Alignment with FDA on Pediatric Study Plan and Accelerated Approval to Treat Bipolar Depression & Akathisia: NASDAQ NRXP

FDA Endorses NRx Pharmaceuticals' Accelerated Approval & Pediatric Study for Bipolar Depression & Akathisia Treatment : NRx Pharmaceuticals, Inc. (Nasdaq: NRXP)

WILMINGTON, DELAWARE, UNITED STATE, July 30, 2024 / EINPresswire.com/ -- Alignment with FDA on Pediatric Study Plan and Accelerated Approval to Treat Bipolar Depression and Akathisia: NRx Pharmaceuticals, Inc. (Nasdaq: NRXP)

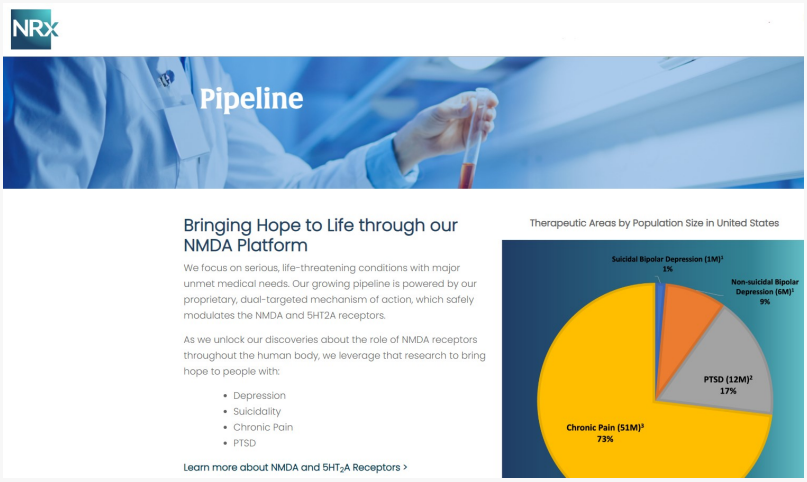
NRXP could Realize Over $150 in Revenue Per Share, Plus HOPE Subsidiary Spinoff Moves Forward
For more information on $NRXP visit: https://www.nrxpharma.com/ and https://compasslivemedia.com/case-study/nrx-pharmaceuticals/

Developing Therapeutics for the Treatment of CNS Disorders, Specifically Suicidal Bipolar Depression, Chronic Pain and PTSD.

Alignment on Initial Pediatric Study Plan is a Gating Requirement for Upcoming Filing of NRX-100 New Drug Application for Suicidal Depression.

On Track to File NDA for NRX-100 in Q4

$NRXP on the NASDAQ

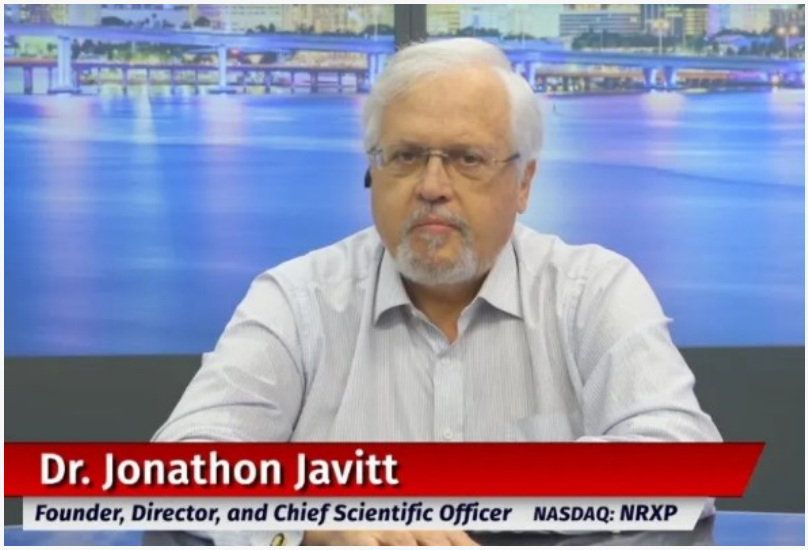


$NRXP Pipeline

2024 & Planned PDUFA Date in Q2 2025.

