Strong Year-End Results, Stock Dividend Approval, and Share Structure Reduction to Counter Short Selling: (Nasdaq: NRXP)

NRx Pharmaceuticals (Nasdaq: NRXP) Achieves Milestones: Approved Stock Dividend, Share Structure Reduction, and Strategic Countermeasures Against Short Selling

WILMINGTON, DELAWARE, UNITED STATES , March 28, 2024 /EINPresswire.com/ -- Strong Year End Results and Accomplishments Announced with Approved Stock Dividend and Share Structure Reduction to Counter Short Selling and Spur Higher Institutional Investment: NRx Pharmaceuticals (Nasdaq: NRXP)

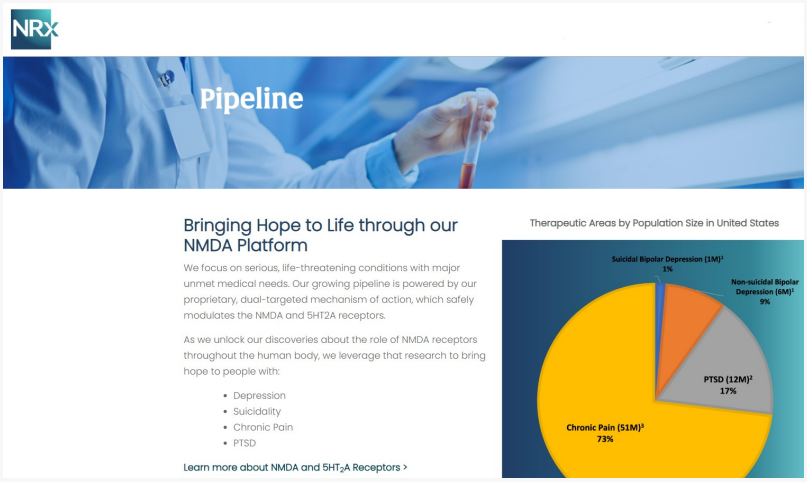
For more information on $NRXP visit: https://www.nrxpharma.com/ and https://axecapitalusa.com/nrxp/

Developing Therapeutics for the Treatment of CNS Disorders, Specifically Suicidal Bipolar Depression, Chronic Pain and PTSD.

MOU Signed with Conversio Health with Immediate Plans to Ship IV Ketamine Product to Full Range of Customers via 503a and 503b Pharmacies.

Reached Last Patient, Last Visit in Phase 2b/3 Trial of NRX-101 for Suicidal

$NRXP on the NASDAQ

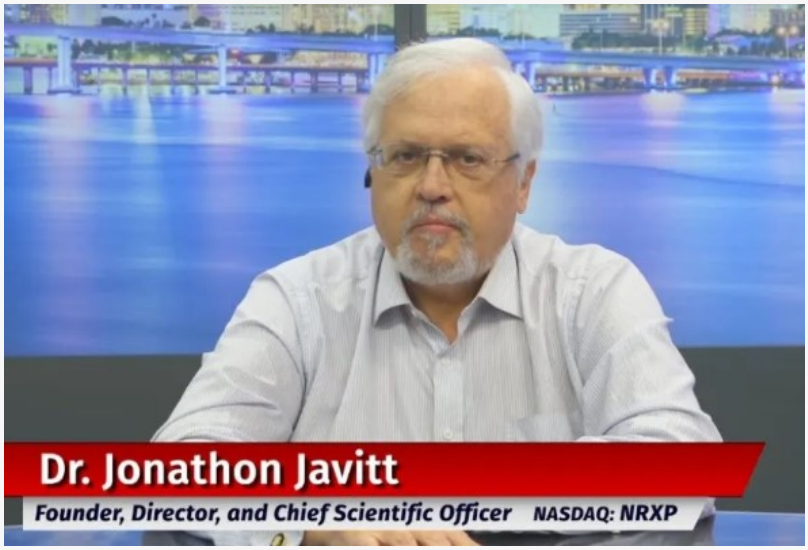


$NRXP Pipeline

Treatment Resistant Bipolar Depression.

