



NRx Pharmaceuticals, Inc. (NASDAQ:NRXP) Reports Third Quarter 2025 Financial Results and Provides Corporate Update

November 17, 2025

- NRx has refiled its Abbreviated New Drug Application for KETAFREE™ (preservative free ketamine), received supportive correspondence from FDA, and expects Q2 2026 GDUFA date.
- HOPE Therapeutics is now operating three revenue-generating facilities in Florida and expects six or more by year-end providing neuroplastic drugs, transcranial magnetic stimulation, hyperbaric therapy, and digital therapeutics to treat suicidal depression and PTSD.
- NRx has secured operating capital anticipated to be sufficient for drug development operations through July 2026. The Company additionally expects to increase revenue from clinical operations.
- NRx received FDA grant of Fast Track Designation for NRX-100 in the treatment of suicidal ideation in patients with depression, including bipolar depression.
- New Real-World Data support the effect of D-cycloserine (NRX-101 active ingredient) in doubling the effectiveness of Transcranial Magnetic Stimulation (TMS). Company has expanded access program for NRX-101 in augmenting TMS in depression, suicidality, and PTSD.

WILMINGTON, Del., Nov. 17, 2025 (GLOBE NEWSWIRE) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals," the "Company"), a clinical-stage biopharmaceutical company, today announced financial results for the quarter ended September 30, 2025, and provided a corporate update.

"In 2025 we have advanced each of our corporate objectives and entered into revenue-generating activity for the first time. For NRX-100 in suicidal depression, we received an expanded Fast Track designation, opened an Expanded Access program and enhanced our regulatory package. Additionally, FDA granted our Suitability Petition for a single patient, preservative free ketamine strength and we have received validation that our ANDA filing is on track with no major deficiencies. In parallel, the Real World Data demonstrating a doubling of antidepressant and antisuicidal effect of Transcranial Magnetic Stimulation (TMS) when D-cycloserine is added creates a new and significant indication for NRX-101 that has potential for approval, if confirmed in an additional phase 3 trial. For HOPE, we continue to execute on building our delivery platform of three active facilities in Florida, with three more planned by year-end. Dr. Rebecca Cohen and LTC Charles Paul, RN (US Army, Ret.) are assembling a network of best-in-class interventional psychiatrists to meet the needs of people, including active duty military, first responders, and veterans, across Florida and beyond," said Jonathan Javitt, MD, MPH, Chairman and CEO of NRx Pharmaceuticals.

Key Research and Development and Corporate Activities

NRX-100 (intravenous ketamine)

NRx is pursuing two paths to market for NRX-100: a distinct innovative pathway via a New Drug Application (NDA) under FDA Fast Track designation to develop NRX-100 for suicidal ideation in depression, including bipolar depression, and a generic pathway via an Abbreviated New Drug Application (ANDA) to supply a preservative-free ketamine (KETAFREE™) into the existing ketamine market. Recent correspondence from the FDA suggests that the latter pathway is on track for a Q2 2026 GDUFA date. The current generic ketamine market is estimated at approximately \$750 million, as previously disclosed. By contrast, the innovative ketamine-based product SPRAVATO® is expected to generate over \$1.6 billion in 2025 sales, although its labeling states that effectiveness in preventing suicide or reducing suicidal ideation has not been demonstrated. This highlights a differentiated opportunity for NRX-100, specifically in suicidal ideation.

A New Drug Application ("NDA") for NRX-100 for suicidal depression, originally initiated during the fourth quarter of 2024, is expected to be completed in the fourth quarter 2025 with the addition of Real World Efficacy Data drawn from more than 60,000 patients treated for depression with intravenous ketamine compared to 6,000 patients treated with intranasal S-ketamine to be submitted as part of the NDA. An interim analysis drawn from the first 20,000 patients suggests that IV ketamine may have a more rapid onset of action and larger magnitude of effect than nasal S-ketamine. The Company has applied to receive a Commissioner's National Priority Voucher (CNPV), which could significantly reduce review time.

The Abbreviated New Drug Application ("ANDA") for NRX-100 was filed, with Priority Review requested, during the third quarter of 2025. After meeting with the FDA in August 2025, the Company re-filed the ANDA, following FDA notification of approval of a Suitability Petition for NRx's proposed strength of preservative-free ketamine, KETAFREE™. On November 6, 2025, the Company received a communication from FDA in which no significant deficiencies were identified in the revised filing. The Company has

additionally submitted a Citizen Petition seeking to have benzethonium chloride, a toxic preservative, removed from all commercial presentations of ketamine.

The Company has manufactured multiple commercial lots of NRX-100 and KETAFREE™ with ongoing stability data supporting a room temperature shelf life of three years.

NRX-101: Oral Treatment for Suicidal Bipolar Depression

Bipolar depression affects over seven million people in the US. Current treatment options carry the risk of suicide and akathisia, a side-effect of serotonin active antidepressants, which is closely related to suicide. People with bipolar depression and akathisia or suicidality are at imminent risk of self-harm. These patients need better treatment options urgently.

