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) **September 24, 2025**

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 No.)

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)

N/A
(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:

☐	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐	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(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	NRXP	The Nasdaq Stock Market LLC
Warrants to purchase one share of Common Stock	NRXPW	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 8.01 Other Events.

On September 24, 2025, NRx Pharmaceuticals, Inc. (the "Company") issued a press release, in which the Company announced that it was notified by the United States Food and Drug Administration that a Suitability Petition has been granted for the strength proposed by the Company for its planned single-patient, preservative-free ketamine product (KETAFREE™). Currently, ketamine is sold in multi-dose vials that contain Benzethonium Chloride, a toxic preservative. The Suitability Petition that has been granted enables immediate re-filing of the Company's Abbreviated New Drug Application for KETAFREE™. A copy of the Press Release is furnished hereto as Exhibit 99.1

The information in this Item 8.01 and in the Press Release furnished as Exhibit 99.1 to this current report shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 8.01 and in the Press Release furnished as Exhibit 99.1 to this current report shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01	**Financial Statements and Exhibits.**

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release, dated September 24, 2025
104	Cover Page Interactive Data File (formatted as Inline XBRL).

SIGNATURES

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

	NRX PHARMACEUTICALS, INC.		
Date: September 26, 2025	By:	/s/ *Jonathan Javitt*	
	Name:	Jonathan Javitt	
	Title:	Interim Chief Executive Officer	

NRx Pharmaceuticals, Inc. (NASDAQ:NRXP) Receives Notification of US Food and Drug Administration Approval of Suitability Petition for NRx's Proposed Strength of Preservative-Free Ketamine

- *Suitability Petition is required for shift from multidose packaging of ketamine to single-patient dose preservative free ketamine*
- *Granting of Suitability Petition enables re-filing of Abbreviated New Drug Application (ANDA) for NRx's patent-pending preservative-free ketamine product*

Wilmington, DE, September 24, 2025 - NRx Pharmaceuticals, Inc. (Nasdaq:NRXP), a clinical-stage biopharmaceutical company, announced that it was notified yesterday by the United States Food and Drug Administration that a Suitability Petition has been granted for the strength proposed by the Company for its planned single-patient, preservative-free ketamine product (KETAFREE™). Currently, ketamine is sold in multi-dose vials that contain Benzethonium Chloride, a toxic preservative. The Suitability Petition that has been granted enables immediate re-filing of the Company's Abbreviated New Drug Application for KETAFREE™. The Company believes that this proposed product addresses two critical policy objectives as articulated by the current administration: (1) the re-shoring of strategically important drugs, particularly sterile products from foreign manufacturing sources, and (2) the "Make America Healthy Again" (MAHA) objective of removing toxic preservatives and colorants from foods and drugs. These objectives have been articulated on numerous occasions by FDA and HHS leadership.

The current market for ketamine is estimated at $750 million. The Company believes that its proposed KETAFREE™ product will be a successful offering in that market, wholly apart from the Company's aim to supply a non-generic formulation of ketamine (NRX-100) as an innovative new drug to treat suicidal depression and PTSD under a New Drug Application.

"Last week, NRx was honored to be selected to attend a 'listening session' hosted by the FDA Commissioner, for biotechnology CEOs. We appreciate FDA's rapid response on the requested Suitability Petition and look forward to bringing our preservative-free presentation of ketamine to the US market at the earliest possible moment," said Jonathan C. Javitt, MD, MPH, 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 recently had a Suitability Petition granted, allowing re-filing of 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 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:

Matthew Duffy
Chief Business Officer, NRx Pharmaceuticals
mduffy@nrxpharma.com

Brian Korb
Managing Partner
(917) 653-5122
brian.korb@astrpartners.co