NGM Bio Provides Business Highlights and Reports Second Quarter 2021 Financial Results

August 5, 2021

- Completed enrollment in 320-patient Phase 2 CATALINA study of NGM621, an anti-complement C3 antibody, for the treatment of geographic atrophy; topline data expected in second half of 2022
- Initiated a Phase 1/2 clinical trial of NGM707, an ILT2/ILT4 dual antagonist antibody, in patients with advanced solid tumors
- Amended collaboration with Merck to focus primarily on advancing novel medicines for retinal and cardiovascular and metabolic diseases; NGM gained worldwide rights to its disclosed oncology portfolio as well as additional assets falling outside of the amended collaboration's narrower scope
- $390.6 million in cash, cash equivalents and marketable securities as of June 30, 2021

SOUTH SAN FRANCISCO, Calif., Aug. 05, 2021 (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, 2021.

"With six disclosed pipeline programs, five of which are in the clinic, and additional undisclosed preclinical and research programs, we continue to make meaningful progress towards achieving our mission to translate complex powerful biology with urgency and rigor to deliver life-changing medicines for patients," said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM Bio. "In our sizable oncology portfolio alone, we continue to advance multiple programs that we believe have the potential to benefit patients with a variety of solid tumors. We were pleased to dose our first patient with NGM707 in a Phase 1/2 study this quarter and look forward to presenting interim results from our Phase 1a/1b dose-finding study of NGM120 at ESMO later this quarter."

"We also continued to make important strides in ophthalmology, with the recent completion of enrollment in our Phase 2 CATALINA study exactly one year after initiation. Our strong balance sheet positions us well to continue progressing our ambitious clinical and research efforts."

Key Second Quarter and Recent Highlights

Retinal diseases

- **Completed enrollment in the Phase 2 CATALINA study of NGM621 in patients with geographic atrophy.** NGM completed enrollment in the Phase 2 CATALINA study, a multi-center, randomized, double-masked, sham-controlled clinical trial to evaluate the safety and efficacy of intravitreal, or IVT, injections of NGM621 every four weeks or every eight weeks in 320 patients with geographic atrophy in one or both eyes secondary to age-related macular degeneration. The primary efficacy endpoint is the rate of change in geographic atrophy lesion area, as measured by fundus autofluorescence, or FAF, imaging, over 52 weeks of treatment. NGM anticipates reporting topline data from the CATALINA study in the second half of 2022. Upon completion of a proof-of-concept study in humans, Merck has a one-time option to license NGM621 and its related molecules as well as the additional one-time option to license NGM621 and its related molecules together with all other ophthalmology compounds included within the scope of our ongoing collaboration with Merck.

Cancer

- **Continued enrollment in a Phase 2 placebo-controlled component of the ongoing Phase 1/2 PINNACLES study testing NGM120 as a first-line treatment in combination with gemcitabine and Abraxane® (paclitaxel protein bound) in patients with metastatic pancreatic cancer.** In March 2021, NGM initiated a multi-center, randomized, single-blind (sponsor unblinded), placebo-controlled component of NGM120 in combination with gemcitabine and Abraxane as a first line treatment in patients with metastatic pancreatic cancer as part of the ongoing Phase 1/2 trial. This Phase 2 component of the Phase 1/2 study is designed to enroll approximately 60 patients and will assess the efficacy, safety and tolerability of NGM120 or placebo in combination with gemcitabine and Abraxane against both cancer and cancer-related cachexia endpoints. The Phase 1a/1b dose-finding portion of the study is still ongoing, and NGM expects to report interim results from that portion of the study at the European Society for Medical Oncology in the third quarter of 2021.
- **Initiated the Phase 1 portion of a Phase 1/2 Study of NGM707 for the treatment of advanced solid tumors.** The Phase 1 portion (n≅60) of the study includes a monotherapy dose escalation arm (Part 1a) and a dose-finding arm in combination with KEYTRUDA® (pembrolizumab) (Part 1b). The Phase 2 portion (n≅120) of the study will employ a basket design that will include expansion cohorts of patients treated with NGM707 monotherapy (Part 2a) or NGM707 in combination with KEYTRUDA (Part 2b).

