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

May 15, 2025

- Company has continued to advance its previously announced plan to obtain FDA approval for two new drugs and to develop a network of clinics focused on neuroplastic therapies to treat severe and suicidal depression, PTSD, and related conditions. Clinic acquisition financing is at the HOPE Therapeutics level and non-dilutive to NRXP shareholders
- In January 2025 completed the third tranche of a convertible note offering and registered direct equity offering to an institutional investor on favorable terms to the Company; expected to provide sufficient cash to support operations through the end of 2025. Deployed capital to meet the objectives listed below
- NRX-100 (preservative-free IV ketamine) planned to complete New Drug Application (NDA) filing in Q2 2025, with expected 2025 PDUFA date; $4.3 million NDA submission fee waived by FDA
- U.S. patent application for NRX-100 filed in May, potentially providing exclusivity to 2045 as the only preservative free ketamine formulation available in the US
- NRX-101 remains on track for NDA submission under Accelerated Approval, with anticipated PDUFA date in 2025; manufacturing stability data, toxicity package and clinical data support regulatory readiness
- HOPE Therapeutics advances clinic network with the planned acquisition, under definitive agreements or binding LOI, of Kadima Neuroscience Institute, Dura Medical, and Neurospa TMS Holdings; clinics expected to represent approximately $15 million in forward looking, pro-forma revenues
- HOPE has also identified and entered into negotiations with four additional clinical entities (not yet publicly identified) estimated to represent ~$20 million in potential pro-forma revenue
- In partnership with BTIG, implemented a broad rollup acquisition initiative. BTIG is a leading global financial services firm specializing in investment banking, institutional trading, research, and related brokerage services for strategic growth opportunities
- HOPE executed a term sheet for debt financing to support acquisition of HOPE Therapeutics clinics and term sheet for a strategic investment, totaling $10.3 million in acquisition capital

WILMINGTON, Del., May 15, 2025 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced financial results for the quarter ended March 31, 2025, and provided a corporate update.

"NRx's 2024 momentum has continued into 2025, as we have advanced regulatory filings for NRX-100 and NRX-101 and advanced the Company's commercial opportunity with potential new IP protection for NRX-100, now added to the Company's already robust NMDA IP portfolio. We also took meaningful steps toward realizing our vision for HOPE Therapeutics as a national

network of interventional psychiatry clinics—beginning with the announcements on the planned acquisition of Kadima, Dura Medical, and Neurospa TMS," said Jonathan Javitt, MD, MPH, Chairman and CEO of NRx Pharmaceuticals. "These accomplishments reflect our team's dedication to advancing mental health innovation and delivering life-saving treatments to patients in urgent need."

Key Research and Development and Corporate Activities

NRX-100: Preservative-Free Ketamine for Suicidal Depression
According to the CDC, more than 13 million adults seriously consider suicide each year; NRX-100 – IV ketamine for Suicidal Depression – is designed to help address this national crisis.

The Company has now completed stability and sterility assays sufficient to document three years of room temperature shelf stability (the maximum allowed by FDA) and remains on track to complete the New Drug Application (NDA) for NRX-100 (preservative-free IV ketamine) for suicidal depression, with an expected PDUFA date in 2025.

The Company also plans to file an Abbreviated New Drug Application (aNDA) for existing ketamine indications in Q2 2025, based on the Company's belief that preservative-free injectable medications will be preferred by physicians, patients, and regulators.

In April 2025, the Company received a filing fee waiver from the U.S. Food and Drug Administration (FDA), exempting NRx from the $4.3 million NDA submission fee under the Prescription Drug User Fee Act (PDUFA), based on both public health benefit and small business status. NRX-100 has received Fast Track Designation as part of a protocol with NRX-101 and is being developed as a first-in-class, FDA-approved treatment for suicidal depression.

The Company initiated development of a plan to file a citizen's petition with the FDA to remove benzethonium chloride, a known neurotoxic and cytotoxic substance from presentations of ketamine intended for intravenous use. Management believes that the preservative-free feature of NRX-100 will be deemed of benefit to patients because of the known toxicity of benzalconium chloride in current drug products.

On May 5, 2025, the Company announced the filing of a U.S. patent application for its proprietary preservative-free ketamine formulation, NRX-100. The patent is based on the Company's demonstration of solubility, stability, and sterility with a preservative-free formulation in the setting of prior art suggesting that preservatives were required to maintain stability and sterility. If granted, the patent could provide protection through 2045 and create a differentiated product profile as the only such formulation developed specifically for patients with depression.

As a next-generation product, the Company has developed a novel, patentable pH neutral formulation of ketamine (designed as HTX-100) based on a proprietary excipient that overcomes ketamine's current dependance on acid formulations. HTX-100 is expected to be suitable for both intravenous and subcutaneous administration. Initial laboratory lots demonstrate shelf stability and ongoing stability is being assessed. This product is expected to undergo clinical testing in 2025/2026 and be ready for FDA approval in late 2026. Ketamine in its current commercial presentations cannot be administered subcutaneously because of its high acidic (pH 3.5-4.0) properties, an acidity range that is known to cause pain and skin ulcers. A ketamine formulation capable of achieving clinical benefit via subcutaneous use – in the manner that diabetes drugs are currently administered – could facilitate far broader clinical use of ketamine to treat life-threatening CNS diseases.

