Development of pH Neutral Ketamine ; Trials Progressing for Suicide Drug Treatment with Strong Q4 Results: NASDAQ: NRXP

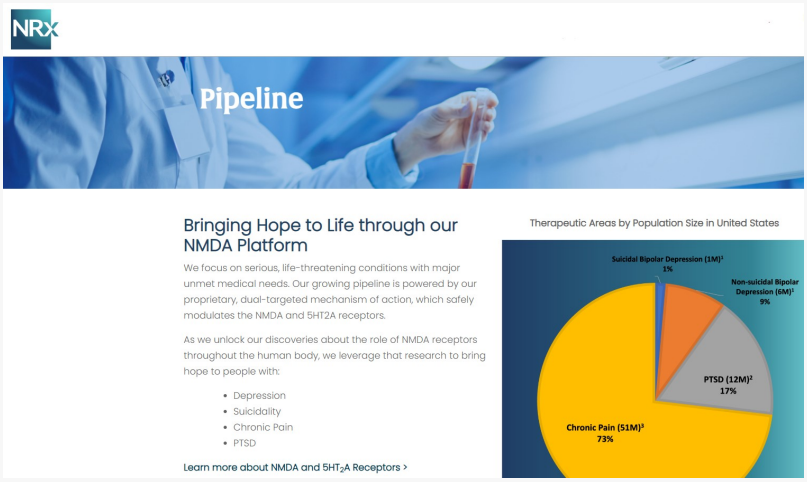
Strong Q4 Results Propel NRx Pharmaceuticals' pH Neutral Ketamine Development Amid Approved Stock Dividend: NRXP

WILMINGTON, DELAWARE, UNITED STATES , April 15, 2024 /EINPresswire.com/ -- Successful Development of pH Neutral Ketamine, Potentially Enabling Both Intravenous and Subcutaneous Use; Trials Progressing for Suicide Drug Treatment After Strong Q4 Results with Approved Stock Dividend: NRx Pharmaceuticals (Nasdaq: NRXP)

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

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

$NRXP on the NASDAQ



$NRXP Pipeline

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.

$NRXP Founder, Director and CSO

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.

> 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*

Development of New, Proprietary Formulation of HTX-100 (IV Ketamine)

On April 15th NRXP announced that the Company has developed a novel, proprietary formulation of IV Ketamine for use as HTX-100. This new NRXP formulation has the key advantage of achieving neutral pH, in contrast to the acidic pH of generic formulations of ketamine. Acidic substances are tolerated when diluted for intravenous use, but cause pain and may cause skin ulcers if administered subcutaneously. This patentable NRXP invention may enable the administration of ketamine in insulin pump-like devices in the clinic setting, eliminating the requirement for intravenous infusion personnel. NeuroRx, Inc. previously executed a joint development agreement with a manufacturer of insulin pumps but has been awaiting a suitable, pH neutral formulation of ketamine.

With this proprietary formulation, developed with partner Nephron Pharmaceuticals, a leading sterile products manufacturer, NRXP is expected to generate one or more patents, such as composition of matter or formulation. HTX-100 is expected to be marketed by HOPE Therapeutics, Inc., a wholly owned subsidiary of NRx.

Data-Lock Achieved in Phase 2b/3 Trial of NRX-101 in Suicidal Treatment Resistant Bipolar

Depression

On April 8th NRXP announced achieving data-lock in its Phase 2b/3 Suicidal Treatment Resistant Bipolar Depression Study with NRX-101. With data-lock the complete data set passed on for statistical analysis; top-line data release expected in April 2024.

With positive data from this study and FDA comment, NRXP becomes eligible to receive the balance of its first milestone (an additional $4 million) from partners Alvogen, Inc. and Lotus Pharmaceuticals, Inc. (1745.TW). These partners would then be responsible for all future development costs in this indication. NRXP retains rights for all other indications, including chronic pain and PTSD. NRXP is then poised to receive $320 million in further milestones along with mid-teen royalties on Net Sales.

NRx Pharmaceuticals, Inc.
1201 N Orange St., Suite 600
Wilmington, DE 19801
Phone: (484) 254-6134
https://www.nrxpharma.com/

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. Company received advance of first milestone payments in 2024 for ongoing development of NRX-101 from Alvogen and Lotus Pharmaceuticals, Inc. (1975.TW)

NRXP announced 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); 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.

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.

DISCLAIMER: https://corporateads.com/disclaimer/
Disclosure listed on the on the CorporateAds website

Matthew Duffy, Chief Business Officer
NRx Pharmaceuticals, Inc.
+1 484-254-6134
email us here
Visit us on social media:
Facebook
Twitter
LinkedIn
