NRx Pharmaceuticals (Nasdaq:NRXP) Reports First Quarter 2026 Financial Results and Provides Corporate Update

May 18, 2026

Key highlights from the first quarter of operations under the expanded management team include the following:

- Anticipated FDA decision on the Company's ANDA for Preservative-Free Ketamine in Q3 2026, with favorable preliminary determinations already received from the FDA Office of Generic Drugs on bioequivalence, labeling, drug product, drug substance, and safety.
- Initiation of commercial manufacturing of Ketamine at the 1 million dose per month level with recent FDA inspection of the manufacturing facility and granting of inspection status consistent with launch of an ANDA drug.
- Completed a Type C meeting with the FDA Division of Psychiatry Products and CDER leadership, in which the Agency expressed openness to existing clinical trial data and Real World Evidence supporting approval without additional trials.
- Presidential Executive Order signed and Congressional Appropriations Language filed encouraging the use of Real World Evidence in the approval of drugs for suicidal depression and PTSD.
- Appointment of Prof. Joshua Brown, MD, PhD (Harvard/McLean) as Chief Medical Innovation Officer, bringing NIH- and DARPA-funded expertise in D-cycloserine and TMS for depression, PTSD, and suicidality.
- FDA acceptance of an Investigational New Drug (IND) application for NRX-101 as an adjunct to robotic-enabled Transcranial Magnetic Stimulation (TMS), with anticipated non-dilutive federal funding supporting study at military and civilian sites.
- Development of a patentable, sustained-release formulation of D-cycloserine designed to enhance TMS efficacy, building on prior trial data showing a doubling of clinical response and 8-fold increase in remission versus standard TMS.
- First revenue generated from five interventional psychiatry clinics treating severe depression and PTSD, with funding from the VA, Department of War, private insurers, and self-pay; footprint expected to expand meaningfully in 2026.
- Pending acquisition of Geneuro, SA assets through a now complete Swiss court-supervised liquidation process, including a patent portfolio, antibodies, cell lines, and Phase 2 data targeting HERVs implicated in Schizophrenia, ALS, MS, Autism, and Type 1 Diabetes.

WILMINGTON, Del., May 18, 2026 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) (“NRx”, the “Company”, “we”, “us” or “our”) a clinical-stage biopharmaceutical company, today announced financial results for the quarter ended March 31, 2026, and provided a corporate update. The quarter was marked by continued progress advancing NRx’s drug candidates toward commercialization, further development of the HOPE Therapeutics subsidiary, FDA acceptance of an IND for a federally-supported trial of NRX-101 as an adjunct to robotic Transcranial Magnetic Stimulation (TMS), and the pending acquisition of a Phase 2 monoclonal antibody portfolio targeting Human Endogenous Retroviruses (HERVs) implicated in Schizophrenia, Amyotrophic Lateral Sclerosis (ALS), Multiple Sclerosis (MS), Autism, and Type 1 Diabetes.

“The first quarter of 2026 was a pivotal one for NRx, as we advanced two lifesaving drugs towards FDA approval with the aim of initiating commercial pharmaceutical operations by the end of this year. We started the year debt-free, and made targeted investments in several critical strategic operating initiatives that drove 1) substantial progress toward the approval of our first drug product, 2) initiated commercial manufacture in anticipation of drug launch, 3) advanced profitable clinic operations with an expanded footprint, 4) burgeoned our overall intellectual property portfolio, 5) augmented our development pipeline and 6) attracted fundamental long-term investors who believe in our mission,” said Dr. Jonathan Javitt, the Company’s CEO and Chairman. “We are deeply grateful for the trust that has been afforded to us by our patients, their families, and our shareholders.”

Key Research and Development and Corporate Activities

NRX-100 and KETAFREE™ (Preservative-Free Ketamine)

NRx advanced both regulatory pathways for its preservative-free ketamine programs during the quarter. The KETAFREE™ ANDA progressed through FDA Office of Generic Drugs review with no major deficiencies, and the FDA reclassified the manufacturing site to "VAI" status, enabling the Company to initiate commercial manufacturing at a one-million-unit-per-batch scale. FDA is endeavoring to complete the product review by Summer 2026. As of April 7, 2026, sterile intravenous ketamine remained listed on the American Society of Health-System Pharmacists (ASHP) national drug shortage database, with ongoing supply constraints reported across multiple manufacturers, underscoring the need for additional reliable, domestically manufactured ketamine supply. The NRX-100 NDA, expected to be filed in Q2 2026, will be supported by clinical trial evidence in more than 1,000 patients and

Real World Evidence on more than 65,000 U.S. patients through a partnership with Osmind, Inc. Following a Type C meeting, the FDA agreed to consider both data sources in its review. Management believes that the current generic ketamine market exceeds $750 million per year, while SPRAVATO® generates approximately $2 billion annually.

