Hope
Science
Life

NASDAQ: **NRXP**

Corporate Overview
December 2024

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Suicide is a Global Crisis

Suicidality kills ~50,000 Americans every year and 500,000 around the world Disproportionately affecting people with Bipolar Disorder

Suicidality takes our best and brightest

https://www.cdc.gov/suicide/facts/data.html

If you know two people with bipolar depression
One will attempt suicide

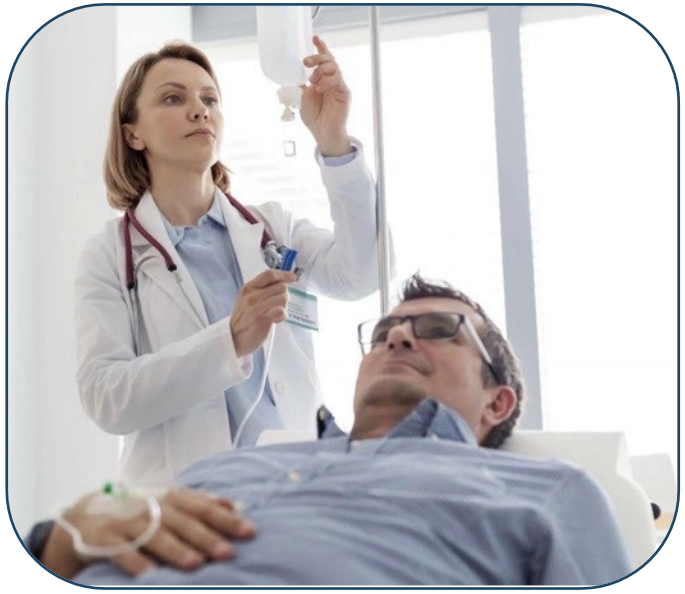
If you know five people with bipolar depression
One will succeed

No FDA-Approved Medication Today for Acute Suicidality

Only FDA-approved therapy is Electro-Convulsive Therapy (ECT)

IV Ketamine is used off-label But not FDA-approved

Intranasal Ketamine (Spravato) is approved but majority practice remains IV Ketamine



Recent panels at psychiatry meetings and evidence for nationwide medical record studies demonstrate strong preference for IV Ketamine over intranasal

NRx Clinical Programs – 2025 Path to Profitability

Suicidal Depression

NRX-100
(IV Ketamine)

- Fast Track NDA in **2024**
- **Expected PDUFA 2025**
- Approvable efficacy data from four studies in hand
- Manufacturing data has reached 12 month stability
- Six-month Ketamine tox data
- Alignment on pediatric plan with FDA
- $2+ billion addressable market

Bipolar Depression

NRX-101
(Oral DCS/Lurasidone)

- Statistically-significant Phase 2 data: first antidepressant to decrease suicidality and/or akathisia
- NDA filing for Accelerated Approval for bipolar patients with akathisia in **2H24**
- Focused initial launch
- 7 million patient broad bipolar addressable market
- > $2 billion market potential

Interventional Psychiatry

HOPE Therapeutics

- A network of Interventional Psychiatry Clinics focused on ketamine and other lifesaving interventions for Suicidal Depression and PTSD
- Targeting $100 million revenue by year-end 2025
- Acquisition Financing in on is committed
- First acquisitions in **2024**
- Expected in profit in **2025**

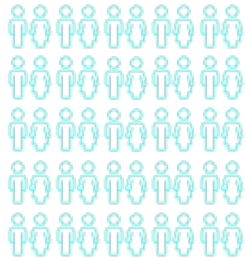
Potential to Reach 70+ Million Lives

Suicidal Depression 3.5 M

- 1 M Bipolar[1]
- 2.5 M Other forms of Depression
- Only approved treatment is ECT

Bipolar Depression 7 M

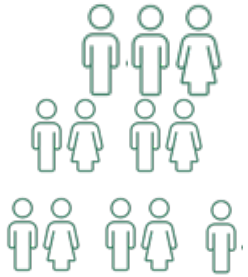
- 1 M Suicidal Depression[1]
- 6 M Non-Suicidal[1]



Chronic Pain 51 M[2]

Global Opioid Crisis
Congressional Funding for EPICNET and HEAL to find new medicines

Early Phase Pain Investigation Clinical Network (EPPIC-Net)
Helping to End Addiction Long-term® Initiative, or NIH HEAL



PTSD 12 M[3]

Currently 2 indicated SSRI drugs:

- Neither relieves PTSD symptoms
- Suicide Warnings on both labels

1. National Institute of Mental Health, https://www.nimh.nih.gov/health/statistics/bipolar-disorder
2. US Dept of Veteran Affairs, https://www.ptsd.va.gov/understand/common/common_adults...
3. Centers for Disease Control and Prevention, https://www.cdc.gov/mmwr/volumes/72/wr/mm7215a1.htm

NRX-100 (IV Ketamine)

for **Suicidal Depression**

Aiming to be the first FDA-approved ketamine product to treat suicidal depression

Everyone is calling for approval of Ketamine

Why is IV Ketamine not approved for depression?

