



NRx Pharmaceuticals (NASDAQ:NRXP) Publishes Shareholder Update Letter

June 10, 2024

- The June 2024 meeting of the American Society for Clinical Psychopharmacology (ASCP) focused heavily on increasing use of intravenous ketamine and intranasal S-ketamine as the emerging standard of care for treating severe depression and suicidality
- Presenters from 3 open label studies at the ASCP suggested that intravenous ketamine is at least equivalent and may have advantages over intranasal S-ketamine
- NRx Pharmaceuticals has now reached the 9-month stability point with its ketamine formulation (NRX-100) and has initiated 3 manufacturing lots for future drug release. Nonclinical safety for short term use of NRX-100 has recently been 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 ketamine approval
- The short-term need for intravenous ketamine as an already-approved, schedule 3 drug, is heightened by recent regulatory decisions that may delay the path of potent, schedule 1 psychedelic drugs that may require more complicated clinical trial designs.

RADNOR, Pa., June 10, 2024 [/PRNewswire/](#) -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced that the Company posted 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 company's progress here: [NRx Email Alerts](#) . (Note: not all updates will be included in a Press Release in the future).

Today's update highlights 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, our 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 treatment of suicidal depression. The FDA panel and emerging guidance highlights the complexity of clinical trials of DEA Schedule 1 hallucinogens that do not have already-approved human uses
- NRx 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. NRX-100 is planned as a single-dose, preservative-free medication.

Please subscribe to the Company's email for future updates. [NRX Email Alerts](#) Not all of these will be the subject of a Press Release in the future.

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 has partnered with Alvogen and Lotus 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.

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 agreement. 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.

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