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

August 18, 2025

NRx Drug Development

- *Grant of expanded Fast Track Designation for NRX-100 from the FDA for all indications and types of depression and related disorders based on its potential to satisfy an unmet medical need.*
- *Represents an approximately 10-fold expansion of the addressable market to 13 million Americans, compared to the original Fast Track Designation issued in 2017 for bipolar depression alone.*
- *The Designation letter contains a specific finding that NRX-100 addresses an "unmet medical need." This is a specific qualifying requirement for the Commissioner's National Priority Voucher Program.*
- *Filing of Commissioner's National Priority Voucher application for intravenous ketamine (NRX-100).*
- *Submission of draft labeling for NRX-100 in the treatment of suicidal depression based on the Fast Track Designation received.*
- *Filing of an Abbreviated New Drug Application (ANDA) for NRX-100 (preservative-free intravenous ketamine).*
- *Submission of stability data for NRX-100 to the manufacturing data on file with FDA sufficient to support three years of room temperature shelf stability for NRX-100.*
- *Completion of a toxicology assessment of Benzethonium Chloride[1], documenting its lack of "Generally Recognized as Safe" (GRAS) status and lack of safety data to support its use in intravenous presentations of ketamine.*
- *Filing of a Citizen's Petition with the U.S. Food and Drug Administration to seek the removal of benzethonium chloride, a toxic preservative, from all ketamine products for intravenous administration.*
- *Filing of a patent application for NRX-100, the Company's proprietary preservative-free formulation of intravenous ketamine.*
- *Receipt of a PDUFA filing fee waiver from the FDA for NRX-100.*
- *Filing of module 3 manufacturing data to support a New Drug Application for NRX-101 in the treatment of patients with suicidal bipolar depression and akathisia despite treatment with already-approved medication.*

HOPE Therapeutics

- *Execution of definitive Purchase Agreement and receipt of final regulatory clearance from Florida's Agency for Health Care Administration ("ACHA") to proceed with closing the acquisition of Dura Medical.*
- *Execution of binding letter of intent to acquire the assets of NeuroSpa TMS Holdings of Tampa, FL.*
- *Execution of a binding letter of intent to acquire a 49% interest in Cohen and Associates, LLC.*
- *Receipt of approval, pending legal stipulations, for $7.8 million of debt financing to support the acquisition of Dura Medical, NeuroSpa TMS Holdings, and Cohen and Associates, LLC.*
- *Execution of a definitive purchase agreement, subject to standard closing conditions and agreement between the parties regarding the resolution of ongoing discussions, to purchase the non-clinical assets of Kadima Neuropsychiatry Institute.*
- *Execution of a non-binding term sheet for a strategic investment from a global medical device manufacturer into HOPE.*

Corporate (subsequent to the filing of form 10-Q)

- *$6.5 million dollar investment to purchase approximately 3.9 million shares of common stock of NRx Pharmaceuticals on August 18, 2025, by a consortium of experienced biotechnology investors led by B Group Capital. The purchase is subject to a one-year lockup on trading, shorting, or otherwise hypothecating said securities. The investment has no warrants, repricing provisions, commissions, or other structure.*
- *The B Group Capital led consortium of ultra long-term healthcare specialist investors is highly strategic with extensive experience in complex clinical, regulatory, and commercial therapeutics but also direct ownership and management of multi-unit retail operations with potentially positive long-term implications for efforts to continue to scale and develop HOPE Therapeutics.*
- *A live webcast of the conference call will be available on the Company's website at 8:00 a.m. ET Wednesday August 20, 2025.*

WILMINGTON, Del., Aug. 18, 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 June 30, 2025, and provided a corporate update.

"NRx has made remarkable progress with all three of our lead programs in recent months. Additionally, as announced today, we have now attracted our first group of fundamental biotechnology investors who have joined us to partner in building a successful commercial enterprise and contributed sufficient capital to reach expected regulatory inflection points. The investor group has aligned its interests in the future growth of our enterprise by purchasing restricted common stock that is subject to a one-year lockup agreement and is devoid of warrants, repricing mechanisms, or other mechanisms that are likely to cause future dilution. Furthermore, the B Group Capital led consortium of investors is strategic as it relates to our efforts to scale-up and develop our HOPE Therapeutics business with the potential to bring future partnerships and operational infrastructure to more quickly realize the potential of our HOPE clinic strategy.

"Last week, we received a markedly expanded Fast Track designation from FDA that establishes the unmet medical need associated with using NRX-100 (preservative-free intravenous ketamine) to treat suicidal depression in more than 13 million Americans each year. Over the past quarter and in subsequent events, we filed an application under the Commissioner's National Priority Voucher Program (CNPV), filed a patent with the USPTO, filed an ANDA for existing indications, and a Citizen's Petition to remove Benzethonium Chloride from IV ketamine products. The Fast Track determination just received qualifies NRX-100 for the stated requirements of the CNPV. We have continued to advance NRX-101 (oral D-cycloserine/lurasidone), initiated filing of an NDA for Accelerated Approval in bipolar depression and akathisia, and advanced our development of the HOPE clinic network," said Jonathan Javitt, MD, MPH, Chairman and CEO of NRx Pharmaceuticals. "This continuing flow of accomplishments reflects our commitment to Bringing Hope to Life by delivering life-saving treatments to soldiers, first responders, veterans, and civilians in urgent need."

