Aggressive Actions to Counter Naked Shorting & Protect Shareholder Value; Pioneering Mental Health Issues: NASDAQ: NRXP

NRx Pharmaceuticals (Nasdaq: NRXP): Pioneering Drug Development in Mental Health and Chronic Pain Treatment

WILMINGTON, DELAWARE, UNITED STATES, March 12, 2024 /EINPresswire.com/ -- Aggressive Actions to Counter Naked Shorting and Protect Shareholder Value for Developer of First Suicidal Bipolar Depression, Chronic Pain and PTSD Drug with Potential for up to $330 Million in Payments and Royalties: NRx Pharmaceuticals (Nasdaq: NRXP)

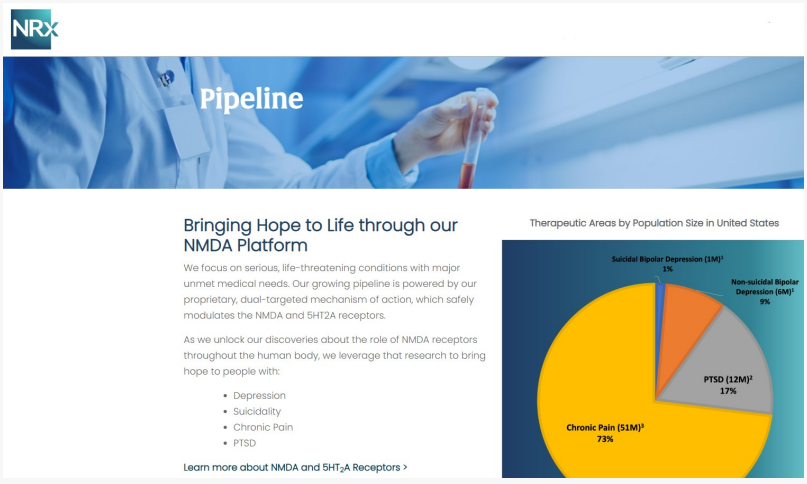
For more information on $NRXP visit: https://www.nrxpharma.com/

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

 New Initiative to Protect Shareholder Value via Compliance with Nasdaq Listing Rules and Elimination of Naked Short Sales Positions.

 Retained Former SEC Enforcement to notify leading brokerages to Prevent Future Accumulation of Naked Short Positions.

$NRXP on the NASDAQ



$NRXP Pipeline

 MOU Signed with Conversio Health with Immediate Plans to Ship IV Ketamine Product to Full Range of Customers via 503a and 503b Pharmacies.

 Reached Last Patient, Last Visit in Phase 2b/3 Trial of NRX-101 for Suicidal Treatment-Resistant Bipolar Depression.

 Study Maintained 95% Concordance Rate Between Study Sites and Central Raters on Primary Endpoint. No Unexpected Serious Adverse Events Reported.

$NRXP Founder, Director and CSO

 Positive Sata and FDA Comment Triggers next $5 Million Payment from Partners Alvogen and Lotus and their Assumption of Development Costs with up to $330 Million in Milestone Payments and a Royalty on Net Sales in the Mid-Teens.

> NRXP intends to provide state-of-the-art patient and reimbursement support for all of its patients and their clinics”
>
> *Matthew Duffy, Chief Business Officer*

 Launch of HOPE Therapeutics, Inc. at the BIO CEO & Investor Conference 2024, Plus Planned Share Dividend to Existing NRXP Shareholders.

 Completed Initial Manufacture of IV Infusion and Plans to File FDA New Drug Application for Acute Suicidality Upon Demonstration of 2-ear Shelf Stability.
 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.

