New Data on Infection Avoidance and Development of pH Neutral Ketamine, for Intravenous & Subcutaneous Use NASDAQ: NRXP

NRx Pharmaceuticals Unveils New Data on Infection Avoidance and pH Neutral Ketamine Development: (Nasdaq: NRXP)

$NRXP on the NASDAQ

WILMINGTON, DELAWARE, UNITED STATES , April 17, 2024 /EINPresswire.com/ -- New Data on Infection Avoidance and Development of pH Neutral Ketamine, for Intravenous and Subcutaneous Use: 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.

No Impact on Gut or Vaginal Flora – Considered Primary Causes of Pseudomembranous Colitis due to C Difficile and Vaginal Yeast Infections.

Received FDA Qualified Infectious Disease Product (QIDP) and Fast Track Designation in Complicated Urinary Tract Infection (cUTI) and Pyelonephritis.

Achieved pH Neutral Formulation of Ketamine, Potentially Enabling Both Intravenous (IV) and Subcutaneous (SQ) Administration.

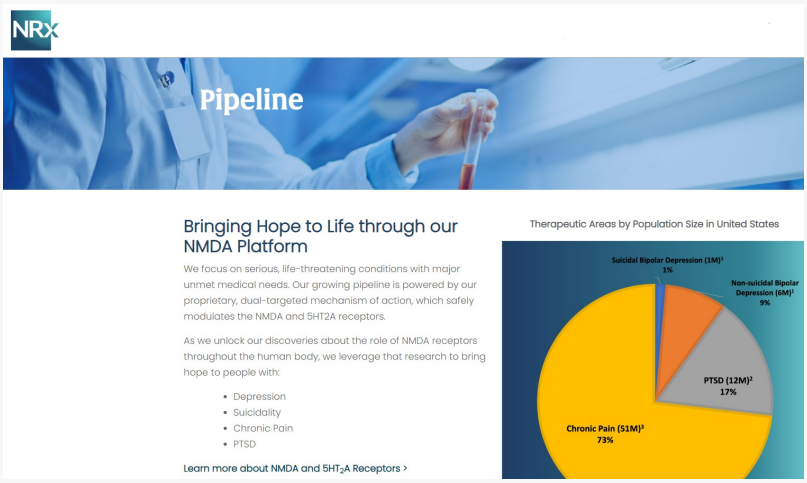
Data-Lock Achieved in Phase 2b/3 Trial of NRX-101 in Suicidal Treatment Resistant Bipolar Depression as needed to Unlock Partner Funding.

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 $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.

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

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



$NRXP Pipeline

$NRXP Founder, Director and CSO

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

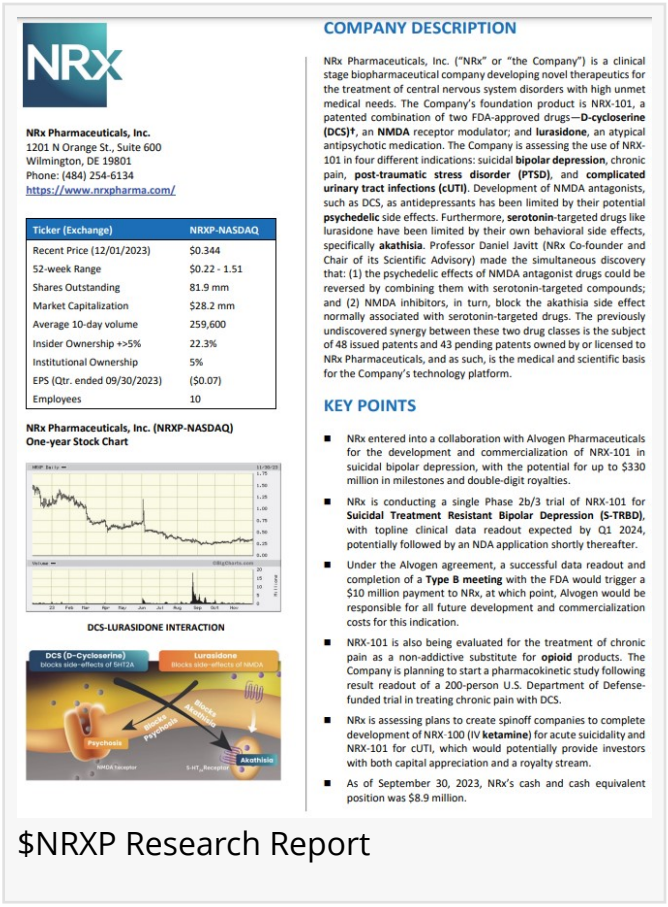
NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) is a clinical-stage biopharmaceutical company developing therapeutics based on its NMDA platform for the treatment of central nervous system disorders, specifically suicidal bipolar depression, chronic pain and PTSD. NRXP is developing NRX-101, an FDA-designated 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.

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.

New Data Demonstrating No Damage to Internal Flora in Validated Models Compared to Standard Antibiotics: Value to Avoidance of Infections

On April 17th NRXP announced new data that demonstrate that in a rodent model, the Company's NRX-101 shows no measurable damage to either intestinal or vaginal flora, compared to the significant negative effect caused by drugs such as ciprofloxacin. Antibiotics commonly used to treat complicated urinary tract infections (cUTI) are associated with pseudomembranous colitis caused by Clostridium difficile (C diff) and vaginal yeast infections, primarily owing to their impact on normal flora.



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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

Whereas most antibiotics have substantial effect in the large bowel, the key component of the NRXP drug NRX-101 (D-cycloserine) is entirely absorbed in the small intestine and excreted unmetabolized in the urine. If the nonclinical data reported today are replicated in patients, The NRXP NRX-101 could represent the first antibiotic for cUTI and pyelonephritis that has essentially no risk of causing C. diff infection or vaginal yeast infection. There is an extensive literature surrounding the use of D-cycloserine to treat tuberculosis and cases of C. Diff are unknown. D-cycloserine's effect as an antibiotic is based on its propensity to substitute for the amino acid alanine in the formation of the bacterial cell wall.

> NRXP primarily focused on NRX-101 as a drug to treat CNS disease, these new and highly provocative findings suggest that NRX-101 could find a home as a first line treatment for cUTI and pyelonephritis"
>
> *Stephen Willard, JD, Chief Executive Officer of NRXP*

"While we have primarily focused on NRX-101 as a drug to treat CNS disease, these new and highly provocative findings suggest that NRX-101 could find a home as a first line treatment for cUTI and pyelonephritis, which afflicts more than 3 million Americans each year. Should the rodent model findings prove applicable to the people, the use of NRX-101 to treat cUTI without increasing the risk of C. diff infection could have multibillion dollar potential," said Stephen Willard, JD, Chief Executive Officer of NRXP.

The NRXP NRX-101 has received FDA Qualified Infectious Disease Product (QIDP) and Fast Track Designation in Complicated Urinary Tract Infection (cUTI) and Pyelonephritis.

NASDAQ: $NRXP Hope Science Life

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.

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.

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

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.

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Disclosure listed on the on the CorporateAds website

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