

Health Care: Biotechnology

# NRx Pharmaceuticals, Inc. (NRXP)

**INITIATING COVERAGE** 

October 21, 2024

# NRx Pharma (NRXP) Initiating Coverage With a Buy Rating and \$31.00 PT, Two Companies in One — Saving Lives on a National Level

Changing the Paradigm of Suicide Prevention. NRx has a vision to address the national crisis around suicide and PTSD. Lives are lost for many reasons, which include unanswered cries for help. This results partly because of a lack of acute efficacy drugs and a chaotic system that just doesn't know how to deal with these patients. The company is working to introduce the first NMDA-targeted drugs, engineered to eliminate the typical side effects of hallucinations, neurotoxicity, and akathisia, all of which limit efficacy. NRX-101 has shown its potential to act rapidly in reducing Acute Suicidal Ideation and Behavior (ASIB). It has the potential to expand to bipolar depression and PTSD-suicide. NRX is seeking approval for NRX-100, an optimized and tamper-resistant formulation of ketamine, with a label & Insurance —removing a key obstacle that's been it back. All prescribed as part of a planned national network of clinics—HOPE Therapeutics.

What is NRX-101, and Why is it Special? It is a composition of matter patented fixed-dose combination of D-Cycloserine (DCS), an NMDA antagonist, and Lurasidone, a 5-HT2A atypical antipsychotic and antidepressant, for the maintenance of remission from severe bipolar depression (SBD). Too often, SBD takes a patient's life before an effective treatment is identified. Recognizing the need, the FDA has granted the company Fast Track and Breakthrough Therapy designations, a Special Protocol Agreement, and a Biomarker Letter of Support. We note that additional indications include Bipolar Depression — a multi-billion dollar market as well as PTSD suicidally, Urinary Tract Infections (UTIs), and pain in the future. NRX-101 solves a unique problem — Akathisia. Akathisia is defined as a state of agitation, distress, and restlessness that is an occasional side effect of antipsychotic and antidepressant drugs. It can be deadly. NRX-101 in clinical trials demonstrated a significant reduction in akathisia compared to Lurasidone alone.

Why is a Pharmaceutical Company Planning to Acquire Ketamine Clinics? NRXP acknowledges the challenges patients in crisis face. Finding a provider with complete treatment tools might be described as glimpsing a unicorn. Many patients, after an initial 24 hours in the ER, are then warehoused in a psych facility only to be discharged days later when insurance runs out. NRx believes that acquiring a national footprint of clinics with dedicated mental health providers can change this. The use of NRX100 (safe ketamine), with a label and insurance reimbursement resolved is likely to see its use expand along with multiple tools that can help these patients in dedicated clinics.

Valuation: Please see our valuation discussion (next page) for complete details.

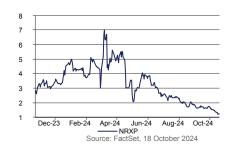
**Risks to our thesis include**: 1. Regulatory Approvals; 2—clinical Science; 3. Intellectual Capital; and 4. Dilution

**Jason Kolbert** jkolbert@efhutton.com

MARKET DATA	
Rating	Buy
Price Target	\$31.00
Price	\$1.25
Average Daily Volume (000)	85
52-Week Range (\$)	\$1.10-\$7.33
Market Cap (M)	\$13
Enterprise Value (M)	\$19
Book Value	(1.42)
Dividend Yield	0.0%
Cash (M)	\$2
<b>Qrtly Burn Rate (M)</b>	\$(6)

ESTIMATES			
	2023A	2024E	2025E
Revenue (M)	\$0.0	\$0.0	\$107.2
Total Expenses (M)	\$28	\$26	\$16
GAAP EPS	\$(0.28)	\$(2.11)	\$1.00

#### **One Year Performance Chart**



Please see analyst certification and important disclosures on page 29 of this report.



#### A Few Extra Thoughts

NRX-100 is Ketamine; Why Develop it Now? Insurance Reimbursement. Once approved to treat ASIB, the product moves from off-label, non-reimbursed use to a reimbursable drug therapy. We see the potential of this one change as expanding the market ten-fold. Recall that ketamine is available as a generic anesthetic and is widely used off-label in psychiatry today. However, it is private pay. The result is that access becomes limited to those who can afford it. The DEA/FDA worries about the potential abuse. NRX-100 is a proprietary formulation of IV Ketamine developed specifically for psychiatric use. NRx has acquired data from multiple clinical studies and received a Special Protocol Assessment (SPA) for approval. Approval positions the company's subsidiary, Hope Therapeutics, to deliver on its vision of addressing a national suicide crisis through a network of empowered providers with the tools necessary to treat patients in crisis.

**Unlocking the Value of Ketamine – Creating HOPE.** NRx Pharmaceuticals (NRxP) has established a subsidiary, Hope Therapeutics, with the potential for this entity to spin out as it grows and executes its core mission. Hope represents a paradigm shift in how patients in psychiatric crises are treated. The current system is fragmented: patients in crisis often encounter first responders, only to end up in hospital emergency rooms, where they are held and often, in the best case scenario, sent to a psychiatric facility for 7-10 days. Upon release, patients are picked up by family and friends with a sheet of paper listing local psychiatrists in the area. Often, these doctor's practices are full. The unspoken truth is that most psychiatrists avoid suicidal patients. Families are left to scramble to find a provider or psychiatrist knowledgeable in using a broad array of tools—drugs, devices, and therapies—to help their loved ones climb out of the deep despair they are experiencing.

Imagine, instead, calling 1-800-Call HOPE and being connected to a specialized center in your region. This is the vision for Hope Therapeutics. Ketamine will be a key component, but it is just one part of a multi-pronged approach. This model includes Electro-Convulsive Therapy (ECT), IV Ketamine, and Transcutaneous Magnetic Stimulation (TMS), all integrated within a national network of providers and clinics. Hope's mission is to deliver a comprehensive, innovative standard of care to help patients recover more effectively and access treatment faster.

A Discussion of Valuation and Potential Spin-Out of Hope Therapeutics. If Hope Therapeutics becomes independent, a thoughtful valuation approach is necessary. This involves assessing the value of NRX-100 relative to NRX-101 and the revenues generated by the clinics. Additionally, the future value of NRX-101 in addressing conditions like Bipolar Depression, PTSD with suicide risk, and even non-CNS indications such as UTI and Pain must be considered. A 65-35 split in future projected value between NRXP and Hope seems reasonable, suggesting that the current \$31 price target should translate to approximately \$20 for NRXP and \$11 for Hope, based on current share counts. These estimates will need adjustment as more details emerge regarding Hope's share count, capitalization, and financial structure following a potential spin-out, as well as the revenues and growth with NRX-100 and 101.

**Valuation:** Our \$31.00 price target is based on the success of NRX-100 and NRX-101, including revenues from the clinic acquisitions (Hope Therapeutics). Our valuation models include Free Cash Flow to the Firm (FCFF), discounted EPS (dEPS), and Sum-of-the-Parts (SOP). We use a 30% discount rate. This is in addition to our revenue models' 30% risk cut or 70% Probability of Success POS factor. We select 30% for micro-capitalized growth companies, representing our highest risk rate. These three models' results are equal-weighted, averaged, and rounded to the nearest whole number to provide a 12-month target price.

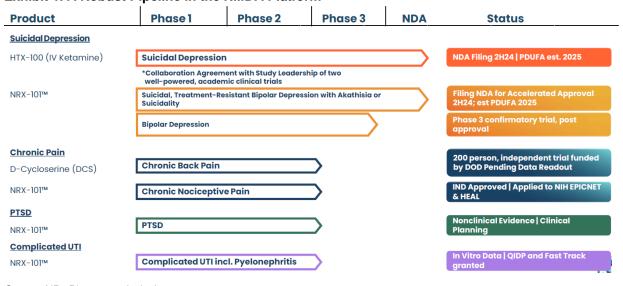


#### **Company Overview**

NRx Pharmaceuticals was founded by Dr. Jonathan Javitt and his brother, Daniel Javitt, PhD, MD. Like many biotechnology executives, these founders saw an unmet medical need and felt they could make a difference to close that gap. Early work done by Daniel in 1987 focused on understanding the NMDA receptor. We know of 250 primary-authored papers and over 28,000 citations around the world regarding his work. The company's core mission originally was the development of therapeutics that can acutely impact mental health and, in the case of Nrx Pharma, the need to address acute depression that too often leads to suicide. That mission has grown and is now best stated as one to address a national suicide crisis by empowering providers and patients with the tools to become healthy functioning members of society. The company's two lead compounds are NRX-100, a proprietary formulation of ketamine, and NRX-101, a patented fixed-dose combination of D-cycloserine and Lurasidone or DCS. Both products have Fast Track designation from the FDA for the treatment of suicidal Bipolar Depression. NRX-101 additionally has a Breakthrough Therapy Designation and a Biomarker Letter of Support. NRX-101 is the only oral antidepressant demonstrated to reduce suicidal ideation in a phase 2 trial. The company is also looking at patients with PTSD suicidality, as the NMDA component of NRX-101 (D-Cycloserine or DCS) appears to reduce "Fear Memory." which is the driver of PTSD symptoms. It has also been learned that NRX-101 has antimicrobial properties. It seems to interfere with cell wall formation in certain bacteria and has demonstrated its ability to kill certain treatment-resistant urinary tract bacteria. Accordingly, NRX-101 has been awarded Qualified Infectious Disease Product Designation and Fast Track Designation by the FDA to treat Complicated Urinary Tract Infections and Pyelonephritis. There is also a strong rationale for NRX-101 as a Pain medication. We address the UTI/Pain opportunity in the appendix of this report, as the company's focus now is in the psychiatric marketplace. The company's strategy today remains the pursuit of therapies for high unmet needs, including lethal conditions such as suicide.

