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NRx Pharmaceuticals Builds on Its Intellectual Property Foundation for Neuropsychiatric Conditions - Adds New U.S. Patent to Portfolio

- Company receives notice of the issuance of a U.S. patent covering the lead formulation, NRX-101, a glycine site NMDA antagonist in clinical trials to treat bipolar depression with acute and subacute suicidality;
- This new patent represents a third patent family, that now totals 48 issued patents worldwide with 42 additional pending patent applications.
- Patent covers the use of NRX-101 to treat patients suffering from depression, including bipolar depression or major depression (MDD) with or without suicidality and strengthens the Company's intellectual property position until at least 2033;
- Upon approval of NRX-101, this newly granted patent is expected to be "listable" in the U.S. Food and Drug Administration (FDA) Orange Book.

RADNOR, Pa., Feb. 22, 2023 /PRNewswire/ -- NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) ("NRx Pharmaceuticals", the "Company"), a clinical-stage biopharmaceutical company, today announced that the U.S. Patent and Trademark Office ("USPTO") has issued U.S. Patent No. 11,576,911.

NRx Pharmaceuticals Builds on Its Intellectual Property Foundation for Neuropsychiatric Conditions-Adds New U.S. Patent

This patent, issued to Glytech LLC, is exclusively licensed to NeuroRx, Inc. ("NeuroRx"), a wholly owned subsidiary of NRx, under the terms of a license agreement with Glytech through which NeuroRx has the sole rights to this and other patents, both U.S. and international. The licensed patents cover certain pharmaceutical formulations and their uses in treating a variety of neuropsychiatric conditions, including bipolar depression, major depressive disorder, PTSD, and suicidality.

In particular, the claims of the new patent cover methods for treating a patient suffering from depression, including bipolar depression or major depression, with or without suicidality by administering to the patient an effective amount of the Company's lead product candidate, NRX-101. Should this drug candidate be approved by the U.S. Food & Drug Administration ("FDA"), this newly issued patent is expected to be listable in the FDA's "Orange Book" for NRX-101, which is currently undergoing clinical trials in the U.S. The 'patent represents the U.S. version of a third patent family owned by or exclusively licensed to NeuroRx that covers the NRX-101 formulation or its methods of use in treating depressive disorders, and such patent coverage is expected to remain in force through at least July 2033 prior to any patent term extensions available under federal law. Previously issued patents cover the NRX-101 composition of matter and methods for preventing akathisia, a common side effect of SSRI antidepressants.

"The grant of this new patent augments the strength of NRx Pharmaceuticals' intellectual property, which consists of about 90 patents and patent applications globally," said Stephen Willard, Chief Executive Officer of NRx Pharmaceuticals. "It validates the novelty or our science and highlights its potential importance in bringing lifesaving treatments to patients with life-threatening neuropsychiatric conditions, including depression and PTSD."

In 2023, the company expects to have additional patents granted from its pending portfolio and to file more patent applications in the U.S. and internationally.

About NRX-101

Up to 50% of individuals with bipolar disorder attempt suicide over their lifetime, and estimates indicate that up to 20% may succumb to suicide. The only FDA-approved treatment for patients with bipolar depression and acute suicidal ideation & behavior (ASIB) remains electroconvulsive therapy (ECT).

Conventional antidepressants can increase the risk of suicide in certain patients; hence their labels contain a warning to that effect. NRX-101 is a patented, oral, fixed dose combination of D-cycloserine and lurasidone, neither of which has shown addiction potential in preclinical models. Based on the results of a Phase 2 proof-of-concept study, NRX-101 received Breakthrough Therapy Designation from the FDA for the treatment of severe bipolar depression in patients with ASIB after initial stabilization with ketamine or other effective therapy.

NRX-101 is one of the first oral antidepressants currently in late-stage clinical studies targeting the NMDA-receptor in the brain, which represents potentially a key new mechanism to treat depression with and without suicidality, as well as PTSD and other indications. To date, NRX-101 is the only oral NMDA investigational medicine focused on bipolar depression in patients with acute and sub-acute suicidality.

About NRx Pharmaceuticals

Clinical-stage biopharmaceutical company developing therapeutics for the treatment of central nervous system disorders, specifically suicidal depression and post-traumatic stress disorder (PTSD). The company's lead program NRX-101, an oral, fixed-dose combination of D-cycloserine and lurasidone, targets the brain's NMDA receptor and is being investigated in a Phase 3 trial under an FDA Special Protocol Agreement and Breakthrough Therapy Designation in patients with bipolar depression and suicidal ideation, an indication for which the only approved treatment is electroshock therapy. NRx Pharmaceuticals has also initiated a Phase 2b clinical trial in patients with Sub-Acute Suicidality, a substantially broader indication. The Breakthrough Therapy Designation and Special Protocol Agreement were awarded by the FDA based on the Company's prior STABIL-B trial that demonstrated substantial improvement over available therapy in reducing depression and suicidality compared to placebo when patients were treated with NRX-101 after a single dose of ketamine.

Cautionary Note Regarding Forward-Looking Statements

This announcement of NRx Pharmaceuticals, Inc. includes "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995, which may include, but are not limited to, statements regarding our financial outlook, product development, business prospects, and market and industry trends and conditions, as well as the Company's strategies, plans, objectives, and goals. These forward-looking statements are based on current beliefs, expectations, estimates, forecasts, and projections of, as well as assumptions made by, and information currently available to, the Company's management.

The Company assumes no obligation to revise any forward-looking statement, whether as a result of new information, future events or otherwise. Accordingly, you should not place reliance on any forward-looking statement, and all forward-looking statements are herein qualified by reference to the cautionary statements set forth above.

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