Results Show Superior Safety & Efficacy for NRX-101; Accelerated FDA Approval sought for Bipolar Depression: NASDAQ NRXP

NRx Pharmaceuticals Reports Promising Results: Akathisia Reduction and Accelerated Approval Plans : NRx Pharmaceuticals, Inc. (Nasdaq: NRXP)

WILMINGTON, DELAWARE, UNITED STATES , May 6, 2024 /EINPresswire.com/ -- Clinical Trial Shows Statistically-Significant 76% Reduction in Akathisia; Plans to Seek Accelerated Approval for Bipolar Depression and Schizophrenia: NRx Pharmaceuticals, Inc. (Nasdaq: NRXP)

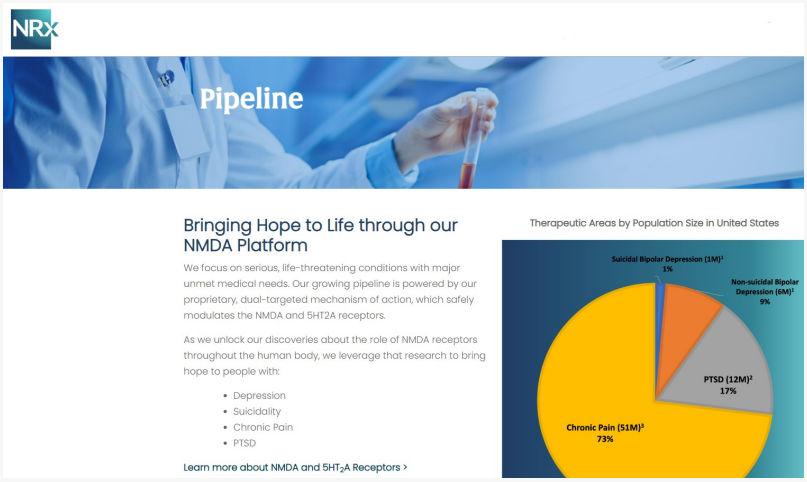
For more information on $NRXP visit: https://www.nrxpharma.com/ and https://axecapitalusa.com/nrxp/

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.

Clinical Trial Success in Proving a Statistically-Significant 76% Reduction in Akathisia in Participants Treated with NRX-101 Compared to Lurasidone.

$NRXP on the NASDAQ



$NRXP Pipeline

Company Plans to Seek Accelerated Approval of NRX-101 for Bipolar Depression and Akathisia and Broaden Indications Including Schizophrenia.

First Oral Antidepressant to Show 33% Advantage in Sustained Remission in Suicidality and 75% Advantage in Relief from Akathisia Relative to Lurasidone.

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

$NRXP Founder, Director and CSO

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

> Patients & key opinion leaders alike have told us clearly that an antidepressant with reduced risk of akathisia & other risk factors for suicidality would be unambiguously preferred in the marketplace"
>
> *Dr. Jonathan Javitt, NRXP Chairman and Chief Scientist*

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

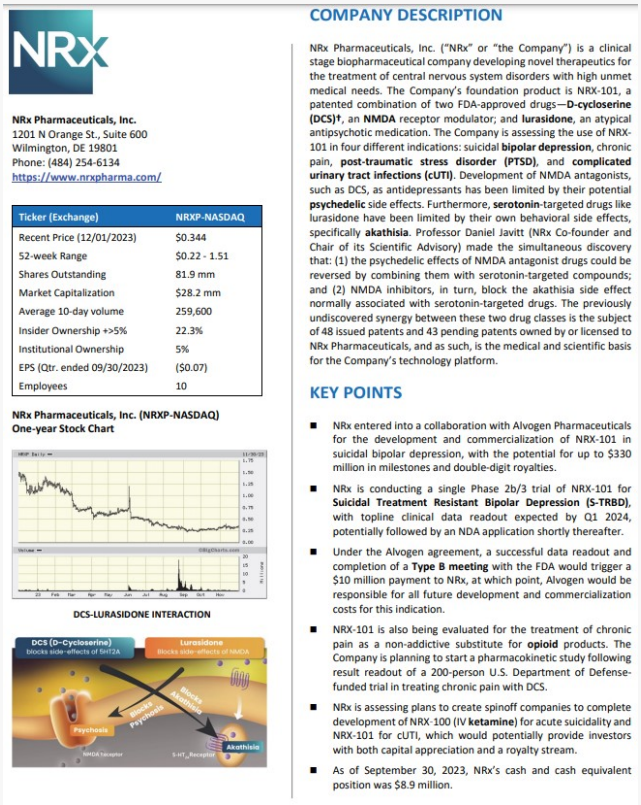
NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) is a clinical-stage biopharmaceutical company developing therapeutics based on its NMDA platform for the treatment of central nervous system disorders, specifically suicidal bipolar depression, chronic pain and PTSD. NRXP is developing NRX-101, an FDA-designated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

Clinical Trial Success in Proving a Statistically-Significant 76% Reduction in Akathisia in Participants Treated with NRX-101 Compared to Lurasidone.

On May 6th NRXP announced a statistically significant safety advantage of NRX-101 compared to the standard of care comparator in its recently completed clinical trial in patients with suicidal bipolar depression. Therefore, NRXP believes that demonstration of reduced akathisia in the setting of comparable antidepressant efficacy constitutes a basis for Accelerated FDA Approval of NRX-101. The full clinical trial results will be presented at the upcoming meeting to the American Society of Clinical Psychopharmacology held May 28-31 in Miami. NRXP will gather Key Opinion Leaders to educate the public on the importance and potentially life-saving implication of this finding.



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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

Based on this safety finding, NRXP plans to seek accelerated approval of NRX-101 for treatment of bipolar depression in patients with akathisia who are at highest risk of suicide, while continuing to develop evidence to support broader indications both in treatment of depression and schizophrenia. Should these data be confirmed in additional large scale trials, NRXP believes that physicians and patients will universally prefer antidepressant and antipsychotic drugs with a reduced akathisia risk. The NRXP patent portfolio supports the development of a broad range of combined NMDA/serotonergic drugs for treatment of depression and psychosis.

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 internal 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 yeast infections, primarily owing to their impact on normal internal flora.

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

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.

$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).

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