Innovative Bipolar Depression Treatment by NRx Pharmaceuticals Featured at ASCP June 2024 Meeting: Nasdaq: NRXP

NRx Pharmaceuticals Showcases First Oral Antidepressant Proven to Reduce Suicidality in Bipolar Depression at ASCP June 2024 Meeting: NRXP

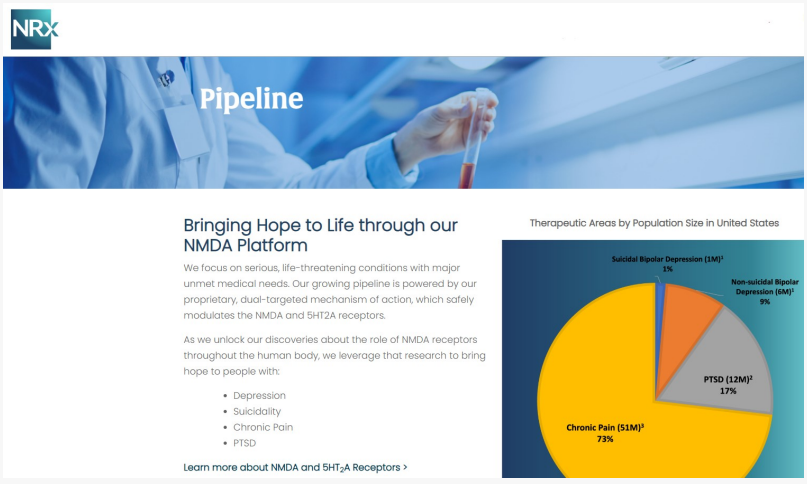
WILMINGTON, DELAWARE, UNITED STATES, June 10, 2024 /EINPresswire.com/ -- Presentations at June 2024 Meeting of American Society of Clinical Psychopharmacology Highlight Multiple Advantages for First Oral Antidepressant Demonstrated to Reduce Suicidality in Bipolar Depression: NRx Pharmaceuticals, Inc. (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.

 June Meeting of the American Society for Clinical Psychopharmacology Focused on Intravenous Ketamine and Intranasal S-Ketamine for Severe Depression and Suicidality.

$NRXP on the NASDAQ

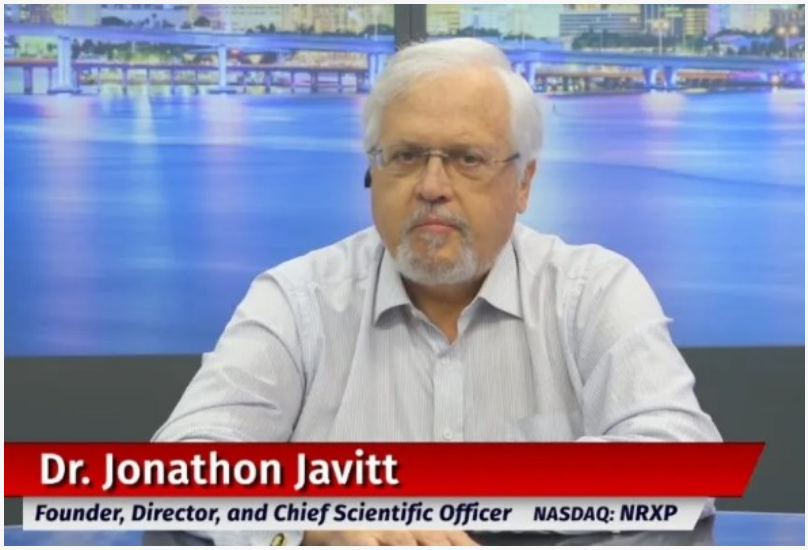


$NRXP Pipeline

 Presenters from 3 Open Label Studies at the ASCP Suggested Intravenous Ketamine is Equivalent or has Advantages over Intranasal S-Ketamine.

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

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



$NRXP Founder, Director and CSO

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

> NRXP has developed patentable pH-neutral formulation for ketamine that will be suitable for both intravenous and subcutaneous administration"
>
> *Dr. Jonathan Javitt, NRXP Chairman and Chief Scientist*

 Short-Term Need for Intravenous Ketamine as an Already-Approved, Schedule 3 Drug Heightened by Recent Decisions that May Delay Schedule 1 Psychedelics.

 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.