Study Maintained 95% Concordance Rate Between Study Sites and Central Raters on Primary Endpoint. No Unexpected Serious Adverse Events Reported.

Positive Sata and FDA Comment Triggers next $5 Million Payment from Partners Alvogen and Lotus and their Assumption of Development Costs with up to $330 Million in Milestone Payments and a Royalty on Net Sales in the Mid-Teens.



$NRXP Founder, Director and CSO

Plan to Distribute Shares of HOPE Therapeutics and Royalty Rights on Ketamine Sales to Existing NRXP Shareholders.

> We are pleased to be taking these concrete steps to unlock the power and value of our Ketamine franchise for the investors who have supported the company and patients who need this lifesaving product"
>
> *Dr. Jonathan Javitt, Founder, Chairman and Chief Scientist of NRXP*

Plan to Greatly Reduce Outstanding Shares from 92 Million to a Much Lower Level to Counter Short Selling and Facilitate Greater Institutional Investments.

Completed Initial Manufacture of IV Infusion and Plans to File FDA New Drug Application for Acute Suicidality Upon Demonstration of 2-ear Shelf Stability.

Received $5 Million Milestone Payment from Partners Alvogen, Inc. and Lotus Pharmaceutical Co. Ltd. (1975.TW)

NRXP Eligible for Additional $324 Million in Development & Sales Milestones, Plus Double-Digit Royalties Upon Approval and Commercialization of NRX-101.

Completing Enrollment for Phase 2b/3 Trial in Suicidal Treatment-Resistant Bipolar Depression in Cooperation with Lotus Pharmaceutical.

Incorporation of HOPE Therapeutics Dedicated to NRX-100 (IV Ketamine) for Suicidal Depression to Patients.

NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) 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. NRXP is developing NRX-101, an FDA-designated investigational Breakthrough Therapy for suicidal treatment-resistant bipolar depression and chronic pain. NRXP has partnered with Alvogen Pharmaceuticals around the development and marketing of NRX-101 for the treatment of suicidal bipolar depression. NRX-101 additionally has potential to act as a non-opioid treatment for chronic pain, as well as a treatment for complicated UTI.

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Ticker (Exchange)	NRXP-NASDAQ
Recent Price (12/01/2023)	$0.344
52-week Range	$0.22 - 1.51
Shares Outstanding	81.9 mm
Market Capitalization	$28.2 mm
Average 10-day volume	259,600
Insider Ownership +>5%	22.3%
Institutional Ownership	5%
EPS (Qtr. ended 09/30/2023)	($0.07)
Employees	10

NRx Pharmaceuticals, Inc. (NRXP-NASDAQ)
One-year Stock Chart

DCS-LURASIDONE INTERACTION

COMPANY DESCRIPTION

NRx Pharmaceuticals, Inc. ("NRx" or "the Company") is a clinical stage biopharmaceutical company developing novel therapeutics for the treatment of central nervous system disorders with high unmet medical needs. The Company's foundation product is NRX-101, a patented combination of two FDA-approved drugs—**D-cycloserine (DCS)†**, an **NMDA** receptor modulator; and **lurasidone**, an atypical antipsychotic medication. The Company is assessing the use of NRX-101 in four different indications: suicidal **bipolar depression**, chronic pain, **post-traumatic stress disorder (PTSD)**, and **complicated urinary tract infections (cUTI)**. Development of NMDA antagonists, such as DCS, as antidepressants has been limited by their potential **psychedelic** side effects. Furthermore, **serotonin**-targeted drugs like lurasidone have been limited by their own behavioral side effects, specifically **akathisia**. Professor Daniel Javitt (NRx Co-founder and Chair of its Scientific Advisory) made the simultaneous discovery that: (1) the psychedelic effects of NMDA antagonist drugs could be reversed by combining them with serotonin-targeted compounds; and (2) NMDA inhibitors, in turn, block the akathisia side effect normally associated with serotonin-targeted drugs. The previously undiscovered synergy between these two drug classes is the subject of 48 issued patents and 43 pending patents owned by or licensed to NRx Pharmaceuticals, and as such, is the medical and scientific basis for the Company's technology platform.

