



NASDAQ: NRXP

BIO CEO 2024
Bringing HOPE to Life

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# **Key NRx Updates**



**Depression** 

Suicidal Bipolar

Data end of Q1

#### **NRX-101**

- FDA Breakthrough designated drug
- Alvogen has advanced first milestone payment
- Last Patient VisitExpected this week
- Trial has maintained95% Rating Reliability
- Top Line Data expected end of 1Q24
- \$330 million in potential milestones plus 15% royalty



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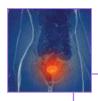
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Chronic

Data end of Q1

#### **NRX-101**

- Enrollment terminated
- Study CompletedJune 2023\*
- Extensive data collection with neuroimaging now complete
- Final statistical analysis plan expected in two weeks
- Top line data to follow
- NRx commercial IND is open with FDA



#### **Seeking Partners**

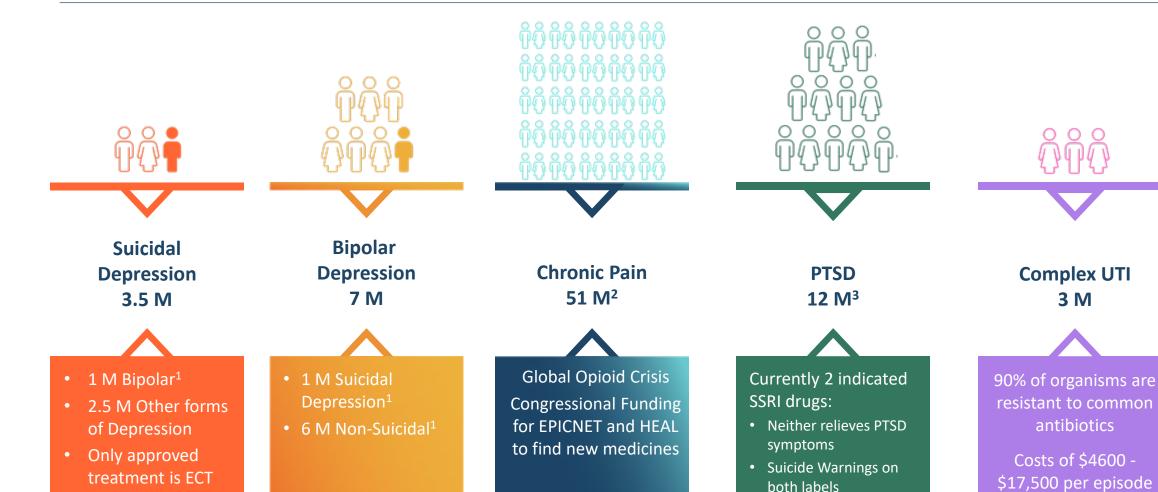
#### **NRX-101**

- IND granted in complicated UTI and Pyelonephritis
- Awarded FDA Qualified
   Infectious Disease Product and
   Fast Track Designation Jan 2024
- Clinical trial supplies on hand for phase 2
- 3 million cases/yr
- 90% of organisms are resistant to common antibiotics
- >\$10 billion market at branded prices

# omplicated UTI



## Potential to Reach 75 Million Lives



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



# We Do Things that Matter

**Launching HOPE Therapeutics** 





an NRx Daughter Co.

HTX-100 (IV Ketamine) for Suicidal Depression

HOPE. Science. Life.

NOTE: Investigational Therapy not currently approved by FDA



# **Suicidality is a National Crisis**

#### Suicidality kills ~50,000 Americans every year





**48,000** people died by

suicide in 2021



death every

11 minutes

Many adults think about suicide or attempt suicide

12.3 million
Seriously thought about suicide

3.5 million
Made a plan for suicide

1.7 million
Attempted suicide

#### It often takes our best and brightest











# Why Spin Out a Separate Company?

- NRx is a pre-commercial drug development company

  HOPE is a commercial company focusing on ketamine and digital therapeutics
- Planned NDA filing for ketamine (HTX-100) in Q2 2024 when stability/sterility data are completed and 3 commercial lots have completed manufacture
- **3** HOPE aims to initiate sales of ketamine under current pharmacy laws by July 2024
- Investor model is based on capital appreciation and royalty payment
- **5** Potential for up to \$300 million+ in sales starting January 2025



# Series A Investment (Reg 506c) Followed by Nasdaq Listing

## Public Financing: \$30 million term sheet for public capital in hand



\$25 million at public listing provides for all launch expenses and required cash reserves (shareholders equity) for Nasdaq Global Markets listing

