Accelerated Approval to Treat Bipolar Depression & Akathisia Could Yield Over $150 in Revenue Per Share; (Nasdaq: NRXP)

NRx Pharmaceuticals Projects Major Revenue Boost with New Bipolar Depression and Akathisia Treatment Approval: NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) $NRXP

WILMINGTON, DELAWARE, UNITED STATES, July 29, 2024 /EINPresswire.com/ -- Accelerated Approval to Treat Bipolar Depression and Akathisia Could Yield Over $150 in Revenue Per Share; Planned HOPE Subsidiary Spinoff to Continue: NRx Pharmaceuticals, Inc. (Nasdaq: NRXP)

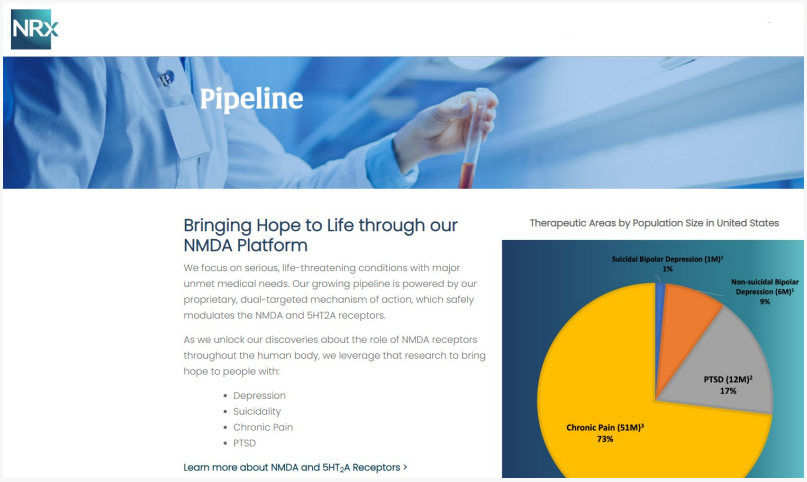
For more information on $NRXP visit: https://www.nrxpharma.com/ and https://compasslivemedia.com/case-study/nrx-pharmaceuticals/

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

 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

$NRXP on the NASDAQ

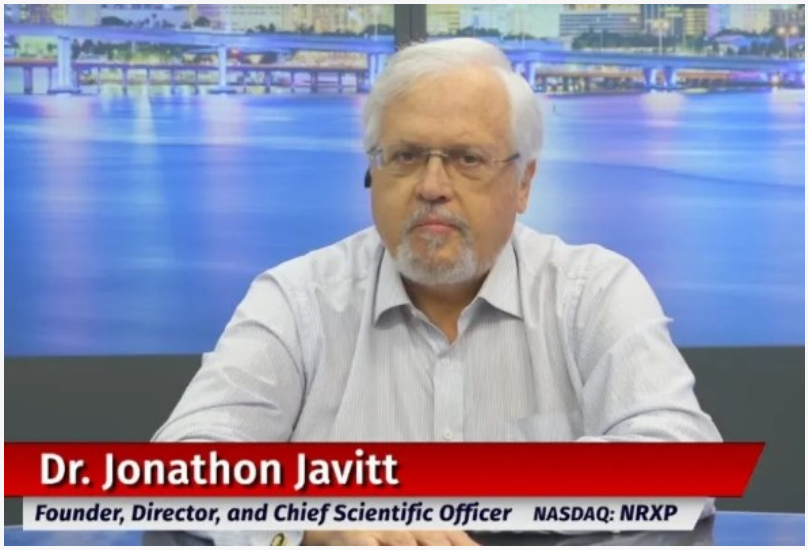


$NRXP Pipeline

People with Bipolar Depression and Akathisia in 2024 with Potential Revenue in 2025.

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

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



$NRXP Founder, Director and CSO

 NRXP Reached 9-month Stability Point with its Ketamine Formulation (NRX-100) and Initiated 3 Manufacturing Lots for Future Drug Release.

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

 Nonclinical Safety for Short-Term Use of NRX-100 Recently Published and Submitted to FDA.

 FDA Leadership, in Public Comments at ASCP, Focused on the Need for Nonclinical Safety Data for Intravenous Ketamine as a Condition of Approval.

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

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.

Arbitration Order Enabling HOPE Therapeutics Spinoff

On July 29th NRXP announced an order from 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.

NRx

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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

DCS (D-Cycloserine) blocks side-effects of 5HT2A
Lurasidone blocks side-effects of NMDA
Blocks Psychosis
Blocks Akathisia
Psychosis
Akathisia
NMDA receptor
5-HT2A Receptor

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

"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 the company's progress.

NRXP to Proceed with Two New Drug Applications in 2024; NRX-101 has Been Returned to the Company for Filing

On June 28th NRXP announced that advice from regulatory counsel, which includes former senior officials from the Food and Drug Administration, supports filing two New Drug Applications (NDAs) in 2024: an application for Accelerated Approval for NRX-101 to treat bipolar depression in patients with akathisia and an application for approval of NRX-100 (IV ketamine) for treatment of suicidal depression.

NRXP will be filing the NRX-101 application without a commercial partner. The addressable market for the accelerated approval indication is such that a compact and efficient salesforce can be constructed by a small company, such as NRXP, and current executives at NRXP have previously held primary responsibility for the launch of similar-sized pharmaceutical assets.

NRX-101 is the NRXP patented (Composition of Matter), oral combination of the NMDA antagonist D-cycloserine and lurasidone for bipolar depression. Data from two active control clinical trials vs. the standard of care, lurasidone, have shown comparable antidepressant efficacy with clinically important reductions in suicidality and/or akathisia. To the Company's knowledge, no other oral agent has demonstrated such a valuable profile.

Up to 15% of people treated with drugs in lurasidone's class develop akathisia7; this would constitute an estimated $3.7 billion initial market for NRXP with NRX-101, with no approved medicines for akathisia. This is a population NRXP can readily address without a large commercial partner, given the relatively small number of psychiatrists who treat high-risk patients. The broad bipolar market constitutes 7 million people and an opportunity greater than $20 billion per year. With a best-in-class product profile, NRXP projects NRX-101 sales in excess of $2 billion.

NRX-101 was awarded Breakthrough Therapy Designation, Fast Track Designation, a Biomarker Letter of Support, and a Special Protocol Agreement by the FDA for the treatment of suicidal bipolar depression.

NRX-100 (IV ketamine) for Suicidal Depression. IV ketamine is widely accepted as a standard of care for acute treatment of suicidal depression, in the absence of an FDA-labeled product; the only treatment currently approved by FDA is electroconvulsive therapy (ECT).
According to the CDC, 3.5 million Americans make a plan for suicide each year. This represents a $3-5 billion market at expected pricing.

Based on the data in the trials referenced above, the NRXP regulatory counsel has encouraged the Company to file an NDA for suicidal depression for NRX-100. This application has been in development and awaits 12-month stability data for filing, which is expected in 2024.

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Disclosure listed on the CorporateAds website

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