Liver and metabolic diseases

- **Reported topline data from the Phase 2b ALPINE 2/3 study of aldafermin in patients with NASH and liver fibrosis stage 2 or 3, or F2 or F3, in May 2021.** The 24-week study assessed the efficacy, safety and tolerability of 0.3 mg, 1 mg and 3 mg doses of aldafermin compared to placebo. The primary objective of the ALPINE 2/3 study was to evaluate a dose response on liver fibrosis improvement by ≥ 1 stage with no worsening of steatohepatitis at week 24. The study did not meet its primary endpoint evaluating a dose response at 24 weeks on liver fibrosis improvement by >1 stage with no worsening of NASH (p=0.55), analyzed using a dose response-driven statistical analysis plan (Multiple Comparison Procedure Modeling, or MCP-Mod). The study achieved 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). Aldafermin was generally well tolerated with an overall safety profile similar to placebo. As previously disclosed, NGM plans not to pursue Phase 3 clinical development of aldafermin in F2/F3 NASH.
- **Continued enrollment in Phase 2b ALPINE 4 study of aldafermin in patients with compensated NASH cirrhosis (liver fibrosis stage 4, or 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. The primary objective of the ALPINE 4 study is to evaluate a dose response at 48 weeks on liver fibrosis improvement by ≥ 1 stage with no worsening of steatohepatitis.
- **Merck continued enrollment in its Phase 2b study of MK-3655 in patients with NASH and F2 or F3 liver fibrosis.** In November 2020, Merck initiated a global Phase 2b multicenter study of MK-3655 for the treatment of patients with F2 or F3 NASH. The 52-week randomized, double-blind study is designed to enroll approximately 320 patients and will assess the efficacy, safety and tolerability of 50 mg, 100 mg and 300 mg once monthly doses of MK-3655 compared to placebo. The primary objective of the Phase 2b study is NASH resolution without worsening of fibrosis after 52 weeks. Merck licensed MK-3655 following NGM's completion of a proof-of-concept study. NGM retains an option, at the initiation of the first Phase 3 clinical trial for MK-3655, to either receive milestone and royalty payments or to co-fund development and participate in a global cost and revenue sharing arrangement of up to 50% for MK-3655.

Corporate

- **Announced appointment of Roger M. Perlmutter to Board of Directors.** On June 8, 2021, NGM announced that the stockholders of the company elected Roger M. Perlmutter, M.D., Ph.D. to the company's board of directors. Dr. Perlmutter brings decades of expertise and renowned leadership in drug discovery and development with global healthcare companies including Merck and Amgen. Dr. Perlmutter is currently Chairman, President and Chief Executive Officer at Eikon Therapeutics, Inc.
- **Amended collaboration with Merck.** In June 2021, NGM and Merck announced that they will continue their research, discovery and development collaboration with a narrower scope, focused primarily on retinal and cardiovascular and metabolic (CVM) targets of interest to Merck. Merck will continue to advance MK-3655, which is currently in a global Phase 2b clinical trial in patients with F2 or F3 NASH. Merck retains its option to license NGM621 and its related molecules, which is currently in the NGM-led Phase 2 CATALINA clinical study in patients with geographic atrophy. Merck will provide approximately $120 million in research and development, or R&D, funding to NGM through March 2024, plus additional potential license option payments. NGM gained worldwide rights to its disclosed oncology portfolio, including NGM120, NGM707 and NGM438, as well as all undisclosed preclinical and research assets falling outside of the amended collaboration's narrower scope.

Second Quarter 2021 Financial Results

- NGM reported a net loss of $36.7 million for the quarter ended June 30, 2021, compared to a net loss of $25.6 million for the same period in 2020.
- Related party revenue from our collaboration with Merck was $16.8 million for the quarter ended June 30, 2021, compared to $19.8 million for the same period in 2020. Related party revenue decreased $3.0 million in the quarter ended June 30, 2021 as compared to the prior year due to the derecognition of a $4.6 million contract asset that was associated with our previous collaboration agreement with Merck.
- R&D expenses were $43.6 million for the quarter ended June 30, 2021, compared to $38.5 million for the same period in 2020. R&D expenses increased $5.1 million in the quarter as compared to the prior year, primarily due to increases in external expenses driven by our ongoing clinical studies of NGM621 and NGM120 and preclinical studies of NGM438, and increases in personnel-related and internal and unallocated R&D expenses. These increases were partially offset by decreases in expenses for our manufacturing activities and our clinical trials of aldafermin and in external expenses related to our other development programs.
- General and administrative expenses were $9.8 million for the quarter ended June 30, 2021, compared to $6.8 million for the same period in 2020. The $3.0 million increase in general and administrative expenses in 2021 was primarily

attributable to increases in personnel-related expenses driven by increased headcount, as well as external expenses to support our operations.