 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)

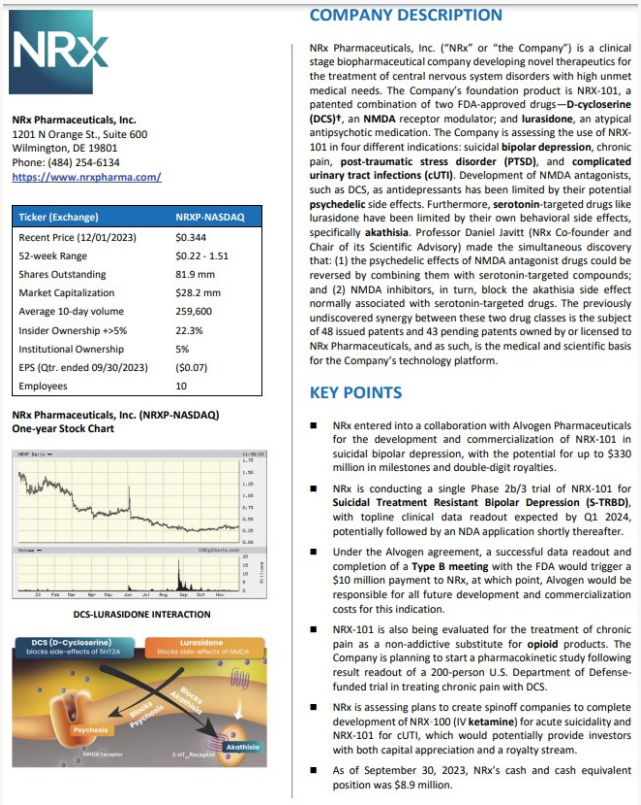
 NRXP Eligible for Additional $324 Million in Development & Sales Milestones, Plus Double-Digit Royalties Upon Approval and Commercialization of NRX-101.

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.



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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

Shareholder Update Letter

On June 10th NRXP issued a new Shareholder Update Letter on its website NRx Shareholder Update and further invites interested parties to subscribe to their email alert service to stay up to date on the company's progress here: NRx Email Alerts

The new NRXP update highlights the potential implications of the Company's recent activities at the annual meeting of the American Society of Clinical Psychopharmacology. The key points include:
Intravenous and intranasal ketamine were highlighted as emerging standards of care for severe

depression and suicidality

Planned NDA filing for NRX-100, the NRXP preservative-free IV ketamine, for Suicidal Depression in 2024, is based on well-controlled trials against both placebo and active comparator. Fast Track Designation was previously granted

An independent FDA advisory panel recently voted against MDMA, a potent, class I psychedelic, refocusing attention on already-approved Schedule 3 drugs such as ketamine for the treatment of suicidal depression. The FDA panel and emerging guidance highlight the complexity of clinical trials of DEA Schedule 1 hallucinogens that do not have already approved human uses

NRXP anticipates that an important issue for longer-term use of ketamine in depression will be the current multidose vial presentation that contains potentially toxic preservatives previously acceptable for one-time use but less suitable for repeated use. The NRXP NRX-100 is planned as a single-dose, preservative-free medication.

NRXP NRX-101 is the First Oral Antidepressant Demonstrated to Reduce Suicidality in Bipolar Depression

On May 28th NRXP announced the presentation of its Phase 2b/3 trial of NRX-101, entitled "A Randomized, Double-Blind Controlled Comparison of NRX-101 (D-cycloserine/lurasidone) to Lurasidone for Adults with Bipolar Depression and Subacute Suicidal Ideation or Behavior" at the American Society of Clinical Psychopharmacology (ASCP) in Miami Beach, FL. The lead author is Prof. Andrew Nierenberg, Director, Dauten Family Center for Bipolar Treatment Innovation, Massachusetts General Hospital, and Professor of Psychiatry, at Harvard Medical School.

The presentation was made on Wednesday, May 29, 2024.

CONCLUSIONS of the Poster are:

The NRXP NRX-101 and lurasidone both demonstrated > 50% response for treating bipolar depression with no difference seen on the primary efficacy endpoint (MADRS)

A clinically meaningful difference was observed on both primary and secondary safety endpoints favoring NRX-101NRX-101 was associated with 58% relative reduction in time to sustained remission from suicidality as measured by the Columbia Suicide Severity Rating Scale (C-SSRS) when stratified by gender, mood stabilizer use, antipsychotic use, lifetime suicide event (P=0.05).NRX-101 was associated with a relative 76% reduction in symptoms of akathisia compared to lurasidone that was sustained over 42 days (Effect Size 0.37; P=0.03) on the Barnes Akathisia Rating Scale

Akathisia was seen in 2% of participants treated with NRX-101 vs. 11% treated with lurasidone.

NRX-101 showed superiority to lurasidone in Akathisia starting at day 7 and continuing through day 42/ET.

No treatment-related serious adverse event was observed in either group. No safety issues were detected except for MedDRA General disorders: NRX-101 - 18.2% vs lurasidone - 0% (p=0.002).

