NRx Pharmaceuticals (Nasdaq:NRXP) Announces FDA Bioequivalence Determination by Office of Generic Drugs for NRx's Preservative-Free Ketamine Application

March 17, 2026

- Determination of bioequivalence to the Reference Listed Drug is essential for approval of an Abbreviated New Drug Application (ANDA).
- FDA has advised NRx in written correspondence that it has not identified any bioequivalence deficiencies in the Company's Preservative-Free Ketamine product. This communication is deemed preliminary until final supervisory review.
- NRx continues to anticipate an FDA GDUFA decision on its ANDA application in Summer 2026 as previously announced.
- The ANDA process is focused on offering a preservative-free alternative in the existing ketamine market through the FDA Office of Generic Drugs and is separate from NRx's path to a New Drug Application to use ketamine in the treatment of depression, being pursued through the FDA Division of Psychiatry Products.

WILMINGTON, Del., March 17, 2026 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a clinical-stage biopharmaceutical company, today announced that it has received a letter from the Bioequivalence Program of the FDA Office of Generic Drugs stating that "FDA has not identified any bioequivalence deficiencies at this time." The determination is deemed preliminary until final supervisory review of NRx's Abbreviated New Drug Application with anticipated approval in Summer 2026.

This determination by FDA is meaningful in that the proposed NRx product is the first ketamine formulation to be free of benzethonium chloride (BZT), a known toxic preservative. Benzethonium chloride is not listed by FDA as Generally Recognized as Safe (GRAS) and is no longer permitted in certain topical consumer applications. Ketamine formulations containing BZT date back to an era when the safety profile of quaternary amine preservatives was less well characterized.

Prior to NRx's preservative-free formulation, it was widely believed that BZT was required to maintain room temperature stability and sterility of ketamine. The Company anticipates demonstrating three years of room temperature stability and sterility for its preservative-free product. NRx has filed patents in the US and Internationally to support its preservative-free formulation and has the potential to create a "branded generic" product.

NRx's preservative free product is manufactured in the United States at a time when the FDA has identified ketamine as a strategically important medication and has emphasized the need for resilient domestic supply chains for critical drugs. The FDA recently awarded a Commissioner's National Priority Voucher to support the establishment of a new U.S. manufacturing source of ketamine drug substance, reflecting broader regulatory and policy focus on re-shoring essential medicines and reducing reliance on foreign supply.

"We deeply appreciate the FDA's timely review of the bioequivalence aspects of our generic drug application and look forward to an ongoing collaborative relationship, particularly as we advance a preservative-free product manufactured in the United States" said Dr. Jonathan C. Javitt, MD, MPH, NRx's CEO and Chairman. "We believe a preservative-free formulation has the potential to meaningfully modernize ketamine therapy while supporting the resilience of the U.S. drug supply chain.

In addition to the pending ANDA application for Preservative Free Ketamine, NRx (as announced yesterday) is preparing a New Drug Application under Fast Track Designation to expand the use of intravenous ketamine to treat patients with severe depression, who may have suicidal ideation.

About NRx Pharmaceuticals, Inc.
NRx Pharmaceuticals, Inc. (www.nrxpharma.com), is a clinical-stage biopharmaceutical company developing therapeutics based on its NMDA platform for the treatment of central nervous system disorders, specifically suicidal depression, chronic pain, and PTSD. The Company is developing NRX-100 (preservative-free intravenous ketamine) and NRX-101, (oral D-cycloserine/lurasidone). NRX-100 has been awarded Fast Track Designation for the treatment of Suicidal ideation in Depression, including Bipolar Depression. NRX-101 has been awarded Breakthrough Therapy Designation for the treatment of suicidal bipolar depression. NRx has filed an Abbreviated New Drug Application (ANDA), and initiated a New Drug Application filing for NRX-100 with an application for the Commissioner's National Priority Voucher Program for the treatment of suicidal ideation in patients with depression, including bipolar depression.

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. The Company has reported regulatory milestones as they have been achieved but has not predicted the outcome of any future regulatory determination. 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.

For further information:

Brian Korb
Managing Partner, astr partners
(917) 653-5122
brian.korb@astrpartners.com