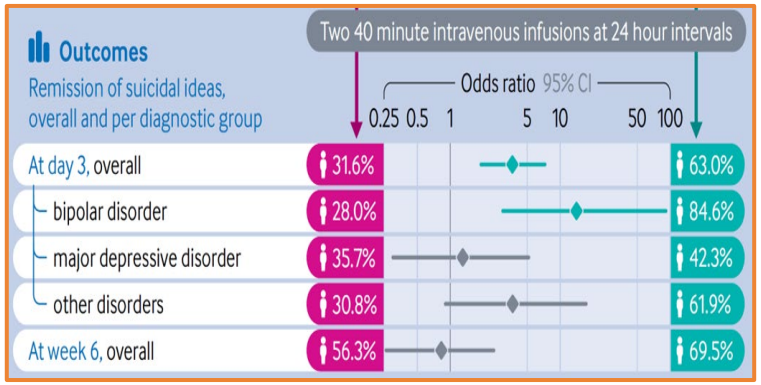
1. **No Company has applied for FDA approval of IV Ketamine to treat depression**
2. No other Company has announced manufacture completion (i.e. FDA Module 3) of an IV Ketamine formulation targeted for the treatment of suicidal depression
3. No other Company has announced patient-level efficacy data demonstrating the effectiveness of IV ketamine in the treatment of suicidal depression
4. No other Company has announced completion of FDA-required neurotoxicity data in support of an application to treat patients with IV ketamine
5. No other Company has announced 12 month real-time stability data associated with a formulation of ketamine to treat suicidal depression

NRx Pharmaceuticals has achieved those milestones and expects to file an NDA under Fast Track designation this year

Efficacy Data in hand to Support a Filing

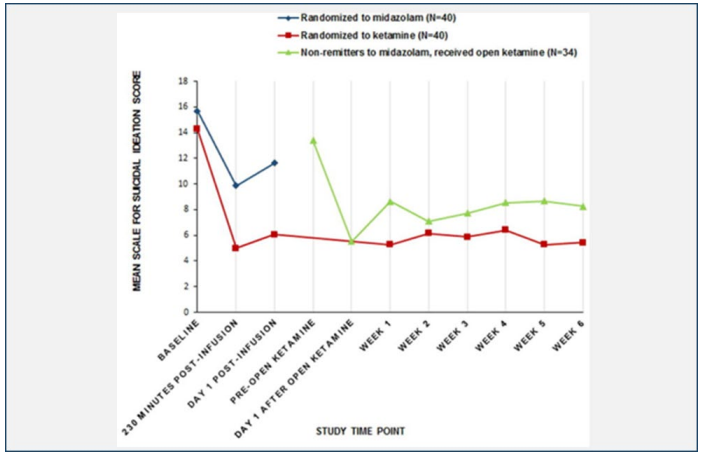
French Gov't Funded: Ketamine vs. Placebo

- 156 Patients, 7 Hospitals
- Admitted with acute suicidality
- Randomized to Ketamine vs. Placebo
- 84% remission on **Ketamine** vs. 28% on Placebo in bipolar depression subgroup
- Odds Ratio P<.0001 on Primary Endpoint



NIH Funded: Ketamine vs. Midazolam

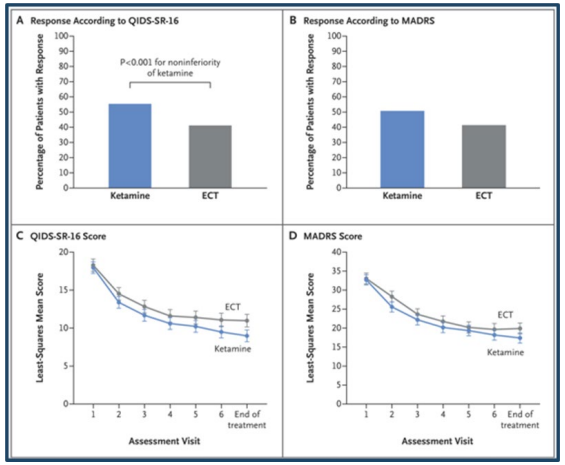
- Initial Randomization to Ketamine vs. midazolam
- Midazolam failures treated with open-label Ketamine
- Ketamine effect following midazolam failure matches effect in those initially randomized to Ketamine



PCORI Funded: Ketamine vs. ECT

Patient-Centered Outcomes Research Institute

- Superiority favoring Ketamine P=.007 (superiority is post-hoc)
- Significant memory loss in ECT vs. none with Ketamine (-9.7 vs. -0.9; P<.0001)
- 6 month relapse ECT 56.3 vs. Ketamine 34.5 (P<.0001)



Noninferior to ECT in treating depression

Broad Support within the Psychiatry Community

JAMA Psychiatry

Viewpoint
October 25, 2023

Choosing Between Ketamine and Electroconvulsive Therapy for Outpatients With Treatment-Resistant Depression—Advantage Ketamine?

