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): February 17, 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
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 February 17, 2026, NRx Pharmaceuticals, Inc. (the "Company") issued a press release regarding a path to a new drug application with real world data and broader proposed indication for NRX-100 (ketamine) Following Type C FDA Meeting.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release dated February 17, 2026
104	Cover Page Interactive Data File (embedded with 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 thereunto duly authorized.

NRx Pharmaceuticals, Inc.

Date: February 17, 2026

By: /s/ *Jonathan Javitt*
Name: Jonathan Javitt
Its: Chief Executive Officer

NRx Pharmaceuticals (Nasdaq:NRXP) Announces Path to New Drug Application with Real World Data and Broader Proposed Indication for NRX-100 (ketamine) Following Type C FDA Meeting.

- NRx together with Osmind, Inc. conducted an in-person meeting with leadership of the FDA Division of Psychiatry Products, Director of the FDA
- Company believes the meeting provides a clear path to filing an application for New Drug Approval of NRX-101 under already-awarded Fast Track Designation based on existing clinical trial data and Real World Evidence.
- FDA comments indicate that NRx's desired endpoints could serve as a basis for full NDA approval, rather than serving as intermediate endpoints for more limited Accelerated Approval.
- Based on the advice at the meeting, NRx will expand the proposed indication for NRX-100 to the serve the larger population of patients with treatment-resistant depression who may have suicidality rather than only the subset with suicidality
- FDA agreed to review NRx and Osmind protocol for analysis of Real World Data expected to provide confirmatory evidence of effectiveness in treating depression with suicidal ideation.
- NRx anticipates submitting the New Drug Application in Q2 aiming for a 2026 PDUFA date.
- FDA comments indicate that nonclinical portions of the IND are sufficient for review in a New Drug Application and indicate no need for bridging studies related to removal of Benzethonium Chloride in the NRX-100 formulation.
- The Abbreviated New Drug Application for preservative-free ketamine based on the current generic label continues to be reviewed with an expected decision date in Summer 2026.

WILMINGTON, Del., February 17, 2026 – NRx Pharmaceuticals, Inc. (Nasdaq: NRXP), a clinical-stage biopharmaceutical company, today announced that it has completed an in-person Type C guidance meeting at the headquarters of the US Food and Drug Administration. Present at the meeting were leaders of the FDA Division of Psychiatry Products, the FDA Office of Neuroscience, and the FDA Center for Drug Evaluation and Research. The guidance meeting followed an in-person FDA listening meeting the prior day with an expanded FDA audience in which leaders of Osmind, Inc., presented in detail the structure and potential information contained in their Real World Evidence database related to the treatment of psychiatric disorders, including the use of ketamine and intranasal S-ketamine.

Based on oral guidance received at the meeting, NRx believes it has a path to filing an application for New Drug Approval of NRX-100 (preservative-free ketamine) based on Substantial Evidence of Effectiveness derived from existing data from adequate and well controlled trials together with confirmatory evidence from more than 65,000 patients identified in the Real World Evidence dataset. A preliminary analysis of a 20,000 person subgroup of that dataset presented in the meeting suggested noninferiority and potentially superiority of intravenous (IV) ketamine compared to intranasal S-ketamine. A 400 person PCORI-funded randomized trial has previously documented non-inferiority of IV ketamine compared to ECT, with a dramatic safety advantage (0% vs. 30%) of IV ketamine vs. ECT in the incidence of short-term memory loss.

Based on the oral guidance received, NRx believes it has sufficient data to apply for a treatment indication of "Treatment-Resistant Depression (TRD) in the context of suicidality," rather than the narrower originally-sought indication of "Suicidal ideation in patients with depression." It is believed that more than 10 million Americans have TRD and the US Centers for Disease Control estimates that 3.6 million experience suicidal ideation each year.

Based on the guidance received, NRx anticipates applying for full New Drug Approval, rather than the originally anticipated Accelerated Approval pathway for the treatment of patients with suicidal depression. The Accelerated Approval pathway would have required confirmatory clinical trials within five years, whereas full approval requires no confirmatory trials.

At the meeting, FDA agreed to work collaboratively with NRx and Osmind in the coming weeks to agree on the statistical analysis protocol for the full 65,000 person dataset, to enable submission of the Real World Evidence to the NDA in compliance with recent FDA guidance. The Company anticipates that this will represent the first time Real World Evidence is incorporated in the review of a CNS drug under FDA's new guidance.

In its comments ahead of meeting, FDA advised NRx that no additional nonclinical data would be required for review of NRx's New Drug Application and that no bridging studies would be needed to support NRx's preservative-free formulation compared to the currently-approved preservative-containing formulation of ketamine. The Company anticipates submitting its application with stability data sufficient to support three years of room temperature shelf stability.

After its discussion of the Osmind database, FDA indicated a willingness to work with the NRx and Osmind in the coming weeks to approve an analysis protocol for submission of the Osmind Real World Data as confirmatory data in support of the existing clinical trials that will be submitted to document Substantial Evidence of Effectiveness consistent with the newly-released Real World Evidence guidance.

Although NRx had anticipated seeking only five years of Accelerated Approval with required confirmatory data, FDA indicated that the clinical endpoints proposed by the Company could be sufficient for full New Drug Approval upon successful review of the NDA. Moreover, based on the guidance received, the Company expects to expand the proposed indication of NRX-100 from just those patients with active suicidal ideation to the broader population of patients with treatment-resistant depression in the setting of suicidal ideation.

In addition to this planned New Drug Application for the innovative formulation of NRX-100 now targeting depression with suicidality, the FDA Office of Generic Drug Products has received the Company's filing of an Abbreviated New Drug Application for a generic version of preservative-free ketamine for use in anesthesia and pain control with a planned decision date in summer 2026.

"We deeply appreciate the FDA's meeting with us at the leadership level and guiding us to pursue a New Drug Application for NRX-100 for the benefit of the millions of Americans who tragically form a plan to end their lives each year," said Dr. Jonathan Javitt, founder, Chairman, and CEO of NRx pharmaceuticals. Based on the guidance received, we will be using the clinical trial data already in hand together with the proposed Real World Data to apply for approval of a lifesaving drug to meet the needs of Americans, particularly Veterans and First Responders."

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:

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