Oral Antidepressants for Reduction in Suicidality Could Deliver New Standard of Care for Bipolar Depression: NASDAQ NRXP

Revolutionizing Bipolar Depression Treatment: The Potential of Oral Antidepressants: NRx Pharmaceuticals, Inc. (Nasdaq: NRXP)

WILMINGTON, DELAWARE, UNITED STATES, April 30, 2024 /EINPresswire.com/ -- Promising Data on Oral Antidepressants for Reduction in Suicidality Could Deliver New Standard of Care for Bipolar Depression: NRx Pharmaceuticals, Inc. (Nasdaq: NRXP)

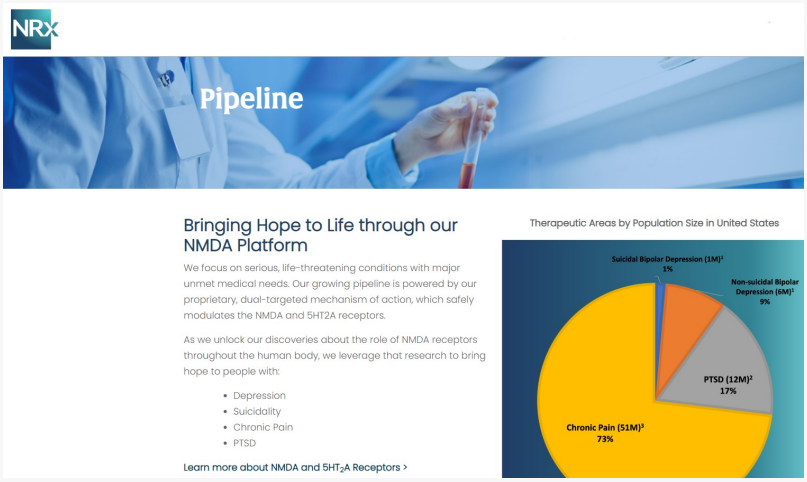
For more information on $NRXP visit: https://www.nrxpharma.com/ and https://axecapitalusa.com/nrxp/

 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.

 Promising Findings in Phase 2b/3 Clinical Trial of NRX-101 vs. Lurasidone for Treatment of Suicidal Bipolar Depression.

$NRXP on the NASDAQ



$NRXP Pipeline

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

 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 (UTI) and Pyelonephritis.

$NRXP Founder, Director and CSO

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

> Our pursuit of breakthrough therapies underscores our unwavering commitment to addressing the complex challenges of conditions like bipolar depression, offering renewed hope and improved outcomes"
>
> *Stephen Willard, JD, Chief Executive Officer of NRXP*

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

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

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

Promising Findings in Phase 2b/3 Clinical Trial of NRX-101 vs. Lurasidone for Treatment of Suicidal Bipolar Depression

On April 30th NRXP announced that its Breakthrough Therapy designated investigational drug NRX-101 vs lurasidone demonstrated a promising, though not yet statistically significant 33% reduction in suicidality together with a 70% reduction (P=.076) reduction in symptoms of akathisia – a side effect of antidepressants that is closely linked to suicide and considered a medical emergency. In the NRXP STABIL-B trial (STABIL-B), NRX-101 was demonstrated to be superior to lurasidone in reducing both depression and suicidality after ketamine while showing a trend towards reducing akathisia (a side effect involving restlessness and agitation that is considered a warning sign of impending suicide). In this trial, without prior use of ketamine, NRX-101 and lurasidone were comparable in their effect on depression.

In the current NRXP study, without prior use of ketamine, NRX-101 and lurasidone exhibited comparable antidepressant effects, each reducing depression (the primary endpoint) on the Montgomery Asberg Depression Rating Scale (MADRS) by about 50% from baseline. Lurasidone is known to reduce symptoms of depression by approximately 4 points in multiple registration trials compared to placebo.

Analysis of suicidality using the Columbia Suicide Severity Rating Scale (C-SSRS) demonstrated a sustained 33% advantage in remission from suicidality favoring the NRXP NRX-101. This difference was not statistically significant at the phase 2 sample size but met the study's original promising zone criteria and, if sustained in a registration trial of 300 or more patients, would be powered to yield a statistically significant result. The reduction in suicidality is comparable to that demonstrated after ketamine, both in the NRXP STABIL-B trial and in an independently conducted trial comparing DCS to placebo after ketamine (Chen, et. al.).

Based on these findings and the widespread adoption of ketamine as the initial treatment for suicidal depression, NRXP believes that NRX-101 may become the drug of choice for potentiating the effect of ketamine in patients with acute and subacute suicidality. The FDA recently affirmed to NRXP that the Special Protocol Agreement for this indication remains in place, subject to NRXP filing a New Drug Approval for ketamine, which is expected by July 2024. Moreover, NRXP aims to explore the role of NRX-101 as primary treatment for the much larger population (approximately 7 million in the US) of patients with bipolar depression who do not have active suicidality and, therefore, do not require prior treatment with intravenous ketamine.

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.

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 an 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 its 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

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).

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 light of these uncertainties, the forward-looking events referred to in this release might not occur.

SOURCE: CorporateAds.com

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