Sanjay J. Mathew, MD; Manish K. Jha, MBBS; Amit Anand, MD

JAMA Psychiatry. 2023;80(12):1187-1188.
doi:10.1001/jamapsychiatry.2023.3979

Viewpoint
January 3, 2024

The Rapidly Shifting Ketamine Landscape in the US

Samuel T. Wilkinson, MD[1,2]; Joseph J. Palamar, PhD[3]; Gerard Sanacora, MD, PhD[1,2]

JAMA Psychiatry. Published online January 3, 2024.
doi:10.1001/jamapsychiatry.2023.4945

NRx Has Toxicity and Manufacturing Data in Support of NDA

1. NRx met with FDA on neurotoxicity protocol in 2016 – Data were accepted
2. 2023: NRx implemented formulation of preservative-free Ketamine
3. 2023: First stability batch in BFS (blow-fill-seal; no glass) with modern container closure
4. 2024: Initial manufacturing completion of first preservative-free formulation
5. Ketamine for anesthesia is on drug shortage and existing suppliers are under pressure to limit supply to approved uses

FDA has advised NRx that nonclinical requirements were met

Importance of Preservative-Free Ketamine

Benzethonium Chloride is good for killing germs, not for saving patients

The preservative is in the bottle used for anesthesia only to enable hospitals to use the same bottle in multiple patients – a practice that is no longer legal in hospitals

- *From the manufacturer's data sheet*

Diarrhea, abdominal pain, vomiting, collapse, convulsions, coma

Benzethonium chloride is toxic when orally ingested, with 1 g reported to be fatal. The risk of toxicity is related to concentration with cationic detergents. Ingestion may lead to diarrhea, abdominal pain, vomiting, collapse, convulsions, coma. Oral exposure to high concentrations of benzethonium may lead to burns of the mouth, pharynx, and esophagus. It is an irritant of the skin, eyes, mucous membranes, and upper respiratory tract. When heated to decomposition, this chemical emits very toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, and hydrogen chloride gas [1] [2]

- *The current formulation of Ketamine (formulated in the 1960s) contains a preservative whose toxicity is now well-known. The preservative was needed because the vial was designed to be used in multiple patients – a practice that is no longer legal in hospitals.*
- *This class of preservatives is good for killing bacteria on the skin, but has never been evaluated for safety on repeated IV administration (Ketamine is indicated for use in anesthesia, not for repeated administration).*

ThermoFisher SCIENTIFIC

SAFETY DATA SHEET

Creation Date 28-Jan-2015 **Revision Date** 24-Dec-2021 **Revision Number** 5

1. Identification

Product Name	**Benzethonium chloride**
Cat No. :	**AC105380000; AC105380025; AC105380050; AC105380250; AC105381000; AC105385000**
CAS No	121-54-0
Synonyms	(Diisobutylphenoxyethoxyethyl)dimethylbenzylammonium chloride
Recommended Use	Laboratory chemicals.
Uses advised against	Food, drug, pesticide or biocidal product use.

Details of the supplier of the safety data sheet

Company

Fisher Scientific Company
One Reagent Lane
Fair Lawn, NJ 07410
Tel: (201) 796-7100

Acros Organics
One Reagent Lane
Fair Lawn, NJ 07410

Emergency Telephone Number

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11
Emergency Number **US:**001-201-796-7100 / **Europe:** +32 14 57 52 99
CHEMTREC Tel. No.**US:**001-800-424-9300 / **Europe:**001-703-527-3887

2. Hazard(s) identification

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute oral toxicity	Category 3
Skin Corrosion/Irritation	Category 1 C
Serious Eye Damage/Eye Irritation	Category 1
Specific target organ toxicity (single exposure)	Category 3
Target Organs - Respiratory system.	

NRX-101

(Oral D-cycloserine/lurasidone)

for **Bipolar Depression with suicidality or akathisia**

Aiming to be the first
non-ketamine,
non-addictive
non-psychedelic product
to treat suicidal depression

First Antidepressant
to demonstrate reduced
akathisia and suicidality
In multiple clinical trials

NRX-101: Oral medication with potential for 2025 NDA filing
First oral antidepressant shown to reduce Suicidality & Akathisia

1. Current efficacy and safety data support filing an NDA for Accelerated Approval in the narrow indication of patients with suicidal bipolar depression and akathisia
2. Market potential for NRX-101 for suicidal bipolar depression and akathisia is well in excess of $2 Billion
3. Narrow initial indication allows focused launch by NRx alone
4. Additional phase 3 trial vs. placebo needed for the broad 7 million person bipolar market; planned to be financed by a partner or new investors
5. NRX-101 Phase 3 investment is not part of use of current capital

All Antidepressants Carry Black-Box Warnings for Suicidality and Akathisia

no antidepressant has ever improved either side effect

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use LATUDA safely and effectively. See full prescribing information for LATUDA.

