NRx Pharmaceuticals, Inc. (NASDAQ:NRXP) Files Initial Section of U.S. New Drug Application to the FDA for NRX-100 (IV Ketamine) for the Treatment of Suicidal Depression

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- *Aiming to be the first FDA-approved medication to treat suicidal depression*
- *Designed to help address the needs of the more than 13 million Americans who seriously consider suicide each year (CDC)*
- *Completion of NDA filing expected in the first quarter of 2025*
- *Company to participate in 1x1 meetings in San Francisco during the Annual J.P. Morgan Healthcare Conference on January 13-16, 2025, in San Francisco, CA. To schedule meetings, please contact jpm@astrpartners.com*

WILMINGTON, Del., Dec. 30, 2024 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx", the "Company"), a clinical-stage biopharmaceutical company, today announced the transmission of first section of its New Drug Application (NDA) for NRX-100 (ketamine) for electronic filing with the U.S. Food & Drug Administration (FDA). NRX-100 was initially granted Fast Track Designation in 2017 for use in combination with NRX-101 (D-cycloserine/lurasidone) for treatment of suicidal bipolar depression. The Company is now seeking to expand the indication to include Suicidal Ideation in Major Depressive Disorder and other forms of depression, based on data from NIH- and European Government-funded trials that have been summarized on the Company's website.

While assembly of the clinical data sections is being completed, FDA has asked the Company to submit the 1800-page manufacturing section (Module 3) of the NDA to enable immediate review prior to submission of final efficacy data and other sections of the NDA expected in the first quarter of 2025.

The NRx presentation of ketamine differs from the form of ketamine used in anesthesia in that it contains no potentially toxic preservatives and utilizes diversion-resistant packaging to enhance the traceability of a medicine known to have abuse potential.

Suicidal depression is considered a national crisis. According to the CDC over 13 million Americans seriously consider suicide each year and 3.8 million make a plan to do so.

"New treatment options are urgently needed for people at risk with acute suicidal depression," said Dr. Jonathan Javitt, Chairman, CEO and Chief Scientist. "Ketamine is already widely-used for the treatment of suicidal depression on an off-label basis and is funded by the Department of Defense and the Department of Veterans Affairs. However, without FDA approval, its use is largely unreimbursed by health insurers, with the exception of VA and DOD."

NRx thanks its shareholders, its clinical team, and the many patients and caregivers who have participated in the clinical trials.

NRX-100 (IV ketamine) for Suicidal Depression

Intravenous ketamine is widely accepted as a standard of care for acute treatment of suicidal depression, in the absence of an FDA-labeled product; the only treatment currently approved by the FDA is electroconvulsive therapy (ECT). According to the CDC, 3.8 million Americans make a plan for suicide each year. This represents a $3-5 billion market at expected pricing. Based on the data in the trials referenced above, the Company's regulatory counsel encouraged the Company to file an NDA for suicidal depression for NRX-100.

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 in patients 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 begun submission of 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.

About HOPE Therapeutics, Inc.

HOPE Therapeutics, Inc. (www.hopetherapeutics.com) is a development stage healthcare delivery company that intends to develop a best-in-class network of precision psychiatry clinics to offer ketamine transcranial magnetics stimulation (TMS) and other lifesaving therapies to patients with suicidal depression and related disorders, 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. 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, liquidity, Hope Therapeutic's ability to consummate the acquisitions of providers for its national network, the Company's ability to raise adequate capital to fund the Hope Therapeutics acquisitions, and the Company's ability to spin-off Hope Therapeutics. 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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