NRx Pharmaceuticals (NASDAQ:NRXP) to Proceed with Two New Drug Applications in 2024; NRX-101 has Been Returned to the Company for Filing

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- *New Drug Application (NDA) for Accelerated Approval planned for NRX-101 in people with bipolar depression and akathisia in 2024, based on two positive trials [1] [2] and Breakthrough Therapy Designation. Potential revenue in 2025*
- *NDA for NRX-100 (IV ketamine) in suicidal depression in advanced preparation for submission in 2024; based on four positive trials [3] [4] [5] [6] and Fast Track Designation. Potential revenue in 2025*
- *Gaining these approvals has the potential to yield more than $150 in revenue per NRXP share in the near term, at current share count*
- *Planning for HOPE Therapeutics share distribution progresses; audit nearing completion – critical step towards a public listing*

RADNOR, Pa., June 28, 2024 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today 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.

While efficacy and safety data are now in hand, filing of the above applications is dependent upon completion of 12-month stability data in manufactured lots as required by FDA regulations.

As disclosed in an 8K filing, NRx 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 NRx, and current executives at NRx have previously held primary responsibility for launch of similar-sized pharmaceutical assets.

NRx continues work to enable the distribution of shares in Hope Therapeutics. This distribution is dependent upon completion of a public audit and successful review of an SEC Form 10.

"The NRx team has worked diligently since the end of the COVID pandemic to achieve these milestones for our shareholders and most importantly the patients we have always sought to help," said Dr. Jonathan Javitt, Chairman and Chief Scientist of NRx. "Given the near-term market opportunity represented by an accelerated approval process, NRx anticipates a higher potential return to NRx investors associated with an NRx-led initiative than that which would likely be achieved with a large commercial partner."

NRX-101 for Bipolar Depression

NRX-101 is the Company's 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 akathisia[7]; this would constitute an estimated $3.7 billion initial market for NRX-101, with no approved medicines for akathisia. This is a population the Company 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, the Company 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 treatment of suicidal bipolar depression.

NRX-100 (IV ketamine) for Suicidal Depression

Intravenous 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.[8] This represents a $3-5 billion market at expected pricing.

Based on the data in the trials referenced above, the Company's 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.

About NRx Pharmaceuticals

NRx Pharmaceuticals 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. The Company is developing NRX-101, an FDA-designated investigational Breakthrough Therapy for suicidal treatment-resistant bipolar depression and chronic pain. NRX-101 additionally has potential to act as a non-opioid treatment for chronic pain, as well as a treatment for complicated UTI.

NRx 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 agreements. NRx 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.

About HOPE Therapeutics, Inc.

HOPE Therapeutics, Inc. (www.hopetherapeutics.com) is a Specialty Pharmaceutical Company, wholly-owned by NRX Pharmaceuticals focused on development and marketing of an FDA-approved form of intravenous ketamine for the treatment of acute suicidality and depression together with a digital therapeutic-enabled platform designed to augment and preserve the clinical benefit of NMDA-targeted drug therapy.

Notice Regarding Forward-Looking Statements

The information contained herein includes forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. These statements include, among others, statements regarding the proposed public offering and the timing and the use of the proceeds from the offering. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "plan," "believe," "intend," "look forward," and other similar expressions among others. These statements relate to future events or to the Company's future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. You should not place undue reliance on forward-looking statements since they involve known and unknown risks, uncertainties and other factors which are, in some cases, beyond the Company's control and which could, and likely will, materially affect actual results, levels of activity, performance or achievements. Any forward-looking statement reflects the Company's current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to the Company's operations, results of operations, growth strategy and liquidity. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's most recent Annual Report on Form 10-K and other filings with the Securities and Exchange Commission. Investors and security holders are urged to read these documents free of charge on the SEC's website at http://www.sec.gov. Except as may be required by applicable law, The Company assumes no obligation to publicly update or revise these forward-looking statements for any reason, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, whether as a result of new information, future events or otherwise.

[1] Nierenberg A, Lavin P, Javitt DC, et. al. NRX-101 vs lurasidone for the maintenance of initial stabilization after ketamine in patients with severe bipolar depression with acute suicidal ideation and behavior; a randomized prospective phase 2 trial. Int J Bipolar Dis 2023;11:28-38, STABIL-B

[2] Nierenberg, et. al., 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. Am Soc Clin Psych Annual Meeting 2024. *ASCP Poster*

[3] Fava, M et. al., Double-blind, placebo-controlled, dose-ranging trial of intravenous ketamine as adjunctive therapy in treatment-resistant depression (TRD) Mol Psychiatry. 2020; 25(7): 1592–1603.

[4] Grunebaum, et. al., Ketamine for Rapid Reduction of Suicidal Thoughts. Am J Psychiatry. 2018 Apr 1: 175(4): 327-335

[5] Abbar, et. al. Ketamine for Acute Treatment of Severe Suicidal Ideation, BMJ 2022; 376

[6] Anand, et. al, Ketamine is non-inferior to ECT for non-psychotic treatment resistant depression. NEJM 2023 388(25):2315-2325

[7] Chow, C, et. Al., Akathisia and Newer Second-Generation Antipsychotic Drugs: A Review of Current Evidence Pharmacotherapy 2020;40(6):565–574

[8] CDC Suicide Data.

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