- Cash, cash equivalents and short-term marketable securities were $390.6 million as of June 30, 2021, compared to $295.2 million as of December 31, 2020.

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 retinal diseases, cancer, and liver and metabolic 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. All of our therapeutics have been generated by our in-house discovery engine; today, we have six disclosed 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 “focused,” “towards,” “anticipates,” “believe,” “look forward to,” “will,” “designed to,” “potential,” “aspire,” “continue,” “expects,” “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 NGM’s mission to translate complex powerful biology with urgency and rigor to deliver life-changing medicines for patients; NGM’s belief that it is advancing multiple programs that have the potential to benefit patients with a variety of solid tumors; the design of NGM’s and Merck’s clinical trials of NGM’s product candidates; the availability and anticipated timing of topline data from Phase 2 CATALINA study of NGM621 in patients with geographic atrophy; the availability and anticipated timing of the interim results from the Phase 1a/1b dose-finding portion of the Phase 1/2 PINNACLES study testing NGM120; NGM plans not to pursue Phase 3 clinical development of aldafermin in F2/F3 NASH; anticipated activities under NGM’s amended collaboration with Merck and the amount of development funding under, and potential option payments to NGM under, the amended collaboration; the potential receipt of milestone and royalty payments by NGM under the amended collaboration with Merck; the therapeutic potential of NGM’s product candidates; 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, reporting data from or completing clinical studies, as well as the risks that results obtained in clinical trials to date may not be indicative of results obtained in ongoing or future trials and that NGM’s product candidates may otherwise not be tolerable and effective treatments in their planned indications; NGM’s ability to maintain its amended collaboration with Merck, including the risk that if Merck were to breach or terminate the amended collaboration or Merck’s development funding obligations, NGM would not obtain all of the anticipated financial and other benefits of the amended collaboration, and the development and/or commercialization of NGM’s product candidates within the scope of the amended collaboration could be delayed, perhaps substantially; 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 aldafermin and its other product candidates; the sufficiency of NGM’s cash resources, including to fund programs that fall outside of the amended collaboration’s narrower scope, and NGM’s 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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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,	
	2021	2020	2021	2020
Related party revenue	$ 16,773	$ 19,755	$ 38,348	$ 44,119
Operating expenses:				
Research and development	43,570	38,494	84,269	76,933
General and administrative	9,823	6,794	18,544	13,389
Total operating expenses	53,393	45,288	102,813	90,322
Loss from operations	(36,620)	(25,533)	(64,465)	(46,203)
Interest income, net	115	388	229	1,563
Other expense, net	(187)	(471)	—	(91)
Net loss	$ (36,692)	$ (25,616)	$ (64,236)	$ (44,731)

Net loss per share, basic and diluted	$ (0.48)	$ (0.38)	$ (0.84)	$ (0.66)
Weighted average shares used to compute net loss per share, basic and diluted	77,096,416	68,305,056	76,568,217	67,850,640

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

	June 30, 2021	December 31, 2020*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 99,403	$ 147,017
Short-term marketable securities	291,147	148,139
Related party receivable from collaboration	3,586	333
Related party contract asset	—	6,100
Prepaid expenses and other current assets	8,993	6,837
Total current assets	403,129	308,426
Property and equipment, net	12,790	14,526
Restricted cash	1,499	1,499
Other non-current assets	5,593	4,592
Total assets	$ 423,011	$ 329,043
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,141	$ 9,663
Accrued liabilities	31,891	29,945
Deferred rent, current	3,048	2,975
Contract liabilities	4,963	—
Total current liabilities	45,043	42,583
Deferred rent, non-current	4,893	6,417
Total liabilities	49,936	49,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value;	—	—
Common stock, $0.001 par value;	77	71
Additional paid-in capital	735,860	578,599
Accumulated other comprehensive income	5	4
Accumulated deficit	(362,867)	(298,631)
Total stockholders' equity	373,075	280,043
Total liabilities and stockholders' equity	$ 423,011	$ 329,043

* Derived from the audited consolidated financial statements.