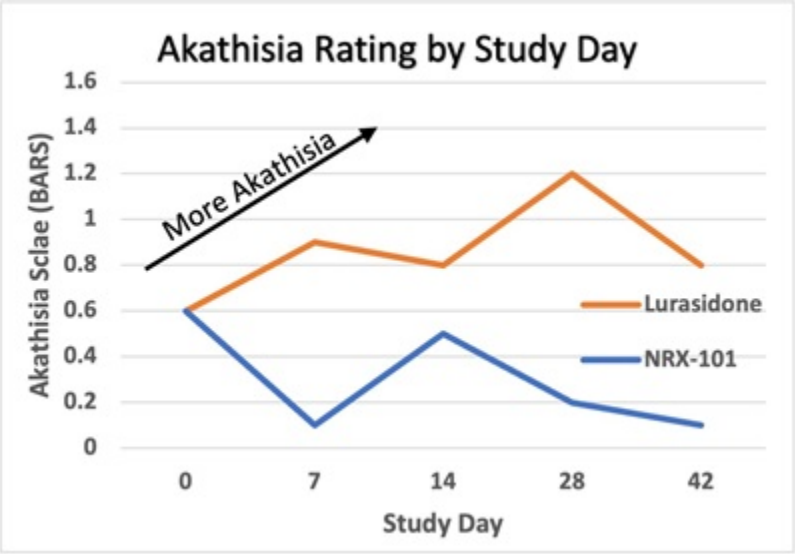
NRx Pharmaceuticals (NASDAQ:NRXP) Reports Third Quarter and Year to Date 2024 Financial Results and Provides Business Update

November 14, 2024

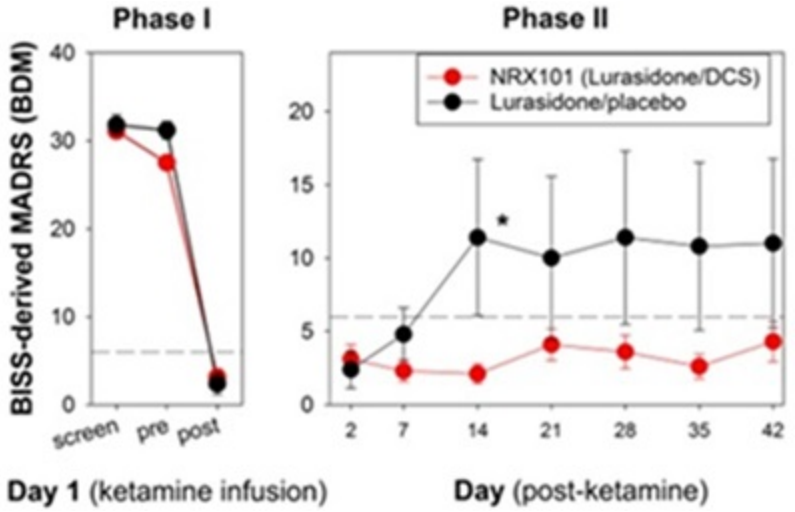
- ***On track to file New Drug Applications (NDAs) for NRX-100 (IV Ketamine) in treating suicidal ideation in depression, including bipolar depression and NRX-101 (Oral D-Cycloserine/Lurasidone) for Accelerated Approval in bipolar depression with suicidality or akathisia by year end 2024 with 2025 PDUFA date forecast.***
- ***HOPE Therapeutics acquiring Interventional Psychiatry Clinics; key to developing a best-in-class network of care to prevent suicide, continues to expect first revenue by year-end 2024.***
- **74% reduction in net operating losses compared to 3rd quarter 2023 with profitability forecast in 2025 from HOPE Therapeutics and from sales of medication.**
- ***Management to host a conference call November 18, 2024 at 4:30 PM ET***

WILMINGTON, Del., Nov. 14, 2024 /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 to date ended September 30, 2024 and provided a business update.

Key Clinical and Business Activities



- **NRX-100** (IV Ketamine) safety and efficacy data have been aggregated from clinical trials in more than 500 patients in collaboration with leading US and French Universities that demonstrate a highly significant reduction in suicidal ideation compared to placebo and active comparator. IV ketamine has been shown to be superior (in post-hoc analysis) to electroshock therapy in treating depression. Stability data has now been generated for three manufacturing lots required for NDA filing in suicidal depression, toxicology data are complete, and alignment with the FDA on its Pediatric Study Plan has been received. If approved, NRX-100 would be the world's first medicine to treat acute suicidality, a condition that kills 1 American every 11 minutes, according to the US Centers for Disease Control.



