Neumora Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

March 7, 2024 12:00 PM EST

On-track to report topline Phase 3 data from the KOASTAL-1 study with navacaprant in MDD in the second half of 2024 and Phase 1 data with NMRA-266 in healthy adult participants mid-2024

Strong financial position with $463.8 million in cash, cash equivalents and marketable securities expected to support operations into 2026

WATERTOWN, Mass., March 07, 2024 (GLOBE NEWSWIRE) -- **Neumora Therapeutics, Inc.** (Nasdaq: NMRA), a clinical-stage biopharmaceutical company redefining neuroscience drug development, today announced financial results for the fourth quarter and full year ended December 31, 2023 and provided a business update.

"2023 was a watershed year for Neumora as we transitioned to a publicly traded company, advanced our KOR antagonist, navacaprant, into three Phase 3 registrational studies, and brought our M4 PAM, NMRA-266, into the clinic ahead of schedule," said Henry Gosebruch, chief executive officer, Neumora. "We have an exciting year ahead as we look forward to a data-rich 2024 including anticipated readouts from two clinically validated programs – our Phase 3 navacaprant program in major depressive disorder and Phase 1 data from our NMRA-266 program – and the initiation of several key clinical studies. Additionally, we continue to build on our leadership position in brain disorders with an industry-leading pipeline of seven clinical and preclinical programs all targeting novel mechanisms of action. We believe we are well on our way to redefine treatment options for people suffering from debilitating brain diseases."

KEY PIPELINE HIGHLIGHTS

Neumora is advancing a therapeutic pipeline of seven clinical and preclinical neuroscience programs that target novel mechanisms of action for a broad range of underserved neuropsychiatric disorders and neurodegenerative diseases.

Navacaprant (NMRA-140): Phase 3 KOASTAL Program On-Track with Major Depressive Disorder (MDD) Data Expected in 2024
Navacaprant (NMRA-140) is a highly selective, novel, once-daily kappa opioid receptor (KOR) antagonist being developed as a potential monotherapy treatment for MDD and other neuropsychiatric disorders. The KOR antagonist approach has been clinically validated in three independent studies.

Neumora is currently enrolling the registrational Phase 3 KOASTAL program, which is designed to evaluate the efficacy and safety of navacaprant monotherapy for the treatment of MDD. KOASTAL-1, KOASTAL-2, and KOASTAL-3 are replicate Phase 3, randomized, placebo-controlled, double-blind studies in adult patients with MDD.

- In February 2024 following a Type D meeting, the U.S. Food and Drug Administration (FDA) provided written feedback that there is no need for the Company to conduct further studies to assess physical dependence with navacaprant.
    - Navacaprant did not demonstrate properties associated with risks of opioid-related abuse in several mode of action profiling studies. Data from these studies were presented at the Annual Meeting of the Society of Biological Psychiatry and College on Problems of Drug Dependence Annual Meeting in 2023.
- Neumora expects to report topline data from the KOASTAL-1 study in the second half of 2024, and topline data from the KOASTAL-2 and KOASTAL-3 studies in the first half of 2025.

Neumora also intends to evaluate the potential of navacaprant as treatment for other neuropsychiatric populations beyond MDD, including bipolar depression (BPD).

- The Company expects to initiate a Phase 2 clinical trial in BPD in the first half of 2024.

NMRA-266: Phase 1 Study Underway with Data in Healthy Adult Participants Expected mid-2024
NMRA-266 is a highly selective positive allosteric modulator (PAM) of the M4 muscarinic receptor that Neumora is developing as a treatment for schizophrenia and other neuropsychiatric disorders.

- Neumora expects to report data from a Phase 1 single ascending dose / multiple ascending dose study evaluating NMRA-266 in healthy adult participants in mid-2024.
- Additionally, Neumora expects to initiate a Phase 1b study in schizophrenia in the second half of 2024, with data from that study anticipated in 2025.

NMRA-511: Phase 1b Study in Alzheimer's Disease Agitation Planned

NMRA-511 is an antagonist of the vasopressin 1a receptor (V1aR), with high selectivity over V1b, V2 (greater than 3,000-fold) and oxytocin receptors (approximately 300-fold). Vasopressin plays a role in the regulation of aggression, affiliation, stress and anxiety response.

- Neumora expects to initiate a Phase 1b study in Alzheimer's disease agitation in the first half of 2024, with data from that study anticipated in 2025.

BUSINESS UPDATES

Announced Key Leadership Appointments

- In October 2023, Neumora announced that Robert Lenz, M.D., Ph.D., had joined Neumora as executive vice president, head of R&D. Dr. Lenz brings more than two decades of neuroscience drug development expertise, most recently serving as senior vice president and head of global development at Amgen.
- In December 2023, Neumora announced the appointment of Jason Duncan as Chief Legal Officer. Mr. Duncan brings more than two decades of legal, compliance, development and operations experience in the life sciences industry.
- In January 2024, Neumora announced the appointment of Kaya Pai Panandiker as Chief Commercial Officer. Ms. Pai Panandiker brings more than 20 years of experience commercializing medicines in areas of significant unmet need, including the commercial launches of blockbuster products, TRINTELLIX® (vortioxetine) and REXULTI® (brexpiprazole) for MDD and schizophrenia.