KEY POINTS

- NRx entered into a collaboration with Alvogen Pharmaceuticals for the development and commercialization of NRX-101 in suicidal bipolar depression, with the potential for up to $330 million in milestones and double-digit royalties.
- NRx is conducting a single Phase 2b/3 trial of NRX-101 for **Suicidal Treatment Resistant Bipolar Depression (S-TRBD)**, with topline clinical data readout expected by Q1 2024, potentially followed by an NDA application shortly thereafter.
- Under the Alvogen agreement, a successful data readout and completion of a **Type B meeting** with the FDA would trigger a $10 million payment to NRx, at which point, Alvogen would be responsible for all future development and commercialization costs for this indication.
- NRX-101 is also being evaluated for the treatment of chronic pain as a non-addictive substitute for **opioid** products. The Company is planning to start a pharmacokinetic study following result readout of a 200-person U.S. Department of Defense-funded trial in treating chronic pain with DCS.
- NRx is assessing plans to create spinoff companies to complete development of NRX-100 (IV **ketamine**) for acute suicidality and NRX-101 for cUTI, which would potentially provide investors with both capital appreciation and a royalty stream.
- As of September 30, 2023, NRx's cash and cash equivalent position was $8.9 million.

$NRXP Research Report

NASDAQ: $NRXP Hope Science Life

NRXP has recently announced plans to submit a New Drug Application for NRX-100 (IV ketamine) in 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. NRXP 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.

Preliminary Fourth Quarter and Full Year Results with Key Highlights

On March 28th NRXP announced anticipated financial results for the quarter and year ended December 31, 2023 and provided the following summary of its expected annual report.

Highlights included the following:
Improvement in negative Earnings per Share to ($0.40) in FY 2023 vs ($0.60) in prior 12 month period. Management projects positive cash flow by year-end 2024 via partnerships and HOPE Therapeutics activities.

NRXP raised $9.2 in new capital during FY 2023 with $7.8 million of additions to working capital during Q1 2024. Reduced corporate indebtedness by more than 50% from $11.0 million to approximately $5.4 through Q1 2024.

NRXP signed a development partnership with Alvogen, Inc., and Lotus Pharmaceuticals, Inc. (1795.TW) under which the partners take over phase 3 and commercial costs for NRX-101 in bipolar depression and fund $330 million in commercial milestones together with a double digit royalty on sales, contingent on successful clinical trial data and FDA meeting.

NRXP completed enrollment and last patient visit of the Phase 2b/3 trial of NRX-101 in Suicidal Bipolar Depression with >94% rater concordance through conclusion of the trial, a measure that substantially exceeds current industry standards. Final Data Lock expected this week with Top line data expected in April 2024.

Acceptance of two new Investigational New Drug applications (INDs) by the FDA in Chronic Pain and Complicated Urinary Tract Infection/Pyelonephritis.

Final statistical analysis plan achieved this week in 200-person DOD-funded trial in treatment of chronic pain with D-cycloserine (DCS), the key component of NRX-101. The study center has indicated that data-lock will occur next week. Top-line data expected in April 2024. Positive data would support a final registration trial in this multi-billion dollar indication.

NRXP incorporated HOPE Therapeutics, Inc. as a specialty pharma company. HOPE is supporting distribution of intravenous ketamine, currently listed by FDA on nationwide drug shortage list to qualified ketamine clinics through nationwide 503a and 503b FDA-inspected pharmacy partners. First manufactured lot released for shipment this week by partner Nephron Pharmaceuticals.

NRXP Obtained patient-level data from three efficacy studies of ketamine funded by US National Institutes of Health (two trials) and Government of France (one trial). Demonstration statistically significant reduction in severe depression and acute suicidality. US Patient Centered Outcomes Research Initiative (PCORI) trial published in 2023 documents non-inferiority of ketamine vs Electroconvulsive Therapy in treatment of Severe Depression with fewer negative side effects compared to ECT.

