NRx Pharmaceuticals, Inc. (NASDAQ:NRXP) Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Corporate Update

March 17, 2025

- Initiated filing of a New Drug Application ("NDA") to the FDA for NRX-100 (IV Ketamine) for the treatment of Suicidal Depression; planned filing of an NDA for Accelerated Approval under Breakthrough Designation and Priority Review of NRX-101 for the treatment of bipolar depression in people at risk of akathisia. Both have anticipated PDUFA dates prior to December 31, 2025
- The Company has accepted non-binding potential terms from a commercial pharmaceutical company to license and distribute NRX-100, providing over $300 million in milestones plus tiered double-digit royalties based on net sales
- Retained a leading regulatory law firm to file a citizen's petition with the US Food and Drug Administration ("FDA") to remove benzethonium chloride – a toxic preservative -- from presentations of ketamine intended for intravenous use; planned 2Q25 filing of an Abbreviated New Drug Application ("ANDA") for the use of preservative-free ketamine in all current indications
- HOPE Therapeutics, a wholly owned subsidiary of NRx, signed non-binding letters of intent to acquire three precision psychiatry centers and is currently completing financial due diligence and definitive agreements. Currently negotiating the terms for the acquisition of six additional centers
- The HOPE acquisitions are planned to form the foundation for a national network offering interventional psychiatry services to treat suicidal depression, post-traumatic stress disorder ("PTSD") and related conditions
- Received and negotiating a term sheet from a publicly-traded strategic investor currently engaged in manufacturing Transcranial Magnetic Stimulation ("TMS") devices to provide capital in support of expansion of further HOPE clinic acquisitions.
- Engaged BTIG as financial advisor for clinic acquisition and capital formation; leading global financial services firm specializing in investment banking, institutional trading, research, and related brokerage services for strategic growth opportunities
- Regained compliance with the NASDAQ market value of listed securities ("MVLS") requirement
- Substantially reduced operating costs compared to prior year
- Management continues to forecast, although no assurances can be given, profitability on a forward-looking run-rate basis by year end 2025

WILMINGTON, Del., March 17, 2025 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced its financial results for the quarter and year ended December 31, 2024, and provided a business update.

"Our work in the fourth quarter of 2024 and into 2025 has driven significant advances for our company and investors. We have retired debt that was impeding the launch of HOPE Therapeutics and brought new investors into the Company who are aligned with our objectives. We launched the filing of a New Drug Application for NRX-100 for the treatment of Suicidal Depression: a major milestone for NRx. We also moved NRX-101 toward it's NDA for Accelerated Approval in bipolar depression in patients at risk of akathisia, and made meaningful progress building HOPE's best-in-class network of Interventional Psychiatry Clinics. Additionally, two potential strategic transactions that are under negotiation could further accelerate our progress. These accomplishments advance our mission of preventing and treating suicide: work that is critical to our patients, their families and our country," said Jonathan Javitt, MD, MPH, Chairman, and CEO of NRx Pharmaceuticals. "I would like to thank our team for its dedication and hard work, and thank our shareholders for their ongoing support of our mission to bring hope to life."

Key Research and Development and Corporate Activities

NRX-100 (IV, preservative-free ketamine)
According to the CDC, more than 13 million adults contemplate suicide each year; NRX-100 – IV ketamine for Suicidal Depression - can help address this national crisis.

The Company filed Module 3 (manufacturing) of its New Drug Application ("NDA") for NRX-100 (preservative-free sterile IV ketamine) in a tamper-resistant, diversion resistant packaging presentation in the fourth quarter of 2024. NRX-100 was previously granted Fast Track Designation by FDA in combination with use of NRX-101. Ketamine efficacy data from four clinical trials are intended to support the filing. Three manufacturing lots are now complete, with filed stability data suitable for shelf life exceeding two years at room temperature. The anticipated PDUFA date for this NDA is prior to December 31, 2025.

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

The Company has accepted non-binding potential terms from a commercial pharmaceutical company to license and distribute

NRX-100 (preservative-free IV ketamine) that provides for over $300 million in potential milestones plus a tiered double-digit royalty, subject to further due diligence and finalized agreement.