An NDA filing for NRX-101 has been initiated with the submission of the Module 3 manufacturing file to publishing. The drug was previously awarded Breakthrough Therapy Designation, and accordingly the Company is requesting rolling review of the NDA. Breakthrough Therapy Designation is granted by the FDA to facilitate the development and expedite the review of drugs to treat serious conditions meet an unmet medical need and have demonstrated preliminary evidence of efficacy, as determined by the FDA.

Recently published Real World Efficacy data provides confirmatory evidence from a prior randomized controlled trial that low-dose D-cycloserine (the active ingredient in NRX-101) more than doubles the anti-depressant and anti-suicidal effect of Transcranial Magnetic Stimulation. The company has more than 25,000 manufactured doses of NRX-101 at the appropriate strength on hand and has launched a nationwide expanded access program to enable physicians to access this medication at no charge to the patient under Expanded Access and Federal Right to Try laws. A confirmatory phase 3 trial of NRX-101 to augment the effects of TMS is planned for early 2026. The market estimate for this newly validated indication for NRX-101 is in excess of \$1 Billion.

HOPE Therapeutics: Interventional Psychiatry Clinic Network

HOPE Therapeutics, Inc., is a medical care delivery organization providing cutting-edge interventional psychiatric treatment of the above conditions with neuroplastic drugs, such as ketamine, Spravato and NRX-101, neuromodulatory devices, such as Transcranial Magnetic Stimulation (“TMS”), hyperbaric therapy, digital therapeutics, and medication management.

On September 8, 2025, HOPE initiated revenue-generation through its acquisition of Dura Medical, LLC (“Dura”) in Naples and Ft. Myers, Florida and subsequently added Cohen and Associates in Sarasota, FL to the HOPE Network. Dr. Rebecca Cohen has been appointed as HOPE’s Medical Director.

Last week, HOPE was the first organization in Florida to launch one day TMS treatment for severe depression with the ONE-D protocol using the Ampa TMS device. The ONE-D protocol has been reported in the peer-reviewed literature to achieve 87% response and 72% remission from severe depression at 6 weeks following a single day of TMS treatment, combined with D-cycloserine. HOPE is in the process of adding three more facilities in 2025 and is in active discussion with numerous acquisition opportunities around the country.

Financial Results for the Quarter Ended September 30, 2025

For the three months ended September 30, 2025, the Company reported a loss from operations of \$4.0 million versus a loss from operations of \$3.0 million for the comparable quarter in 2024. The difference was primarily attributable \$800,000 of additional research and development expense to support our FDA initiatives for NRX-100 and NRX-101, including the previously discussed ANDA submission for preservative-free IV ketamine; and, \$400,000 of additional general and administrative expense, which included our efforts to close, operate and identify clinic acquisition targets for HOPE. As of September 30, 2025, NRx Pharmaceuticals had approximately \$7.1 million in cash and cash equivalents. Including approximately \$3.1 million from a subscription receivable, for which the Company received the cash in early October, total cash as of September 30, 2025 would have been \$10.3 million. For the third quarter ended September 30, 2025, the Company reported revenue for the first time in its history driven by the acquisition of Dura Medical, which closed September 8, 2025. While revenue of approximately \$240,000 was relatively modest, it only reflects twenty-two days of the full quarter and a single clinic group. Management anticipates the ability to include results from the full period for Dura in future quarters; closing anticipated additional acquisitions; and organic growth of previously acquired clinics will drive meaningful revenue growth in the fourth quarter and through 2026. Transactions where we acquire a non-controlling interest are expected to improve our overall financial condition but not directly increase revenue. Finally, we remain in active discussions with several additional potential acquisition candidates, and while no assurances can be given that we will close any or all such opportunities, together they represent total revenue of more than \$20 million on an annual basis.

The Company believes that its current cash position will support operations at least through the second quarter of 2026, as well as provide sufficient capital to reach expected regulatory inflection points and complete potential additional select acquisition opportunities to expand the growing footprint of HOPE clinics.

Detailed financials can be found in our recent Form 10-Q filing, available on our website, at <https://ir.nrxpharma.com/sec-filings>.

Conference Call and Webcast Details

A live webcast of the conference call will be available on the Company's website at 8:30am ET today, at [NRx Events](#). An archive of the webcast will be available on the Company's website for 30 days. 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 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 re-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.

About HOPE Therapeutics, Inc.

HOPE Therapeutics, Inc. (www.hopetherapeutics.com), a subsidiary of NRx Pharmaceuticals, is a healthcare delivery company that is building a best-in-class network of interventional psychiatry clinics to offer ketamine and other neuroplastic medications, transcranial magnetic stimulation (TMS), Hyperbaric Oxygen Therapy, and other lifesaving therapies to patients with suicidal depression and related disorders, together with a digital therapeutic-enabled platform designed to augment and preserve the clinical benefit of NMDA-targeted drug therapy. HOPE is the first network in Florida to offer the AMPA One Day (ONE-D) treatment that combines TMS, physician-prescribed D-cycloserine, and lisdexamfetamine to achieve remission from treatment resistant 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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