



NRx Pharmaceuticals, Inc. (Nasdaq:NRXP) Announces Completion of Twelve Months of Stability on the First Manufactured Commercial Scale Lot of NRX-100 (Ketamine)

September 30, 2024

- Stability milestone supports submission of FDA New Drug Application by NRx for the use of intravenous ketamine to treat Suicidal Depression
- Ketamine is currently used off-label for this indication. However, FDA approval is typically required for patients to obtain insurance reimbursement
- NRX-100 is the first preservative-free formulation of Ketamine, potentially avoiding toxic side effects of preservatives used in current preparations designed for single dose anesthetic use

RADNOR, Pa., Sept. 30, 2024 [/PRNewswire/](#) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a clinical-stage biopharmaceutical company, ("NRx," the "Company"), today announced that twelve-month real-time stability on the first manufactured lot of NRX-100 (Ketamine) at Nephron Pharmaceuticals, utilizing commercial scale processes, was reached on September 24, 2024. In this process, no degradation of the active ingredient was observed. These findings are consistent with projected room temperature shelf stability in excess of three years. Accelerated stability on additional manufactured lots of preservative-free product is congruent with stability seen in this initial lot.

Demonstrating the ability to manufacture drug product, and prove its stability, are critical components of the drug approval process with the US FDA. Filing of the NDA for NRX-100 is on track for 2024. The NRX-100 formulation is the first sterile, single dose vial prepared with without the addition of preservatives, which may have toxic effects with repeated use.

"We are pleased to reach this important milestone in our preparation of the NDA for NRX-100, a drug we believe can significantly benefit the 3.8 million people who make a plan to commit suicide in the United States each year¹," said Jonathan Javitt, MD, MPH, Chairman and Chief Scientist of NRx Pharmaceuticals. "I would like to congratulate the manufacturing team from our partner Nephron Pharmaceuticals for helping us take this important step forward in bringing hope to life."

About NRx Pharmaceuticals, Inc.

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 plans to file an NDA for Accelerated Approval for NRX-101 inpatients with bipolar depression and suicidality or akathisia. 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 NRX-100 (IV ketamine) for 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.

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. 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.

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¹ <https://www.cdc.gov/suicide/facts/data.html>

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