LATUDA (lurasidone hydrochloride) tablets, for oral use
Initial U.S. Approval: 2010

WARNINGS:
INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; AND SUICIDAL THOUGHTS AND BEHAVIORS
See full prescribing information for complete boxed warning.

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.**
- **LATUDA is not approved for the treatment of patients with dementia-related psychosis (5.1).**
- **Increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants (5.2)**
- **Monitor for worsening and emergence of suicidal thoughts and behaviors (5.2)**

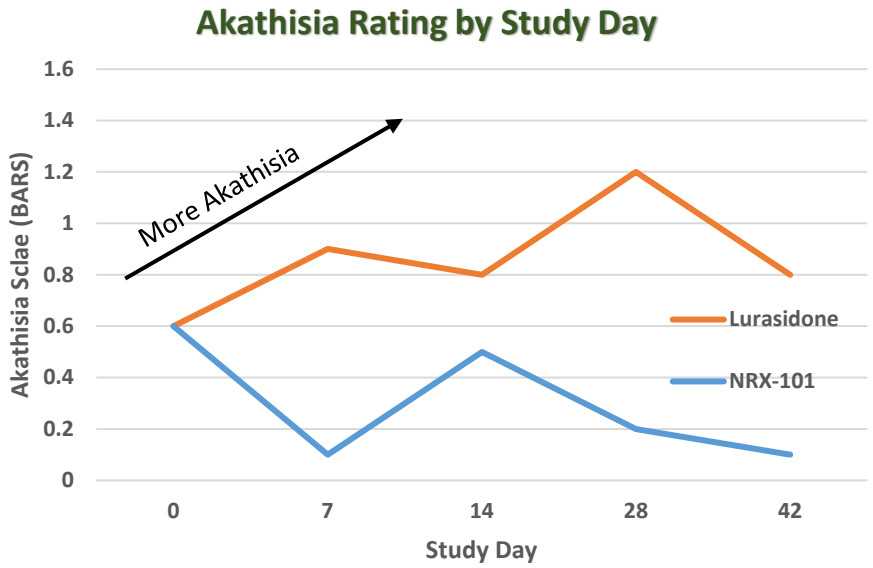
----------RECENT MAJOR CHANGES----------

Boxed Warnings, Suicidal Thoughts and Behaviors (5.2)	m/20xx
Indications and Usage, Bipolar Depression (1.2)	m/20xx
Dosage and Administration, Bipolar Depression (2.1)	m/20xx
Warnings and Precautions (5.2, 5.6, 5.7, 5.9, 5.10, 5.11, 5.13, 5.14)	m/20xx

NRX-101 demonstrates reduced Akathisia and Time to Suicidality Remission in Suicidal Bipolar Depression: *No Ketamine Pre-treatment*

Phase 2b/3, randomized, double blind trial on NRX-101 vs Standard of Care (lurasidone) in Suicidal Treatment Resistant Bipolar Depression (n=93)

- Similar (50% reduction) in depression vs. SoC
- Significant reduction in akathisia vs. SoC, p=0.03
- Decreased Time to Sustained Remission from Suicidality on C-SSRS scale vs. lurasidone (p<0.05)

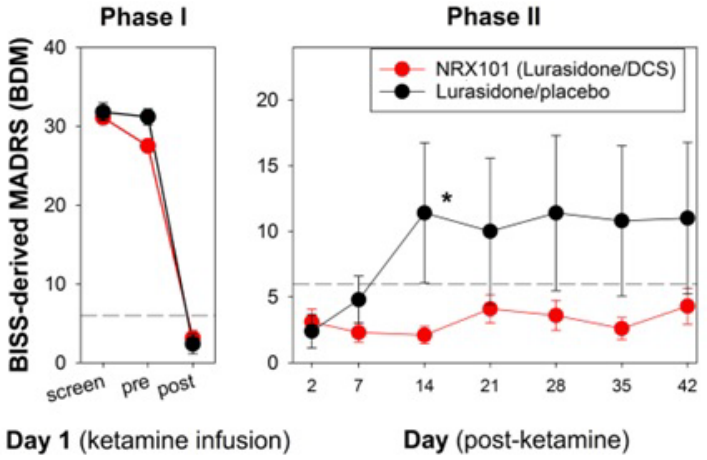


- ➢ *KOLs have advised us that an antidepressant with Standard of Care level efficacy and a significant reduction in akathisia / suicidality can become the new standard in bipolar depression*
- ➢ *"Akathisia is the worst side effect of current treatment"*
- ➢ *This is the first clinical trial ever to enroll, rather than exclude suicidal patients*