- **NRX-101** NDA for accelerated approval in bipolar depression with suicidality or akathisia advancing, based on data from the Phase 2b/3 trial in suicidal patients with bipolar depression, which demonstrated depression efficacy comparable to standard of care and significant reduction of akathisia (P=0.025) and time to sustained remission from suicidality (P=.05). These data, along with data from our STABIL-B trial, support a possible best-in-class suicidal bipolar depression medication profile. This is a multi-billion-dollar market in the US.

Efficacy Measures: Repeated Measures Mixed Model LS Mean Differences								
	Through Day 28				Through Day 42			
	LOCF No		LOCF yes		LOCF No		LOCF yes	
MADRS Depression	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean Δ	p-value
Score	-4.0	0.09	-7.7	0.03	-3.7	0.04	-7.7	0.04
Suicidality Rating	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean Δ	p-value
Scale C-SSRS	-0.5	NS	-1.3	0.04	-0.6	NS	-1.5	0.02
Clinical Global	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean Δ	p-value
Impression CGI-SS	-0.4	NS	-2.9	0.05	-0.6	NS	-2.9	0.02

- **HOPE Therapeutics**, the Company's wholly owned subsidiary, announced signing of two Letters of Intent (LOI) to acquire foundational Interventional Psychiatric Clinics, a key to developing a best-in-class network of clinics that offer a complete range of lifesaving therapies to patients with suicidal depression and PTSD. These are revenue generating, EBITDA positive acquisitions.

- Secured $10.8 million in convertible-debt funding from an institutional investor; funds targeted to support FDA New Drug Applications for NRX-100 (ketamine) and NRX-101 and retirement of prior debt. Funding at a reduced in interest rate, conversion discount, and other financial terms compared to prior debt.

- Retired Streeterville debt and settlement of litigation at a substantial discount.

Key Upcoming 2024 Milestones

- **NRX-100** New Drug Application (NDA) filing for treatment of suicidal ideation in depression, including bipolar depression, based on data from four clinical trials in more than 500 participants demonstrating highly significant efficacy compared to placebo and active comparator, together with a 420-person non-inferiority trial compared to electroshock therapy planned to be filed in 2024.

- Company plans to file a New Drug Application (NDA) for Accelerated Approval under Breakthrough Therapy Designation and Priority Review of **NRX-101** (D-cycloserine+lurasidone) in treatment of bipolar depression in people akathisia or suicidality, based on the Phase 2b/3 and STABIL-B data in 2024. Akathisia is considered a lethal condition and there is no approved product for this indication.

- **HOPE** Therapeutics continuing to build its nationwide network of Interventional Psychiatry Clinics; the company is planned to be spun out as a separate entity to be owned by NRx, current NRx shareholders, and new investors.

- **NRx continues to forecast first corporate revenues by year-end 2024 with profitability forecast in 2025.**

"Our work in recent months has set the stage for major advances in our business. Moving forward on new drug applications for NRX-100 and NRX-101, along with building HOPE's best-in-class network of Interventional Psychiatry Clinics, significantly advances our mission of preventing and treating suicide. This is vital for patients, their families and our country," said Jonathan Javitt, MD, MPH, Chairman, CEO and Chief Scientist of NRx Pharmaceuticals. "I would like to commend our team on its hard work and dedication, and thank our shareholders for their ongoing support of our mission to bring hope to life."

Third Quarter Clinical, Regulatory and Corporate Highlights

Progress towards an NDA for NRX-100 (IV ketamine) in the treatment of Suicidal Depression

Intravenous ketamine has now become a de-facto standard of care for acute treatment of suicidal depression, in the absence of an FDA-labeled product and has been identified as such by the US Department of Defense and the Veterans Health Administration. Intranasal Esketamine is approved by the FDA (SPRAVATO®) but its label specifies that it has not demonstrated a benefit on suicidality and is not approved for use in patients with bipolar depression. Attempts to use intranasal racemic ketamine for suicidal depression have failed.

The Company has formed data-sharing partnerships to license clinical trial data from a French Government-funded trial together with multiple NIH-funded trials all of which demonstrate efficacy of racemic Intravenous ketamine against suicidal ideation in depression, including bipolar depression. The Company's role is to reformat these data into the required presentation required for review by the FDA.