NRX-100 is poised to address the >$3 billion Suicidal Depression market in the US.

NRX-101: Oral Treatment for Suicidal Bipolar Depression
Bipolar depression affects approximately 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.

NRX-101 continues to progress toward NDA filing for Accelerated Approval in patients with bipolar depression and suicidality or akathisia. The filing is expected to be based on based on the strong efficacy and safety profile demonstrated in its Phase 2b/3 and STABIL-B trials. NRX-101 has previously been granted Breakthrough Therapy Designation, and three manufacturing lots have been completed, with stability data supporting a shelf life of over two years at room temperature. The Company anticipates a PDUFA date before year-end 2025.

The Company estimates that the market for the initial indication is over $2 billion, while the broad bipolar market could exceed $5 billion.

HOPE Therapeutics: Interventional Psychiatry Clinic Network Expansion
HOPE Therapeutics, a wholly owned subsidiary of NRx Pharmaceuticals, is developing a new clinical paradigm for the treatment of depression, PTSD, obsessive-compulsive disorder, and related CNS conditions. 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. HOPE is focused on delivering integrated, neuroplastic treatment to the millions of patients with suicidal depression, PTSD, and related

CNS conditions through a national network of interventional psychiatry clinics.

The Company has announced Kadima Neuropsychiatry Institute (CA), Dura Medical (FL) and Neurospa TMS Holdings (FL) as HOPE's initial clinic acquisitions. These initial acquisitions, with purchase agreements executed for Kadima and Dura and a binding Letter of Intent for NeuroSpa, 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 approximately ~$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.

Financings
In January 2025, the Company raised a total of $8.9 million in gross proceeds from Anson Funds, composed of both 1) a $5.4 million convertible debt offering and 2) $3.5 million above-the-market registered direct equity and warrant offering. The proceeds strengthened the Company's balance sheet and support both near-term regulatory and operational priorities, including the advancement of NRX-100 and NRX-101.

Subsequent to the end of Q1, the Company has signed financing agreements for a total of $10.3 in acquisition capital that is non-dilutive to NRx shareholders. In April 2025, the Company announced the signing of a term sheet for a $2.5 million strategic investment to support HOPE clinic acquisitions. The transaction, which contemplates a $50 million pre-money valuation, is expected to close in conjunction with upcoming HOPE acquisitions and provides for potential board representation within the subsidiary.

Today, the Company announced signing of a term sheet with Universal Capital, LLC for a $7.8 million debt facility to fund HOPE Therapeutics already announced acquisitions, with future funding planned as additional clinics join the HOPE network. The term sheet anticipates closing of the first financing tranche by June 19, 2025.

Financial Results for the Quarter Ended March 31, 2025
For the three months ended March 31, 2025, the Company reported a net loss of $5.5 million versus a net loss of $6.5 million for the comparable quarter in 2024, and a loss from operations of $3.8 million versus a loss from operations of $6.0 million for the comparable quarter in 2024. Research and development and general and administrative expenses were $0.8 million and $2.9 million as compared to $1.7 million and $4.3 million for the comparable quarter ended March 31, 2024, respectively. As of March 31, 2025, NRx Pharmaceuticals had approximately $5.5 million in cash and cash equivalents.

The Company believes that its current capital position, combined with ongoing financing discussions and partnerships, will support operations through at least the end of 2025.

Conference Call and Webcast Details

A live webcast of the conference call will be available on the Company's website at 4:30 p.m. ET Thursday May 15, 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 bipolar depression, chronic pain, and PTSD. The Company is developing NRX-101, an FDA-designated investigational Breakthrough Therapy for suicidal treatment-resistant bipolar depression and chronic pain. NRx plans to file an NDA for Accelerated Approval for NRX-101 in patients with bipolar depression and suicidality or akathisia. NRX-101 additionally has potential as a treatment for complicated UTI.

NRx has recently initiated a New Drug Application filing for NRX-100 (IV ketamine) for the treatment of suicidal depression, based on results of well-controlled clinical trials conducted under the auspices of the US National Institutes of Health and newly obtained data from French health authorities, licensed under a data sharing agreement. NRx was awarded Fast Track Designation for development of ketamine (NRX-100) by the US FDA as part of a protocol to treat patients with acute suicidality.

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. These statements include,

among others, statements regarding the satisfaction of closing conditions necessary to consummate the acquisition of Kadima, Neurospa and Dura, and obtaining financing necessary to consummate the acquisitions. 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. 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, uncertainties and assumptions relating to the Company's operations, results of operations, growth strategy, liquidity, Hope Therapeutic's ability to consummate the acquisitions of providers for its national network, the Company's ability to raise adequate capital to fund such acquisitions, and the Company's ability to spin-off Hope Therapeutics. 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	***Brian Korb***
Co-CEO, Hope Therapeutics, Inc.	Managing Partner, astr partners
Chief Business Officer, NRx Pharmaceuticals, Inc.	(917) 653-5122
mduffy@nrxpharma.com	brian.korb@astrpartners.com

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