Prior Phase 2 Success (2018): STABIL-B trial Showed Superiority of NRX-101 vs Lurasidone in Reducing Depression (primary endpoint) *after Ketamine Pre-treatment*

Patients received one infusion of IV Ketamine vs. placebo. Responders were randomized to NRX-101 vs lurasidone, a Standard of Care

- Mean 7.7 point benefit on MADRS (Primary Endpoint, P=.03) through day 42 vs. lurasidone.
- 40% relapse in control group, no relapse in NRX-101 group (P=.07)
- 1.5 point advantage vs SoC on Columbia Suicide Severity Rating Scale (C-SSRS) (P=.02)
- Decreased akathisia in the NRX-101 group on the BARS akathisia scale with large effect size (P=.14, because of small sample size)



	Efficacy Measures: Repeated Measures Mixed Model LS Mean Differences							
	Through Day 28				Through Day 42			
	LOCF No		LOCF yes		LOCF No		LOCF yes	
MADRS Depression	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean Δ	p-value
Score	-4.0	0.09	-7.7	0.03	-3.7	0.04	-7.7	0.04
Suicidality Rating	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean Δ	p-value
Scale C-SSRS	-0.5	NS	-1.3	0.04	-0.6	NS	-1.5	0.02
Clinical Global	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean Δ	p-value
Impression CGI-SS	-0.4	NS	-2.9	0.05	-0.6	NS	-2.9	0.02

Barnes Akathisia Rating Scale (BARS)
Montgomery–Åsberg Depression Rating Scale (MADRS)
**J Clin Psychiatry* 2022 May 30;83(4):21m14345

Potential Product Profile of NRX-101 in Suicidal Bipolar Depression

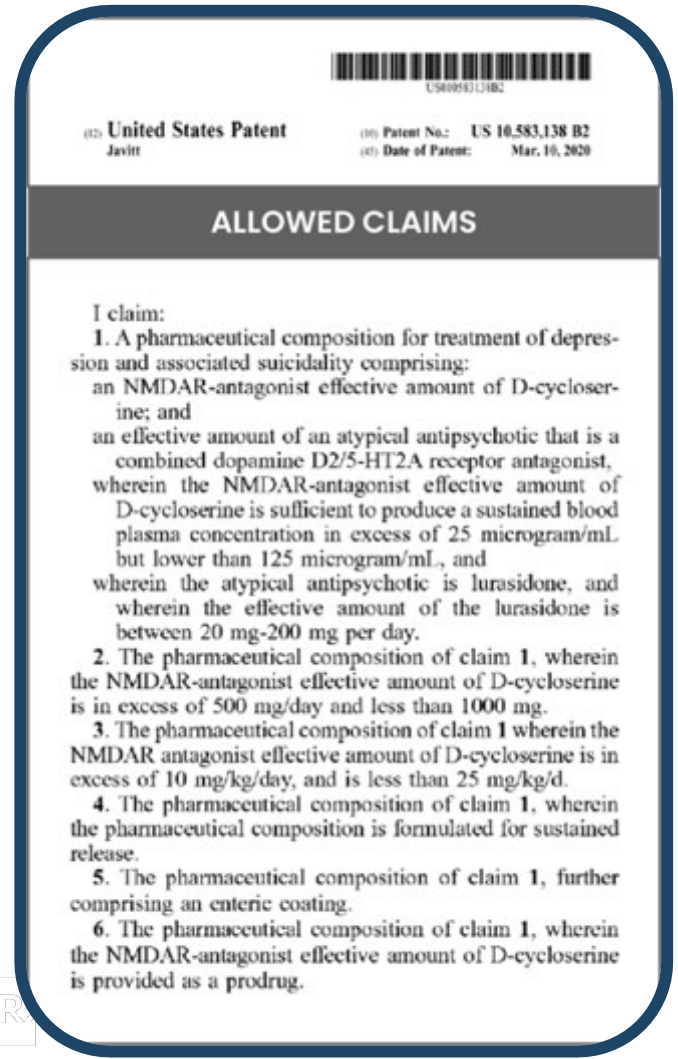
- NRX-101 reduces depression scores by ~50% -- similar to SoC
- NRX-101 is the only drug to demonstrate clinically meaningful reduction in akathisia and suicidality vs SoC

➢ *We believe an antidepressant with this profile can* ***become the new Standard of Care*** *in bipolar depression*

➢ *We believe NRX-101 can be that medication*

NRX-101: Robust Composition of Matter Patent Protection

Patent Estate of 48 issued, 43 pending patents
Enables a platform of CNS drugs based on NMDA / $5HT_{2A}$ Synergy.