In contrast to nasal ketamine, Intravenous racemic ketamine demonstrates dramatic and immediate reduction of suicidality in patients with both Major Depressive Disorder and Bipolar Depression. Grunebaum and colleagues demonstrated a rapid and statistically significant reduction in Suicidal Ideation (SSI) at day 1 (p=0.0003) and in depression (P=0.0234), as measured by the Profile of Mood States (POMS) among patients randomized to IV Ketamine compared to those randomized to midazolam. This trial was published in the American Journal of Psychiatry Grunebaum, et.al.[1] Abbar and colleagues similarly published 84% remission from suicidality on the Columbia Suicide Severity Rating Scale (C-SSRS) in patients treated with ketamine, vs. 28% in those treated with placebo (P<.0001). This trial was published in the British Medical Journal[2]. Data are expected to be transmitted to FDA by in 2024.

In November 2023, the Company initiated manufacture of ketamine together with Nephron Pharmaceuticals, Inc. (West Columbia, SC) to develop a single patient presentation of ketamine without the toxic preservative currently contained in the form of ketamine approved for anesthesia. Last month, the Company reported adequate stability data on hand to file an NDA. Multiyear room-temperature shelf stability is expected based on current manufacturing data.

NRx's presentation of ketamine is uniquely packaged in a traceable, tamper-resistant and diversion-resistant vial that becomes commercially relevant as enforcement actions increasingly scrutinize unauthorized use and diversion of ketamine products. NRX-100 does not contain the preservative included in currently-available vials of ketamine for anesthesia, (Benzanthonium Chloride), that is designed to preserve sterility in the vial when multiple doses are drawn for multiple patients. Benzanthonium Chloride is a potentially toxic preservative and no data have been published to support its safety in repeated intravenous administration. Data were collected 20 years ago that demonstrated the toxic effect of this class of preservatives when applied repeatedly to the surface of the eye, which led to the current generation of preservative-free eye drops.

A long-term challenge with ketamine is that the current formulation (KETALAR®) is highly acidic. While it is suitable for intravenous use, it cannot be administered subcutaneously. In March 2024 the Company demonstrated the formulation of a pH neutral patentable form of IV ketamine that it anticipates will have widespread applicability both in treatment of depression and chronic pain.

Development of NRX-101 for Suicidal Treatment-Resistant Bipolar Depression

The company is working to file an NDA with the FDA for Accelerated Approval of NRX-101 in patients suffering from bipolar depression with suicidality or akathisia. NRX-101 is the only antidepressant medication that has demonstrated a reduction in suicidality or akathisia vs standard of care. This application will be supported by two clinical trials along with robust Manufacturing and Toxicity packages.

Akathisia is a side effect of all currently approved antidepressant medicines and is closely-linked to suicide. If approved, NRX-101 would be the first antidepressant medication demonstrated to reduce suicidality and akathisia compared to current standard of care medications in this at-risk patient group.

Data from the recently completed phase 2b/3 trial of NRX-101 in suicidal bipolar depression[3] at the annual meeting of the American Society of Clinical Psychopharmacology's by Professor Andrew Nierenberg of Harvard Mass General Hospital. These data demonstrated a significantly improved safety profile versus the standard of care, as demonstrated by a clinically significant reduction in akathisia (P=0.025) and time to sustained remission from suicidality (P=0.05). Akathisia is an adverse event seen with antidepressant medications considered by many experts to be a precursor to suicide. Given the vital need for safer medications in this at-risk population, we plan to submit an NDA for Accelerated Approval to the US FDA for treatment of bipolar depression patients with suicidality or akathisia, based on these data as well as additional data from our STABIL-B[4] trial.

Progress with HOPE Therapeutics

HOPE Therapeutics, the Company's wholly owned subsidiary, announced signing of two Letters of Intent to acquire foundational Interventional Psychiatric Clinics and is currently in negotiation with additional clinical networks. These initial acquisitions provide key Clinical and Operational leadership to HOPE, which aims to develop a national network of precision psychiatry clinics that combine treatment with ketamine, Transcranial Magnetic Stimulation, and other therapies to patients with suicidal depression and PTSD.

Unlike the core business of NRx Pharmaceuticals that is focused on biotechnology Research and Development, HOPE is organized around consolidating existing best-in-class precision psychiatry care into a nationwide network. This approach is demonstrating successful results for patients and a profitable operating model at a time when ketamine "medspas" frequently fail

and are under increasing regulatory scrutiny. As currently designed, the HOPE acquisition model is likely to be funded as a separate entity, through bond offerings and, thus, to be non-dilutive to NRx shareholders. Over the past quarter, HOPE leadership has identified the clinics that are most likely to participate in the first $100 million consolidation, has completed the audit required for a public listing of HOPE shares, and has identified appropriate underwriters for a future bond offering.

