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): August 7, 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.

As previously disclosed, NRx Pharmaceuticals Inc. (the "Company") filed an Abbreviated New Drug Application ("ANDA") for preservative free ketamine in September 2025. The FDA advised the Company on July 30, 2026 of a final determination on first-round review that there were no major deficiencies related to the drug components of the product. The FDA did ask the company to update the label of the product to reflect a labeling change filed by the manufacturer of the Reference Listed Drug (Ketalar®) and identified a major deficiency related to the twist-off cap of the product's luer lock vial, where an FDA reviewer expressed concern that the vial tip had the potential to deform in clinical use. The FDA sought confirmation that this could not pose a risk to patient safety. The classification as major is required because the matter affects the container closure.

Management advised the FDA that the luer lock vial has been used in three previously-approved ANDA products and 11.9 million doses of those products have been shipped in the past 12 months without complaints, returns, or recalls. The ANDA contained testing information on 3,500 vials randomly selected from the first 7 manufacturing batches in which the proper function of the luer lock tip was assessed and no defects were observed in any tested vial. The Company additionally provided verification data from an independent reference laboratory documenting that the torque (measured in Newton-Centimeters) required to open the vial was within the design specifications of the product and the three currently-approved ANDA products.

The FDA granted the Company a clarification meeting that was held on August 6, 2026 to identify the exact information that the Company will be required to provide to address the FDA's concern about the proper function of the luer lock vial tip. The FDA requested that the company submit certifications from its manufacturer that the preservative-free ketamine ANDA product is manufactured on the same manufacturing lines with the same machinery, plastics, and other characteristics as the three approved ANDA products already in commercial distribution. This information was included in the ANDA as submitted and will now be supplied to the FDA as signed certifications from the Company's manufacturers.

Based on the meeting, the FDA committed to immediately reinitiate review of the ANDA in order to resolve this single identified major deficiency and committed to completing the review in the shortest-possible review cycle. The meeting was attended both by leadership of the Office of Generic Drugs and by Senior Leadership of the FDA Center for Drug Evaluation and Research (CDER). FDA recognized that ketamine is a strategic drug that appears on the current FDA drug shortage list.

NRx management views the completion of a first-round ANDA review with no drug-related major deficiencies as a positive outcome, given that only 14% - 18% of ANDAs are estimated to achieve approval on first-round review. Although no assurances can be given on regulatory determinations, management is optimistic that the identified concern related to packaging will be resolved in a timely manner, consistent with first commercial sales in 2026, given that FDA has recognized the current drug shortage and lack of U.S.-based supply of ketamine and has committed to completing the review in the shortest possible review time frame. HHS leadership has identified ketamine as a strategic drug, as have other agencies and departments of the Federal Government.

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.

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: August 7, 2026

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