(12) United States Patent
Javitt

(10) Patent No.: US 10,583,138 B2
(45) Date of Patent: Mar. 10, 2020

ALLOWED CLAIMS

I claim:

1. A pharmaceutical composition for treatment of depression and associated suicidality comprising:

an NMDAR-antagonist effective amount of D-cycloserine; and

an effective amount of an atypical antipsychotic that is a combined dopamine D2/5-HT2A receptor antagonist,

wherein the NMDAR-antagonist effective amount of D-cycloserine is sufficient to produce a sustained blood plasma concentration in excess of 25 microgram/mL but lower than 125 microgram/mL, and

wherein the atypical antipsychotic is lurasidone, and wherein the effective amount of the lurasidone is between 20 mg-200 mg per day.

2. The pharmaceutical composition of claim **1**, wherein the NMDAR-antagonist effective amount of D-cycloserine is in excess of 500 mg/day and less than 1000 mg.

3. The pharmaceutical composition of claim **1** wherein the NMDAR antagonist effective amount of D-cycloserine is in excess of 10 mg/kg/day, and is less than 25 mg/kg/d.

4. The pharmaceutical composition of claim **1**, wherein the pharmaceutical composition is formulated for sustained release.

5. The pharmaceutical composition of claim **1**, further comprising an enteric coating.

6. The pharmaceutical composition of claim **1**, wherein the NMDAR-antagonist effective amount of D-cycloserine is provided as a prodrug.

- Five patent families, 90+ filed applications, 48 issued patents in US/EU/CN/JP/KR/AU.
- Protects NRX-101 to at least 2033 with potential for protecting NMDA/5HT2A class.
- Also covers drugs for PTSD, Major Depressive Disorder, Obsessive Compulsive Disorder, and other targets.
- Combinations involving dextromethorphan, d-methadone, and S-Ketamine are identified in the spec of US 10,583,138.

NRX-101: Commercial-Ready Manufacture

- GMP manufacturing initiated in the US in 2022
- Phase 3 drug, produced using expected Commercial Scale manufacturing process.
- FDA Type C manufacturing meeting conducted in January 2022 with concurrence on CMC, stability, and etc.
- 1 million phase 3 (commercial process) capsules on hand in our warehouse

HOPE Therapeutics

The first nationwide network of Interventional Psychiatry Clinics focused on suicidal depression and PTSD

A Trailblazing Precision Psychiatry Network

A trailblazing precision psychiatry network providing interventional pharmaceutical therapy, TMS, Digital Therapeutics, and supportive therapy for suicidal depression, PTSD, anxiety, OCD and more.

Our Mission

To offer state of the art interventional psychiatry care to render suicidal depression and PTSD curable diseases with overnight results, offering HOPE to patients and families without stigma

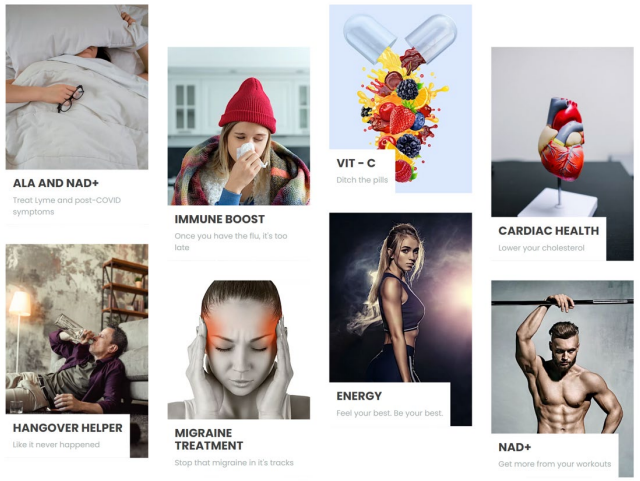
Our Vision

When people tell the story of their mental health journey in the US, they and their family end the story by saying:

"***We went to HOPE and were cured***."

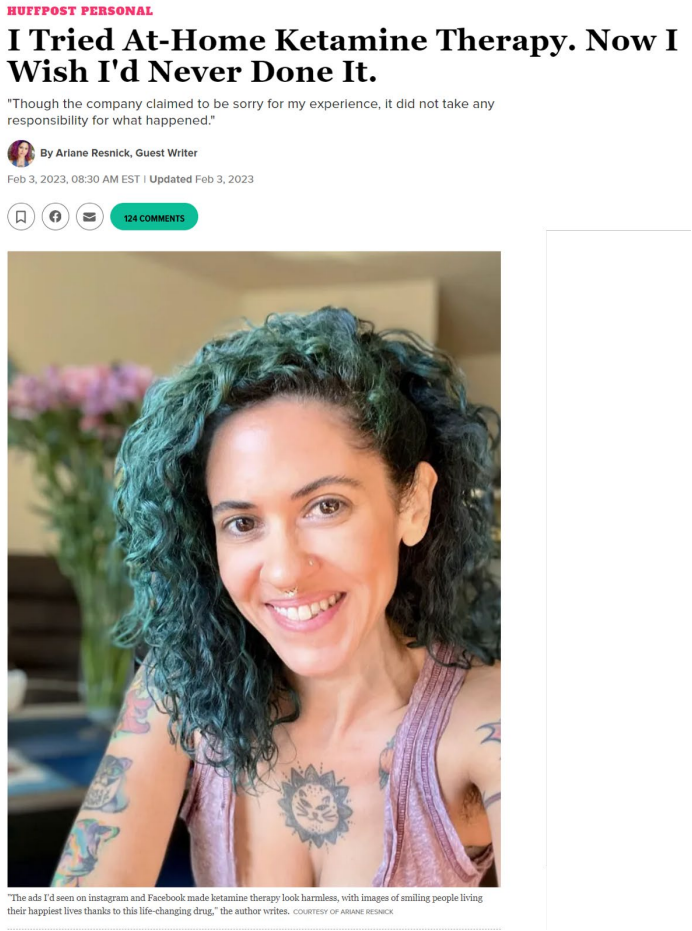
We Need both the Means and Systems of Care

