NGM Bio Provides Business Highlights and Reports Second Quarter 2020 Financial Results

August 12, 2020

--Sustained progress across clinical development programs spanning liver, retinal and metabolic diseases and cancer--

--Aldafermin continues to advance toward late-stage clinical development in non-alcoholic steatohepatitis (NASH) with ongoing Phase 2b ALPINE 2/3 and ALPINE 4 clinical studies--

--Initiated Phase 2 CATALINA study of NGM621, a complement C3 inhibitory antibody to treat patients with geographic atrophy (GA)--

--$312.1 million in cash, cash equivalents and marketable securities as of June 30, 2020--

SOUTH SAN FRANCISCO, Calif., Aug. 12, 2020 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM) (Nasdaq: NGM), a biotechnology company focused on discovering and developing transformative therapeutics for patients, today provided business highlights and reported financial results for the period ending June 30, 2020.

"We continue to progress across our clinical-stage programs spanning liver, retinal and metabolic diseases as well as cancer, despite the ongoing challenges presented by the COVID-19 pandemic, thanks to the dedication and tireless efforts of our team, and the ongoing support and commitment from our clinical collaborators," said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM. "We're thrilled to have achieved our most recent clinical milestone, the advancement of NGM621 into Phase 2 development for the treatment of patients with GA. GA is a highly prevalent and progressive retinal degenerative disease that can have a devastating, irreversible impact on patients' vision and quality of life. Based on NGM621's novel profile as a complement C3 inhibitory monoclonal antibody, we believe it has the potential to be an important treatment option for this significantly underserved patient population. It is gratifying to now have two programs in Phase 2 clinical development in two distinct therapeutic areas, both for the treatment of serious unmet needs."

Dr. Woodhouse further commented, "Within the diverse NASH development landscape, we are pleased with the impressive and highly consistent clinical performance of aldafermin to date, with robust, placebo-controlled data demonstrating statistically significant dual activity in reversing fibrosis and resolving NASH. Our Phase 2b ALPINE 2/3 and ALPINE 4 clinical studies remain on track, and we are hard at work on Phase 3 readiness in anticipation of an ALPINE 2/3 topline data readout in the first half of next year."

Key Second Quarter and Recent Highlights

Liver and metabolic disease

- **Continued enrollment in Phase 2b ALPINE 2/3 study of aldafermin in NASH.** NGM has continued enrollment in the Phase 2b ALPINE 2/3 clinical study of aldafermin in patients with biopsy-confirmed NASH and stage 2 or 3 (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. Enrollment activities have increased since our first quarter update, and we reiterate our expectation of announcing topline data from the study in the first half of 2021.

- **Continued enrollment in Phase 2b ALPINE 4 study of aldafermin in NASH patients with compensated cirrhosis**. NGM has continued enrollment in the Phase 2b ALPINE 4 study of aldafermin in patients with biopsy-confirmed compensated NASH cirrhosis (F4). The 48-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.

- **Data from 24-week double-blind, randomized, placebo-controlled Phase 2 study (Cohort 4) of aldafermin in NASH patients published in *Gastroenterology*.** Comprehensive findings and analysis from the 24-week Cohort 4 reported by NGM in February 2020 were published this month in the journal *Gastroenterology*. The 24-week double-blind, randomized, placebo-controlled Phase 2 clinical study demonstrated statistically significant dual activity in reversing fibrosis and resolving NASH. In the study, aldafermin continued to demonstrate a favorable tolerability profile. Cohort 4 was the final reported cohort from NGM's adaptive Phase 2 clinical study of aldafermin in NASH, and the results observed in Cohort 4 were consistent with data from the three previous cohorts.

- **Continued enrollment in Phase 1 study of NGM395 in overweight and obese healthy adults.** NGM has continued to enroll patients in 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.

- **Completed Phase 1 study of NGM217 in adults with autoimmune diabetes.** We recently completed a Phase 1 study of

NGM217, an antibody binding an undisclosed target, which assessed the safety, tolerability and pharmacokinetics of NGM217 in adults with autoimmune diabetes. The study demonstrated that NGM217 was well tolerated. However, as NGM continues to advance multiple clinical-stage programs and anticipates advancing earlier-stage discovery programs into clinical development, the company has decided to suspend activities related to NGM217 to concentrate its resources on the development of other product candidates.

Retinal disease

- **Initiated Phase 2 CATALINA study of NGM621 in patients with GA.** As announced in July 2020, NGM initiated the Phase 2 CATALINA study, a multicenter, randomized, double-masked, sham-controlled clinical trial to evaluate the safety and efficacy of intravitreal injections (IVT) of NGM621 in patients with GA secondary to age-related macular degeneration (AMD). Dysregulated activation of the complement system, a key component of the immune system, has been implicated in the onset and progression of GA. NGM621 is a humanized IgG1 monoclonal antibody engineered to potently inhibit activity of complement C3 with the treatment goal of reducing disease progression in patients with GA, and with the potential for extended every eight week dosing without PEGylation. Designed as a Phase 3-enabling study, the Phase 2 CATALINA study is expected to enroll 240 patients diagnosed with GA in one or both eyes.