**Share Dividend** 

Q1 2024 Reg 506c anticipated

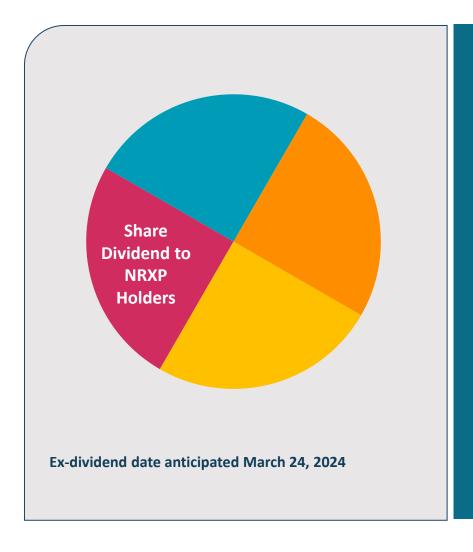
Q2

Nasdaq listing anticipated

Q3 2024



## **Share Dividend to NRXP Shareholders**



Anticipate distributing 50% of founding shares in HOPE Therapeutics to existing NRXP shareholders

Dividend recipients will also receive a royalty coupon for sales of HTX-100

Dividend recipients will be required to sign a no-shorting covenant to be eligible for Share Dividend and Royalty Coupon

HOPE Royalty Coupon is not anticipated to be a liquid security and aims to provide a cash return to current NRXP shareholders

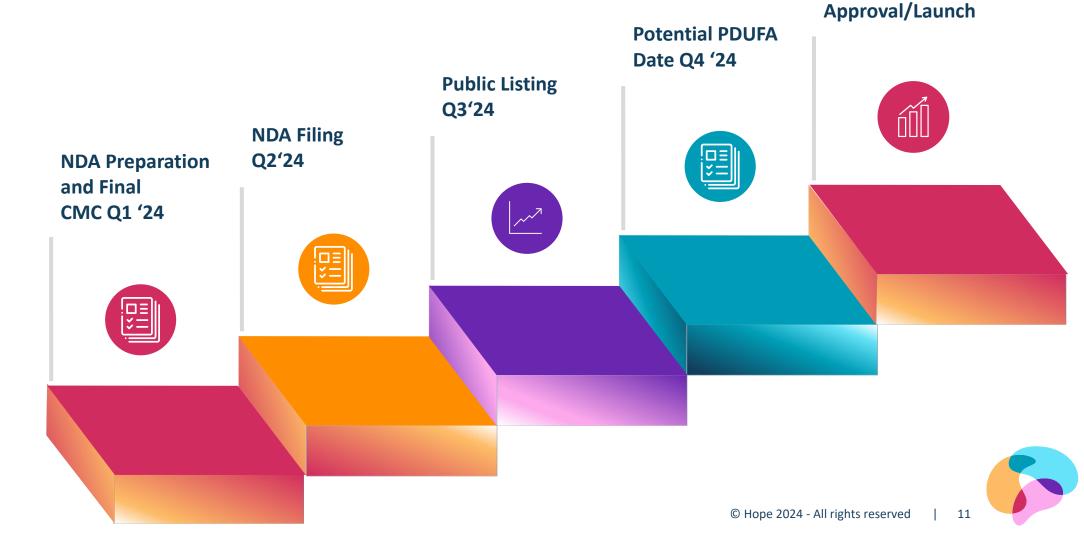
Short positions with "fails to deliver" will need to deliver both the HOPE share certificate and royalty coupon as of the ex-dividend date

\* These elements are subject to NRXP board approval



# **Next Steps for HOPE**

Bringing HTX-100 (IV Ketamine) to market in Q4 2024 \$3.5 Billion Addressable Market



**Potential Product** 

# No FDA-Approved Medication Today for Acute Suicidality

Only <u>FDA-approved</u> therapy is Electro-Convulsive Therapy (ECT)



IV Ketamine is used off-label
But not <u>FDA-approved</u>
Not reimbursed by Payers
Inconsistent in quality



Esketamine is currently approved for treatment of depression in patients at risk of self-harm but may not be used in patients with bipolar depression



# Data in Support of HTX-100 Approval for Suicidal Depression

- (1) NIH-funded ketamine dose-ranging trial establishing 0.5 mg/kg dose
- Prench government-funded trial of 156 patients in 7 hospitals (P<.0001 on 1° endpoint)
- NIH-funded Columbia University trial in 80 patients (P<.015 on 1° endpoint)
- PCORI trial demonstrating advantage over ECT in 420 patients (P=.007)
- **5** Extensive literature of smaller trials demonstrating ketamine effect



# **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

<u>Samuel T. Wilkinson, MD<sup>1,2</sup></u>; <u>Joseph</u> <u>J. Palamar, PhD<sup>3</sup></u>; <u>Gerard Sanacora, MD, PhD<sup>1,2</sup></u>