NRX-101 (D-cycloserine/lurasidone)

NRX-101 advanced on two tracks during the quarter. In its original indication of suicidal bipolar depression, the Company initiated an NDA filing with submission of the Module 3 manufacturing file and is requesting rolling review, building on Breakthrough Therapy Designation previously awarded by the FDA. Separately, the Company received FDA clearance to proceed with the MIND1 trial, a Phase 2b/3 study of NRX-101 versus placebo as an adjunct to robotic-assisted Transcranial Magnetic Stimulation in conjunction with an accelerated one-day TMS protocol (ONE-D). The trial is designed to enroll 400 participants across Military Treatment Facilities, HOPE Therapeutics clinics, and a prominent university teaching hospital, with non-dilutive U.S. Government funding anticipated. The Company also achieved non-clinical validation of a proprietary extended-release form of D-cycloserine designed to support TMS augmentation.

NRx Defense Systems, Inc.

To advance its military-focused neuroplastic therapy initiatives, the Company incorporated NRx Defense Systems, Inc. in April 2026 to support the MIND1 trial and broader development of military-grade TMS technology. The subsidiary is led by Dr. Dennis K. McBride, PhD (CAPT US Navy, Ret.), a former Program Manager at DARPA and senior executive at the National Defense University and Office of the Secretary of Defense, with development conducted in partnership with Zeta Surgical (Cambridge, MA).

HOPE Therapeutics, Inc.

HOPE Therapeutics, a majority-owned subsidiary, continued to scale its interventional psychiatry network during the quarter, operating five Florida clinics with eight or more locations anticipated by the end of Q2 2026. In February 2026, HOPE appointed Prof. Joshua Brown, MD, PhD, of Harvard/McLean as Chief Medical Innovation Officer, joining Rebecca Cohen, MD, as Medical Director. The subsidiary further expanded its footprint through partnerships with neurocare AG, focused on NRX-101 as a TMS-enhancing therapy, and EMOBOT, Inc., to deploy continuous patient monitoring across HOPE's clinical network.

Geneuro, Inc.

NRx broadened its therapeutic platform through the formation of Geneuro, Inc., a Florida-based subsidiary focused on the anticipated acquisition of a portfolio of assets targeting Human Endogenous Retroviruses (HERVs) implicated in Schizophrenia, Multiple Sclerosis, ALS, Autism, and Optic Neuritis. The portfolio was offered through a Swiss court-supervised liquidation sale process of Geneuro, SA, and the Company was recently notified that it had submitted the winning bid. The acquisition is expected to close during the second quarter of 2026 with cash in an existing, prefunded escrow account, and includes a broad patent portfolio, cell lines, antibodies, regulatory files, and data from three completed human clinical trials. Dr. Hervé Perron, PhD, formerly Chief Scientist of Geneuro, SA, has joined as Chief Scientist alongside Prof. Marion Leboyer, MD, PhD, who will lead the anti-HERV-W antibody program. The Company anticipates supporting Geneuro through non-dilutive investment channels.

Financial Results for the Quarter Ended March 31, 2026

For the three months ended March 31, 2026, NRx reported a net loss of $1.4 million, versus a net loss of $5.5 million during the comparable quarter in 2025. The change was primarily related to the impact of certain fair value accounting measurements and other non-recurring charges incurred during the three months ended March 31, 2025. For the three months ended March 31, 2026, NRx reported a net operating loss of $4.7 million versus a net operating loss of $3.8 million for the comparable quarter in 2025. The change was primarily driven by certain costs related to several targeted strategic initiatives advanced during the quarter ended March 31, 2026, which management believes will drive significant short and long-term value for shareholders including, but not limited to, progress toward the approval of our first drug product, aligning resources for an anticipated near-term commercial launch, augmenting and expanding profitable clinic operations, enhancing our overall intellectual property portfolio, and growing our development pipeline with new assets. As of March 31, 2026, the Company had approximately $6.7 million in cash and cash equivalents. Management believes current cash resources, anticipated growth in clinic revenue, ongoing cost reduction initiatives, and continued availability under the Company's active at-the-market offering will be sufficient to support operations through 2026. Subsequent to quarter-end, the Company generated approximately $7 million in gross proceeds from its at-the-market (ATM) facility through the sale of common stock. Detailed financials are available in the Company's Form 10-Q.

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.

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