

NRx Pharmaceuticals (NASDAQ:NRXP) Announces Development of New, Proprietary Formulation of HTX-100 (IV Ketamine)

- Formulation based on prior patents by NRx founder
- Achieved pH neutral formulation of ketamine, potentially enabling both intravenous (IV) and subcutaneous (SQ) administration
- Company expects Composition of Matter patent protection
- Company previously executed joint development agreement with US manufacturer of insulin pumps

RADNOR, Pa., April 15, 2024 / PRNewswire / -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", "NRx", the "Company"), a clinical-stage biopharmaceutical company, today announced that the Company has developed a novel, proprietary formulation of IV Ketamine for use as HTX-100. This new formulation has the key advantage of achieving neutral pH, in contrast to the acidic pH of generic formulations of ketamine. Acidic substances are tolerated when diluted for intravenous use, but cause pain and may cause skin ulcers if administered subcutaneously. This patentable invention may enable the administration of ketamine in insulin pump-like devices in the clinic setting, eliminating the requirement for intravenous infusion personnel. NeuroRx, Inc. previously executed a joint development agreement with a manufacturer of insulin pumps but has been awaiting a suitable, pH neutral formulation of ketamine.

With this proprietary formulation, developed with our partner Nephron Pharmaceuticals, a leading sterile products manufacturer, NRx is expected to generate one or more patents, such as composition of matter or formulation.

HTX-100 is expected to be marketed by HOPE Therapeutics, Inc., a wholly owned subsidiary of NRx.

"The current formulation of IV Ketamine was developed for battlefield use in the 1960s and has remained relatively static since then. With our new formulation, and Nephron's state of the art manufacturing expertise, we are pleased to be approaching the market with an improved formulation ready for use in modern medicine," said Dr. Jonathan Javitt, Founder, Chairman and Chief Scientist of NRx Pharmaceuticals. "Development of a pH-neutral, subcutaneous form of ketamine administration enables a significantly less complex route of administration in the outpatient setting. Moreover, advances in insulin pump technology create the potential to monitor the brain wave activity and other physiologic parameters associated with ketamine administration and modulate ketamine therapy based on the patient's individual physiologic response."

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 HTX-100 (IV ketamine), through Hope Therapeutics, 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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