Ketamine does not belong in MedSpas or at home



HOPE Therapeutics

- A network of Interventional Psychiatry Clinics focused on ketamine and other lifesaving interventions for Suicidal Depression and PTSD
- Psychiatrist led
- Safety-focused
- Common protocols
- Measured Outcomes
- **It's not just ketamine**



HUFFPOST PERSONAL

I Tried At-Home Ketamine Therapy. Now I Wish I'd Never Done It.

"Though the company claimed to be sorry for my experience, it did not take any responsibility for what happened."

By Ariane Resnick, Guest Writer

Feb 3, 2023, 08:30 AM EST | **Updated** Feb 3, 2023

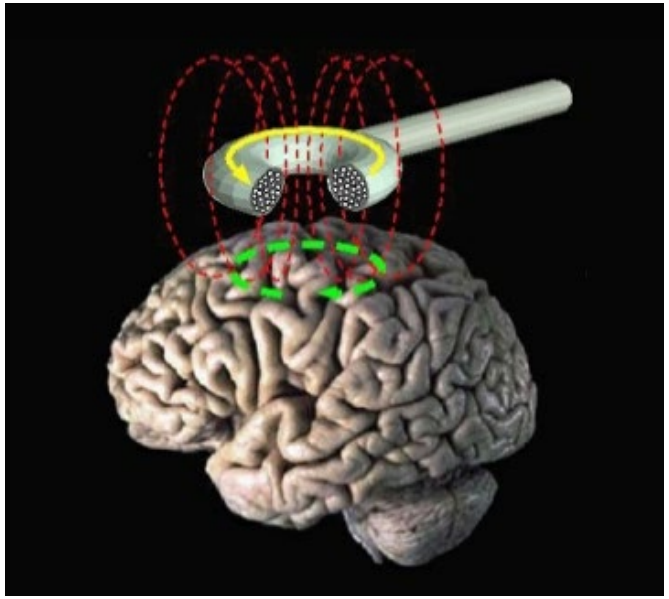
124 COMMENTS

"The ads I'd seen on instagram and Facebook made ketamine therapy look harmless, with images of smiling people living their happiest lives thanks to this life-changing drug," the author writes. COURTESY OF ARIANE RESNICK

Ketamine is not Enough: We Need a new System of Care

Ketamine must be supplemented with TMS, Digital Therapeutics and Supervised Care!

TMS

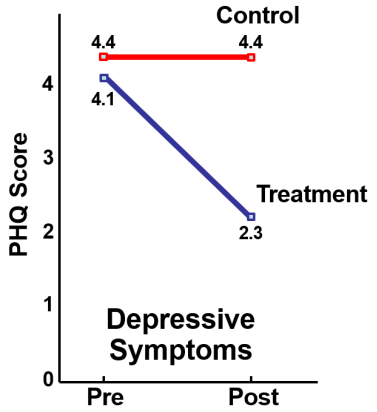


An FDA-approved treatment. TMS is shown to achieve remission in 50% of patients

HOPE Therapeutics

- A network of Interventional Psychiatry Clinics focused on ketamine and other lifesaving interventions for Suicidal Depression and PTSD
- Psychiatrist led
- Safety-focused
- Common protocols
- Measured Outcomes
- **Integrated Care with Ketamine, TMS, Digital Therapeutics**

Digital Therapeutics



Proven in DARPA and US DOD-funded trials. In development by NRx/HOPE for civilian use

