# NRx Pharmaceuticals, Inc. (NASDAQ:NRXP) Announces FDA Award of Filing Fee Waiver for Upcoming NRX-100 (preservative free ketamine) New Drug Application to Treat Patients with Suicidal Depression

April 30, 2025

- *Waiver exempts NRx from paying a $4.3 million New Drug Application filing fee under the Prescription Drug User Fee Act (PDUFA)*
- *Company is on track for Q2 2025 completion of NDA filing and PDUFA date by year end with currently available corporate resources*
- *NRX-100, together with NRX-101, was granted Fast Track designation by FDA for treatment of suicidal bipolar depression in 2018*
- *Company notes recent statements by Secretary of Health and Human Services regarding the public health importance of approving psychedelic drugs such as ketamine to treat suicidal depression and PTSD*

MIAMI, April 30, 2025 /PRNewswire/ -- NRx Pharmaceuticals, Inc., (Nasdaq:NRXP or "the Company"), today announced the grant of a filing fee waiver by the US Food and Drug Administration ("FDA") to exempt the Company from a $4.3 million fee to file its New Drug Application for NRX-100 (preservative-free ketamine). The waiver is granted at the discretion of the FDA to Small Business Entities and for drugs that are deemed to be necessary for Public Health. The Company anticipates that this waiver enables the completion of its New Drug Application for NRX-100 with currently-available corporate resources. The NDA filing is anticipated by the end of the second quarter of this year (Q2 2025).

NRX-100 is a preservative-free preparation of ketamine in a single-patient presentation. Currently-available forms of ketamine contain preservative – benzethonium chloride – the safety of which has never been demonstrated for repeated use. The preservative was added in the 1970s when ketamine was originally formulated as an anesthetic and the practice at the time was to package anesthetic drugs in multi-use vials that required a preservative to maintain sterility. Although benzethonium chloride has not demonstrated toxicity in anesthesia, this class of preservatives has been shown to be neurotoxic and cytotoxic to the tissues of the eye when incorporated in eye drops. NRx has now demonstrated stability and sterility sufficient to maintain more than two years of shelf life in a preservative-free presentation. This patent-pending process is anticipated to yield long-term exclusivity should NRX-100 be approved by the FDA.

As previously announced, NRx will be submitting data from controlled clinical trials that demonstrate ketamine to be superior to both a placebo and an active comparator, as well as either non-inferior or superior to electroshock therapy in treating various forms of depression, including patients with active suicidal ideation. Although ketamine in various forms is increasingly used to

treat depression and related disorders, it is approved by FDA only for use as an anesthetic and, therefore, not reimbursed by most insurance carriers for treatment of suicidality or depression. By applying for FDA approval to treat suicidal depression with NRX-100, the Company hopes to make this potentially life-saving therapy available to all Americans, not just those who are able to pay out of pocket.

The Company notes recent statements by the Secretary of Health and Human Services supporting the importance of psychedelic drugs to treat severe depression and PTSD. Ketamine is believed to have a beneficial effect through its role in blocking the NMDA receptor of the brain and causing increased levels of beneficial neurotransmitters in the brain, with resulting formation of new brain cell connections (synapses).

"We at NRx are encouraged by this important fee waiver from the FDA and by the posture expressed by the new leadership of the Department of Health and Human Services in support of new psychedelic drugs to treat the more than 3 million Americans who consider suicide every year and currently have no approved treatment other than electroshock therapy," said Dr. Jonathan Javitt, CEO and Chairman of NRx Pharmaceuticals. "NRx aims to make its preservative-free ketamine available to physicians who care for patients with suicidal depression and PTSD."

**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.

**Notice Regarding Forward-Looking Statement**
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, including uncertainties and assumptions relating to the Company's operations, results of operations, growth strategy, and, among other things, 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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