NGM Bio Provides Business Highlights and Reports Third Quarter 2022 Financial Results

November 3, 2022

--Announced that the CATALINA Phase 2 trial of NGM621 in patients with geographic atrophy secondary to age-related macular degeneration did not meet primary endpoint of statistically significant rate of change in GA lesion area using slope analysis over 52 weeks for NGM621 versus sham--

--Presented updated preliminary findings from Phase 1a and Phase 1b cohorts evaluating NGM120 for the treatment of cancer at the ESMO Annual Congress and at the AACR Special Conference: Pancreatic Cancer--

--Updated cash runway guidance with $300.2 million in cash, cash equivalents and marketable securities as of September 30, 2022, expected to be sufficient to fund operations into the fourth quarter of 2024--

SOUTH SAN FRANCISCO, Calif., Nov. 03, 2022 (GLOBE NEWSWIRE) -- NGM Biopharmaceuticals, Inc. (NGM Bio) (Nasdaq: NGM), a clinical-stage biotechnology company focused on discovering and developing transformative therapeutics for patients, today provided business highlights and reported financial results for the quarterly period ended September 30, 2022.

“We are disappointed that the CATALINA trial did not meet its primary endpoint and we continue to evaluate the study results to gain a better understanding of that outcome,” said David J. Woodhouse, Ph.D., Chief Executive Officer at NGM Bio. “We remain committed to advancing our portfolio of clinical-stage oncology programs in a capital efficient manner to generate proof-of-concept data and look forward to sharing initial clinical data from the Phase 1a NGM707 trial in the fourth quarter of this year.”

Key Third Quarter and Recent Highlights

Oncology

- Presented updated preliminary findings from Phase 1a and Phase 1b cohorts evaluating NGM120, an antagonist antibody that binds GFRAL and inhibits GDF15 signaling, for the treatment of cancer at the ESMO Annual Congress and at the AACR Special Conference: Pancreatic Cancer.
- Initiated a Phase 1b cohort of the ongoing Phase 1/1b trial evaluating NGM120 in combination with one or more lines of hormone therapies in patients with metastatic castration-resistant prostate cancer (mCRPC.)
- Initiated a Phase 1b cohort of the Phase 1/1b trial evaluating NGM831, an ILT3 antagonist antibody product candidate, in combination with KEYTRUDA® (pembrolizumab) for the treatment of patients with advanced solid tumors.
- Continued enrollment in the Phase 1b cohort of the Phase 1/2 trial evaluating NGM707, an ILT2/ILT4 antagonist antibody product candidate, in combination with KEYTRUDA® (pembrolizumab) for the treatment of patients with advanced solid tumors.
- Continued enrollment in the Phase 1a cohort of the Phase 1/1b trial evaluating NGM438, a LAIR1 antagonist antibody product candidate, for the treatment of patients with advanced solid tumors.

Retinal Disease

- Announced that the Phase 2 CATALINA trial evaluating NGM621, a monoclonal antibody product candidate engineered to potently inhibit complement C3 for patients with geographic atrophy, in patients with geographic atrophy (GA) secondary to age-related macular degeneration did not meet its primary endpoint of statistically significant rate of change in GA lesion area using slope analysis over 52 weeks for NGM621 versus sham.

Liver and Metabolic Diseases

- Merck, known as MSD outside of the United States and Canada, continued to progress enrollment in a global Phase 2b trial of MK-3655 for the treatment of non-cirrhotic (F2/F3) NASH. MK-3655 is an agonistic antibody product candidate binding to fibroblast growth factor receptor 1c-beta-klotho that Merck licensed from NGM Bio.
- Remained on track for topline data readout of ALPINE 4, the Phase 2b trial of aldafermin, an engineered FGF19 analog product candidate, in patients with compensated NASH cirrhosis (F4 NASH) in the first half of 2023.

Third Quarter 2022 Financial Results

- NGM Bio reported a net loss of $47.3 million for the quarter ended September 30, 2022, compared to a net loss of $28.9 million for the same period in 2021.

- Related party revenue from our collaboration with Merck Sharp & Dohme LLC, or Merck, was $7.9 million for the quarter ended September 30, 2022, compared to $18.6 million for the same period in 2021. In 2021, we entered into an amended and restated research collaboration, product development and license agreement with Merck, or the Amended Collaboration Agreement. Under the narrowed scope of the Amended Collaboration Agreement, our related party revenue from Merck has decreased substantially and is expected to continue to remain at a significantly lower level through March 31, 2024.
- R&D expenses were $46.1 million for the quarter ended September 30, 2022, compared to $38.7 million for the same period in 2021. R&D expenses increased $7.4 million in the third quarter as compared to the same period in 2021, primarily due to costs related to our ongoing clinical trials of NGM707, NGM438, NGM831 and NGM120, our completed Phase 2 trial of NGM621, and personnel-related expenses, partially offset by decreased expenses for our manufacturing activities and our clinical trials of aldafermin.
- General and administrative expenses were $10.1 million for the quarter ended September 30, 2022, compared to $8.9 million for the same period in 2021.
- Cash, cash equivalents and short-term marketable securities were $300.2 million as of September 30, 2022, compared to $366.3 million as of December 31, 2021. NGM Bio expects its cash, cash equivalents and marketable securities will be sufficient to fund its planned operations into the fourth quarter of 2024.

About NGM Biopharmaceuticals, Inc.