With Hope ownership as an asset of NRx, this will further strengthen the NRx balance sheet and aims to further enhance NRx shareholder value.

NRX-101 for Treatment of Chronic Pain and Urinary Tract Infection (UTI) / Urosepsis

Although the company is currently fully focused on the three opportunities discussed above, Chronic Pain and treatment of UTI with MNRX-101 remain pipeline opportunities, to be pursued following achievement of nearer-term corporate goals.

Funding for FDA filings of NRX-100 and NRX-101

The Company executed a Convertible Debt instrument with Anson Funds of Toronto for $10.8 million in funding designed to retire existing debt and to support FDA New Drug filings of NRX-100 and NRX-101. Terms have been disclosed in 8K filings but are at an interest rate and conversion rate substantially lower than prior corporate indebtedness. This agreement removes impediments to a planned dividend of HOPE Therapeutics shares to NRx shareholders.

Retirement of current debt and settlement of litigation

Concurrent with the Anson investment, the Company has settled its outstanding litigation with Streeterville Capital, LLC at a substantial discount to the amounts claimed in litigation.

Financial Results for the Quarter and Year to Date 2024

For the three months ended September 30, 2024, NRx Pharmaceuticals reduced its operating net loss from $6.1 million in the third quarter of 2023 to $1.6 million in 2024, representing nearly a 75% improvement year over year. For that same period, research and development expenses decreased from $3.3 million in 2023 to $0.6 million in 2024. The $2.7 million decrease is related primarily to a decrease of $2.1 million in clinical trial and development expenses due to the conclusion of the phase 2b/3 study relating to NRX-101 and the Company's cash conservation efforts. Also, in that 3-month period NRx achieved a slight decrease in general and administrative expenses, from $2.5 million in 2023 to $2.4 million in 2024. The decrease of $0.1 million is related primarily to lower insurance expenses.

For the nine months ended September 30, 2024, NRx Pharmaceuticals reduced its net loss to $16.1 million compared to $25.8 million in the prior year. These efficiencies represent an improvement in net loss of $9.7 million year over and a $1.89, or 54%, improvement in net loss per share year over year. Over that nine-month period we recorded $5.2 million of research and development expenses compared to $10.8 million for the same period in 2023 representing a 53% decrease year over year. The decrease of $5.7 million is related primarily to a decrease of $6.1 million in clinical trial and development expenses due to the conclusion of the phase 2b/3 study relating to NRX-101, offset by $1.3 million related to the Alvogen warrants and $0.2 million related to fees paid to regulatory and development consultants. Also, in that nine-month period, we decreased G&A by $1.4 million, from $12.3 million in 2023 to $10.9 million in 2024, representing an 11% decrease year over year.

As of September 30, 2024, we had $1.6 million in cash and cash equivalents. Subsequent to September 30, 2024, we closed tranche two of the Secured Debt Financing from Anson Funds in the amount of $5.4 million. This financing is expected to support filing of New Drug Applications for NRX-100 (ketamine) and NRX-101, general corporate purposes as well as retire historical debt with more favorable terms, and a lower annual interest rate.

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-Q, 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 4:30 p.m. ET Monday November 18, 2024, 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 to act as a non-opioid treatment for chronic pain, as well as a treatment for complicated UTI.

NRx has recently announced plans to submit a New Drug Application 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 healthcare delivery company developing a best-in-class network of precision psychiatry clinics that currently 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 proposed public offering and the timing and the use of the proceeds from the offering. 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 and 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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[1] Grunebaum, et. al., Ketamine for Rapid Reduction of Suicidal Thoughts. Am J Psychiatry. 2018 Apr 1: 175(4): 327-335

[2] Abbar, et. al. Ketamine for Acute Treatment of Severe Suicidal Ideation, BMJ 2022; 376

[3] Nierenberg, et. al., A Randomized, Double-Blind Controlled Comparison of NRX-101 (D-cycloserine/ lurasidone) to Lurasidone for Adults with Bipolar Depression and Subacute Suicidal Ideation or Behavior. Am Soc Clin Psych Annual Meeting 2024.

[4] Nierenberg et al. International Journal of Bipolar Disorders (2023) 11:28 https://doi.org/10.1186/s40345-023-00

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