In December 2024 the company demonstrated long term stability and sterility of a patentable formulation of preservative-free ketamine, despite longstanding commercial practice of adding benzethonium chloride as a preservative to commercially supplied ketamine. This preservative is a known caustic and toxic substance that has previously demonstrated corneal neurotoxicity and conjunctival toxicity in patients, and generalized neurotoxicity in the laboratory at microgram concentrations. The concentration in current ketamine preparations is substantially higher, with an extensive body of scientific literature documenting concern. Additionally, chronic administration of ketamine is known to increase the risk of cystitis (Ref); the relationship of this adverse event to benzethonium chloride is unknown. Now that a long-term stable and sterile preservative-free formulation is available, the Company is filing a citizens petition to seek removal of benzethonium chloride from the human and veterinary ketamine drug supply.

The Company believes that the preservative-free feature of NRX-100 will be deemed of benefit to patients and is consistent with evolving federal policy on toxic preservatives in the US food and drug supply chain. Therefore, in addition to the NDA designed to add treatment of depression to the current ketamine label, the Company plans to file an Abbreviated New Drug Application ("ANDA") in the second quarter of 2025 for the use of preservative-free ketamine in all currently indicated human and veterinary applications. The Company believes it has met all requirements of the ANDA approval process, has demonstrated manufacturing capacity in excess of one million vials per month, and is prepared to supply the broad ketamine market.

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 insolubility, that will be suitable for both intravenous and subcutaneous administration. Initial laboratory lots demonstrate shelf stability and ongoing stability is being assessed. 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. This product is expected to undergo clinical testing in 2025/2026 and be ready for FDA approval in late 2026. Oral forms of ketamine and intranasal racemic ketamine have failed to demonstrate sufficiently stable blood levels to replace intravenous ketamine. However, 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.

The Company has retained a leading regulatory law firm to file the citizen's petition with the US Food and Drug Administration to remove benzethonium chloride, a known neurotoxic substance, from presentations of ketamine intended for intravenous use. The Company believes that the preservative-free feature of NRX-100 will be deemed of benefit to patients because of the known toxicity of benzethonium chloride in current generic products.

NRX-101 (oral D-cycloserine/lurasidone)
Bipolar depression affects approximately seven million people in the US. Current treatment options all 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.

The Company announced its intention to file an NDA for Accelerated Approval under Breakthrough Designation and Priority Review of NRX-101 for the treatment of bipolar depression in people at risk of akathisia, based on the Phase 2b/3 and STABIL-B data. Three manufacturing lots are now complete with more than 12 months of room temperature shelf-stability. The anticipated PDUFA date for this application is prior to December 31, 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
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. While there is clinical evidence that NMDA-targeted drugs such as NRX-100 and NRX-101 have the potential to offer clinical benefit, many patients additionally require neuromodulatory techniques, such as Transcranial Magnetic Stimulation ("TMS"), digital therapeutics, traditional psychotherapy and medication management to achieve long-term remission from suicidal depression and PTSD. Despite the proliferation of "ketamine clinics" in the US, few psychiatrist-led entities are successful in offering a comprehensive solution to patients and families.

During the second half of 2024, the Company began outlining the plan for HOPE Therapeutics as a national and ultimately international network of Interventional Psychiatry centers that will combine NMDA-targeted and future psychedelic drugs with neuroplastic treatments in an integrated and reproducible manner. The business model for HOPE Therapeutics is similar to that of leading national dialysis providers, companies that were instrumental in making kidney dialysis reliable and reproducible in a manner that transformed the industry and routinely trade at double digit P/E multiples.

In 2024, the Company announced a non-binding Letter of Intent to acquire Kadima, LLC, a pioneering interventional psychiatry clinic in La Jolla, CA. Kadima's founder, Dr. David Feifel agreed to serve as HOPE's Chief Medical Innovation Officer post-acquisition. He is one of the first academic psychiatrists to move ketamine and TMS therapy to the community care model and was recently featured on Dr. Sanjay Gupta's broadcast entitled "The Wild West of Ketamine Treatment" as an advocate for how ketamine therapy can be delivered reliably and responsibly. Link: *Wild West of Ketamine*.