The History of NeuroRx. As stated, the company was founded in 2015 by Professors Jonathan Javitt, MD, MPH, and his brother Daniel Javitt, PhD, MD. Initially, the company was a privately funded, R&D-focused entity targeting drug development for psychiatric conditions. The team successfully raised capital and initiated a phase 2b/3 trial (DCS) in 2016. Over the subsequent three years, it formulated and manufactured clinical supplies of the drug, initiated and completed the STABIL-B trial, and established the first Special Protocol Agreement issued by the FDA Division of Psychiatry Products.

Exhibit 1. A Robust Pipeline in the NMDA Platform





What's so Special About NRX-101? Its Dual Mechanism of Action. The development of D-Cyclosrine or DCS as an antidepressant has been limited by its potential side effects. Professor Daniel Javitt of Columbia University discovered that the psychedelic effects of NMDA drugs could be reversed by combining them with serotonin-targeted drugs, such as Lurasidone. A major limitation in the use of serotonin-targeted drugs is the behavioral side effects they can induce. Specifically, akathisia (a state of agitation, distress, and restlessness associated with generating or exacerbating suicidality in psychotic or depressed patients. Professor Javitt made the simultaneous discovery that NMDA inhibitors, in turn, block the akathisia side effect normally experienced with the use of serotonin-targeted drugs. When administered together, DCS and Lurasidone appear to mitigate the most common side effects of the other. Lurasidone reduces the risk of psychosis and mania, while DCS reduces the occurrence of akathisia<sup>1</sup>.

The previously undiscovered synergy between these two drug classes in the treatment of CNS disorders, as illustrated in the figure below, combined with the efficacy of DCS in the treatment of depression and PTSD, is the subject of 48 issued patents and more than 43 pending patents owned by or licensed to NRx Pharmaceuticals, and as such, is the medical and scientific basis for the company's technology platform<sup>2</sup>.

Exhibit 2. The Patented NMDA Discovery: 90 Patents & Patent Applications Globally

# DCS (D-Cycloserine) blocks side-effects of 5HT2A Blocks side-effects of NMDA Blocks side-effects of NMDA Blocks side-effects of NMDA Receptor Akathisia S-HT<sub>2x</sub>Receptor

Simultaneous Blockade of NMDA and 5-HT2A Blocks NMDA Side Effects

Source: NRx Pharmaceuticals, Inc.

<sup>2</sup> NRX Pharma – NRx Pharma and Crystal Research Associates



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<sup>1</sup> Authorea's D-Cycloserine for the Treatment Of Chronic Pain, 2023 and NRX Pharma – Crystal Research Associates.

**Akathisia.** A major limitation in the use of serotonin-targeted drugs, such as Lurasidone, as therapeutic agents is its possible behavioral side effects, especially anxiety, agitation, and akathisia—all of which are associated with generating or exacerbating suicidality in psychotic or depressed patients. However, Professor Javitt made the simultaneous discovery that NMDA inhibitors, in turn, block the akathisia side effect normally experienced with the use of serotonin-targeted drugs.<sup>3</sup> Since then, NRx scientists have demonstrated, in clinical studies, that combining NMDA and serotonin-targeted agents (in the forms of DCS and Lurasidone, respectively) achieves an antidepressant effect that is comparable to that of leading antidepressants while at the same time eliminating the psychedelic effects of NMDA receptor antagonists and blocking akathisia while reducing suicidal ideation. At a minimum, this creates a significant market opportunity for those patients most at risk for Bipolar Depression-Suidality with a risk of Akathisia.

#### Exhibit 3. Akathisia, or the Lack of it, Could be a Major Factor of Differentiation for NRX-101

### Akathisia occurs in up to 15% of patients on antidepressants

Akathisia is the side effect of antidepressants most closely linked to suicide



#### The New Hork Times

By Roni Caryn Rabin Sept. 11, 2017

- Stewart Dolin was a successful and well-liked partner at Reed Smith in Chicago. He developed an episode of depression and was treated with Paxil. That night, his family noticed that he could not stop tapping his feet at dinner and could not sit still.
- In the early afternoon on July 15, 2010, Stewart Dolin walked to a Chicago Transit Authority station shortly after a business lunch with a colleague. A woman at the station noticed that Mr. Dolin was pacing and appeared to be agitated as he looked in the direction of an approaching train that was not yet in sight. When the moving train appeared, the woman watched Mr. Dolin leap in front of the train.

In his memory, the family founded the MISSD foundation to explain akathisia to the public. www.missd.co contains illustrative material

#### 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 dementiarelated 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 m/20xx Dosage and Administration, Bipolar Depression (2.1) w/20xx m/20xx Warnings and Precautions (5.2, 5.6, 5.7, 5.9, 5.10, 5.11, 5.13, 5.14) m/20xx

Source: NRx Pharmaceuticals, Inc.

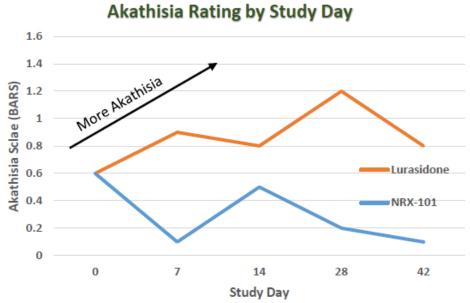
All Antidepressants Carry Black-Box Warnings for Suicidality and Akathisiano antidepressant has ever improved either side effect

3 Composition and method for treatment of depression and psychosis in humans, U.S. Patent and Trademark Office #US10583138B2 & NRX Pharma – Crystal Research Report.



**Latest Clinical Data – NRX-101.** On April 20, 2024, the company announced the results of a Phase 2b/3 trial of NRX-101 for suicidal Treatment-Resistant Bipolar Depression (S-TRBD). The data showed that NRX-101 vs. Lurasidone alone demonstrated a promising, though not yet statistically significant, 33% reduction in suicidality together with a 70% reduction (P=.076) reduction in symptoms of akathisia – a side effect of antidepressants that are closely linked to suicide and considered a medical emergency. Because of the high-risk nature of these patients, a placebo group could not be employed. Recall that NRX-101 is a fixed-dose combination of D-cycloserine (DCS) and Lurasidone. This was compared to Lurasidone alone (the standard of care), as a straight placebo is considered unethical.

**Exhibit 4.** Results from the Recent (April 2024) Phase 2b/3, n=93, randomized, double-blind trial of NRX-101 versus Standard of Care (Lurasidone) in Suicidal Treatment-Resistant Bipolar Depression. Conclusions from the study: 1. Similar (50% reduction) in depression vs. SoC; however, a significant reduction in akathisia vs. SoC, p=0.03, was observed. 2. Decreased Time to Sustained Remission from Suicidality on C-SSRS scale vs. lurasidone (p<0.05). KOLs advise that an antidepressant with Standard of Care level efficacy and a significant reduction in akathisia/suicidality can become the new standard in Bipolar Depression and point out that "Akathisia is the worst side effect of current treatment." This is the first clinical trial ever to enroll rather than exclude suicidal patients.

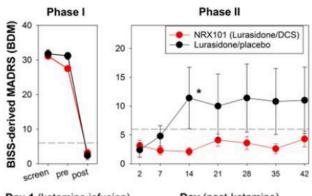


Source: NRx Pharmaceuticals. Inc.

**Prior Phase 2 Data –** The STABIL-B trial showed the superiority of NRX-101 vs Lurasidone in Reducing Depression (the primary endpoint) after ketamine pre-treatment. Patients received one infusion of IV Ketamine vs. placebo. In this study, Respondents were randomized to NRX-101 vs Lurasidone, a standard of care. A mean 7.7-point benefit on MADRS (Primary Endpoint, P=.03) through day 42 vs. lurasidone was observed. A 40% relapse in the control group versus no relapse in the NRX-101 group (P=.07) was observed. A 1.5-point advantage vs SoC on the Columbia Suicide Severity Rating Scale (C-SSRS) (P=.02) was observed. A decrease in akathisia in the NRX-101 group on the BARS akathisia scale with a large effect size (P=0.14 because of the small sample size) was observed.



