NRx Pharmaceuticals Begins Selling U.S.-Made, Preservative-Free Ketamine Amid Long-Running Shortage

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- A veteran, trained, and certified 17-person sales force, commenced sales operations this week, providing national coverage with customers responsible for approximately 80% of current U.S. ketamine sales
- Initial supply agreements and preorders are targeted for late 2026, with product shipments scheduled to begin in January 2027
- Efficiencies in blow-fill-seal (BFS) manufacturing and the sales structure are expected to result in gross and net sales margins in excess of 50%, margins commonly associated with innovative drugs
- Innovative, drug/device combination vial provides barriers to competition
- NRx has contracted with German suppliers for additional BFS manufacturing lines to expand its sterile injectable portfolio through the new sales channels

WILMINGTON, Del., Nov. 11, 2026 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP, "NRx" or "the Company"), a commercial biopharmaceutical company developing medicines that target depression, PTSD and suicidality, today announced that it commenced selling its newly approved preservative-free ketamine providing a guaranteed, U.S.-manufactured supply of a drug listed as in shortage since 2018.

All ketamine injection products currently available in the U.S., having been in short supply since 2018, contain the preservative benzethonium chloride (BZT), which FDA has not determined to be generally recognized as safe and effective (GRASE) for OTC antiseptic hand rubs. NRx's injectable ketamine is preservative-free and comes in a needle-free blow-fill-seal (BFS) vial with a luer-lock tip that attaches directly to a sterile syringe. NRx's preservative free-ketamine is being sold by veteran sales representatives, most of whom have decades of experience in the sterile injectable market, and who have existing relationships with purchasers controlling approximately 80% of the current US market.

"By enlisting seasoned sales representatives who already sell sterile injectable drugs, we are able to drive considerable efficiency in costs of sales and marketing," said Jonathan Javitt, MD, MPH, chief executive officer of NRx. "Our representatives already have strong relationships with hospital and group purchasing responsible for the vast majority of ketamine and other sterile injectable drugs sold in the U.S."

New packaging for an old drug

NRx has focused on converting sterile injectable products from traditional glass bottles, which are increasingly costly to manufacture, to Blow-Fill-Seal (BFS) technology, in which a polypropyline vial is formed, filled and sealed in a single manufacturing step. Until recently, this technology was only suited to eyedrops and other noninjectable products. The vial's luer-lock tip attaches directly to a sterile syringe used by the health care professional. These attributes allow preservative-free ketamine and other sterile injectable products to benefit from the same manufacturing and cost of goods sold (COGS) efficiencies as other products implementing BFS technology. NRx has prior experience with the high glass vial COGS during Covid and recognized the potential to restore profitability to old sterile generic products using BFS. At the same time, the inherent cost of BFS manufacturing equipment and the complexity of achieving FDA certification of the luer vial provide meaningful competitive advantages for the Company. While the product seems simple, it is a rigorously-controlled FDA drug/device combination product that required extensive medical device validation for approval.

Needle-free and preservative-free

The NRx product offers needle-free handling and provides safety benefits to pharmacy staff, while reducing staff time. When pharmacists, nurses and doctors draw injectable products from traditional glass vials, they must mount a needle on a syringe, pierce a rubber stopper with a needle, and safely dispose of the needle. CDC estimates that hospital-based health care personnel in the United States sustain approximately 385,000 needlestick and other sharps injuries each year, a figure that likely understates the true burden because it excludes non-hospital settings and surveys indicate that 50% or more of injuries go unreported.[1,2] In addition, the NRx luer vial does not generate "sharps" medical waste, which is costly and complex to dispose of. Staff safety and staff time are at a premium in every U.S. hospital, and customers have applauded the value of the NRx BFS solution.

Under current regulations, inactive ingredients in drugs, including preservatives, must be GRASE - or proven not to be unsafe. The FDA has declined to designate BZT as GRASE. Ketamine, first formulated in 1970, is one of the few remaining old drugs that

contain BZT. NRx expects the market to increasingly welcome its preservative-free product as the toxicity of BZT becomes better understood.

NRx has filed a citizen petition asking the FDA to remove BZT from ketamine, and an expert toxicology report is available to the public on the FDA docket.[3,4,5] The report, compiled by a board-certified toxicologist under the supervision of a leading regulatory law firm, documents that patients receiving ketamine at dosages routinely used in hospitals and clinics for labeled indications may be exposed to levels of BZT that exceed the FDA's published maximum daily intravenous injection exposure of 1 milligram. [2]

Addressing an ongoing shortage

Ketamine has been listed in shortage since 2018, and customers have indicated a willingness to enter into long-term agreements in exchange for guaranteed supply. When hospitals cannot buy FDA-approved ketamine, they are forced to buy non FDA-approved product from compounding pharmacies. Beyond lacking FDA approval, most states limit the legal maximum beyond use date for compounded sterile products to 90 days[6,7], compared with an initial two-year expiration for the NRx product, which NRx anticipates extending.

Beyond ketamine, federal policymakers have recognized the risk posed by a U.S. sterile injectable drug supply that is largely manufactured overseas and vulnerable to shortages. Traditional, labor-intensive glass-bottle manufacturing of these drugs has not been economically viable in the U.S. for decades. facturing of these drugs has not been economically viable in the U.S. for decades. NRx's prior experience with glass bottling suggests that the COGS may represent 70% or more of the sales price to hospitals, while the BFS process reduces COGS to less than 20%, restoring old products to commercial viability. NRx's ketamine presentation demonstrates that manufacturing of old-line sterile injectable drugs can be reshored to the U.S. for the benefit of American patients, workers and investors.

With the preservative-free ketamine FDA approval achieved, NRx has contracted with German manufacturers of BFS technology to double its manufacturing footprint in South Carolina , creating the potential to add more U.S.-manufactured sterile injectable products.

About NRx Pharmaceuticals Inc.

NRx Pharmaceuticals, Inc. (www.nrxpharma.com), is a commercial-stage biopharmaceutical company developing therapeutics based on its NMDA receptor platform for the treatment of central nervous system disorders, specifically suicidal depression, chronic pain, and PTSD. The Company has been awarded an Abbreviated New Drug Approval (ANDA) for Preservative-Free Ketamine and is seeking New Drug Approval for a presentation of intravenous ketamine (NRX-100) with approved claims for treating depression and suicidality.

In October 2026 the Defense Advanced Research Projects Agency awarded an $11.25 million contract to NRx to conduct a phase 3 trial of its oral drug NRX-101, (D-cycloserine/lurasidone) combined with Robotic Neuronavigated Transcranial Magnetic Stimulation as a one-day treatment for patients with depression. 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.

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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