Key Research and Development and Corporate Activities

NRX-100

We have undertaken two paths to market for NRX-100: a generic-approval path under an Abbreviated New Drug Application (ANDA) to address the current generic market for ketamine, and an innovative drug path under a New Drug Application (NDA) to develop ketamine for use in treating suicidal depression. The ANDA market is estimated at $750 million today and we anticipate entering this market in early 2026. There is one innovative ketamine-based drug currently marketed for treatment of depression whose manufacturer recently reported $1.3 billion in 2024 sales. The label of that product specifies that it does not reduce suicidal ideation. Our objective is to achieve an accelerated approval of NRX-100 as the first drug to treat suicidal ideation in depression, including bipolar depression. Detailed information is in our 10-Q filing for the quarter ended June 30, 2025. With recent positive changes in the regulatory environment, we similarly anticipate entering the innovative market for ketamine in mid-2026.

Our proprietary, preservative free formulation is the subject of a US patent filing that has potential to confer orange-book exclusivity. In addition, we have filed a Citizen's Petition with FDA noting that the Benzethonium Chloride (BZT) preservative in all current commercial forms of ketamine is not Generally Recognized as Safe (GRAS) and has not been demonstrated to be safe in the context of this product. Historically, BZT was added to ketamine to enable multidose use and multi-patient use from a single vial. Those uses are no longer common in US healthcare facilities. We have performed an extensive review of the toxicology literature around BZT and determined that FDA no longer allows BZT to be used in hand cleansers and topical antiseptics. BZT is part of a class of quaternary amines that have been shown to be toxic to corneal and conjunctival cells. A related compound in this class, Benzalkonium Chloride, has been removed from many eyedrops because of this demonstrated toxicity. The toxicology review link suggests that while single dose administration of preserved ketamine is generally thought of as safe, the cumulative dose of BZT with repeated intravenous administration may approach a toxicologically-concerning exposure to this compound.

In general, we anticipate that a preservative-free form of ketamine will be welcomed by physicians and patients, which may enable NRX-100 to gain a larger share of the existing ketamine market than would be available to an undifferentiated product. However, should the Citizen's Petition be granted the share of the generic market captured by NRX-100 could be considerably higher.

Our path to New Drug Approval of Ketamine for treatment of depression was substantially augmented on August 8, 2025 by award of an expanded Fast Track Designation (FTD) to NRX-100 by the FDA Division of Psychiatry Products. This is a major expansion of the 2017 designation awarded to NRX-100 which was limited to the treatment of suicidal bipolar depression. Last week's designation for "treatment of suicidal ideation in depression, including bipolar depression," addresses the 13 million Americans that develop suicidal ideation each year, with 1.5 million attempting suicide and an American dying of suicide every 11 minutes.

FDA further augmented the potential path to market of NRX-100 by establishing the Commissioner's National Priority Voucher Program (CNPV). The key criteria are shown below, taken from the FDA website. To receive a CNPV, a product must meet at least one of the criteria below. Management believes that NRX-100 meets all five criteria.

- Addressing a U.S. public health crisis.
- Delivering more innovative cures for the American people.
- Addressing a large unmet medical need.
- Onshoring drug development and manufacturing to advance the health interests of Americans and strengthen U.S. supply chain resiliency.
- Increasing affordability.

Receipt of a CNPV would afford a substantially faster review time of 1-2 months vs. 10-12 months, enhance communication throughout the review process, and create potential for accelerated approval of NRX-100. CNPV requires that a Company's module 3 manufacturing data be on file, a requirement that was met in December 2024, with stability data updated in July 2025 to

support three years of room temperature shelf stability.

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.

During Q2 2025 and in subsequent events, management has focused on preparing the New Drug Application of NRX-101, submitting more than 80,000 pages of manufacturing, non-clinical, and clinical material in July 2025. Breakthrough Therapy Designation was awarded to NRX-101 by the FDA in 2018. Clinical progress related to NRX-101 is documented in recently filed reports with the Securities and Exchange Commission under Forms 10-K and 10-Q.

As noted previously, NRX-101 demonstrated a statistically-significant benefit in reduction of suicidality and reduction of akathisia in a randomized, well-controlled trial against lurasidone. These findings confirm the initial results reported in the Company's STABIL-B trial. The Company anticipates filing an NDA for Accelerated Approval of NRX-101 for treatment of "Suicidal Bipolar Depression in patients with Akathisia and Active Suicidal Ideation despite standard of care therapy." NRX-101 is the only oral medicine that has ever been demonstrated in two randomized trials to reduce active suicidality and akathisia, to the Company's knowledge. The Company is in active discussion with an academic medical center that has already demonstrated leadership in the successful phase 2 trial to conduct the confirmatory research required post Accelerated Approval under an already-funded national multicenter trial. The Company is currently applying for a PDUFA fee waiver for NRX-101 from FDA on the grounds of overwhelming public health need.