**Exhibit 5. Results from the STABIL-B Trial.** Data demonstrated the superiority of NRX-101 vs. Lurasidone.



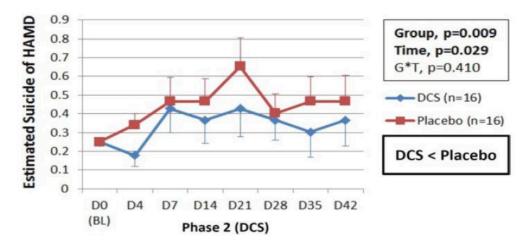
Day 1 (ketamine infusion)

Day (post-ketamine)

	Eff	ficacy Meas	ures: Repeat	ed Measu	res Mixed M	odel LS Me	an Difference	es	
		Through	Day 28	Through Day 42					
	LOCI	F No	LOCE	yes	LOC	F No	LOCE	yes	
MADRS Depression	LS Mean Δ	p-value	LS Mean Δ	p-value	LS Mean A	p-value	LS Mean A	p-value	
Score	-4.0	0.09	-7.7	0.03	-3.7	0.04	-7.7	0.04	
Suicidality Rating	LS Mean A	p-value	LS Mean Δ	p-value	LS Mean A	p-value	LS Mean A	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	

Source: J Clin Psychiatry 2022 May 30;83(4):21m14345

**Exhibit 6. Prior Phase 2 Confirmation** Study (2019). Chen et. al. Showed a Reduction in Suicidality vs. Placebo with DCS after Ketamine Pre-treatment (p<0.05). Specifically, patients with treatment-resistant Depression (n=32, MDD & Bipolar) who responded to IV Ketamine enrolled DCS was superior to placebo in HAMD item 3 (suicide), p=0.009. A comparable effect was seen on depression (HAMD). The effect may have been more substantial in bipolar patients.



Source: Neuropsychopharmacology.2019 Nov; 44(12): 2112-2118

What Conclusion Can We Make? NRX-101 reduces depression scores by ~50% -- similar to Standard of Care (SoC) but is also the only drug that has demonstrated a clinically meaningful reduction in akathisia and suicidality vs SoC.



What is the Path to Approval for NRX-101? In the near term, we see the potential for accelerated approval in BPD-AS patients. In the long term, we expect an additional clinical trial vs. SoC to achieve a label as a first-line therapy in BPD. It's important to understand that beating the SoC is highly likely, given that NRx demonstrated an antidepressant effect comparable to Lurasidone, which has beaten the placebo in multiple registration trials, but NRX-101 has demonstrated equivalence to Lurasidone in terms of that specific measure of efficacy. We believe an accelerated approval is possible. An accelerated approval allows for five years of market approval for drugs to treat a life-threatening condition without other approved therapies when efficacy has been demonstrated on one or more intermediate clinical endpoints. The FDA had previously determined that suicidal Bipolar Depression is a life-threatening condition and an unmet medical need when it was awarded Breakthrough Therapy Designation to NRX-101. NRx has received regulatory guidance from counsel and former FDA officials that an application for accelerated approval is warranted with a commitment to conduct additional trials over the subsequent five years to demonstrate long-term patient benefits. One path for confirmatory data is the PCORI program in Bipolar Depression, which currently lacks a treatment arm for patients with suicidality and akathisia on standard medication.

Exhibit 7. FDA Approval Roadmap – Breakthrough Designation and SPA

Based on STABIL-B findings, FDA awarded NRX-101 Breakthrough Therapy Designation together with Special Protocol Agreement (SPA) in Bipolar Depression with Acute Suicidality

SPA allows NRx to apply for NDA with successful Phase 3 trial of ~70 Patients using similar methodology to STABIL-B

Agreed upon path to submit

NDA in 2023

Source: NRx Pharmaceuticals, Inc.

Can the Company Make Enough of the Drug? NRX-101 is "Commercial-Ready." GMP manufacturing was initiated in the U.S. in 2022. A phase 3 drug supply has been produced using the expected Commercial-Scale manufacturing process. An FDA Type C manufacturing meeting was conducted in January 2022, with concurrence on CMC, stability, and other metrics. One million phase 3 commercial-process capsules are on hand in the company's facility. The company's manufacturing readiness is positive for anticipated manufacturing costs and margins. It ideally positions the company to support additional expanded clinical trials as needed.

Exhibit 8. The NMDA Landscape is Complex and Represents "Blockbuster" Size

	Clinical Target	NMDA Mechanism	Molecule	Phase	BTD	SPA	Composition of Matter	MADRS Difference	Suicidality Difference
AUVELITY®	MDD	Channel Blocker	Dextrome- thorphan / bupropion	Approved	x			3.9 pts	*
SPRAVATO®	MDD	Channel Blocker	esketamine	Approved	x			3.9 pts	*
NRX-101	Bipolar/PTSD Suicidality	Glycine Site Antagonist	Cycloserine / Lurasidone	Filing	×	х	х	7.7 pts	2.7 pts
REL-1017	MDD	Channel Blocker	esmethadone	3				NS	*
SLS-002	MDD	Channel Blocker	ketamine	3				pending	pending



#### **Product Market Assumptions**

- We assume the prevalence of Bipolar Depression at eight million patients and assume that 3.8M of those patients have shown suicidal ideation (Making plans). Based on the research, we assume that 13% of that sub-group experiences Akathisia. The net result is a patient pool of nearly half a million people annually.
- 2. We assume the price of comparator therapies (before they were generically available) supports the pricing of \$10,100 annually. Given the serious nature of these patients, we do not anticipate push-back from managed care providers based on our discussion and experience.
- 3. Based on the FDA review and the accelerated approval pathway, we assume a product launch is possible by 2025.
- 4. We initially assume a modest market share ramp but believe the company can realize a 36% outyear market share with the superior product profile in this market segment. One could argue that the share could be even higher.
- 5. We apply a 70% probability of success factor to our therapeutic model, which is independent of our risk rate in our valuation models.

Exhibit 9. Market Model: NRX-101 in Bipolar Depression with Akathisia

		-		-							
NRX-101 BiPolar Depression with Akathisia		2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
BiPolar Depression	•	8,000,000	8,000,000	8,000,000	8,000,000	8,000,000	8,000,000	8,000,000	8,000,000	8,000,000	8,000,000
BiPolar Depression - Suicidal Ideation (making plans)	•	3,825,000	3,825,000	3,825,000	3,825,000	3,825,000	3,825,000	3,825,000	3,825,000	3,825,000	3,825,000
Akathisia Prevalence		13%	13%	13%	13%	13%	13%	13%	13%	13%	13%
Akathisia Patients		497,250	497,250	497,250	497,250	497,250	497,250	497,250	497,250	497,250	497,250
Cost of Therapy (price)		\$10,100	\$10,100	\$10,100	\$10,100	\$10,100	\$10,100	\$10,100	\$10,100	\$10,100	\$10,100
Market Share		2%	3%	6%	10%	30%	35%	36%	36%	36%	38%
Revenue (\$) M		100	151	301	502	1,507	1,758	1,808	1,808	1,808	1,908
Probability of Success		70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Risk Adjusted U.S. Revenue (\$M)		\$70	\$105	\$211	\$352	\$1,055	\$1,230	\$1,266	\$1,266	\$1,266	\$1,336

Source: EF Hutton & Incidence Data: https://www.cdc.gov/suicide/pdf/NCIPC-Suicide-FactSheet-508\_FINAL.pdf

What About Other Indications in the Psychiatric Space? We could argue that approval in BP with Akathisia opens the door to the larger BP marketplace. For conservatism, we do not include any revenues for NRX-101 beyond the BPD-AS indication. Given the size of the BPD marketplace, even a small piece represents a blockbuster drug, as is seen in the model below.

**Exhibit 10. Market Model: Bipolar Depression** 

NRX-101 BiPolar Depression	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
BiPolar Depression	8,000,000	8,000,000	8,000,000	8,000,000	8,000,000	8,000,000	8,000,000	8,000,000	8,000,000	8,000,000
Patients Seeking Alternative Therapy				10%	12%	14%	16%	18%	20%	22%
Patients Seeking Alternative Therapy (10%)	800,000	800,000	800,000	800,000	960,000	1,120,000	1,280,000	1,440,000	1,600,000	1,760,000
Cost of Therapy (price)			\$10,100	\$10,100	\$10,100	\$10,100	\$10,100	\$10,100	\$10,100	\$10,100
Market Share					1%	2%	5%	10%	12%	15%
Revenue (\$) M					97	226	646	1,454	1,939	2,666
Probability of Success				50%	50%	50%	50%	50%	50%	50%
Risk Adjusted U.S. Revenue (\$M)	\$0	\$0	\$0	\$0	\$48	\$113	\$323	\$727	\$970	\$1,333

Source: EF Hutton

What About Indications Outside of the Psychiatric Space – UTI and Pain? Here, too, we do not yet include any revenues from these potential indications—clinically, it's still in the early days. We like that the unique properties of NRX-101 suggest a product portfolio in a single platform molecule. With adequate resources, the company is likely to pursue additional indications. Please see the Appendix at the end of this report.



**NRX-100** (**IV Ketamine**) in **Acute Suicidality.** We all, unfortunately, seem to know someone we have lost to suicide. One of the most significant issues that people in crisis face is the lack of acute therapies. It can take months, sometimes years, for a combination of pharmacologic agents and behavioral therapy to impact a person's state of mind. Suicide knows no boundaries, rich or poor, educated or not; it can affect any of us at any time. IV ketamine may offer hope to address the crisis phase of an individual who is recognizing their depression.

Exhibit 11. If You Know Two People With Bipolar Depression, One Will Attempt Suicide



Source: NRx Pharmaceuticals, Inc.

#### Exhibit 12. No FDA Approved Medication Exists for Acute Suicidality

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



Source: NRx Pharmaceuticals, Inc.