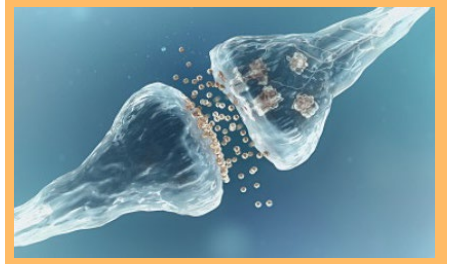
Pillars of HOPE Therapeutics

Rewiring the brain in suicidal depression

Patient Total Care Umbrella

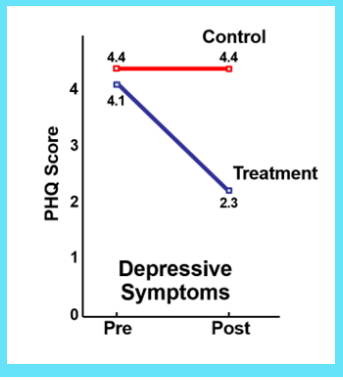
Precision Psychiatry and Medication Management

Ketamine and NMDA Therapy



Transcranial Magnetic Stimulation

Digital Therapeutics



HOPE Therapeutics: Why Spin Out a Separate Company?
Expected 2025 profitability

1. NRx is a Biotechnology company focused on Research and Development
   HOPE is a Care Delivery company focused on Interventional Psychiatry and digital therapeutics
2. **Focus on TMS and Digital Therapeutics in addition to ketamine and oral meds**
3. **Insurance-reimbursable:** transforms a "cash and carry" market
4. **Immediate sales** of Ketamine under 503b pharmacy license by mid-2024
   Development of HTX-100 (pH neutral Ketamine for SubQ dosing) – improved formulation
5. **Financing independent of NRXP:** equity and bond issuance

Hope Therapeutics Near-Term Investor Highlights:
Make Good Clinics Great

- **Acquisition and management of ~30+ Ketamine clinics through 2025**
  - Target $100 million/yr run-rate with positive EBITDA
  - Starting with industry-leading mental health practices that set the standard and scale for future acquisitions; ongoing revenue and positive EBITDA
  - ***Make good clinics great***: increase revenues via offerings and access, grow EBITDA via product mix, efficiencies and operational optimization
- **Disciplined financing strategy**
  - Clinic acquisition:
    - Market EBITDA multiples with performance based earn-outs
    - Cash via corporate bonds and/or other debt financing expected
  - IPO: planned as the company begins to scale & generate meaningful revenue
- **Building shareholder value**
  - Market value of clinics is largely based on EBITDA multiples
    - ***Growing total EBITDA, via increased integration of services, directly enhances shareholder value; debt financing avoids dilution***

Leadership Team

Jonathan Javitt, MD, MPH – Founder, Chairman & Chief Scientist; Co-CEO HOPE Therapeutics

40 years in pharmaceutical and medical device development. Blockbuster drug and device development programs with Allergan, Eyetech, Merck, Novartis, Pfizer, and Pharmacia. Advisor to four White House administrations.

Matthew Duffy – Chief Business Officer; Co-CEO HOPE Therapeutics

35+ years of biotechnology-related business and investment banking expertise. Business leadership roles at Pfizer and Medimmune. Investment banking and research roles at Roberts Mitani, LifeSci Advisors, and Laidlaw. Series 7, 63, and 65 Securities Licenses.

Rick Panicucci, PhD – Chief Technology Officer

25 years pharmaceutical manufacturing leadership and process development. Leader on multiple approved New Drug Applications. Head of CCP, Novartis. VP of Manufacturing, WuXi Apptec.

Michael Abrams – Chief Financial Officer

Michael Abrams is a senior finance professional with almost three decades of experience as an executive officer, investment banker, director and senior advisor, which includes serving as the Chief Financial Officer of Arch Therapeutics, RiseIT Solutions. and FitLife Brands.

NRx/HOPE Scientific Advisory Board

Daniel Javitt, PhD, MD

Professor of Psychiatry at Columbia University. Initial discovery on the role of NMDA antagonists in psychiatric disorders. More than 760 publications in the field. Inventor of the NRx patent portfolio

Marion Leboyer, MD, PhD – EU Principal Investigator

Professor of Psychiatry Inserm (Paris). More than 1300 publications related to clinical psychiatry and infectious / genetic triggers of psychiatric disease.

Andrew Nierenberg, MD – US Principal Investigator

Professor of Psychiatry at Harvard University, Director, Dauten Family Center for Bipolar Treatment Innovation. More than 875 publications in the field. Director of the national Patient Centered Outcomes Research Initiative in treatment of Bipolar Depression.

Gerard Sanacora, PhD, MD – REMS Chair

George and Esther Gross Professor of Psychiatry at Yale University. Director, Yale Depression Research Program. Pioneer in the use of ketamine to treat suicidal depression and development of standards to assure patient safety for the outpatient use of ketamine

Philip Lavin, PhD – Lead Methodologist

NRx Lead Methodologist. Clinical Professor, Harvard Medical School and Harvard School of Public Health. FDA Special Government Employee in Statistics. More than 78 Drug and Medical Device Approvals and more than 350 scientific publications.

Hope
Science
Life

NASDAQ: **NRXP**

Corporate Overview
December 2024