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



# **Beyond Sales of Ketamine**

- $\begin{pmatrix} \mathbf{1} \end{pmatrix}$  The pharmacologic effect of ketamine lasts for < 1 week
- 2 Patients need ongoing support and Cognitive-based therapy is insufficient
- Research sponsored by DARPA demonstrates measurable benefit of Digital Therapeutic approach in reducing physiologic measures of depression and stress
- Recent advances in consumer-targeted sensors (iWatch® and others) together with gaming app advances makes this deployable
- **5** Development of the "ketamine-clinic" creates a consumer platform

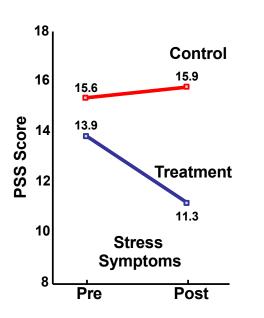
Digital Therapeutics are regulated by the FDA as medical devices and may not make claims of health benefit without FDA clearance or approval

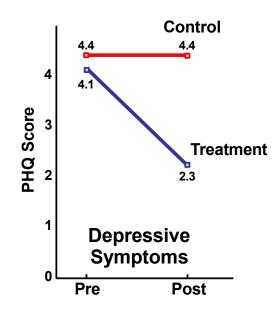


# **Example of Digital Therapeutic Use in US Navy Personnel**

#### Methodology:

- 71 personnel from US Navy Coastal and Riverine Expeditionary Group and Squadron
- 8-week Digital Therapeutic Use compared to Control
- Measures are Perceived Stress Scale, Patient Health Questionnaire and Usage Report





Participants
demonstrated high
acceptance and
Digital Therapeutic
Use (75%) compared
to control

#### Key Results:

- Large reductions in Perceived Stress and Depression compared to Control group
- Digital therapeutic use before and during stress events is significantly greater than for Control
- Quantitative improvements in both performance and mental health



# Five Elements of the HOPE Therapeutics Value Proposition

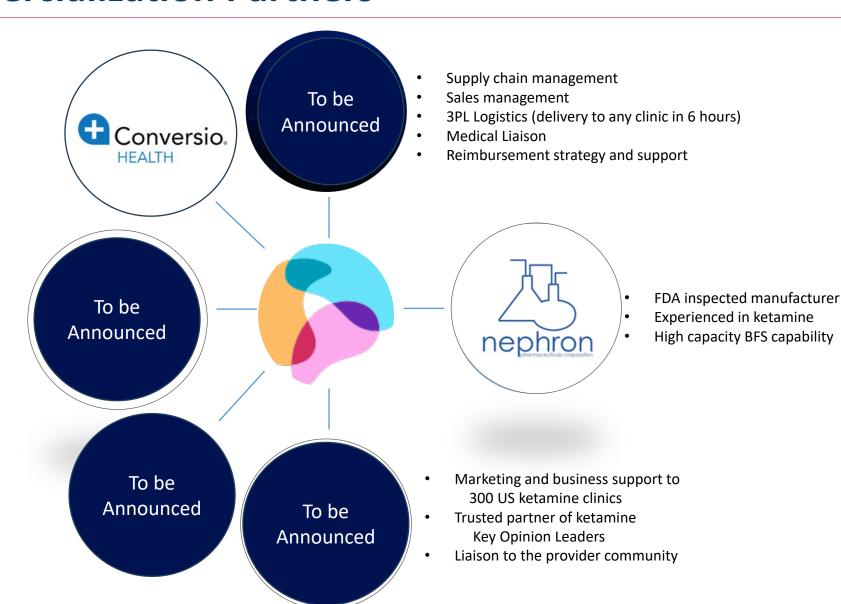
- Sales of HTX-100 (IV ketamine)
- 2 Delivery of REMS (Risk Evaluation and Management Strategy) support to prescribers
- **3** Digital Therapeutic solutions to extend the HTX-100 clinical effect
- 4 Ongoing patient-engagement tools
- (5) Managed Care Reimbursement and full support program

By the time HTX-100 loses market exclusivity, elements 2,3,4 & 5 will maintain a sustained marketplace advantage



#### **HTX-100 Commercialization Partners**

- Nationwide 503a Pharmacy and DEA licensure for ketamine sales pre-approval
- Extensive payer and market access relationships for managed care programs post-approval
- Psychiatry-specialized EMR
- Adopted in 600 practices
- Electronic implementation of existing REMS programs
- Patient portal/Patient app
- Digital therapeutics delivery
  - Digital therapeutics development
  - Based on DARPA-funded product proven in war-fighters and first responders
  - Already approved for sale throughout DOD





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