# IV Ketamine is used off-label But not <u>FDA-approved</u>

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



#### Clinical Status of NRX-100 IV Ketamine

NRx met with the FDA in January 2023. It is our understanding that regulators encouraged the company to develop NRX-100 (Ketamine) as a labeled drug. For regulators, this is preferable to relying on older prior stabilization studies of suicidality and depression achieved via the common clinical practice of infusing generic Ketamine compounded in licensed pharmacies.

Ketamine has been shown in multiple randomized clinical trials to induce nearly immediate short-term remission from depressive symptoms and suicidal ideation. Despite the promising clinical findings and its widely off-label use in these settings for the treatment of acute suicidality, ketamine is not approved by the FDA for these indications. The company believes that patients first stabilized with ketamine represent an opportunity for NRX-101 in patients with Bipolar Depression and ASIB. For such a trial to be run, ketamine itself requires an NDA. Thus, the idea of the opportunity to seek label approval was sparked. Fast forward, and NRx has fully developed that idea, creating a company dedicated to addressing the acute needs of these patients, HOPE Therapeutics.

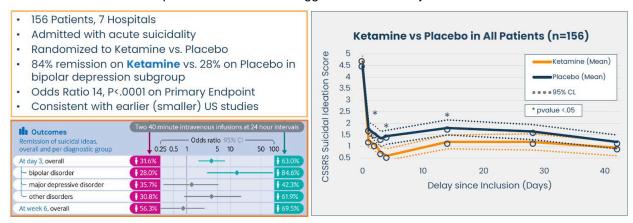
**Ketamine Data Sharing Agreement.** To facilitate its NDA application for ketamine, the company has signed a data-sharing agreement with the study leadership of a placebo-controlled trial of ketamine on n=156 patients hospitalized for acute suicidality and depression in seven French Government Hospitals (the KETIS trial). Top-line data from this trial, published in the British Medical Journal (BMJ Vol. 376, 2022), demonstrated a dramatic and statistically significant reduction in suicidal ideation among patients treated with intravenous Ketamine compared to those on placebo. Under the data sharing agreement, NRx has translated the clinical study report, which will be submitted to the FDA, and is converting the electronic, patient-level data files to a form suitable for FDA review.

#### Exhibit 13. "Everyone" is calling for the approval of Ketamine.

- No Company has applied for FDA approval of Ketamine to treat depression
- In order to seek drug approval, you need a manufactured drug in hand (NRx has manufactured drug in hand)
- 3 In order to seek drug approval you need patient-level efficacy data (NRx has it)
- In order to seek drug approval you need FDA quality tox data (NRx has it)
- In order to seek drug approval you need 12 months stability and 3 manufactured lots of commercial drug (NRx will have it in September)



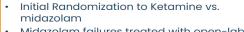
**Exhibit 14. The French Data.** The "Abbar Study" was funded by Gov't of France and the *Fondation Fondamental*. The data is presented below and suggests clear efficacy.



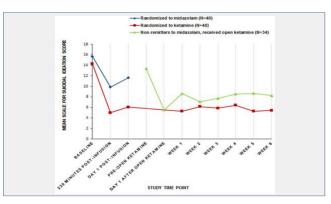
Source: NRx Pharmaceuticals, Inc. and Abbar et al. Ketamine for Acute Treatment of Severe Suicidal Ideation. BMJ 2022;376

The company has access to patient-level data from a National Institutes of Health (NIH)-funded U.S.-based clinical trial, the findings of which confirm the KETIS trial's results. NRx believes that these multicenter, randomized prospective trials are sufficient to demonstrate the preliminary safety and efficacy of intravenous Ketamine in acutely suicidal patients.<sup>4</sup>

**Exhibit 15. NRx and Columbia University Sign a Deal for Ketamine Data**. Grunebaum (Columbia University), single-center trial, N=80. Ketamine vs. Midazolam (effect size 0.76, P=.0015). In December 2023, NRx announced signing a License Data and Technical Information Agreement with Columbia University for rights to data from the trial.



- Midazolam failures treated with open-label Ketamine
- Note that open label Ketamine effect following midazolam failure matches effect in those initially randomized to Ketamine



Source: NRX Pharmaceuticals and Grunebaum et al., Ketamine for rapid reduction of suicidal thoughts. Am J Psychiatry 2018, 175(4): 327-335

Furthermore, on November 6, 2023, the company announced a development and manufacturing agreement with Nephron Pharmaceuticals, Inc. (NEPH-Not rated) to develop and manufacture a presentation of ketamine suitable for treating suicidal depression. This agreement, which encompasses GMP manufacturing capabilities and the data-sharing agreements related to the studies above, provides NRx with the requirements for the submission and approval of ketamine. <sup>5</sup>.

<sup>&</sup>lt;sup>5</sup> Adapted from the Crystal Research Associates report, December 2023



<sup>&</sup>lt;sup>4</sup> Adapted from the Crystal Research Associates report, December 202

Exhibit 16. Why Does NRx's Formulation Matter? Current formulations may be responsible for a host of side effects.

# Why Should Anyone Care about Preservative-Free Ketamine

#### Benzethonium Chloride is good for killing germs, not for treating patients

· 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, como. 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 furnes of carbon monoxide, carbon dioxide, nitrogen oxides, and hydrogen chloride gas [1] [3]

- 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).



Source: NRx Pharmaceuticals, Inc.

#### Exhibit 17. NRX-100 - Multiple Changes to the Ketamine Landscape

An approval of IV Ketamine depression yields FDA exclusivity for 3 years

2 Approval yields Reimbursement for approved indication(s)

Provide REMS (Risk Evaluation and Management Strategy) & support to prescribers

Subsequent development of pH neutral Ketamine formulation enables subcutaneous and other forms of administration plus 20 year patent protection

Addition of Digital Therapeutic technology to Ketamine label further extends IP

By the time NRX-100 loses market exclusivity, elements 2-5 will maintain a sustained marketplace advantage

Source: NRx Pharmaceuticals, Inc.



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Planning for HOPE. NRX Pharma is working to establish Hope Therapeutics, as described earlier, as a national network of clinics dedicated to Suicide/PTSD patients, many in crisis. Originally, we looked at the idea of the company acquiring clinics that we recognize can support the use of ketamine for patients in crisis as extreme. For us, our thinking has changed. This is based on our interviews with Key Opinion Leaders and patients. We have come to understand how broken the system is for patients in crisis. For example, what can we do when a loved one is dealing with depression and shows warning signs of suicide? If you are lucky, you can find a psychiatrist who accepts insurance and is willing to see a new patient. That can be nearly impossible in some places; big cities like New York, LA, and Chicago tend to be private pay only, and most psychiatrists are not accepting new patients. An unspoken truth is that nobody wants patients who are really in trouble, i.e., suicidal. In other places, such as the urban Midwest, little professional help is available. Patients in crisis often end up in emergency rooms across the country. The standard protocol is 24 hours and release to a facility, if one is available, followed by discharge after a few days with good luck. You are basically on your own. NRx has the vision to change that by operating highly specialized centers that have the complete armamentarium of tools to treat the acute nature of suicide and PTSD. This includes ketamine (NRX-100) and NRX-101, but it is also likely to include electro-convulsive therapy (ECT) and transcutaneous magnetic stimulation (TMS). TMS can alter brain pathways. TMS is also known to extend the ketamine effect. Digital Therapeutics are new, and most practicing clinicians are unaware of their benefits. Research sponsored by DARPA demonstrates the measurable benefit of the Digital Therapeutic approach in reducing depression and stress.

The vision of the company is to start at the top. Management has identified key opinion leaders in the field who see the flaws in the system. As a result, many KOLs pioneered their own clinics. What if a network of KOLs is created, empowered with capital and resources, to standardize the treatment of these acute patients? Imagine creating a National Patient Relationship Management (PRM) system, leveraging Al-driven Telepsychiatry, Common Protocols, and a state-of-the-art armamentarium of tools managed by thought leaders nationwide.

**HOPE's Goal**. Hope will be dedicated to providing an FDA-approved presentation of IV ketamine, manufactured to current federal standards, in a diversion- and abuse-deterrent presentation. A new drug application (NDA) is planned for this year based on more than 1,000 patients treated in well-controlled trials of ketamine in suicidal depression. The company intends to provide state-of-the-art reimbursement support for all its providers and patients. Access to insurance coverage is critical for treating this vulnerable population and can only be achieved by developing an FDA-approved product. Additionally, providing an approved, compliant product for patients allows clinics to deliver state-of-the-art care to people suffering from suicidality without fear of legal and regulatory actions. Breaking the stigma of ketamine therapy has the potential to expand the market.

Where is HOPE now? In advance of FDA approval, HOPE is partnered with national 503b and 503a pharmacies to address the ketamine shortage declared by the FDA. We understand that there are some preliminary commercial product sales through these pathways. As we stated previously, HOPE is planned to be spun out as a separate company owned by NRx and current NRx shareholders via a tax-free dividend and to new investors. In terms of clinic acquisitions, our understanding is that the company has several LOIs (letters of Intent) to acquire the first few clinics, representing up to \$25M in topline revenues.

