October 31, 2023

NRx Pharmaceuticals Announces Signing of a Development Agreement for the Manufacture of Ketamine to Treat Suicidality and Depression

- *FDA-compliant manufacture of intravenous Ketamine is a required component of a New Drug Application*
- *Intravenous Ketamine has become widely used for treating depression and suicidality but has never been presented to FDA for approval*
- *Potential to file New Drug Application for Ketamine in 2024 based on existing clinical data and newly-developed, modern commercial manufacturing protocols*
- *Further information is anticipated to be released in an upcoming 8K securities filing*

RADNOR, Pa., Oct. 31, 2023 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company today announced the signing of a development contract to manufacture a presentation of ketamine suitable for intravenous administration under current FDA manufacturing regulations. Existing supplies of Ketamine are not labeled for treatment of depression and suicidality and often do not conform to modern manufacturing requirements for single-dose injectable medications. NRx and its manufacturing partner plan to release further information in an upcoming 8K filing.

As intravenous Ketamine becomes more widely used to treat depression and suicidality, the supply of Ketamine – which today is approved only for use as an anesthetic – becomes increasingly tenuous. Moreover, suppliers of Ketamine are increasingly challenged by FDA warnings to patients and healthcare providers about potential risks associated with compounded Ketamine products.[1] Compounded products are distributed under state pharmacy laws by compounding pharmacies and may not comply with various aspects of the Food, Drug, and Cosmetics Act.

"We at NRx are excited to have identified a strong manufacturing partner for the development of what we anticipate will be a lifesaving product that has the potential to be available for patients by the end of 2024. We and our partner look forward to sharing further information as the manufacturing, regulatory, and business plans are finalized," said Stephen Willard, JD, CEO of NRx Pharmaceuticals.

About NRx Pharmaceutical

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's lead program NRX-101, an oral, fixed-dose combination of D-cycloserine and lurasidone, targets the brain's N-methyl-D-aspartate (NMDA) receptor and is being investigated in a Phase 2b/3 clinical trial for suicidal treatment-resistant bipolar depression (S-TRBD), which includes patients with both acute and sub-acute suicidality, an indication for which the only approved treatment is electroshock therapy. The Company has partnered with Alvogen Pharmaceuticals, who owns the worldwide rights to NRX-101 for treatment of S-TRBD, to help bring NRX-101 to a global population of patients with unmet medical need. NRx Pharmaceuticals is currently exploring NRX-101's potential to act as a non-opioid chronic pain treatment option and has recently announced a renewed focus on the use of intravenous ketamine for treatment of acute suicidality.

Cautionary Note Regarding Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995, which may include, but are not limited to, statements regarding our financial outlook, product development, business prospects, and market and industry trends and conditions, as well as the Company's strategies, plans, objectives, and goals. These forward-looking statements are based on current beliefs, expectations, estimates, forecasts, and projections of, as well as assumptions made by, and information currently available to, the Company's management. Actual results could differ materially from those contemplated by the forward-looking statements. A discussion of these and other factors, including risks and uncertainties with respect to the Company, is set forth in the Company's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K, as may be supplemented, or amended by the Company's Quarterly Reports on Form 10-Q. Given these risks, uncertainties, and factors, you are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by these cautionary statements.

The Company assumes no obligation to revise any forward-looking statement, whether as a result of new information, future events or otherwise. Accordingly, you should not place reliance on any forward-looking statement, and all forward-looking statements are herein qualified by reference to the cautionary statements set forth above.

[1] https://www.fda.gov/drugs/human-drug-compounding/fda-warns-patients-and-health-care-providers-about-potential-risks-associated-compounded-ketamine

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