



NRx Pharmaceuticals (Nasdaq:NRXP) Announces Initiation of Commercial Manufacturing for Preservative Free Ketamine

May 5, 2026

- Based on FDA Office of Generic Drugs guidance previously announced, NRx has transmitted an initial GMP manufacturing order to its US-based manufacturer.
- NRx has completed confirmatory GMP audits of manufacture and is prepared for pre-approval inspection.
- Initial manufacture rate is sufficient to support significant market penetration in first year sales and can be readily scaled based on blow-fill-seal manufacturing process.

WILMINGTON, Del., May 05, 2026 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a biopharmaceutical company that focuses on neuroplastic therapies for depression, PTSD, and related conditions, today announces initiation of a first commercial manufacturing order of its preservative free ketamine product in anticipation of approval under the Generic Drug User Fee Act in Summer 2026. The order is based on stability observed in more than 3 manufactured registration batches and the Company's successful third-party audit of the manufacturing facility.

The Company expects that the initial manufacturing pace will be sufficient to support initial substantial yearly revenues and notes the ability to rapidly scale manufacturing as demand grows. The Company recently announced the appointment of Mr. Glenn Tyson as its Chief Commercial Officer and is in the process of retaining a full commercial team.

The NRx product is the first US-manufactured preservative-free ketamine presentation. Manufacturing is accomplished via a blow-fill-seal process that achieves more than 10-fold higher manufacturing throughput than traditional sterile bottling techniques that rely on glass vials and traditional seals.

NRx's presentation of ketamine differs from existing products in that it does not contain a known toxic preservative, Benzethonium Chloride. This preservative is no longer allowed to be included in new drugs and according to FDA policy cannot even be included in hand cleansers and topical antiseptics.

As of April 7, 2026, sterile intravenous ketamine remains listed on the American Society of Health-System Pharmacists (ASHP) national drug shortage database. ASHP reports ongoing supply constraints across multiple manufacturers, including product discontinuations, back orders, and reliance on short-dated inventory for certain ketamine injection presentations, particularly higher-concentration vials commonly used in hospital and outpatient settings. These recurring disruptions have periodically required healthcare providers to adjust sourcing and clinical use, highlighting the need for additional reliable, domestically manufactured ketamine supply.

"NRx thanks its manufacturing partner for the care and support that has been invested in this project and looks forward to being able to serve Americans with a safe and convenient US-made ketamine product. We hope to alleviate the supply shortages that have frequently been reported in association with sterile ketamine," said Dr. Jonathan Javitt, Chairman and CEO of NRx Pharmaceuticals.

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 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.

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