Based on these findings, together with the earlier STABIL-B trial, NRXP believes that NRX-101 has the potential to become a standard-of-care drug for treating bipolar depression, an addressable population of 7 million patients in the US and many times that around the world.

First Quarter 2024 Financial Results and Business Update Highlights

On May 14th NRXP announced its First Quarter Operating Results and Business Highlights which included the following key points:

Executed Term Sheet from an institutional investor for an initial $7.5 million note, subject to common closing requirements, primarily to replace current debt, clearing the path to a Hope Therapeutics share distribution, with provision for funding up to $30 million to fund pipeline opportunities.

Positive data from a Phase 2b/3 trial of NRX-101 in Treatment Resistant Bipolar Depression (TRBD); trial demonstrated depression efficacy comparable to standard of care and significant reduction of akathisia (P=0.025). Akathisia is a potentially lethal side effect of all serotonin-targeted antidepressants and is associated with suicide. The study additionally demonstrated a 30% advantage in sustained remission from suicidality that was not statistically-significant at this sample size.

The above findings of reduced suicidality mirror the results of the NRXP prior STABIL-B trial in acutely suicidal patients and also mirror the results of an independently published trial.
NRXP plans to file a New Drug Application (NDA) for Accelerated Approval under Breakthrough Therapy and Priority Review of NRX-101 in the treatment of bipolar depression in people at risk of akathisia, based on the Phase 2b/3 and STABIL-B data.

NRXP has developed a patentable pH-neutral formulation for ketamine that will be suitable for both intravenous and subcutaneous administration. Ketamine efficacy data are in hand from 4 clinical trials. Three manufacturing lots are now initiated (required for NDA) and NRXP plans to initiate the NDA by July

HOPE Therapeutics (which focuses on care delivery, not drug development) has partnered with representatives of ketamine clinic providers nationwide to construct a care platform that will include ketamine, operational support, and digital therapeutic extensions. In advance of FDA approval, HOPE is actively in the sales process to supply ketamine under 503b pharmacy licensure to meet the national ketamine shortage declared by FDA. HOPE is planned to be spun

out as a separate company to be owned by NRx, current NRx shareholders, and new investors; Term Sheets received from prospective anchor investors for $60 million of new investment, once publicly listed.

Data expected shortly in 200-person DOD-funded trial of D-cycloserine (DCS), the key component of NRX-101, to treat chronic pain, conducted by Northwestern University. Statistical analysis plan and data unlock have been approved by Northwestern IRB.

NRXP NRX-101 in the treatment of Complicated Urinary Tract Infection (cUTI) granted Qualified Infectious Disease Product (QIDP), Fast Track, and Priority Review designations. NRXP has now demonstrated that NRX-101 does not damage the microbiome of the gut, in contrast to all other advanced antibiotics, and is less likely to cause C. Difficile infection (a potentially lethal side effect of antibiotic treatment). NRXP is reviewing partnership options.

Executed Memorandum of Understanding with Fondation FundaMental for rights to develop potential disease-modifying drug for Schizophrenia. If successful, this would represent the first drug to reverse the underlying disease mechanism of schizophrenia, rather than simply treating symptoms.

Financial Results for the Quarter and Year Ended December 31, 2023

For the three months ended March 31, 2024, NRXP reduced net loss from $11.0 million in the first quarter of 2023 to $6.5 million in 2024, representing a 41% improvement year over year. For that same period, Research and Development expenses decreased from $3.7 million in 2023 to $1.7 million in 2024, as clinical trial enrollment concluded. The $2.0 million decrease is related primarily to a decrease of $1.6 million in clinical trial expenses, $0.2 million in regulatory and process development costs, and $0.1 million in stock-based compensation. NRXP also recorded a 26% reduction in general and administrative expenses during the quarter, from $5.8 million in 2023 to $4.3 million in 2024. The decrease of $1.5 million is related primarily to a decrease of $1.2 million in insurance expenses, $0.4 million in employee expenses, and slightly offset by other general and administrative expenses.

As of March 31, 2024, NRXP had $1.3 million in cash and cash equivalents, not including the $5.1 million of working capital committed by Alvogen. This included a reduction of corporate indebtedness to Streeterville LLC of $2.2 million. Subsequent to March 31, 2024, NRXP increased working capital by $3.3 million from equity sales. Over the first three months of 2024, NRXP improved access to working capital by $8 million in total, representing $2.9 million from equity sales and $5.1 million from the Alvogen milestone advance, while reducing corporate indebtedness by 50%.

NRXP continues to implement operational efficiencies to extend the cash runway and maintain focus on its path to generating revenue and value for shareholders.

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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