UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 30, 2026

NRX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-38302	82-2844431
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

1201 Orange Street, Suite 600 Wilmington, Delaware	19801
(Address of principal executive offices)	(Zip Code)

(484) 254-6134
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.424)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common Stock, par value $0.001 per share	NRXP	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On October 30, 2026, NRx Pharmaceuticals, Inc. (the "Company") announced that the U.S. Food and Drug Administration (the "FDA") has approved the Company's Abbreviated New Drug Application ("ANDA") for Preservative-Free Ketamine, ahead of the November 10, 2026 goal date established under the Generic Drug User Fee Amendments ("GDUFA").

The Company also hosted a conference call and live webcast at 8:30 a.m. Eastern Time on October 30, 2026 to discuss the approval.

A copy of the press release announcing the approval is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Current Report on Form 8-K contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements may include, among other things, statements regarding the Company's financial outlook, product development activities, regulatory matters, business prospects, market and industry trends and conditions, and the Company's strategies, plans, objectives and goals.

Forward-looking statements are based on the current beliefs, expectations, estimates, forecasts and projections of, and assumptions made by and information currently available to, the Company's management. Words such as "expect," "anticipate," "should," "believe," "hope," "target," "project," "goal," "estimate," "potential," "predict," "may," "will," "might," "could," "would," "seek," "plan," "intend" and similar expressions, or the negative of such terms, are intended to identify forward-looking statements.

Forward-looking statements are subject to significant risks and uncertainties, many of which are beyond the Company's control, that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, among others, the Company's limited operating history; its ability to obtain regulatory approval for, develop, manufacture and commercialize its product candidates; the timing and results of regulatory submissions, reviews and decisions; manufacturing difficulties or delays; competition and technological developments; changes in applicable laws and regulations; the Company's ability to protect and enforce its intellectual property rights; its ability to retain key personnel, manage growth and obtain additional financing; general economic, market and industry conditions; and the risks described under the heading "Risk Factors" in the Company's filings with the Securities and Exchange Commission. There can be no assurance that any product candidate will receive the necessary regulatory approvals or, if approved, will be commercially successful.

Forward-looking statements speak only as of the date of this Current Report on Form 8-K. Except as required by applicable law, the Company undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. Readers are cautioned not to place undue reliance on these forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated October 30, 2026
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NRx Pharmaceuticals, Inc.

Date: November 2, 2026

By: /s/ *Michael Abrams*
Name: Michael Abrams
Its: Chief Financial Officer

NRx Pharmaceuticals (Nasdaq:NRXP) Receives FDA Approval of Preservative-Free Ketamine Ahead of November 10 FDA Goal Date

October 30, 2026

- Preservative-Free Ketamine is an American-manufactured presentation of ketamine that contains no benzethonium chloride (BZT), a toxic antimicrobial preservative that is not Generally Recognized as Safe (GRAS) by the FDA. Current law requires preservatives and other inactive ingredients of drugs, foods, and cosmetics to be GRAS or demonstrated to be unsafe.
- Benzethonium Chloride is known to be toxic to the cells that line the body's organs (epithelial cells) and is banned from new drugs, consumer hand cleansers, wipes, healthcare or surgical hand rubs [1,2]
- Ketamine, originally formulated in 1970 is one of the last remaining sterile drugs to contain Benzethonium Chloride.
- NRx aims to return sterile, injectable drug manufacture to the United States and to end the current shortage of traditional glass-bottled ketamine through modern, high-volume "blow-fill-seal" technology, manufactured in the United States with Nephron Pharmaceuticals in West Columbia, South Carolina.
- This approval demonstrates that sterile, injectable drug manufacturing can be reshored to the United States from current overseas sources of supply using modern technology for the benefit of American patients, workers, and their families.
- The Company will host a conference call Friday, October 30, at 8:30 a.m. ET.

WILMINGTON, Del., Oct. 30, 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 the U.S. Food and Drug Administration (FDA) has approved the Company's Abbreviated New Drug Application (ANDA) for Preservative-Free Ketamine. The approval comes ahead of the FDA-announced November 10, approval goal date.

"We are excited to bring Preservative-Free Ketamine to market and to give patients and their physicians an option for repeat treatments without the potential dangers of a preservative that has been classified as unacceptable for inclusion in multiple product categories by the US Food and Drug Administration," said Jonathan Javitt, MD, MPH, the company's Chairman and Chief Executive Officer. "Ketamine injection has been in short supply since 2018 and currently appears on the FDA drug shortage list with some manufacturers discontinuing production. The Secretary of Health and FDA Commissioner have previously identified ketamine as a strategic drug whose supply in the US must be assured. With manufactured commercial supply on hand, we can now label our product and supply American hospitals and clinics. In those settings, ketamine is used primarily for anesthesia and pain control, including in labor and delivery, where it is the only IV anesthetic that minimizes suppression of breathing in the baby. We are pleased to work with our partners at Nephron Pharmaceuticals in West Columbia, South Carolina, who have helped us prove that sterile, preservative-free injectables can be made in America."

Currently all available ketamine injection products contain benzethonium chloride (BZT). According to current regulation, inactive ingredients in drugs (including preservatives) must be Generally Recognized as Safe ("GRAS") or proven not to be unsafe. The FDA has declined to designate Benzethonium Chloride as GRAS. Under current FDA policy, benzethonium chloride cannot be included in new drugs, consumer hand cleansers, wipes, healthcare or surgical hand rubs nor in intravenous formulations above a threshold concentration for toxicological reasons.[1,2] Ketamine is one of the few remaining old drugs, initially formulated in 1970 to contain BZT. Prior to NRx's novel formulation, it was widely believed that BZT was required for long-term stability and sterility of ketamine.

The Company has filed a Citizen Petition with FDA seeking to have BZT removed from ketamine and an expert Toxicology report is available to the public on the FDA docket. That 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 published FDA maximum daily exposure of 1 milligram.[2]

Federal policymakers have addressed the threat to the United States of a sterile injectable drug supply that is largely manufactured offshore. Traditional, labor-intensive, glass bottle manufacturing of these drugs has not been economically viable in the United States for decades. NRx's presentation of Ketamine demonstrates that manufacture of old-line sterile, injectable drugs can be reshored to the United States for the benefit of American patients, workers, and investors.

The approval of Ketamine ahead of its Generic Drug User Fee Act (GDUFA) goal date by the FDA Office of Generic Drugs demonstrates FDA's commitment to timely and efficient approval of drug-shortage drugs.

Conference Call Details

The Company will host a conference call at 8:30 a.m. ET on Friday, October 30, 2026, to discuss the FDA approval of Preservative-Free Ketamine. A live webcast of the conference call will be available on the Company's website at **https://ir.nrxpharma.com/events**. Participants that are unable to join the webcast can access the conference call via telephone by dialing domestically 1-800-717-1738 or internationally 1-646-307-1865.

About NRx Pharmaceuticals, Inc.

NRx Pharmaceuticals, Inc. (www.nrxpharma.com), is a clinical-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 a 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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References

1. U.S. Food and Drug Administration. (2019). Safety and effectiveness of consumer antiseptic rubs; topical antimicrobial drug products for over-the-counter human use. *Federal Register, 84*(71), 14847–14864.
2. U.S. Food and Drug Administration. (n.d.). *Inactive ingredient search for approved drug products: Benzethonium chloride*. Retrieved October 29, 2026, from https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm
3. https://www.regulations.gov/document/FDA-2025-P-3577-0004