NRXP completed first commercially-manufactured lot of ketamine (NRX100/HTX-100) in proprietary diversion-resistant presentation and initiated manufacture of two additional commercial batches. Anticipates filing of New Drug Application for treatment of Acute Suicidality by June 2024 upon completion of required 9 month stability and CMC with anticipated 2024 PDUFA date.

HOPE has received term sheets for more than $60 million in funding from new investors upon public listing and is expected to be spun out as a separate company to be owned by NRx, current NRx shareholders, and new investors upon completion of final audit and financial

statements.

IND for NRX-101 in the treatment of Complicated Urinary Tract Infection (cUTI) is based on in vitro data just accepted for peer-reviewed publication in Antibiotics, an MDPI journal. On the basis of these findings, FDA granted Qualified Infectious Disease Product (QIDP),Fast Track and Priority Review designations NRx is seeking a clinical phase partner for this multi-hundred million dollar indication.

NRXP elected nationally recognized attorney in highly regulated industries, and healthcare specialist, Janet Rehnquist, Esq., to the Company's Board of Directors.

NRXP management has taken action to restore Nasdaq listing compliance and combat illegal naked shorting of NRx securities.

Successful Vote to Reduce Share Structure to Counter Short Sellin and Attract Greater Institutional Investment

On Match 21st NRXP announced the results of a Special Meeting of Shareholders giving the Board of Directors authority to effect a reverse stock split of all of the outstanding shares of NRXP stock in the range of 1-for-2 to 1-for-15, with such ratio to be determined at a later date. NRXP management expects the effect of a greatly reduced outstanding share count will serve to significantly counter short selling activity and also help make NRXP into a much more attractive choice institutional investors. The expectation is that the next result will boost both the company’s working capital and also NRXP shareholder value over the long term.

Plan to Distribute Shares of HOPE Therapeutics and Royalty Rights on Ketamine Sales to Existing NRx Shareholders

On March 18th NRXP announced that its Board of Directors has authorized its Chairman and management to take all necessary steps to affect a Dividend of HOPE Therapeutics ("HOPE") stock along with a royalty right of 1% of Ketamine sales to NRXP Shareholders and applicable warrant holders. The intent of NRXP is to distribute 49% of HOPE stock in this dividend. Shares of HOPE are planned to be publicly listed.

"This Dividend is another important step to building value for all of the Company's stakeholders. We are pleased to be taking these concrete steps to unlocking the power and value of our Ketamine franchise for the investors who have supported the company and patients who need this potentially lifesaving product," said Dr. Jonathan Javitt, Founder, Chairman and Chief Scientist of NRXP and co-CEO of Hope Therapeutics. "As we build HOPE into a thriving, publicly-traded Specialty Pharmaceutical company we look forward to continuing to reward our investors."

HOPE Therapeutics was recently formed to advance HTX-100 (IV Ketamine) to a New Drug

Application filing and subsequent commercialization in the near term, and also facilitate sales of ketamine through high quality 503 a and 503b licensed pharmacies beginning in 2Q24. HOPE will additionally focus on digital therapeutics and other technologies to extend the pharmacologic effect of ketamine. Together, these efforts are intended to create a revenue generating Specialty Pharmaceutical company in 2024.

Memorandum of Understanding and Collaborations with Distribution Partners for HTX-100 (IV Ketamine)

On March 11th NRXP announced completion of a Memorandum of Understanding with Conversio Health, a national 503a pharmacy, and a strong, ongoing partnership with Nephron Pharmaceuticals, a manufacturer of Ketamine and 503b pharmacy to provide IV Ketamine to patients and clinics across the country, subject to board approval. These are important steps to providing a full suite of ketamine options for customers across the country, and preparation for potential approval of HTX-100 by regulatory authorities worldwide.