Petition for Temporary Restraining Order Brought by Streeterville Capital, LLC to Prevent Spinoff of HOPE Therapeutics to NRXP Shareholders Denied.

New Drug Application (NDA) for Accelerated Approval Planned for People with Bipolar Depression and Akathisia in 2024 with Potential Revenue in 2025.



$NRXP Founder, Director and CSO

NDA for NRX-100 (IV ketamine) for Suicidal Depression in Advanced Preparation for 2024. with Potential Revenue in 2025.

> This arbitration decision enables us to keep our promise to shareholders and spin out up to 49% of HOPE Therapeutics shares to NRXP shareholders"
>
> *Prof. Jonathan Javitt, Founder and Chairman of NRXP*

Gaining Approvals Could Yield More Than $150 in Revenue per NRXP Share in the Near Term at Current Share Count.

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.

Alignment with FDA on Pediatric Study Plan for NRX-100 (ketamine)

On July 29th NRXP announced a communication from the US Food and Drug Administration (FDA) providing feedback and alignment on the Company's proposed initial Pediatric Study Plan (iPSP) for NRX-100 (ketamine) in the treatment of suicidal depression. Congress required the submission of an iPSP as a precondition to filing a New Drug Application in the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA).

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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

In support of its upcoming NDA filing, NRXP will be submitting existing data supporting the safety and efficacy of ketamine to treat suicidal depression in adults. FDA has now documented its recognition that suicide is a serious and growing public health concern in adolescents as well. Based on the guidance received, NRXP will commit to conducting a clinical trial of NRX-100 in adolescents aged 9-17 with suicidal depression, but will not be required to study the effects of NRX-100 in younger age groups, following initial approval of NRX-100 in adults. Additional neurotoxicity studies will be conducted to support the safety of intravenous ketamine in this younger population.

Arbitration Order Enabling HOPE Therapeutics Spinoff

On July 29th NRXP announced an order of the Utah arbitrator denying the petition of Streeterville Capital, LLC to enjoin the planned spinoff of 49% of shares in HOPE Therapeutics to current shareholders of NRXP. The purpose of this spinoff was both to provide NRXP shareholders with valuable consideration and to provide HOPE Therapeutics (currently a wholly-owned subsidiary of NRXP) with a sufficient shareholder base to enable future listing on a public securities exchange. The arbitrator also denied Streeterville's petition to enjoin NRXP from selling additional shares of NRXP stock to finance ongoing operations.

“As we have previously shared with the public, HOPE Therapeutics is in the process of developing a best-in-class network of clinics that currently offer ketamine and other lifesaving therapies to patients with suicidal depression. This arbitration decision enables us to keep our promise to shareholders to spin out up to 49% of HOPE Therapeutics shares held by NRXP to NRXP shareholders as of an ex-dividend date to be announced, subject to approval of a Form 10 filing by the US Securities and Exchange Commission and approval of the NRx Board of Directors. We appreciate the support and loyalty of our shareholders as we work to bring HOPE to life,” said Prof. Jonathan Javitt, Founder and Chairman of NRXP and Co-CEO of HOPE Therapeutics.

July Shareholder Update Letter

On July 1st NRXP announced a new Shareholder Update Letter has been posted on its website via this link: NRx Shareholder Update (https://www.nrxpharma.com/management-answers-to-shareholder-questions/). This detailed update covers the company’s potential paths to revenue and profitability in 2025 and all of the latest and most important company developments. NRXP further invites interested parties to subscribe to their email alert service to stay up to date on company's progress.

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Disclosure listed on the CorporateAds website

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