseases

- Reported positive liver histology and biomarker data from a Phase 2 24-week study (Cohort 4) of aldafermin in patients with non-alcoholic steatohepatitis (NASH) in February 2020.
- Initiated a Phase 2b study of aldafermin in patients with NASH with F4 liver fibrosis (ALPINE 4) in February 2020.
- Completed enrollment in the Phase 2b study of aldafermin in patients with NASH with stage 2 (F2) or F3 liver fibrosis (ALPINE 2/3) in September 2020.
- Our partner, Merck, initiated a global Phase 2b study of MK-3655 in patients with NASH with F2/F3 fibrosis in the fourth quarter of 2020.

Retinal diseases

- Initiated the Phase 2 CATALINA study of NGM621 for the treatment of geographic atrophy (GA) in July 2020.
- Presented Phase 1 safety and pharmacokinetics data for NGM621 in patients with GA at the American Academy of Ophthalmology in November 2020.

Cancer

- Completed enrollment in dose-finding Phase 1a/1b studies of NGM120 for the treatment of cancer anorexia/cachexia syndrome (CACS) and cancer in November 2020.

- In the fourth quarter of 2020, announced two new oncology clinical candidates, NGM707 and NGM438, which are designed to broaden and deepen anti-tumor immune responses for patients with advanced solid tumors by reversing key myeloid and stromal resistance mechanisms.

2021 Strategic Priorities and Anticipated Milestones

NGM has several strategic priorities for 2021 intended to further the company's discovery engine and growing portfolio of programs. NGM's strategic priorities and anticipated key milestones in 2021 include:

Liver and metabolic diseases

- Report topline data from Phase 2b ALPINE 2/3 study of aldafermin in patients with NASH with F2/F3 liver fibrosis in the second quarter of 2021.
- Continue advancement of Phase 2b ALPINE 4 study of aldafermin in patients with NASH with F4 liver fibrosis.
- Continue planning for aldafermin Phase 3 development program.

Retinal diseases

- Continue advancement of the Phase 2 CATALINA study of NGM621 in patients with GA.

Oncology

- Report data from ongoing dose-finding Phase 1a/1b study of NGM120 in CACS and cancer patients in the second half of 2021.
- Initiate Phase 1b, placebo-controlled, expansion study of NGM120 in patients with metastatic pancreatic cancer, assessing both cancer and CACS endpoints, in the first quarter of 2021.
- Initiate Phase 1 studies of NGM707 and NGM438 in mid-2021 and the fourth quarter of 2021, respectively.

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, retinal diseases and oncology. 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.

About the NGM-Merck Collaboration

Merck has a one-time option to license certain NGM pipeline programs – not including aldafermin, NGM395 and NGM386 – following human proof-of-concept trials under the terms of the companies' ongoing strategic collaboration. Upon exercising any such option, 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 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.
In November 2018, Merck exercised its first option under the collaboration to license MK-3655, previously referred to as NGM313.

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 "build," "plans," expects," "anticipates," "designed to," "continue," "potential" 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 productivity of NGM's research and advancement of NGM's clinical and preclinical pipeline, including its vision to build the next iconic biologics company with multiple approved products; the continued progress of, and the timing of enrollment and results of, NGM's clinical trials, including timing of the initiation of Phase 1 studies for NGM707 and NGM438, topline data readout for the Phase 2b ALPINE 2/3 study, topline data readout for the Phase 1a/1b study of NGM120; and the design, timing, enrollment, safety, tolerability and efficacy of, and continued development of, NGM's product candidates, including aldafermin (NGM282), MK-3655 (NGM313), NGM621, NGM120, NGM707, NGM438 and any of our future product candidates. 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 pharmaceutical product development process and the uncertainty of clinical success, including risks related to failure or delays in successfully enrolling or completing clinical studies, the risk that the results obtained to date in NGM's clinical trials may not be indicative of results obtained in subsequent pivotal or other late-stage trials, and the risk that NGM's ongoing or future clinical studies in humans may show that aldafermin is not a tolerable and effective treatment for NASH patients; the ongoing COVID-19 pandemic, which has adversely affected, and could materially and adversely affect in the future, our business and operations; the time-consuming and uncertain regulatory approval process; NGM's reliance on third-party manufacturers for aldafermin and its other product candidates; the sufficiency of NGM's cash, cash equivalents and short-term marketable securities and need for additional capital; and other risks and uncertainties affecting NGM and its development programs, as well as those discussed in the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" in our quarterly report on Form 10-Q for the quarter ended September 30, 2020, the section titled "Risk Factors" in exhibit 99.1 to our current report on Form 8-K filed with the United States Securities and Exchange Commission (SEC) on January 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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