Strong Q4 Results and Milestones Announced Including Approved Stock Dividend & 8 Million More in Capital: (Nasdaq: NRXP)

NRx Pharmaceuticals (Nasdaq: NRXP) Reports Strong Q4 Results and Milestones Achieved

WILMINGTON, DELAWARE, UNITED STATES , April 1, 2024 /EINPresswire.com/ -- Strong Q4 Results and Milestones Announced Including Approved Stock Dividend and Share Structure Reduction to Counter Short Selling and Spur Higher Institutional Investment: NRx Pharmaceuticals (Nasdaq: NRXP)

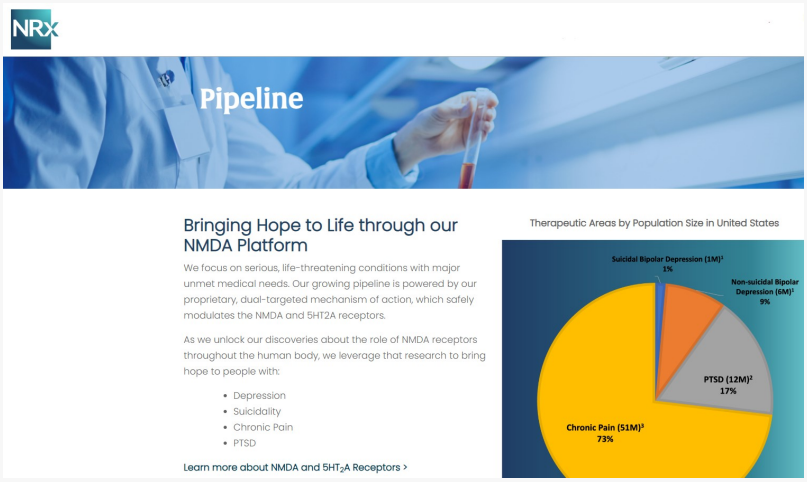
For more information on $NRXP visit: https://www.nrxpharma.com/ and https://axecapitalusa.com/nrxp/

 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 Treatment-Resistant Bipolar Depression.

$NRXP on the NASDAQ



$NRXP Pipeline

 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 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 the potential to act as a non-opioid treatment for chronic pain, as well as a treatment for complicated UTI.

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 the development of ketamine (NRX-100) by the US FDA as part of a protocol to treat patients with acute suicidality.

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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

Fourth Quarter and Full Year 2023 Financial Results Plus Business Update

On April 1, 2024, NRXP announced its fourth quarter results and provided a recap of recent key business developments. These included four potential near-term milestones, including data from two clinical trials, an NDA filing, and an upcoming share dividend. Additional accomplishments covered in the announcement were as follows:

NRXP delivered a 50% reduction in corporate overhead and 25% reduction in overall net loss in 2023, compared to 2024 with $0.20 per share improvement in negative earnings. Additions to working capital of $8 million in Q1 2024.
NRXP forecasts first commercial revenue in 2024 from sales of ketamine and related technologies. The company received an advance of the first milestone payments in 2024 for

ongoing development of NRX-101 from Alvogen and Lotus Pharmaceuticals, Inc. (1975.TW)

NRXP announced a new partnership around the first drug to potentially modify the underlying cause of schizophrenia

Data lock this week and top-line data expected this month, after completed enrollment of the Phase 2b/3 trial of NRX-101 in Treatment-Resistant Bipolar Depression (TRBD); the trial demonstrated 94% rater concordance, far in excess of industry norms and exceeded industry norms in medication compliance

Two NRXP Investigational New Drug applications (INDs) accepted by the US Food and Drug Administration (FDA) for NRX-101 in Chronic Pain and Complicated UTI.

Data lock expected this week in 200-person DOD-funded trial of D-cycloserine (DCS), the key component of NRX-101, to treat chronic pain, conducted by Northwestern University

Grant of Qualified Infectious Disease Product (QIDP), Fast Track and Priority Review designations for NRX-101 in the treatment of Complicated Urinary Tract Infection (cUTI); Publication last week of QIDP-qualifying data in a peer-reviewed journal. NRx is reviewing partnership options

NRXP established HOPE Therapeutics to develop and launch IV Ketamine together with related technologies with FDA New Drug Application to be submitted this year. In advance of FDA approval, HOPE is partnered with national 503b and 503a pharmacies to address the ketamine shortage declared by FDA. HOPE is planned to be spun out as a separate company to be owned by NRx, current NRx shareholders via a tax-free dividend, and new investors; Term Sheets received from prospective anchor investors for $60 million of new investment, once publicly listed

HOPE is presenting data from four randomized, prospective trials demonstrating safety and efficacy in 800 patients of IV Ketamine in treating severe and suicidal depression as the clinical basis for New Drug Application (NDA) for HTX-100 (IV Ketamine); expecting stability and CMC data sufficient for NDA filing by June 2024.

NRXP has added over $8 million in working capital, including an advance of a $5.1 million milestone payment from partners Alvogen, Inc. and Lotus Pharmaceuticals
NRXP has 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 actions to address NASDAQ listing compliance and 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 for 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 an 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."

Disclaimer/Safe Harbor:

These news releases and postings may contain forward-looking statements within the meaning of the Securities Litigation Reform Act. The statements reflect the Company's current views with respect to future events that involve risks and uncertainties. Among others, these risks include the expectation that any of the companies mentioned herein will achieve significant sales, the failure to meet schedule or performance requirements of the companies' contracts, the companies' liquidity position, the companies' ability to obtain new contracts, the emergence of competitors with greater financial resources and the impact of competitive pricing. In the light of these uncertainties, the forward-looking events referred to in this release might not occur.

SOURCE: CorporateAds.com

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