**Exhibit 18. Clinic Acquisition Model** 

= Minibit Tol Ollillo Moquioliloli										
Clinic—Expert Centers	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
Acquired Centers	25	50	75	100	125	150	160	170	180	190
EBITDA Pos. Cash Flow / Clinic - Average	1,000,000	1,040,000	1,071,200	1,103,336	1,125,403	1,147,911	1,159,390	1,170,984	1,182,694	1,194,521
Growth of EBITDA		4%	3%	3%	2%	2%	1%	1%	1%	1%
Revenue (\$) M	25,000,000	52,000,000	80,340,000	110,333,600	140,675,340	172,186,616	185,502,381	199,067,243	212,884,851	226,958,905
Probability of Success	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Risk Adjusted U.S. Revenue (\$M)	\$18	\$36	\$56	\$77	\$98	\$121	\$130	\$139	\$149	\$159

Source: EF Hutton estimates

<sup>6</sup> NRX Pharma Press Release, "NRx Pharmaceuticals, Inc. (Nasdaq: NRXP) Announces the Incorporation of HOPE Therapeutics, Inc., and Planned Share Dividend/Royalty Coupon" February 2024.



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#### Update from the annual (June 2024) American Society of Clinical Psychopharmacology Meeting.

- Intravenous and intranasal ketamine were highlighted as emerging standards of care for severe depression and suicidality
- Planned NDA filing for NRX-100, a preservative-free IV ketamine for suicidal depression in 2024, is based on well-controlled trials against both placebo and active comparator. Fast Track Designation was previously granted
- An independent FDA advisory panel recently voted against MDMA, a potent, class I psychedelic, refocusing attention on already-approved Schedule 3 drugs such as ketamine for the treatment of suicidal depression. The FDA panel and emerging guidance highlight the complexity of clinical trials of DEA Schedule 1 hallucinogens that do not have already approved human uses
- NRx anticipates that an essential issue for longer-term use of ketamine in depression will be the
  current multidose vial presentation that contains potentially toxic preservatives previously
  acceptable for one-time use but less suitable for repeated use. NRX-100 is planned as a singledose, preservative-free medication.

**Exhibit 19. HOPE Summarized – Near Term Highlights**. Management sees Hope as a separate ketamine-focused entity working to standardize the treatment of suicidal Bipolar Depression.

#### • Acquisition and management of ~30 Ketamine clinics in coming 24 months

Target \$45 million/yr run-rate

#### • HOPE Solutions – Comprehensive practice acceleration program

- IV Ketamine from Nephron's 503b pharmacy
- · Customized marketing programs
- Financial & administrative support

#### · Immediate availability of IV Ketamine

- IV Ketamine from Nephron's 503b pharmacy
- HOPE clinics sole provider
- Responsive supply of Ketamine in shortage situations

#### • Development of HTX-100 (pH neutral Ketamine)

 Proprietary formulation and digital therapeutic: allow subcutaneous dosing and enhance market exclusivity



**Exhibit 20. HOPE Digital—The Future of Therapy.** In the digital age, there is an opportunity to combine smart tech with pharmacologic therapy to drive better efficacy and outcomes. A good example is the impact that smartwatches are having on exercise regimens. Apply the same logic to depression awareness and behavioral therapy management.



- 2 Patients need ongoing support and Cognitive Behavioral 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
- Addition of a digital therapeutic component to the HTX-100 label prevents generic substitution once market exclusivity period ends

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

Source: NRx Pharmaceuticals, Inc.

#### Exhibit 21. \$2.2B Market Opportunity Potential in Psychiatry

# Advantage NRX-100 for Suicidal Depression

#### Proper use of a potent but potentially dangerous drug

- A new single-dose formulation with reliable potency and shelf stability
   Anesthesiologists and veterinarians will tell you that non-branded generics don't work reliably
   (Clinics cannot use multidose anesthesia packaging (hence the need for compounding)
- A label that guides physicians to proper use for depression (not anesthesia) and that appropriately discloses risks and their mitigation
- A REMS (Risk Evaluation and Mitigation Strategy) program that provides for physician training

#### **Improved Patient Access**

- · With an FDA label, Hope Therapeutics can market and establish trust with physicians and patients
- With an FDA label, insurance is likely to reimburse for Ketamine treatment, providing access to people who cannot afford to pay cash

#### Compliance with the Law

- In the setting of an FDA label for use, compounding of ketamine is largely illegal
- · Ketamine is a Schedule III drug whose use is overseen by both FDA and DEA
- Diversion/Misuse carry significant penalties
- Significant Protection for practitioners who prescribe ketamine under a REMS



#### Exhibit 22. Model Dynamics – Just How Many People Are at Risk?

Patients in clinics and outpatient being treated for Bipolar Depression with Suicidality



- There are no approved drugs for Suicidal Bipolar Depression
- Suicide kills ~50,000 Americans annually, disproportionately affecting people with Bipolar Depression
  - ½ of people who suffer from Bipolar Depression attempt suicide
    - 1/5 people with BPD commit suicide

Source: NRx Pharmaceuticals, Inc.

#### Therapeutic Model Assumptions - NRX-100 IV Ketamine

- 1. We assume Regulatory approval by 2025.
- 2. We see a patient pool of 542,000 annually. This is based on certain assumptions and published data on the incidence and prevalence of suicidality.
- 3. We assume a third of patients initially present in crisis in a hospital emergency room setting. We assume only one treatment in this setting, as patients are typically moved into a psychiatric care facility. We assume six treatments in a clinic or psychiatric care center over three months.
- 4. We assume pricing of \$850 per treatment.
- 5. We apply a probability of success factor of 70% in our model. This is in addition to the discount rate we use in our FCFF, discounted EPS, and the sum of the parts models.
- 6. We expect once HOPE is spun out, we revise our model accordingly.

Exhibit 23. Market Model for Ketamine - NRX-100

NRX-100 (IV Ketamine)	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
· · · · · · · · · · · · · · · · · · ·										
Patients with Suicidal Ideaology (Making Plans)	3,800,000	3,800,000	3,800,000	3,800,000	3,800,000	3,800,000	3,800,000	3,800,000	3,800,000	3,800,000
Eligible Patients with Severe Depression	3,000,000	3,000,000	3,000,000	3,000,000	3,000,000	3,000,000	3,000,000	3,000,000	3,000,000	3,000,000
Eligible Patients with PTSD	1,200,000	1,200,000	1,200,000	1,200,000	1,200,000	1,200,000	1,200,000	1,200,000	1,200,000	1,200,000
Suicidal Ideaology Patients Seeking Care	10%	11%	12%	12%	12%	12%	12%	12%	12%	12%
Eligible Patients with Severe Depression	5%	6%	7%	7%	8%	8%	9%	9%	9%	9%
Eligible Patients with PTSD	1%	2%	3%	4%	5%	5%	5%	5%	5%	5%
Total Patients	542,000	622,000	702,000	714,000	756,000	756,000	786,000	786,000	786,000	786,000
Hospital	33%	33%	33%	33%	33%	33%_	33%	33%_	33%_	33%
Outpatient/Clinic	67%	67%	67%	67%	67%	67%	67%	67%	67%	67%
Market Share - Hospital	1%	1%	20%	40%	50%	65%	65%	65%	65%	65%
Market Share - Clinic	2%	5%	20%	50%	64%	70%	70%	70%	70%	70%
Revenue per Therapeutic Course	\$850	\$850	\$850	\$850	\$850	\$850	\$850	\$850	\$850	\$850
Treatments Per Patients (Hospital)	1	1	1	1	1	1	1	1	1	1
Treatments Per Patients (Clinic)	2	3	4	4	5	5	6	6	6	6
Hospital Revenue (\$) M	\$2	\$2	\$39	\$80	\$106	\$138	\$143	\$143	\$143	\$143
Clinic Revenues (\$) M	\$12	\$53	\$320	\$813	\$1,378	\$1,507	\$1,880	\$1,880	\$1,880	\$1,880
Combined Revenues (\$) M	\$14	\$55	\$359	\$893	\$1,484	\$1,645	\$2,023	\$2,023	\$2,023	\$2,023
Probability of Success	70%	70%	70%	70%	70%	70%	70%	70%	70%	70%
Risk Adjusted U.S. Revenue (\$M)	\$10	\$38	\$251	\$625	\$1,039	\$1,151	\$1,416	\$1,416	\$1,416	\$1,416

Source: EF Hutton



**Valuation:** Our valuation for NRx Pharmaceuticals is driven by the revenue projections associated with the company's two lead therapeutics, NRX101 (DCS) and NRX100 (IV ketamine). We include revenues associated with the planned acquisitions and operations of expert psychiatric centers, but those revenues add up at \$1M FCF per clinic and the potential of 100-200 clinics; still, compared to therapeutics, they are not the "performance" drivers. We need to recognize that a link exists between the therapeutics and the clinics, especially for ketamine use, but also for NRX101. KOLs are the drivers for prescribing. A network of KOLs in a nationwide footprint of clinics becomes a dynamic launch strategy for NRX-101.

