

NRx Pharmaceuticals, Inc.

Q2 about inline. Phase 3 trial positive data. Major opportunities in IV ketamine and NRX-101. Raising P/T to \$44.

Q2 inline: NRx recently (on August 14) reported its Q2 2024 (ending June) results. Net loss was \$7.9 million or EPS of \$(0.75) compared with our and consensus estimates of \$(0.58). There was no company guidance. NRx is a clinical stage drug development company so it generates no revenue.

Operating expenses: Operating expenses were \$7.1 million, up from Q1's \$6.0 million on higher R&D costs.

No guidance: Management did not provide forward guidance.

Adjusting estimate: We are adjusting our 2024 EPS estimate to \$(2.84) from \$(2.42).

Focused on Bipolar Disorder: Its main drug is NRX-101 (D-cylcoserine/Lurasidone) for the treatment of bipolar depression in patients with suicidality (the risk of suicide). NRX-101 aims to be the first oral therapeutic for the treatment of Bipolar Depression in patients with Acute Suicidal Ideation and Behavior ("ASIB") and Sub-Acute Suicidal Ideation and Behavior ("SSIB").

NRX-101: NRX-101 is a dual-targeted therapy regimen consisting of an initial treatment with NRX-100 (intravenous ketamine) followed by 6-week treatment with NRX-101 (combined DCS and lurasidone). Ketamine is a generic drug and has been widely used for a long time as an antidepressant, although its effect does not last long (usually about a week). NRX-101 is designed to extend ketamine's proven anti-suicidal and antidepressant benefits without its drawbacks.

Large market potential: There is no medicine approved to treat patients with bipolar depression suffering suicidal ideation. According to the NIH, an estimated 2.8% of the U.S. adult population had bipolar disorder in the past 12 months, and the lifetime prevalence is 4.4% of adults in the U.S. Lifetime suicide behavior occurs in 25% to 56% of people with bipolar depression.

Positive clinical trials data: In May, the company announced final positive clinical trials data in its Phase 2b/3 Clinical Trial of NRX-101 vs. Lurasidone for Treatment of Suicidal Bipolar Depression. The company believes that the findings when combined with the prior STABIL-B trial, demonstrate a basis for seeking accelerated drug approval of NRX-101 based on improved safety related to akathisia and suicidality in the setting of comparable antidepressant efficacy. This includes reductions in symptoms of akathisia – a side effect of antidepressants that is closely linked to suicide and considered a medical emergency.

HOPE Therapeutics spinoff: The company is developing NRX-100 (intravenous ketamine) as a labeled drug to treat acute depression and suicidality. The company plans to file a NDA for NRX-100 in 2024, with potential for revenue in 2025. The company plans to partially spin off HOPE Therapeutics to shareholders.

NRX-100: NRX-100 is Intravenous (IV) ketamine which has now become a standard of care for acute treatment of suicidal depression, in the absence of an FDA-labeled product.

Chronic Pain data readout soon: NRx plans to investigate NRX-101 in Chronic Pain and UTI as additional indications. The company has filed an Investigational New Drug (IND) Application with the FDA for these new indications and has received approvals. Data readout for its Chronic Pain clinical trial is expected soon (current Q3).

Balance sheet: As of Q2, the company has \$2 million in cash and \$9 million in debt. The company is currently finalizing a \$30 million capital raise. The company also recently announced a financing of up to ~\$16 million in debt (~\$5 million of which has already closed).

Reverse stock split: In April 2024, the company effected a 1:10 reverse stock split.

New CEO search: In August, Stephen Willard, the company's CEO, has recommended the company find a new CEO with commercial pharmaceutical experience, particularly drug launch experience. Mr. Willard will stay as CEO during the search.

Current valuation attractive: We are maintaining our BUY rating, but raising our 12-month price target to \$44 from \$43 based on a NPV analysis. This represents significant upside from the current share price and we believe this valuation appropriately balances out the high risks with large upside opportunities.

Company Description

NRx Pharmaceuticals, based in Wilmington, DE, is a clinical stage biopharmaceutical company developing drugs to treat mental health disorders.

United States
Healthcare

September 11, 2024

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COMPANY UPDATE

Rating: BUY

Ticker: NRXP

Price: \$1.69

Target: \$44
(from \$43)

Stock Data

Exchange:	NasdaqGM
52-week Range:	1.59 – 7.33
Shares Outstanding (million):	11
Market cap (\$million):	\$19
EV (\$million):	\$26
Debt (\$million):	\$9
Cash (\$million):	\$2
Avg. Daily Trading Vol. (\$million):	\$0.2
Float (million shares):	8
Short Interest (million shares):	0.5
Dividend, annual (yield):	\$0 (NA%)

Revenues (US\$ million)

	<u>2024E</u> <u>(Cur.)</u>	<u>2024E</u> <u>(Old)</u>	<u>2025E</u> <u>(Cur.)</u>	<u>2025E</u> <u>(Old)</u>
Q1 Mar	0A		0E	
Q2 Jun	0A	0E	0E	
Q3 Sep	0E		0E	
Q4 Dec	0E		0E	
Total	0E		0E	
EV/Revs	N/A		N/A	

