NRx Pharmaceuticals, Inc. (NASDAQ:NRXP) Files Abbreviated New Drug Application (ANDA) for Preservative-Free IV Ketamine

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- Ketamine faces a current US drug shortage not expected to abate in the near future[1]
- Current ketamine market estimated at $750 million and projected to reach $3.35 billion globally in 2034.[2] NRx anticipates marketing ketamine for all approved uses
- Company anticipates priority review based on current and anticipated drug shortage
- NRX-100 to provide innovative, preservative-free IV ketamine formulation to eliminate benzethonium chloride preservative, in keeping with current HHS priorities to eliminate toxic preservatives from foods and drugs
- The Company anticipates filing a citizen's petition with the FDA to remove benzethonium chloride, a known neurotoxic and cytotoxic substance, from all presentations of ketamine intended for intravenous use
- This filing complements the ongoing NDA submission for NRX-100 in suicidal depression; PDUFA anticipated in late 2025

WILMINGTON, Del., June 5, 2025 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a clinical-stage biopharmaceutical company, today announced the transmission of its Abbreviated New Drug Application (ANDA) for electronic filing to the U.S. Food and Drug Administration (FDA) for NRX-100, its preservative-free IV ketamine formulation, for use in all existing approved indications such as anesthesia and pain management.

The current annual ketamine market is estimated at $750 million, with global demand for ketamine projected to grow to $3.35 billion by 2034. This does not include the widespread use of compounded ketamine by clinics unable to obtain manufactured drug. NRx aims to capture a significant share of that existing market. According to a 2021 survey, an estimated 5.1 million Americans had received ketamine for medical uses in their lifetime[3], a number that continues to grow with increased clinical focus on this important medication. Ketamine currently faces a severe drug shortage according to the American Society of Hospital Pharmacist with no short-term abatement. Accordingly, NRx is seeking priority review from FDA.

The Company anticipates filing a citizen's petition with the FDA to remove benzethonium chloride, a known neurotoxic and cytotoxic substance, from presentations of ketamine intended for intravenous use. Management believes that the preservative-free feature of NRX-100 will be deemed of benefit to patients because of the known toxicity of closely related benzalkonium chloride in current drug products. Preservatives were originally added to sterile injectable products in an era when a single vial of medication was used to treat multiple patients, a practice no longer allowed in US hospitals. NRx has demonstrated that there is no need for such preservatives to maintain stability and sterility in ketamine presentations intended for single-patient use. Should the citizen's petition be granted, all formulations of ketamine sold in the US could face a regulatory requirement to be preservative free.

Today's filing supplements the New Drug Application currently being completed by the Company to extend the labeled indications of ketamine to include the treatment of suicidal depression. The Company anticipates submitting clinical trials data from more than 1,000 patients and real-world data from more than 180,000 patients in which ketamine demonstrated superiority to placebo and active placebo, with noninferiority to electroconvulsive therapy.

"This submission comes at a time when the demand for ketamine in the US market is rapidly increasing and the available supply is inadequate. We at NRx believe that safer, preservative-free formulations of ketamine will be increasingly preferred by physicians, patients, and regulators in this large and growing market." said Jonathan Javitt, MD, MPH, Chairman and CEO of NRx Pharmaceuticals. "NRX-100 is designed to replace older formulations that rely on potentially neurotoxic and cytotoxic preservatives for stability and sterility. We have filed a US patent on our novel, preservative-free formulation, which anticipates three years of room-temperature shelf stability."

In April 2025, the FDA granted a waiver of the $4.3 million NDA fee under the PDUFA, recognizing both the product's public health value and NRx's qualification under small business provisions. NRX-100 was previously granted Fast Track Designation in a protocol with NRX-101. With regulatory filings underway, patent protection sought through 2045, and a growing body of clinical and technical validation, NRx believes NRX-100 is well-positioned to become a next-generation standard in both the emerging mental health market and the current $750 million ketamine market, offering physicians and patients a safer, more reliable alternative to legacy ketamine products.

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 as a treatment for complicated UTI.

NRx has recently initiated a New Drug Application filing for NRX-100 (preservative free 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 and has filed a patent for this novel formulation with the US Patent and Trademark Office.

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.

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 satisfaction of closing conditions necessary to consummate the acquisition of Kadima, Neurospa 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, uncertainties and assumptions relating to the Company's operations, results of operations, growth strategy, liquidity, whether the USPTO approves the Company's patent, and whether the FDA will approve the Company's NDA. 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.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=391

[2] https://www.factmr.com/report/injectable-ketamine-market
[3] https://www.radars.org/system/publications/NMURx%20Ketamine%20Use%20Poster_fin2.pdf

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