We estimate the potential future revenues for each therapy in its lead indication and model this out to 2034. The markets are quite large for Depression, Bipolar Depression, Acute Bipolar Depression with Suicidality, and Bipolar Depression with Akathisia, as well as PTSD and earlier potential indications such as UTI and Pain. We note that success in one area leads to other indications. For model purposes, we assume NRX-101's initial focus is on the Bipolar Depression market but restricted to patients with Akathisia. For NRX-100, we focus on patients identified with a suicidal ideology. Both programs represent well-vetted science and are essentially pivotal, complete, and ready for NDA submission by year-end. As such, we adjust for the associated approval risks with a 70% probability of success factor in our therapeutic models. The subsequent revenues for both products are then fed into our income statement. To the income statement metrics, we then model a target valuation. We assume the company does raise additional capital, and as such, our valuation math is based on the 2034 fully diluted share count. The company is likely to repurchase stock in the out years; however, for conservatism, we hold off on making this assumption for the moment. We assume rising SG&A and R&D as the company commercializes its products and expands its pipeline – clinical development, coupled with an improving cost of goods sold (COGS) initially at 20% and at scale falling to just 10%.

**Our valuation models**, Free Cash Flow to the Firm (FCFF), discounted EPS (dEPS), and Sum-of-the-Parts (SOP), use a 30% discount rate. This is in addition to our revenue models' 30% risk cut and 70% POS factor. We select 30% for micro-capitalized growth companies, representing our highest risk rate. These three models' results are equal-weighted, averaged, and rounded to the nearest whole number to provide a 12-month target price.

**Exhibit 24. Free Cash Flow Model** 

Pric	e Target \$ 29 Year 2024														
DCF Valuation Using FCF (mln):															
units ('000)			2022A	2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
EBIT			(39,816)	(30,150)	(21,098)	64,313	93,488	353,885	781,036	1,755,275	1,996,859	2,250,630	2,277,159	2,384,144	2,447,128
Tax Rate			0%	0%	0%	0%	5%	8%	10%	18%	24%	28%	30%	31%	33%
EBIT(1-t)			(39,816)	(30,150)	(21,098)	64,313	88,813	325,574	702,932	1,439,325	1,517,613	1,620,454	1,594,011	1,645,059	1,639,576
CapEx															
Depreciation															
Change in NWC															
FCF			(39,816)	(30,150)	(21,098)	64,313	88,813	325,574	702,932	1,439,325	1,517,613	1,620,454	1,594,011	1,645,059	1,639,576
PV of FCF			(67,289)	(39,195)	(21,098)	49,471	52,552	148,190	246,116	387,652	314,413	258,246	195,409	155,128	118,932
Discount Rate		30%													
Long Term Growth Rate		1%													
Terminal Cash Flow		5,710,246													
Terminal Value YE2033		538,474													
Torrinar Value 122000		000,474													
NPV		2,404,291													
NPV-Debt		-													
Shares out (thousands)		82,494	2034E												
NPV Per Share		\$ 29.15													
Source: EF Hutton e	estimates														



#### **Exhibit 25. Discounted EPS Model**

Current Year	2024
Year of EPS	2034
Earnings Multiple	15
Discount Factor	30%
Selected Year EPS	\$ 32.20
NPV	\$ 35.04

Source: Company reports and EF Hutton

		Discou	unt Rate and Ea	arnings Multiplo 2034		ar is Constant	
	35.0	5%	10%	15%	20%	25%	30%
Earnings							
Multiple	5	\$98.85	\$62.08	\$39.80	\$26.01	\$17.29 \$	11.68
	10	\$197.70	\$124.16	\$79.60	\$52.01	\$34.58 \$	23.36
	15	\$296.55	\$186.24	\$119.40	\$78.02	\$51.87 \$	35.04
	20	\$395.40	\$248.31	\$159.20	\$104.02	\$69.16 \$	46.72
	25	\$494.25	\$310.39	\$199.00	\$130.03	\$86.44 \$	58.40
	30	\$593.10	\$372.47	\$238.80	\$156.03	\$103.73 \$	70.08
	35	\$691.95	\$434.55	\$278.61	\$182.04	\$121.02 \$	81.76
	40	\$790.80	\$496.63	\$318.41	\$208.04	\$138.31 \$	93.44

#### Exhibit 26. Sum-of-the-Parts Model

NRx Pharmaceuticals	LT Gr	Discount Rate `	Yrs. to Mkt Peak	% Success	Peak Sales MM's	Term Val
NRX-101 for BPD - Akathisia	1%	30%	3	70%	\$1,908	\$6,581
NPV						\$17.79
NRX-101 for BPD	1%	30%	6	0%	\$2,666	\$9,194
NPV						\$0.00
NRX-101 for Complex UTIs	1%	30%	7	0%	\$1,000	\$3,448
NPV						\$0.00
NRX-101 for Pain	1%	30%	7	0%	\$1,000	\$3,448
NPV						\$0.00
NRX-100 (IV Ketamine)	1%	30%	5	70%	\$2,023	\$6,977
NPV						\$11.16
Clinic—Expert Centers	1%	30%	5	70%	\$227	\$783
NPV						\$1.25
						70%
MM Shrs OS (2034E)						82
Total						\$30.21

Source: EF Hutton estimates



**Intellectual Property.** NRx Pharmaceuticals has 48 issued patents and more than 43 pending patents owned by or licensed to NRx Pharmaceuticals. This is due to the discovery of synergy between the two drug classes in NRX-101 (D-cycloserine and lurasidone) in the treatment of CNS disorders, combined with the efficacy of D-cycloserine in the treatment of depression and PTSD.

We are unaware of any other company with a composition of matter patent on a combination of two drugs. We believe this is because patent office regulators recognized the unique science, the mechanism of action by which the two drugs work together.

The company breaks down its IP across five patent families, 90+ filed applications, and 48 issued patents in the U.S./EU/CN/JP/KR/AU. These patents protect NRX-101 to at least 2033, potentially protecting the NMDA/5HT2A class. Included are drugs for PTSD, Major Depressive Disorder, Obsessive Compulsive Disorder, and other targets. Combinations involving dextromethorphan, d-methadone, and S-Ketamine are identified in U.S. 10.583.138.

#### **Exhibit 27. Robust Composition of Matter Patent Protection**

Patent Estate of 47 issued and 43 pending patents enables a platform of CNS drugs based on NMDA / 5HT<sub>2A</sub> Synergy.

- Five patent families, 90+ filed applications, 47 issued patents in US/EU/CN/JP/KR/AU.
- Protects NRX-101 to at least 2033 with potential for protecting NMDA/5HT2A class.
- 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.

I claim:

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

an effective amount of an atypical antipsychotic that is a combined dopamic place at the control of the con

Source: NRx Pharmaceuticals, Inc.

Risks to our thesis include: 1. Regulatory Approvals; 2—clinical Science; 3. Intellectual Capital 4. Dilution

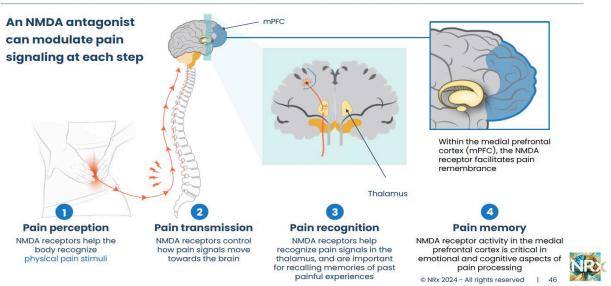
- **Regulatory Approvals**. The company's products require regulatory approvals, and there can be no assurance that the requirements to achieve these approvals can be met. Furthermore, regulators may limit its use or marketing even if a drug product is approved.
- **Clinical Science:** The company must demonstrate to its "sophisticated" clients (doctors and other physicians) that the product is effective, reliable, accessible, and marketable.
- The Competitive Landscape and IP. The company does have intellectual properties and knows how to protect the utility of its drugs; however, any patent position can be challenged.
- **Dilution**: The company is likely to incur losses in the near term until it can generate sufficient revenue from product sales. Our model assumes a rising share count. There can be no assurances that the company can successfully raise the capital required to execute its business strategy.



#### **APPENDIX**

**Exhibit 28. NRX-101 Shows Promise for Treating Pain.** D-cycloserine (DCS) has been shown to modulate the Pain Pathway at each point in the neural chain of pain: transmission at the dorsal horn of the spinal cord, pain perception in the thalamus, the paleo brain, and pain memory and processing between the paleo brain and the cortex. In experimental models and clinical studies, NMDA antagonists have demonstrated attenuation of pain and shown potential to reduce opioid craving. DCS has demonstrated no potential for addiction, unlike ketamine and other NMDA antagonists that bind to the "mu" opioid receptor.

# The NMDA Receptor is integral to Pain Signaling

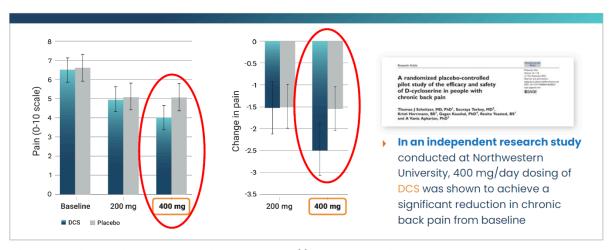




**Exhibit 29. Clinical Evidence is Promising.** DCS was evaluated in a pilot study at Northwestern University and showed efficacy at higher dose levels (Schnitzer, 2016). DCS is currently being examined in a confirmatory trial funded by the US Department of Defense under the Congressionally Directed Medical Research Program. The trial seeks to recruit approximately 200 participants with chronic low back pain at Northwestern University (clinicaltrials.gov NCT03535688). Data collection is complete, and statistical results are expected in the coming months.

