

[111] SUICIDE IS A DRUGGABLE TARGET: TREATING SUICIDAL DEPRESSION AND PTSD WITH A SMALL MOLECULE NMDA/5-HT_{2A} DUAL-TARGETED DRUG PLATFORM

Jonathan Javitt¹, Daniel Javitt¹, Eyal Fruchter², Joshua Kantrowitz³, John Mann⁴, ¹ NeuroRx, Inc., ² Technion University, ³ Columbia University, ⁴ Columbia University ; Chief, Division of Molecular Imaging & Neuropathology; Department of Psychiatry
Company Presentation: NeuroRx

Questions for Biotech/Pharma; Medical Devices and Health IT/Digital Health categories are:

- **Investment Rational**
NeuroRx has patented and is developing a novel platform of dual-targeted NMDA/5-HT_{2A}-inhibiting small molecule drugs to treat suicidal depression and PTSD.
- **Business Strategy**
We are an Israel and US incorporated company seeking regulatory approval by 2020 in the US, EU, and Asia. The addressable market opportunity for severe depression and PTSD exceeds USD 20 billion.
- **Core Technology**
More than 1 million people die of suicide each year. There is no approved pharmacotherapy for suicidal depression or post-traumatic stress disorder (PTSD). All currently-marketed antidepressants have a labelled increased risk for suicide. The only approved treatment today is up to 10 sessions of electroconvulsive therapy (ECT) under general anesthesia. Severe depression and PTSD have been shown to be linked to low levels of Glutamate/Glutamine in the Anterior Cingulate Cortex of the brain and ECT is recently shown to raise levels of Glx. NeuroRx's platform drugs are shown in early human studies to raise Glx even more effectively than ECT and this increase in Glx has been linked to decreased depression (50%) and suicidal ideation (75%) in human phase 2 studies.
- **Product Profile/Pipeline**
The first candidate drug NRX-101 (Cyclurad®) has been awarded FAST TRACK designation by the US FDA for the treatment of Severe Bipolar Depression with Acute Suicidal Ideation and Behavior and is now in phase 2b/3 clinical trials.
- **What's Next?**
NeuroRx is currently enrolling patients in a US-based phase 2b/3 clinical trial of NRX-101 under a special protocol agreement (SPA) with the US FDA. Phase 2 biomarker studies in bipolar depression and PTSD using MR Spectroscopy are being conducted as part of the FDA 21st Century Cures Biomarker Program at Columbia University (New York) and the Rambam Healthcare Campus (Haifa). Development of second generation pipeline drugs is underway with development partners in Nes Tziona.