NGM Bio is focused on discovering and developing novel, potentially life-changing medicines for people whose health and lives have been disrupted by disease. The company's biology-centric drug discovery approach aims to seamlessly integrate interrogation of complex disease-associated biology and protein engineering expertise to unlock proprietary insights that are leveraged to generate promising product candidates and enable their rapid advancement into proof-of-concept studies. As explorers on the frontier of life-changing science, NGM Bio aspires to operate one of the most productive research and development engines in the biopharmaceutical industry. All therapeutic candidates in the NGM Bio pipeline have been generated by its in-house discovery engine, always led by biology and motivated by unmet patient need. Today, the company has seven programs in clinical development, including four in Phase 2 or 2b studies, including the recently completed NGM621 CATALINA trial, across three therapeutic areas: cancer, retinal diseases and liver and metabolic diseases. Visit us at www.ngmbio.com for more information.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

Abbreviations (in Alphabetical Order)

F2/F3/F4=stage 2 or 3 or 4 liver fibrosis; GDF15=Growth Differentiation Factor 15; GFRAL=Glial Cell-derived Neurotrophic Factor Receptor Alpha-like; ILT2=Immunoglobin-Like Transcript 2; ILT3=Immunoglobin-Like Transcript 3; ILT4=Immunoglobin-Like Transcript 4; LAIR1=Leukocyte-Associated Immunoglobulin-Like Receptor 1; mCRPC=Mestastic Castration-Resistant Prostate Cancer; NASH=non-alcoholic steatohepatitis

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 "will," "may," "look forward," "expect," "engineered to," "potential," "promising," "plan," "aspires," "aims" 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 therapeutic potential of NGM Bio's product candidates; NGM Bio's continued pipeline development and research and development output; NGM Bio's expectation of providing updates and meeting multiple milestones, including the availability and anticipated timing of clinical data readouts from the Phase 1 trial of NGM707 in the fourth quarter of 2022 and NGM438 and NGM831 programs in 2023; and other statements that are not historical fact. Because such statements deal with future events and are based on NGM Bio's current expectations, they are subject to various risks and uncertainties, and actual results, performance or achievements of NGM Bio 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 the risk that NGM621 may be unable to demonstrate future clinical benefit in patients with GA, particularly in light of the failure to achieve the primary endpoint in the Phase 2 CATALINA trial; 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 preclinical or clinical trials to date may not be indicative of results obtained in future trials and that post-hoc analyses performed after unmasking trial results can result in the introduction of bias, have other limitations and may not be predictive of results obtained in future trials; NGM Bio's reliance on its amended collaboration with Merck, including the risks that if Merck fails to exercise its option to license NGM621, NGM Bio would need to partner the NGM621 program in order to further clinical development of NGM621, if any, which NGM Bio may be unable to do in a timely manner or at all, which could delay or preclude the further development of and/or commercialization of NGM621; the ongoing COVID-19 pandemic, which has adversely affected, and could materially and adversely affect in the future, NGM Bio's business and operations, including NGM Bio's ability to timely supply, initiate, enroll and complete its ongoing and future clinical trials; the time-consuming and uncertain regulatory approval process; NGM Bio's reliance on third-party manufacturers for its product candidates and the risks inherent in manufacturing and testing pharmaceutical products; the sufficiency of NGM Bio's cash resources and NGM Bio's need for additional capital; and other risks and uncertainties affecting NGM Bio and its development programs, including those discussed in the section titled "Risk Factors" in NGM Bio's quarterly report on Form 10-Q for the quarter ended June 30, 2022 filed with the United States Securities and Exchange Commission (SEC) on August 4, 2022 and future filings and reports that NGM Bio makes from time to time with the SEC. Except as required by law, NGM Bio 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.

Investor Contact:
Brian Schoelkopf
ir@ngmbio.com

Media Contact:
media@ngmbio.com

NGM BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Related party revenue	$ 7,911	$ 18,575	$ 37,152	$ 56,923
Operating expenses:				
Research and development	46,106	38,714	134,345	122,983
General and administrative	10,109	8,867	30,759	27,411
Total operating expenses	56,215	47,581	165,104	150,394
Loss from operations	(48,304)	(29,006)	(127,952)	(93,471)
Interest income, net	965	106	1,684	335
Other income, net	78	35	38	35
Net loss	$ (47,261)	$ (28,865)	$ (126,230)	$ (93,101)
Net loss per share, basic and diluted	$ (0.59)	$ (0.37)	$ (1.59)	$ (1.21)
Weighted average shares used to compute net loss per share, basic and diluted	80,623	77,409	79,331	76,852

NGM BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share amounts)
(Unaudited)

	September 30, 2022	December 31, 2021*
ASSETS		
Current assets:		
Cash and cash equivalents	$ 101,449	$ 151,795
Short-term marketable securities	198,701	214,458
Related party receivable from collaboration	4,380	4,945
Prepaid expenses and other current assets	11,170	8,082
Total current assets	315,700	379,280
Property and equipment, net	8,320	10,071
Operating lease right-of-use asset	2,596	4,045
Restricted cash	3,954	1,499
Other non-current assets	5,296	7,492
Total assets	$ 335,866	$ 402,387
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,565	$ 5,246
Accrued liabilities	32,757	33,258
Operating lease liability, current	5,307	5,077
Contract liabilities	6,967	17,774
Total current liabilities	48,596	61,355
Operating lease liability, non-current	1,381	5,385
Total liabilities	49,977	66,740
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value	—	—
Common stock, $0.001 par value	82	78
Additional paid-in capital	831,918	754,664
Accumulated other comprehensive loss	(915)	(129)
Accumulated deficit	(545,196)	(418,966)
Total stockholders' equity	285,889	335,647
Total liabilities and stockholders' equity	$ 335,866	$ 402,387

* Derived from the audited consolidated financial statements.