Subsequent to the Kadima commitment, the Company has, or anticipates, contracting to acquire and/or partner with eight facilities in Florida, aiming for 15-20 facilities in Florida by year-end 2025.

The clinical centers that are being incorporated in the 2025 acquisition program are currently operating and profitable centers that the Company believes can experience substantial revenue growth through the addition of a broader array of comprehensive services. Management estimates that the acquisition of 20 clinic networks, each with current revenue of approximately $5 million will be required to meet its 2025 growth target.

Financings

The Company has consummated a series of financing agreements with an institutional investor for up to $16.3 million in debt capital, for which we closed on $10.9 million in 2024 and subsequently closed $8.5 million in a combination of convertible debt and an above-market common stock and warrant offering in January 2025. Subsequently, we terminated a planned $2 million investment from a smaller fund with less favorable terms.

The Company has also received and is currently negotiating a term sheet with a publicly-traded entity engaged in the manufacture of FDA-cleared devices for Transcranial Magnetic Stimulation to provide acquisition capital to support the expansion of HOPE Therapeutics clinics. In addition, it is negotiating with several commercial lenders to support expansion of HOPE clinics with standard commercial loans. Although business plans are subject to change, assuming consummation of the financings on terms currently contemplated by management, the Company would achieve its objective of financing less than 50% of the proposed acquisition costs, thereby enabling the Company to optimize its cost of acquisition capital as it expands the HOPE clinic network.

Our current financing activities are intended to supplant the previously announced equity investment in HOPE on more favorable terms.

Financial Results for the Quarter and Year Ended December 31, 2024

For the three months ended December 31, 2024, NRx Pharmaceuticals reduced its loss from operations by approximately $2.0 million to $2.4 million from $4.4 million in the fourth quarter of 2023, representing nearly a 45% improvement quarter over quarter primarily driven by lower research and development costs and a settlement gain, which were partially offset by an increase in general and administrative expense. For the three months ended December 31, 2024, research and development expense decreased by approximately $1.5 million to $1.0 million as compared to $2.5 million during the fourth quarter ended December 31, 2023. The $1.5 million decrease is primarily related to a decrease in clinical trial and development expense due to the conclusion of the phase 2b/3 study for NRX-101. Finally, general and administrative expense for the three month period ended December 31, 2024 increased by approximately $0.7 million to $2.6 million as compared to approximately $1.9 million for the three month period ended December 31, 2023, which was primarily driven by higher consulting fees related to the potential acquisition of several psychiatry clinics in support of the growth model for HOPE Therapeutics.

For the year ended December 31, 2024, NRx Pharmaceuticals reduced its loss from operations by approximately $9.3 million, or 33.5%, to $18.5 million from $27.8 million for the year ended December 31, 2023, which was primarily driven by a decrease in research and development expense. For the year ended December 31, 2024, research and development expense decreased by approximately $7.2 million, or 53.6%, to $6.2 million as compared to $13.4 million for the year ended December 31, 2023 primarily driven by a decrease in clinical trial and development expense due to the conclusion of the phase 2b/3 study for NRX-101. Finally, general and administrative expense for the year ended December 31, 2024 decreased by approximately $0.7 million to $13.5 million as compared to $14.2 million for the year ended December 31, 2023 primarily driven by a reduction in insurance and employee costs, and partially offset by an increase in consulting fees related to the potential acquisition of several psychiatry clinics in support of the growth model for HOPE Therapeutics.

As of December 31, 2024, we had approximately $1.4 million in cash and cash equivalents. As noted above, in January 2025, the Company completed two financings with aggregate gross proceeds of approximately $8.5 million. Management believes that current available cash resources will be sufficient to support ongoing operations through at least the end of 2025.

NRx continues to implement operational efficiencies to extend cash runway and maintain focus on our path to generating revenue and value for our shareholders.

Please see detailed financials on our Form 10-K, filed with the SEC and available on our website.

Conference Call and Webcast Details

A live webcast of the conference call will be available on the Company's website at 8:30 a.m. ET Monday March 17, 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

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 to act as a non-opioid treatment for chronic pain, as well 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) is a development stage healthcare delivery company that intends to develop 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. 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 risks arising from 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.

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