NRx Pharmaceuticals, Inc. (NASDAQ:NRXP) Files Patent Application for NRX-100, its Proprietary, Preservative Free Formulation of IV Ketamine

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- Patent expected to be Orange Book listable, if granted
- NRX-100, preservative free, IV ketamine, is designed to avoid potential toxicity concerns linked to benzethonium chloride, used in currently available formulations of ketamine
- Filing strengthens NRx's leadership in advancing safe and effective treatments for suicidal depression

WILMINGTON, Del., May 5, 2025 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced the filing of a patent application for NRX-100, its preservative-free intravenous ketamine formulation for the treatment of suicidal depression. The application discloses pharmaceutical compositions, methods of treatment and methods of manufacture and currently includes twenty claims. While subject to the patent review process of the US Patent and Trademark Office, if granted, the patent would provide NRX-100 exclusivity into 2045.

NRX-100 is specifically formulated without benzethonium chloride or other preservatives, which have been associated with cytotoxic or neurotoxic effects. Current governmental leadership has expressed strong interest in delivering medications without unnecessary or unproven preservatives. Demonstration of room temperature shelf stability in the absence of toxic excipients represents a novel pharmaceutical composition that has the potential to be listed in the FDA Orange Book. This patent filing builds on the Company's recently initiated filing of an NDA for NRX-100 and its prior Fast Track Designation, with NRX-101, from the FDA. If granted, the patent will help protect the innovation behind this formulation as NRx advances its commercialization strategy.

"We are committed to delivering safer, more effective treatments for patients with suicidal depression," said Jonathan Javitt MD MPH, CEO of NRx Pharmaceuticals. "NRX-100 eliminates the need for benzethonium chloride, a compound with well-documented safety concerns, and reflects our belief that patients in crisis deserve therapies formulated with their long-term well-being in mind. With the recent FDA fee waiver now in place, we remain on track to complete our NDA submission this quarter — a critical step toward bringing this innovation to patients in need."

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 recently initiated a New Drug Application filing 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), a subsidiary of NRx Pharmaceuticals, is a Healthcare delivery company that is building a best-in-class network of interventional 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.

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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 satisfaction of closing conditions necessary to consummate the acquisition of Kadima and Dura, and obtaining financing necessary to consummate the acquisitions. 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, including the risk that the transactions contemplated by the LOI are not consummated, 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 such 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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