NRXP has further entered into a business relationship with an organization that currently serves the business needs of more than 100 ketamine clinics nationwide. NRXP has been given a target delivery date prior to the end of March 2024 for initial stock of ketamine for sale to licensed end users. Sales are planned to commence once technical and logistical elements are finalized. Details for ordering will be available on our website as soon as they are available. www.hopetherapeutics.com

In contrast to NRXP, which is structured as a Biotechnology research and development company, HOPE Therapeutics is structured as a Specialty Pharmaceutical company that aims to supply a variety of therapeutic products to clinics that are treating suicidal depression and PTSD, including both traditional and digital therapeutics.

NRXP Announces Last Patient, Last Visit in its Phase 2b/3 Trial of NRX-101 in Suicidal Treatment Resistant Bipolar Depression

On March 4th NRXP announced that the 74th and last evaluable patient has completed their day 42 visit in its Phase 2b/3 study of NRX-101, the Company's patented combination of the NMDA antagonist D-cycloserine and lurasidone, in Suicidal Treatment Resistant Bipolar Depression. The NRXP database is being cleaned, finalized, and locked; statistical analysis will then be performed, with top-line data to follow shortly thereafter. As previously disclosed, positive data from this trial triggers a milestone payment from Alvogen to NRXP. Alvogen will then be responsible for further development and commercialization costs for this program.

The NRXP NRX-101 treatment has been awarded Breakthrough Therapy Designation, Fast Track Designation, a Biomarker Letter of Support, and a Special Protocol Agreement by the FDA for treatment of suicidal bipolar depression. It is the only oral medication to have demonstrated reduced suicidal ideation in patients with bipolar depression, a lethal disease that claims the

lives of one in five who live with it.

The Phase 2b/3 NRXP trial (www.clinicaltrials.gov NCT 03395392) is a randomized, prospective, multicenter, double-blind study comparing NRX-101 to lurasidone over six weeks. The Principal Investigator is Prof. Andrew Nierenberg of Harvard Massachusetts General Hospital. The primary efficacy endpoint is reduction in depression as measured on the MADRS scale and the secondary endpoint is reduction of suicidal ideation as measured by the Clinical Global Impression Suicidality Scale (CGI-SS). As previously disclosed, treatment compliance and concordance of local raters to central raters scores was in excess of 94%, well above the industry standard that is normally seen in CNS trials.

$5 Million Milestone Payment from Partners Alvogen, Inc. and Lotus Pharmaceutical Co. Ltd. (1975.TW)

On February 12th NRXP announced the advance of the first $5 million milestone payment based on the Company's partnership agreement with Alvogen, Inc. and Lotus Pharmaceutical Co. Ltd. (1975.TW).

NRXP will immediately receive $5 million of the first milestone, which the Company will use to fund development of NRX-101 through the phase 2 meeting with FDA. As compensation for advancing the milestone, Alvogen and Lotus will receive 4.1 million warrants to purchase NRXP common stock, at a strike price of $0.40 with a three (3) year term. The second portion of the milestone will be $4 million and, as before, be triggered by a positive response to the Company's planned end of phase 2 meeting with FDA.

NRXP then remains eligible to receive up to $320 million in future development and sales milestones, as well as royalty payments escalating to mid-teen percentages on Net Sales, subject to achievement of certain sales volumes. Additionally, Alvogen and Lotus will be responsible for future development and commercialization costs for the NRXP NRX-101 in treatment of bipolar depression with suicidality.

Comments by Strategic Partner Lotus Pharmaceutical Co. Ltd. (1975.TW) in Recent Financial Report

On February 9th NRXP announced that its Asia Pacific strategic partner Lotus Pharmaceutical Co. Ltd (1975.TW) identified enrollment completion of the NRXP clinical trial in bipolar depression as a material event in is February 7 financial filing. Lotus provides the Asia Pacific component of the NRXP global partnership with Alvogen, Inc.

Lotus reported in the accompanying press release that "Lotus Pharmaceutical's strategic partner, NRXP, has achieved a significant milestone by completing enrollment for its phase 2b/3 trial of NRX-101 in suicidal treatment-resistant bipolar depression. The readout for this trial is anticipated in Q2 of this year."

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