March 28, 2024

NRx Pharmaceuticals (NASDAQ:NRXP) Reports Preliminary Fourth Quarter and Full Year 2023 Financial Results and Provides Year End Highlights

Four potential near-term milestones, including data from two clinical trials, an NDA filing and a share dividend

RADNOR, Pa., March 28, 2024 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announces its anticipated financial results for the quarter and year ended December 31, 2023 and provides the following summary of its expected annual report to be filed later today.

- *Improvement in negative Earnings per Share to ($0.40) in FY 2023 vs ($0.60) in prior 12 month period. Management projects positive cash flow by year-end 2024 via partnerships and HOPE Therapeutics activities.*

- *Raised $9.2 in new capital during FY 2023 with $7.8 million of additions to working capital during Q1 2024. Reduced corporate indebtedness by more than 50% from $11.0 million to approximately $5.4 through Q1 2024.*

- *Signed a development partnership with Alvogen, Inc., and Lotus Pharmaceuticals, Inc. (1795.TW) under which the partners take over phase 3 and commercial costs for NRX-101 in bipolar depression and fund $330 million in commercial milestones together with a double digit royalty on sales, contingent on successful clinical trial data and FDA meeting.*

- *Completed enrollment and last patient visit of the Phase 2b/3 trial of NRX-101 in Suicidal Bipolar Depression with >94% rater concordance through conclusion of the trial, a measure that substantially exceeds current industry standards. Final Data Lock expected this week with Top line data expected in April 2024.*

- *Acceptance of two new Investigational New Drug applications (INDs) by the FDA in Chronic Pain and Complicated Urinary Tract Infection/Pyelonephritis.*

- *Final statistical analysis plan achieved this week in 200-person DOD-funded trial in treatment of chronic pain with D-cycloserine (DCS), the key component of NRX-101. The study center has indicated that data-lock will occur next week. Top-line data expected in April 2024. Positive data would support a final registration trial in this multi-billion dollar indication.*

- *Incorporated HOPE Therapeutics, Inc. as a specialty pharma company. HOPE is supporting distribution of intravenous ketamine, currently listed by FDA on nationwide drug shortage list to qualified ketamine clinics through nationwide 503a and 503b FDA-inspected pharmacy partners. First manufactured lot released for shipment this week by partner Nephron Pharmaceuticals.*

- *Obtained patient-level data from three efficacy studies of ketamine funded by US National Institutes of Health (two trials) and Government of France (one trial). Demonstration statistically significant reduction in severe depression and acute suicidality. Patient Centered Outcomes Research Institute (PCORI) trial*

published in 2023 documents non-inferiority of ketamine vs Electroconvulsive Therapy in treatment of Severe Depression with fewer negative side effects compared to ECT.

- *Completed first commercially-manufactured lot of ketamine (NRX100/HTX-100) in proprietary diversion-resistant presentation and initiated manufacture of two additional commercial batches. Anticipates filing of New Drug Application for treatment of Acute Suicidality by June 2024 upon completion of required 9 month stability and CMC with anticipated 2024 PDUFA date.*

- *HOPE has received term sheets for more than $60 million in funding from new investors upon public listing and is expected to be spun out as a separate company to be owned by NRx, current NRx shareholders, and new investors upon completion of final audit and financial statements*

- *IND for NRX-101 in the treatment of Complicated Urinary Tract Infection (cUTI) is based on in vitro data just accepted for peer-reviewed publication in Antibiotics, an MDPI journal. On the basis of these findings, FDA granted Qualified Infectious Disease Product (QIDP),Fast Track and Priority Review designations NRx is seeking a clinical phase partner for this multi-hundred million dollar indication.*

- *Elected nationally recognized attorney in highly regulated industries, and healthcare specialist, Janet Rehnquist, Esq., to the Company's Board of Directors*

- *Management has taken action to restore Nasdaq listing compliance and combat illegal naked shorting of NRx securities*

- *Management to host a conference call April 1, 2024 at 8:30am (conference call to be conducted after Easter market holiday.*

"Over the past year the Company has navigated the most challenging business environment in the history of the biotechnology industry. Despite unprecedented headwinds, we negotiated a critical commercial partnership for our lead compound in bipolar depression, while retaining rights to the far larger indications of chronic pain and PTSD," said Stephen Willard, J.D., Chief Executive Officer and Director of NRx Pharmaceuticals. "We augmented our intellectual property portfolio to include the use of our lead compound in chronic pain and anticipate results of a 200-person efficacy trial that could open a multibillion dollar opportunity in this therapeutic area. We have acquired sufficient data on safety and efficacy of ketamine to support a New Drug Application for ketamine in acute suicidality. We established the foundation of a specialty pharmaceutical business around ketamine that we expect to yield positive cash flow by the end of 2024. Finally, we received unanticipated data supporting the use of our lead compound to treat complicated Urinary Tract Infection and Pyelonephritis, a condition that affects 3 million Americans and results in more than 15,000 deaths annually. We believe that NRx is poised for substantial growth in 2024 look forward sharing further results in our upcoming filing and conference call."

A final press release on the 10-k filing will be issued Monday April 1, following the market holiday.

About NRx Pharmaceuticals

NRx Pharmaceuticals is a clinical-stage biopharmaceutical company developing therapeutics based on its NMDA platform for the treatment of central nervous system disorders, specifically suicidal bipolar depression, chronic pain and PTSD. The Company is developing NRX-101, an FDA-designated investigational Breakthrough Therapy for suicidal treatment-resistant bipolar depression and chronic pain. NRx has partnered with Alvogen and Lotus around the development and marketing of NRX-101 for the treatment of suicidal bipolar depression. NRX-101 additionally has potential to act as a non-opioid treatment for chronic pain, as well as a treatment for complicated UTI.

NRx has recently announced plans to submit a New Drug Application for HTX-100 (IV ketamine), through Hope

Therapeutics, in the treatment of suicidal depression, based on results of well-controlled clinical trials conducted under the auspices of the US National Institutes of Health and newly obtained data from French health authorities, licensed under a data sharing agreement. NRx was awarded Fast Track Designation for development of ketamine (NRX-100) by the US FDA as part of a protocol to treat patients with acute suicidality.

About HOPE Therapeutics, Inc.

HOPE Therapeutics, Inc. (www.hopetherapeutics.com) is a Specialty Pharmaceutical Company, wholly-owned by NRX Pharmaceuticals focused on development and marketing of an FDA-approved form of intravenous ketamine for the treatment of acute suicidality and depression together with a digital therapeutic-enabled platform designed to augment and preserve the clinical benefit of NMDA-targeted drug therapy.

Notice Regarding Forward-Looking Statements

The information contained herein includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended, including statements about the planned dividend of shares of HOPE Therapeutics, the potential effects of the Company's reverse stock split, potential future stock splits, data from clinical trials that have not yet been released, and planned filings with the FDA. These statements include, among others, statements regarding the proposed public offering and the timing and the use of the proceeds from the offering. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "plan," "believe," "intend," "look forward," and other similar expressions among others. These statements relate to future events or to the Company's future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond the Company's control and which could, and likely will, materially affect actual results, levels of activity, performance or achievements. Any forward-looking statement reflects the Company's current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to the Company's operations, results of operations, growth strategy and liquidity. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's most recent Annual Report on Form 10-K and other filings with the Securities and Exchange Commission. Investors and security holders are urged to read these documents free of charge on the SEC's website at http://www.sec.gov. Except as may be required by applicable law, The Company assumes no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, whether as a result of new information, future events or otherwise.

SOURCE NRx Pharmaceuticals, Inc.

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