  NGM also successfully completed a first-in-human open-label Phase 1 study in which treatment with single- and multiple-dose IVT injections of NGM621 in patients with GA was well tolerated, supporting advancement to the Phase 2 CATALINA study. NGM plans to present the data from the Phase 1 study at the American Academy of Ophthalmology (AAO) 2020 Virtual Annual Meeting from November 13-15, 2020. In addition, NGM presented NGM621 preclinical findings at The Association for Research in Vision and Ophthalmology Annual Meeting, held virtually in June 2020. The presentations are available on NGM's website.

Cancer

- **Continued enrollment in Phase 1a/1b study of NGM120 in patients with cancer anorexia/cachexia syndrome (CACS) and cancer.** NGM continues to enroll patients in 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 (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.

Corporate

- **Expanded leadership with key management team and board appointments.** NGM announced the appointment of a new executive team member, Siobhan Nolan Mangini, as Chief Financial Officer effective July 13, 2020 and announced the appointment of Carole Ho, M.D. to its Board of Directors. Dr. Ho currently serves as Chief Medical Officer and Head of Development at Denali Therapeutics.

Merck Collaboration

Merck has a one-time option to license NGM pipeline programs, other than NGM's wholly-owned programs aldafermin and NGM395, 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, 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. In January 2019, Merck exercised its first option under the collaboration to license NGM313, also referred to as MK-3655.

Second Quarter Financial Results

- For the quarter ended June 30, 2020, NGM reported a net loss of $25.6 million compared to a net loss of $7.7 million for the corresponding period in 2019.

- Related party revenue from our collaboration with Merck for the quarter ended June 30, 2020 was $19.8 million compared to $25.3 million for the corresponding period in 2019. The decrease in related party revenue was primarily attributable to the completion of all remaining obligations associated with the upfront payment at the conclusion of the initial five-year term of the Merck collaboration.

- Research and development expenses for the quarter ended June 30, 2020 were $38.5 million compared to $28.8 million for the corresponding period in 2019. The increase in research and development expenses was mainly attributable to increases in external research and development expenses associated with the advancement of NGM's growing pipeline, primarily expenses related to our aldafermin, NGM621 and NGM395 programs, and personnel-related expenses driven by increased headcount.

- General and administrative expenses for the quarter ended June 30, 2020 were $6.8 million compared to $6.2 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 and legal expenses to support our operations as a public company.

- Cash, cash equivalents and short-term marketable securities were $312.1 million as of June 30, 2020, compared to $344.5 million as of December 31, 2019.

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, retinal and metabolic 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, 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 “progress,” “advance,” “believe,” “potential,” “continue,” “expect,” “anticipates,” “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 ongoing 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 topline results of the ALPINE 2/3 study and the presentation of data from the Phase 1 study of NGM621 in patients with GA; the potential of NGM621 to be an important treatment option for patients with GA; NGM’s ability to advance aldafermin toward Phase 3 clinical development for NASH patients; the safety, tolerability and efficacy of NGM’s product candidates; and continued development of additional product candidates, including NGM621, NGM395 and NGM120. 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 “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our quarterly report on Form 10-Q for the quarter ended March 31, 2020 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Related party revenue	$ 19,755	$ 25,341	$ 44,119	$ 50,893
Operating expenses:				
Research and development	38,494	28,819	76,933	58,346
General and administrative	6,794	6,229	13,389	11,596
Total operating expenses	45,288	35,048	90,322	69,942
Loss from operations	(25,533)	(9,707)	(46,203)	(19,049)
Interest income	388	2,044	1,563	3,154
Other expense, net	(471)	(6)	(91)	(42)
Net loss	$ (25,616)	$ (7,669)	$ (44,731)	$ (15,937)
Net loss per share, basic and diluted	$ (0.38)	$ (0.13)	$ (0.66)	$ (0.47)
Weighted average shares used to compute net loss per share, basic and diluted	68,305,056	61,044,450	67,850,640	34,078,099 (1)

(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, and 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)

	June 30, 2020	December 31, 2019*
Assets		
Current assets:		
Cash and cash equivalents	$ 249,317	$ 245,598
Short-term marketable securities	62,778	98,913
Related party receivable from collaboration	3,079	5,206
Prepaid expenses and other current assets	7,448	5,531
Total current assets	322,622	355,248
Property and equipment, net	17,321	19,475
Restricted cash	1,874	1,874
Other non-current assets	5,467	3,806
Total assets	$ 347,284	$ 380,403
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,934	$ 9,026
Accrued liabilities	26,792	22,991
Deferred rent, current	2,902	2,829
Deferred revenue, current	2,074	4,872
Total current liabilities	33,702	39,718
Deferred rent, non-current	7,941	9,392
Other non-current liabilities	4,188	—
Early exercise stock option liability	289	574
Total liabilities	46,120	49,684
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value;	—	—
Common stock, $0.001 par value;	69	67
Additional paid-in capital	541,833	526,771
Accumulated other comprehensive gain	137	25
Accumulated deficit	(240,875)	(196,144)
Total stockholders' equity	301,164	330,719
Total liabilities and stockholders' equity	$ 347,284	$ 380,403

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