Recent evidence suggests that NRX-101 may confer a significant added advantage to the clinical results of Transcranial Magnetic Stimulation (TMS).[2] The Company is initiating an expanded-access protocol to make NRX-101 available for this application and is organizing a phase 2b/3 randomized clinical trial to confirm this finding. If NRX-101's synergistic effects in combination with TMS are confirmed, NRX-101 could be an excellent strategic fit with our HOPE clinic network and its patients and caregivers.

HOPE Therapeutics: Interventional Psychiatry Clinic Network
HOPE Therapeutics, a wholly owned subsidiary of NRx Pharmaceuticals, is creating a clinic network to develop and implement a new, enhanced clinical paradigm for the treatment of depression, PTSD, obsessive-compulsive disorder, and related CNS conditions.

HOPE is committed to delivering integrated, neuroplastic treatment to the millions of patients with suicidal depression, PTSD, and related CNS conditions – at the highest level of care, and with each of these services offered in the same location. We believe that mental health treatment has been fragmented for too long, and through its national network of interventional psychiatry clinics, HOPE aims to seamlessly deliver comprehensive care.

A major clinical paradigm shift is underway, whereby "neuroplastic therapies" – i.e. those that create new connections (synapses) between brain cells – are seen to markedly reduce symptoms of depression, PTSD, and suicidality. Sometimes these treatments are called psychedelic treatments because of their hallucinatory side effects. Neuroplastic therapies include NMDA-targeted drugs, such as NRX-100 and NRX-101, Transcranial Magnetic Stimulation ("TMS"), hyperbaric therapy, digital therapeutics, and some forms of psychotherapy. Properly deployed, these treatments can deliver remission from depression and suicidality within hours and be maintained over the long term.

The Company has announced initial clinic acquisitions as detailed in the 10-Q and additional public filings. These initial acquisitions are moving toward closing in the near term, subject to certain closing conditions and finalizing financing. Together, these clinics are expected to be accretive to HOPE revenues and EBITDA in 2025, with potential forward pro forma revenues of more than ~$15 million.

The Company is also in negotiation to acquire and/or partner with a number of facilities in Florida, the Mid-Atlantic and Midwest, aiming for $100 million in total, forward pro-forma revenue by year-end 2025. Each of the clinical centers being incorporated has already demonstrated profitability that the Company believes can expand through the addition of a broader array of comprehensive services and operational efficiencies. Management estimates that the acquisition of a portion of these clinic networks will allow the Company to meet its 2025 growth targets.

Financial Results for the Quarter Ended June 30, 2025
For the three months ended June 30, 2025, the Company reported a net loss of $17.6 million versus a net loss of $7.9 million for the comparable quarter in 2024. The change was primarily attributable to fair value accounting measurements, which are non-cash. For the three months ended June 30, 2025, the Company reported a loss from operations of $3.7 million versus a loss from operations of $7.1 million for the comparable quarter in 2024. As of June 30, 2025, NRx Pharmaceuticals had approximately $2.9 million in cash and cash equivalents.

The Company believes that its current cash position will support operations into 2026 and provide sufficient capital to reach expected regulatory inflection points.

Conference Call and Webcast Details

A live webcast of the conference call will be available on the Company's website at 8:00 a.m. ET Wednesday August 20, 2025,

at https://ir.nrxpharma.com/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 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; the company recently filed module 3 manufacturing data to support the New Drug Application for NRX-101.

NRx has recently filed an Abbreviated New Drug Application (ANDA) and initiated a New Drug Application filing for NRX-100 (IV ketamine) with an application for the Commissioner's National Priority Voucher Program for the treatment of suicidal depression. The filing is based on results of well-controlled clinical trials conducted under the auspices of the US National Institutes of Health and the Government of France, licensed under a data sharing agreement.

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, transcranial magnetics stimulation (TMS), 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.

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
Co-CEO, Hope Therapeutics, Inc.
Chief Business Officer, NRx Pharmaceuticals, Inc.
mduffy@nrxpharma.com

Brian Korb
Managing Partner, astr partners
(917) 653-5122
brian.korb@astrpartners.com

---

[1] Sapko, M. T., Panicucci, R., & Javitt, J. (2025). Toxicological Evaluation of Benzethonium Chloride in Ketamine Formulations. Zenodo. https://doi.org/10.5281/zenodo.16883346

[2] Cole J, et.al. Efficacy of Adjunctive D-Cycloserine to Intermittent Theta-Burst Stimulation for Major Depressive Disorder: A Randomized Clinical Trial. JAMA Psychiatry. 2022;79(12):1153–1161. doi:10.1001/jamapsychiatry.2022.3255