Research conducted by NRx Pharmaceuticals demonstrated a 25  $\mu$ g/ml dose at which D-cycloserine becomes an NMDA antagonist. The 400mg dose presented in the confirmatory trial at Northwestern University is at the lower end of the threshold. It suggests increasing the D-cycloserine dose beyond 400mg, where Lurasidone is used to prevent CNS side effects in NRX-101.

## First Clinical Evidence of DCS effect on Chronic Pain



Back pain intensity ratings over a six-week, dose escalating, placebo or DCS treatment. (a) Across subject average back pain, assessed on the primary outcome measure of 0–10 numeric rating scale. (b) Within subject change in pain, relative to baseline, using the 0–10 numeric rating scale. Adapted from Schnitzer 13, Torbey S, Hermann K, Kaushal G, Yeasted R, Vania Apkarian A. A randomized placebo-controlled pilot study of the efficacy and safety of D-cycloserine in people with chronic back pain. Mol Pain. 2016 Nov 15;12:1744806916678627. Note that this trial did not meet its primary endpoint because separation was not seen at all dosages/timepoints.

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Source: NRx Pharmaceuticals, Inc.



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<sup>&</sup>lt;sup>7</sup> https://classic.clinicaltrials.gov/ct2/show/NCT03535688

**Exhibit 30. Open IND.** NRx Pharmaceuticals announced in October 2023 that the FDA Division of Anesthesiology, Addiction Medicine, and Pain Medicine announced a "Study May Proceed" letter regarding NRX-101 as an investigative new drug for pain. The letter authorizes the company to open a pharmacokinetic study under the newly established Investigational New Drug file for the treatment of Chronic Pain. This is a formal letter that generally follows clearance of an IND and outlines nonclinical and clinical requirements suggested by the review division.

# Confirmatory 200 person Trial Complete: NRX-101 IND Open

#### **Data Release Pending**

- Five year \$4.9 million trial funded by US Department of Defense
- DCS vs. placebo at 400mg/day
- Trial completed
- Awaiting study results

#### NRx research demonstrates a 25µg/ml dose at which DCS becomes an NMDA antagonist

- The 400mg dose in this trial is at the lower end of that threshold
- There may be therapeutic space to increase the DCS dose beyond 400mg. However, the lurasidone component of NRX-101 will likely be needed to prevent CNS side effects



https://clinicaltrials.gov/study/NCT03535688?term=DCS,%20refractory%20low%20back%20pain&rank=1

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**Exhibit 31. Urinary Tract Infections (UTI) Remains a Big Problem.** Complicated urinary tract Infections afflict approximately 3 million Americans each year, and pathogens have become increasingly resistant to commonly used antibiotics. New treatment options are urgently needed; as such, regulators are encouraging the development of new drugs and/or re-tasking old ones for use.

The D-cycloserine (DCS) component of NRX-101 is well-known as an antibiotic and is excreted unmetabolized in the urine, setting up a strong bio-availability argument. It was learned that the NMDA-antagonist effects of DCS caused its disuse in the United States. We note that it remains a widely used anti-tuberculosis agent by the World Health Organization. NRx's patented discovery that combining DCS with small amounts of lurasidone counters the CNS side effects. It renders NRX-101 an important, patented antibiotic at a time when Americans are increasingly facing intravenous antibiotic therapy and even hospitalization and death from pathogens that were readily controlled a generation ago.

# Complicated UTI Affects 3 Million Lives each year

More than 15,000 Lives Lost per Year - Antibiotics we've relied on for decades often fail



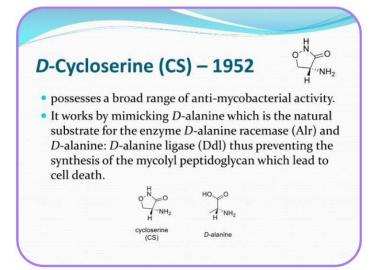
- Congress established the Qualified Infectious Disease Product (QIDP) Program to reward innovation against resistant pathogens that underlie the crisis<sup>1</sup>
- Demonstration of in-vitro efficacy earns 5 additional years of market exclusivity, Fast Track, and Priority Review
- NRx has Composition of Matter patent protection through at least 2033
- 10% of the Complicated UTI market is valued at more than \$1 billion revenue

Source: NRx Pharmaceuticals, Inc.

Exhibit 32. ReTasking an Old Drug for an Emerging Problem



DCS is uniquely concentrated in the urine and can address patients who otherwise require advanced and toxic Intravenous antibiotics





**Exhibit 33. QIDP and Fast Track Could Attract a Development Partner.** QIDP designation confers particular advantages, including priority review by the US Food and Drug Administration (FDA) and fast-track designation, which can accelerate product development, and an additional five years' market exclusivity if a product is licensed.

# **Award of QIDP and Fast Track Designations**



IND 169429

GRANT QUALIFIED INFECTIOUS DISEASE PRODUCT DESIGNATION

NeuroRx, Inc. Attention: M. Daniel Gordin, PhD Regulatory Affairs 913 North Mark Street, Suite 200 Wilmington, DE 10020

We refer to your request for Qualified Infectious Disease Product (QIDP) designation, received on November 14, 2023, for your NRX-101 (D-cycloserine and lurasidone) capsule (fixed dose combination) for oral use. We have reviewed your request and conclude that it meets the criteria for QIDP designation for the requested indication. Therefore, we are designating your NRX-101 (D-cycloserine and lurasidone) capsule (fixed dose combination) for oral use as a QIDP for the following indication:

 Treatment of complicated urinary tract infections (cUTI) including acute pyelonephritis



NRx Pharmaceuticals: Income Statement																
000 .: YE December 31	2023A	1Q24A	2Q24A	3Q24E	4Q24E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034E
Product sales	-	-	-	-	-	-	-									
NRX-101 for BPD - Akathisia	-	-	-	-	-	-	70,311	105,467	210,933	351,556	1,054,667	1,230,445	1,265,601	1,265,601	1,265,601	1,335,912
NRX-100 (IV Ketamine)							9,707	38,415	251,449	625,350	1,038,634	1,151,314	1,416,339	1,416,339	1,416,339	1,416,339
PTSD / Pain												-	-	-	-	-
Total Product Sales	-	-	-				80,018	143,882	462,383	976,906	2,093,302	2,381,759	2,681,939	2,681,939	2,681,939	2,752,250
Clinic-Psyc Center Revenues Net to Parent							17,500	36,400	56,238	77,234	98,473	120,531	139,347	149,019	149,019	158,871
Total Revenues	-	-	-		-		107,225	180,282	518,621	1,054,139	2,191,774	2,502,290	2,821,286	2,830,959	2,830,959	2,911,122
Expenses																
Product COGS								34,532	92,477	175,843	313,995	357,264	402,291	375,472	268,194	275,225
COGS %								24%	20%	18%	15%	15%	15%	14%	10%	10%
Research and Development	13,371	1,748	2,804	2,500	2,500	9,552	12,000	12,500	15,000	18,000	19,800	27,720	38,808	58,600	64,460	70,906
General and Administrative	14,216	4,250	4,246	3,800	3,900	16,196	16,358	16,522	16,687	20,858	25,030	28,785	30,224	30,526	30,831	31,140
Total Operating Expenses	27,837	5,998	7,050	6,300	6,400	25,748	16,358	51,053	109,163	196,701	339,025	386,049	432,515	405,998	299,025	306,365
Loss from Operations	(27,837)	(5,998)	(7,050)	(6,300)	(6,400)	(25,748)	63,660	92,829	353,220	780,204	1,754,276	1,995,711	2,249,425	2,275,942	2,382,914	2,445,886
Other (income) Expenses																
Gain on extinguishment of debt																
Interest income	(494)	(27)	(7)													
Interest expense - Convertible note	120	230	849													
Change in fair value of warrant liability	2,707	318	23													
Change in fair value of Earnout Cash liability	(20)	9	(18)													
Total other (income) expense		530	847													
Net Loss	(30,150)	(6,528)	(7,897)	(6,300)	(6,400)	(25,748)	63,660	92,829	353,220	780,204	1,754,276	1,995,711	2,249,425	2,275,942	2,382,914	2,445,886
Deemed Dividend (& other)	(3)	-	-	-	-	-	-	4,641	28,258	78,020	315,770	478,971	629,839	682,783	738,703	807,142
Tax Rate	0%	0%	0%	0%	0%	0%	0%	5%	8%	10%	18%	24%	28%	30%	31%	33%
GAAP Net Income (loss)	(30,147)	(6,528)	(7,897)	(6,300)	(6,400)	(27,125)	63,660	88,187	324,962	702,184	1,438,507	1,516,740	1,619,586	1,593,159	1,644,211	1,638,743
GAAP-EPS	(0.40)	(0.74)	(0.75)	(0.45)	(0.36)	(2.29)	(0.47)	1.78	6.54	14.08	28.74	30.18	32.10	31.45	32.38	32.19
GAAP EPS (dil)	(0.28)	(0.74)	(0.75)	(0.45)	(0.36)	(2.11)	1.00	1.10	4.04	8.69	17.74	18.63	32.10	31.45	32.38	32.19
Wgtd Avg Shrs (Bas) ' 000	75,762	8,852	10,517	14,000	18,000	12,842	41,180	49,457	49,655	49,854	50,054	50,255	50,456	50,658	50,785	50,912
Watd Ava Shrs (Dil) '000	109,406	8.852	10,517	14.000	18,000	12.842	63.906	80.137	80,458	80,780	81,104	81,429	81,755	82,082	82,288	82,494

