

June 3, 2019



# NeuroRX to Present Phase 2 Efficacy Data for NRX-101 at 2019 BIO International Convention

## First drug targeting suicidal bipolar depression, awarded FDA Breakthrough Therapy Designation

PHILADELPHIA, June 3, 2019 /PRNewswire/ -- NeuroRX, a clinical-stage biopharma company developing the first oral therapy for Severe Bipolar Depression with Acute Suicidal Ideation or Behavior, will present phase 2 efficacy results from its trial of NRX-101, at today's BIO International Convention in Philadelphia, PA. NRX-101 is a fixed dose combination of D-cycloserine and lurasidone in patients presenting to acute care. Jonathan Javitt, MD., M.P.H., Chief Executive Officer, will present the findings, which demonstrated a statistically significant reduction on the Montgomery Asberg Depression Rating Scale for patients treated with NRX-101 vs. those treated with lurasidone alone and a lower likelihood of relapse in depression and/or suicidality. In addition to the presentation, Dr. Javitt and Dr. Fred Grossman, the Company's Chief Medical Officer will be available for 1x1 meetings.

### 2019 BIO International Convention

Date: June 3, 2019

Time: 2:30 pm Eastern Time

Location: Pennsylvania Convention Center, Theater 1

### About Bipolar Depression and Acute Suicidal Ideation and Behavior (ASIB)

Bipolar disorder, which affects 5.7 million Americans, is characterized by significant changes in mood, from mania or hypomania to depression, often quite severe. The depressive phase can trigger suicidal thoughts and behaviors. Currently the only FDA-approved treatment for suicidal bipolar depression is electroconvulsive therapy (ECT), which is shown to increase levels of glutamate/glutamine (Glx) in the brain. Despite its effectiveness, ECT has a myriad of well-known adverse side effects, including confusion and memory loss. Unfortunately, most commonly-used antidepressants require an FDA mandated warning label identifying

the potential to increase the risk of suicide.

Each day, approximately 100 Americans, and more than 2,100 people worldwide, end their lives by suicide, according to the American Foundation for Suicide Prevention (AFSP) and the World Health Organization (WHO). Individuals who suffer from bipolar depression are at far greater risk of suicide than those with major depressive disorder and are believed to represent between 25% and 40% of the 45,000 who end their lives each year in the United States. 11%-20% of those diagnosed with bipolar disorder are believed to take their lives at some point. Overall, suicide has become a national epidemic and is the 10th leading cause of death in the United States.

### **About NRX-101**

NRX-101 is a patented, oral, fixed-dose combination of two FDA approved drugs: D-cycloserine, a N-methyl-D-aspartate (NMDA) receptor modulator, and lurasidone, which has D2/5-HT2a receptor antagonist activity. D-cycloserine has shown activity against depression in four clinical studies. It has also shown an effect on suicidality in some of these studies. NRX-101 is designed to address bipolar depression with suicidal ideation, an indication for which there is no currently approved drug and for which the only FDA-approved treatment remains electroconvulsive therapy (ECT). NeuroRx was granted Fast Track designation, Breakthrough Therapy Designation, and a Special Protocol Agreement by the U.S. FDA for this indication.

### **About NeuroRX, Inc.**

NeuroRx draws upon 30 years of basic science and clinical expertise in the role of N-methyl-D-aspartate (NMDA), a receptor that regulates human thought processes, particularly depression and suicidality, as well as PTSD. The company is privately funded and led by former senior executives of Johnson & Johnson, BMS, Pfizer Inc., Eli Lilly, and Sunovion. NeuroRx's Board of Directors and Advisors includes Hon. Sherry Glied, former Assistant Secretary for Planning and Evaluation, Department of the U.S. Health and Human Services; Chaim Hurvitz, former President, TEVA International Group; Wayne Pines, former Associate Commissioner of the U.S. Food and Drug Administration, and Daniel Troy, former Chief Counsel, U.S. Food and Drug Administration.

Learn more at [www.Neurorxpharma.com](http://www.Neurorxpharma.com)

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