FOURTH QUARTER AND FULL YEAR FINANCIAL RESULTS

- **Cash Position:** As of December 31, 2023, Neumora had cash, cash equivalents and marketable securities of $463.8 million.
- **Financial Guidance:** The Company expects that its cash, cash equivalents and marketable securities as of December 31, 2023, will enable it to fund its operating plan into 2026.
- **R&D Expense:** Research and development expenses for the fourth quarter of 2023 were $38.9 million, as compared to $23.5 million for the same period in 2022. Research and development expenses for the full year ended December 31, 2023 were $142.7 million, compared to $91.7 million for the same period in 2022. This increase was primarily due to advancement of clinical and preclinical programs and related start-up activities for Phase 3 clinical trials evaluating navacaprant as a monotherapy treatment for MDD. Additionally, full year 2023 results include $63.9 million of primarily non-cash acquired in-process research and development costs (IPR&D) and full year 2022 results include $13.0 million of acquired IPR&D costs related to milestone payments from our collaborations.
- **G&A Expense:** General and administrative expenses for the fourth quarter of 2023 were $11.2 million, as compared to $7.2 million for the same period in 2022. General and administrative expenses for the full year ended December 31, 2023, were $45.5 million, as compared to $31.1 million for the same period in 2022. This increase was primarily due to personnel-related costs, including stock-based compensation and professional services to support the continued expansion of administrative functions.
- **Net Loss:** The Company reported a net loss of $108.7 million for the fourth quarter of 2023, as compared to $28.1 million for the same period in 2022. Neumora reported a net loss of $235.9 million for the full year ended December 31, 2023, as compared to $130.9 million for the same period in 2022.

About Neumora
Neumora Therapeutics, Inc. is a clinical-stage biopharmaceutical company founded to confront the global brain disease crisis by taking a fundamentally different approach to the way treatments for brain diseases are developed. Our therapeutic pipeline currently consists of seven clinical and preclinical neuroscience programs that target novel mechanisms of action for a broad range of underserved neuropsychiatric disorders and neurodegenerative diseases. Our work is supported by an integrated suite of translational, clinical, and computational tools to generate insights that can enable precision medicine approaches. Neumora’s mission is to redefine neuroscience drug development by bringing forward the next generation

of novel therapies that offer improved treatment outcomes and quality of life for patients suffering from brain diseases.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements about Neumora Therapeutics, Inc. (the "Company," "we," "us," or "our") within the meaning of the federal securities laws, including statements related to: Neumora's intention to redefine neuroscience drug development by bringing forward the next generation of novel therapies that offer improved treatment outcomes and quality of life for patients suffering from brain diseases; the timing, progress and plans for its therapeutic development programs, including the timing of initiation and data read outs for its programs and studies, as well as its clinical trial and development plans; timing and expectations related to regulatory filings and interactions; expectations and projections regarding future operating results and financial performance, including the sufficiency of its cash resources and expectation of the timing of its cash runway; its ability to create significant value and; other statements identified by words such as "could," "expects," "intends," "may," "plans," "potential," "should," "will," "would," or similar expressions and the negatives of those terms. Other than statements of historical facts, all statements contained in this press release, are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements are subject to risks and uncertainties that could cause the actual results or to be materially different from the information expressed or implied by these forward-looking statements, including, among others: the risks related to the inherent uncertainty of clinical drug development and unpredictability and lengthy process for obtaining regulatory approvals; risks related to the timely initiation and enrollment in our clinical trials; risks related to our reliance on third parties, including CROs; risks related to serious or undesirable side effects of our therapeutic candidates; risks related to our ability to utilize and protect our intellectual property rights; and other matters that could affect sufficiency of capital resources to fund operations. For a detailed discussion of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Neumora's business in general, please refer to the risk factors identified in the Company's filings with the Securities and Exchange Commission (SEC), including but not limited to its Registration Statement on Form S-1, as amended (File No. 333-274229), filed with the SEC on September 11, 2023, and related Prospectus dated September 14, 2023 filed under 424(b)(4) of the Securities Act of 1933, as amended. Forward-looking statements speak only as of the date hereof, and, except as required by law, Neumora undertakes no obligation to update or revise these forward-looking statements.

Financial Tables

NEUMORA THERAPEUTICS, INC.
Unaudited Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Three months ended December 31,		Year ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 38,864	$ 23,523	$ 142,719	$ 91,749
Acquired in-process research and development	63,904	—	63,904	13,000
General and administrative	11,236	7,195	45,475	31,121
Total operating expenses	114,004	30,718	252,098	135,870
Loss from operations	(114,004)	(30,718)	(252,098)	(135,870)
Other income (expense):				
Interest income	5,646	2,285	16,611	4,561
Other income (expense), net	(104)	287	(170)	405
Total other income	5,542	2,572	16,441	4,966
Net loss before income taxes	(108,462)	(28,146)	(235,657)	(130,904)
Provision for income taxes	268	—	268	—
Net loss	(108,730)	(28,146)	(235,925)	(130,904)
Other comprehensive income (loss):				
Unrealized gain (loss) on marketable securities	235	380	698	(774)
Comprehensive loss	$ (108,495)	$ (27,766)	$ (235,227)	$ (131,678)
Net loss per share, basic and diluted	$ (0.71)	$ (0.99)	$ (3.63)	$ (4.81)
Weighted-average shares outstanding, basic and diluted	152,832	28,293	65,021	27,207

Unaudited Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 463,827	$ 395,395
Total assets	496,195	426,234
Total liabilities	27,119	29,397
Total stockholders' equity (deficit)	469,076	(446,850)

Neumora Contact
Helen Rubinstein
+1 (315) 382-3979
Helen.Rubinstein@neumoratx.com