Source: Company reports and EF Hutton



NB BI																
NRx Pharmaceuticals: Balance Sheet '000																
Assets	2023A	1Q24A	2Q24A	3Q24E	4Q24E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	2034
Cash and Cash Equivilents	\$4,595	\$1,319	\$1,898	\$4,050	\$7,851	\$7,851	\$68,916	\$157,669	\$483,228	\$1,186,042	\$2,625,213	\$4,142,655	\$5,762,980	\$7,356,921	\$9,001,646	\$10,640,926
PrePaid Expenses & Other Assets	2,289	2,028	2,982	2,982	2,982	2,982	2,982	2,982	2,982	2,982	2,982	2,982	2,982	2,982	2,982	2,982
Total current assets	\$6,884	\$3,347	\$4,880	\$7,032	\$10,833	\$10,833	\$71,898	\$160,651	\$486,210	\$1,189,024	\$2,628,195	\$4,145,637	\$5,765,962	\$7,359,903	\$9,004,628	\$10,643,908
Other Assets	23	441	384	441	441	441	441	441	441	441	441	441	441	441	441	441
Clinics																
Total Revenues																
Total assets	\$7,315	\$3,788	\$5,264	\$7,473	\$11,274	\$11,274	\$72,339	\$161,092	\$486,651	\$1,189,465	\$2,628,636	\$4,146,078	\$5,766,403	\$7,360,344	\$9,005,069	\$10,644,349
Liabilities:																
Accounts Payable	4,632	6,265	5,015	5,015	5,015	5,015	5,015	5,015	5,015	5,015	5,015	5,015	5,015	5,015	5,015	5,015
Accrued and other current liabilities	4,714	5,296	9,594	9,594	9,594	9,594	9,594	9,594	9,594	9,594	9,594	9,594	9,594	9,594	9,594	9,594
Accrued clinical site costs	524	491	444	444	444	444	444	444	444	444	444	444	444	444	444	444
Earnout Cash Liability	-	-	7,651	7,651	7,651	7,651	7,651	7,651	7,651	7,651	7,651	7,651	7,651	7,651	7,651	7,651
Warrant liabilities	17	26	8	8	8	8	8	8	8	8	8	8	8	8	8	8
Note payable and accrued interest	9,161	6,779	943	943	943	943	943	943	943	943	943	943	943	943	943	943
Total current liabilities	\$19,048	\$18,857	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655
		-														
Related-party convertible notes, net, less short-term portion  Total liabilities	\$19.048	\$18.857	\$23,655	\$23,655	\$23,655	\$23.655	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655	\$23,655	\$23.655	\$23,655	\$23,655
Stockholders' equity:	\$19,040	φ10,007	\$23,000	φ23,000	\$23,000	φ23,000	φ23,000	φ23,000	φ23,000	\$23,000	\$23,000	\$23,000	\$23,000	\$23,000	\$23,000	φ23,000
Preferred stock									_			_	_			
Common stock	84	10	- 11	- 11	11	11	- 11	- 11	11	11	11	11	11	11	11	- 11
Additional paid-in capital	241.330	244.599	249,173	257.966	268,167	268,167	345,590	346.156	346.753	347.383	348.047	348,749	349,489	350.270	350.784	351.321
	,	,		- ,				,	,	. ,	,-	, .	,	, .	, .	, -
Accumulated deficit	(253,147)	(259,675)	(267,575)	(274,159)	(280,559)	(280,559)	(296,917)	(208,730)	116,232	818,416	2,256,923	3,773,663	5,393,248	6,986,408	8,630,618	10,269,362
Total Stockholders' Equity (deficit)	(11,733)	(15,066)	(18,391)	(16,182)	(12,381)	(12,381)	48,684	137,437	462,996	1,165,810	2,604,981	4,122,423	5,742,748	7,336,689	8,981,414	10,620,694
Total Liab & Stockholders' Equity (deficit)	\$7,315	\$3,788	\$5,264	\$7,473	\$11,274	\$11,274	\$72,339	\$161,092	\$486,651	\$1,189,465	\$2,628,636	\$4,146,078	\$5,766,403	\$7,360,344	\$9,005,069	\$10,644,349
Shares Iss'd (000)	80,200	8,852	10,517	14,000	18,000	18,000	49,334	49,532	49,730	49,929	50,129	50,330	50,532	50,734	50,861	50,988
Shares Out (000)	151,000	8,852	10,517	14,000	18,000	18,000	79,937	80,257	80,579	80,901	81,225	81,551	50,532	50,734	50,861	50,988

Shares Out (000)
Source: Company reports and EF Hutton



00001	10011	00044	00045	4004	0004	0000	0000	00077	0000	2222	0000	0004	0000	2000	0000
															<b>2034</b> 1,638,743
(30, 130)	(0,526)	(14,425)	(20,725)	(27,125)	(27,123)	(10,336)	00,107	324,902	702,104	1,436,507	1,516,740	1,019,500	1,595,159	1,044,211	1,030,743
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	242				-										
(20)	9		(9)	(9)	(9)										
(20)	0		1 226	1 226	1 226										
2,707	310	849	849	849	849										
250															
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2.040	250														
						(40.050)	00.407	004.000	700.404	4 400 507	4.540.740	4 040 500	4 500 450	4.044.044	4 000 740
(21,677)	(3,662)	(6,233)	(12,874)	(19,274)	(19,274)	(16,358)	88,187	324,962	702,184	1,438,507	1,516,740	1,619,586	1,593,159	1,644,211	1,638,743
0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	(
											, i	, i			
9.293	1.523	4.665	13.458	23.659	23.659	77.422	566	597	630	665	701	740	781	514	537
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	(2.155)	(2.156)	(2.156)	(2.156)	(2.156)										
0															
-	.,	.,	.,	.,	.,										
9,293	395	3,536	12.329	22.530	22,530	77,422	566	597	630	665	701	740	781	514	537
								-							1,639,280
	4,595	4,595	4,595	4,595	4,595	7,851	68,916	157,669	483,228		2,625,213			7,356,921	9.001.646
20.054	4.595		4.595							1.186.042	2.625.213	4.142.655			
	9,293 0 9,293 (15,476)	(30,150) (6,528)  5 1 387 242 (20) 9 (20) 9 (20) 318  250  3,040 250 2,655 2,091 (531) (54) (21,677) (3,662)  0 0  9,293 1,523 (2,155) 0 1,027	(30,150) (6,528) (14,425)  5 1 2  387 242 339 (20) 9 (9)  341 (20) 9 1,336 2,707 318 849  250  3,040 250 (648) 2,655 2,091 4,209 (531) (531) (54) 943 (21,677) (3,662) (6,233)  0 0 0  9,293 1,523 4,665 (2,155) (2,156) 0 1,027 1,027	(30,150) (6,528) (14,425) (20,725)  5	(30,150) (6,528) (14,425) (20,725) (27,125)  5	(30,150) (6,528) (14,425) (20,725) (27,127) (27,127) (27,	(30,150) (6,528) (14,425) (20,725) (27,125) (27,125) (16,358)  5	(30,150) (6,528) (14,425) (20,725) (27,125) (27,125) (16,358) 88,187  5	(30,150)	14,425   (20,725)   (27,125)   (27,125)   (16,358)   88,187   324,962   702,184     5	30,150    (6,528)   (14,425)   (20,725)   (27,125)   (27,125)   (16,358)   88,187   324,962   702,184   1,438,507     5	(30,150)   (6,528)   (14,425)   (20,725)   (27,125)   (27,125)   (16,358)	(30,150) (6,528) (14,425) (20,725) (27,125) (27,125) (16,358) 88,187 324,962 702,184 1,438,507 1,516,740 1,619,586  5	30,150    (6,528)   (14,425)   (20,725)   (27,125)   (27,125)   (16,358)   88,187   324,962   702,184   1,438,507   1,516,740   1,619,586   1,593,159   1   2   2   2   2   2   339   339   339   339   (9)   (9	(30,150) (6,528) (14,425) (20,725) (27,125) (27,125) (16,358) 88,187 324,962 702,184 1,438,507 1,516,740 1,619,586 1,593,159 1,644,211  5



#### **Important Disclosures**

#### **Analyst Certification**

I, Jason Kolbert, certify that all of the views expressed in this research report accurately reflect my personal views about the subject security(ies) and subject company(ies). I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this research report.

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**BUY (B)** - Total return expected to exceed S&P 500 by at least 10%

**HOLD (H)** - Total return expected to be in-line with S&P 500

SELL (S) - Total return expected to underperform S&P 500 by at least 10%

#### Distribution of Ratings/IB Services EF Hutton

			IB Serv./Pa	st 12 Mos.
Rating	Count	Percent	Count	Percent



#### NRx Pharmaceuticals, Inc. Rating History as of 10/18/2024