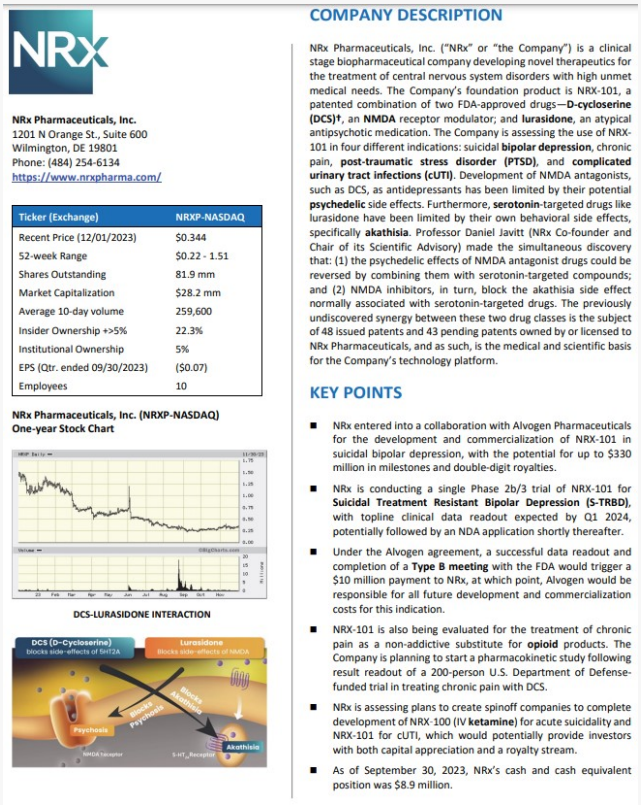
 Completing Enrollment for Phase 2b/3 Trial in Suicidal Treatment-Resistant Bipolar Depression in Cooperation with Lotus Pharmaceutical.

 Incorporation of HOPE Therapeutics Dedicated to NRX-100 (IV Ketamine) for Suicidal Depression Patients.

 HOPE Therapeutics to be Initially Owned by NXRP and current NXRP Shareholders via a

Planned Tax-Free Dividend.

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.



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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

NRXP has recently announced plans to submit 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.

New Initiative Strategy to Combat Short Sales

On March 12th NRXP initiated actions to combat short sellers in the Company's stock. NRXP announced a proposal to simultaneously change the CUSIP under which the Company's shares are traded, together with changing the name of the Company to NRx Therapeutics, Inc. NRXP plans to accompany these actions with a required exchange of the underlying stock certificates. This certificate change is expected to be seamless for those investors holding NRXP shares in electronic form and similarly for investors who may have established short positions in

NRXP by borrowing the underlying shares from a registered shareholder. Any party holding a short position in NRXP shares who has not complied with the legal requirement to borrow the underlying shares of stock (i.e. "a naked short") may be unable to exchange that position for a position in the new security.

NRXP is working with attorneys who formerly served in leadership positions at the SEC Division of Enforcement to correspond with corporate counsel and compliance heads at leading brokerages to emphasize the current legal prohibitions against naked short sales. As identified in previous announcements, NRXP was advised by ShareIntel in September 2023 that substantial naked short positions in the Company's securities had been identified at major brokerage firms.

Memorandum of Understanding and Collaborations with Distribution Partners for HTX-100 (IV Ketamine)

On March 11th NRXP announced the completion of a Memorandum of Understanding with Conversio Health, a national 503a pharmacy, and a strong, ongoing partnership with Nephron Pharmaceuticals, a manufacturer of Ketamine and 503b pharmacy to provide IV Ketamine to patients and clinics across the country, subject to board approval. These are important steps to providing a full suite of ketamine options for customers across the country, and preparation for potential approval of HTX-100 by regulatory authorities worldwide.

NRXP has further entered into a business relationship with an organization that currently serves the business needs of more than 100 ketamine clinics nationwide. NRXP has been given a target delivery date prior to the end of March 2024 for an initial stock of ketamine for sale to licensed end users. Sales are planned to commence once technical and logistical elements are finalized. Details for ordering will be available on our website as soon as they are available. www.hopetherapeutics.com

In contrast to NRXP, which is structured as a Biotechnology research and development company, HOPE Therapeutics is structured as a Specialty Pharmaceutical company that aims to supply a variety of therapeutic products to clinics that are treating suicidal depression and PTSD, including both traditional and digital therapeutics.

NRXP Announces Last Patient, Last Visit in its Phase 2b/3 Trial of NRX-101 in Suicidal Treatment-Resistant Bipolar Depression

On March 4th NRXP announced that the 74th and last evaluable patient has completed their day 42 visit in its Phase 2b/3 study of NRX-101, the Company's patented combination of the NMDA antagonist D-cycloserine and lurasidone, in Suicidal Treatment Resistant Bipolar Depression. The NRXP database is being cleaned, finalized, and locked; statistical analysis will then be performed, with top-line data to follow shortly thereafter. As previously disclosed, positive data from this trial triggers a milestone payment from Alvogen to NRXP. Alvogen will then be

responsible for further development and commercialization costs for this program.

The NRXP NRX-101 treatment has been awarded a 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. It is the only oral medication to have demonstrated reduced suicidal ideation in patients with bipolar depression, a lethal disease that claims the lives of one in five who live with it.

The Phase 2b/3 NRXP trial (www.clinicaltrials.gov NCT 03395392) is a randomized, prospective, multicenter, double-blind study comparing NRX-101 to lurasidone over six weeks. The Principal Investigator is Prof. Andrew Nierenberg of Harvard Massachusetts General Hospital. The primary efficacy endpoint is reduction in depression as measured on the MADRS scale and the secondary endpoint is reduction of suicidal ideation as measured by the Clinical Global Impression Suicidality Scale (CGI-SS). As previously disclosed, treatment compliance and concordance of local raters to central rater's scores was in excess of 94%, well above the industry standard that is normally seen in CNS trials.

NRXP to Launch HOPE Therapeutics, Inc. at the BIO CEO & Investor Conference 2024, Plus Planned Share Dividend to Existing NRXP Shareholders

On February 20th NRXP announced that Dr. Jonathan Javitt, its Chairman and Chief Scient, would present a corporate overview at the BIO CEO & Investor Conference, held February 26-27, 2024 in New York City. Presenting with him would be Matthew Duffy, the newly appointed co-CEO of HOPE Therapeutics.

Concurrent with the presentation, NRXP plans to file a proxy statement, subject to board approval, for NRXP shareholders outlining the share structure and seeking a shareholder advisory vote to support the planned share dividend for HOPE Therapeutics. NRXP has received consistent advice from public shareholders that the planned share dividend and royalty coupon be distributed only to shareholders and warrant-holders who execute a covenant not to participate in short sales of the Company's stock.

$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).
NRXP will immediately receive $5 million of the first milestone, which the Company will use to fund the development of NRX-101 through the phase 2 meeting with FDA. As compensation for advancing the milestone, Alvogen and Lotus will receive 4.1 million warrants to purchase NRXP common stock, at a strike price of $0.40 with a three (3) year term. The second portion of the milestone will be $4 million and, as before, be triggered by a positive response to the Company's

planned end-of-phase 2 meeting with FDA.

NRXP then remains eligible to receive up to $320 million in future development and sales milestones, as well as royalty payments escalating to mid-teen percentages on Net Sales, subject to achievement of certain sales volumes. Additionally, Alvogen and Lotus will be responsible for future development and commercialization costs for the NRXP NRX-101 in the treatment of bipolar depression with suicidality.

Comments by Strategic Partner Lotus Pharmaceutical Co. Ltd. (1975. TW) in Recent Financial Report

On February 9th NRXP announced that its Asia Pacific strategic partner Lotus Pharmaceutical Co. Ltd (1975.TW) identified enrollment completion of the NRXP clinical trial in bipolar depression as a material event in is February 7 financial filing. Lotus provides the Asia Pacific component of the NRXP global partnership with Alvogen, Inc.

Lotus reported in the accompanying press release that "Lotus Pharmaceutical's strategic partner, NRXP, has achieved a significant milestone by completing enrollment for its phase 2b/3 trial of NRX-101 in suicidal treatment-resistant bipolar depression. The readout for this trial is anticipated in Q2 of this year."

Incorporation of HOPE Therapeutics & Planned Share Dividend/Royalty Coupon

On February 5th NRXP announced the incorporation of HOPE Therapeutics™, a biotechnology company dedicated to bringing NRX-100 (IV Ketamine), which will be re-designated HTX-100, a potentially lifesaving treatment option for patients with Suicidal Depression. The company will initially be owned by NRXP and its current shareholders, who will receive their shares in the form of a dividend with an accompanying royalty coupon tied to future sales of HTX-100, subject to Board approval. This is designed with counsel to not be a taxable event for NRXP shareholders.

HOPE is dedicated to providing an FDA-approved presentation of IV Ketamine, manufactured to current federal standards, in a diversion- and abuse-deterrent presentation. A New Drug Application (NDA) is planned for the first half of 2024, based on more than 1,000 patients treated in well-controlled trials of ketamine in Suicidal Depression together with HOPE's expertise in sterile product formulation.
Importantly, NRXP intends to provide state-of-the-art patient and reimbursement support for all of its patients and their clinics. Access to insurance coverage is critical for providing treatment to this vulnerable population and can only be achieved through the development of an FDA-approved product. Additionally, providing an approved, compliant product for patients allows clinics to deliver state-of-the-art care to people suffering from suicidality without fear of legal and regulatory actions.

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