Earnings per Share (pro forma)

	<u>2024E</u> <u>(Cur.)</u>	<u>2024E</u> <u>(Old)</u>	<u>2025E</u> <u>(Cur.)</u>	<u>2025E</u> <u>(Old)</u>
Q1 Mar	(0.74)A		(0.60)E	(0.47)E
Q2 Jun	(0.75)A	(0.58)E	(0.60)E	(0.46)E
Q3 Sep	(0.66)E	(0.57)E	(0.59)E	(0.46)E
Q4 Dec	(0.69)E	(0.56)E	(0.59)E	(0.46)E
Total	(2.84)E	(2.42)E	(2.39)E	(1.85)E
P/E	N/A		N/A	

*Reflects a 1:10 reverse stock split in April 2024.

Important Disclosures

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For analyst certification and other important disclosures, refer to the Disclosure Section, located at the end of this report, beginning on page 20.

Exhibit 1: NRx Pharmaceuticals, Inc. Corporate Overview



Recent clinical developments enable FDA filing in 2024 with Potential for 2025 Commercial Revenue



NASDAQ: NRXP

THIS YEAR

- **New Drug Application planned for NRX-100 (IV Ketamine) in Suicidal Depression**

Potential for \$100 million+ revenue in 2025 with peak in excess of \$1 billion

- **Accelerated Approval application planned for NRX-101 in Bipolar Depression with Suicidality or Akathisia**

Enabled by Prior Breakthrough Therapy designation for NRX-101

- **Launch of HOPE Therapeutics with Expected 2024 Revenue; NRXP majority owner**

Initial \$100 million mental health clinic rollup; independent funding via bond issuance; NRXP shareholders to receive share distribution

FUTURE YEARS

- **Path to 2026 approval as first antibiotic to treat cUTI without risk of *C. Difficile* infection based on QIDP and Fast Track awards**

Requires Phase 2/3 Trial

Source: Company reports.

Exhibit 2: NRx's Investment Summary

NRx Clinical Programs – 2024/25 Upside Potential



NRX-100 (Ketamine)

Suicidal Depression

- Fast Track NDA filing in **2H24**
- Approvable efficacy data from four studies in hand
- Manufacturing data reaches 12 month stability in 2H24 (required for filing)
- Six-month Ketamine tox data
- A reimbursable form of Ketamine has a \$2 billion addressable market



NRX-101 (DCS/Lurasidone)

Bipolar Depression

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



HOPE Therapeutics

Interventional Psychiatry

- NRXP: spin out to be majority owned; shareholders receive distribution
- Mental health/Ketamine clinic rollup; bond financing targeted
- Provides launch platform for HTX-100
- Separate financing – nondilutive to NRx investors
- Expected in profit in **2025**

Source: Company reports.

Exhibit 3: NRX-101

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

NRX-101[™] For Suicidal Treatment-Resistant Bipolar Depression

First oral medicine in development for Suicidal Treatment-Resistant Bipolar Depression

- Non-addictive
- Non-neurotoxic
- Non-hallucinogenic

NRX-101 blocks the psychedelic effects of NMDA antagonists with evidence that the antidepressant and anti-suicidal properties can be preserved

Source: Company reports.

Exhibit 4: NRx's Product Pipeline (as of July 2024)

Our Pipeline

Leveraging our Multi-Billion Dollar NMDA Platform

Product	Phase1	Phase2	Phase3	NDA	Status
<u>Suicidal Depression</u>					
HTX-100 (IV Ketamine)	Suicidal Depression			NDA Filing 2H24 PDUFA est. 2025	
	*Collaboration Agreement with Study Leadership of two well-powered, academic clinical trials				
NRX-101™	Suicidal, Treatment-Resistant Bipolar Depression with Akathisia or Suicidality			Filing NDA for Accelerated Approval 2H24; est PDUFA 2025	
	Bipolar Depression			Phase 3 confirmatory trial, post approval	
<u>Chronic Pain</u>					
D-Cycloserine (DCS)	Chronic Back Pain			200 person, independent trial funded by DOD Pending Data Readout	
NRX-101™	Chronic Nociceptive Pain			IND Approved Applied to NIH EPICNET & HEAL	
<u>PTSD</u>					
NRX-101™	PTSD			Nonclinical Evidence Clinical Planning	
<u>Complicated UTI</u>					
NRX-101™	Complicated UTI incl. Pyelonephritis			In Vitro Data QIDP and Fast Track granted	

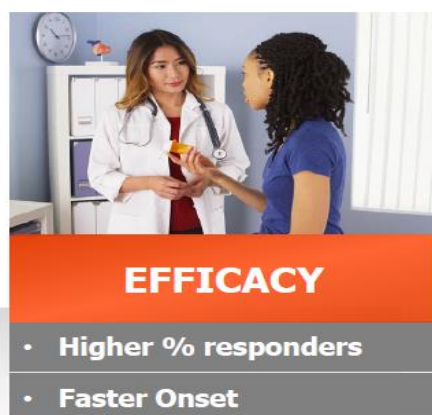
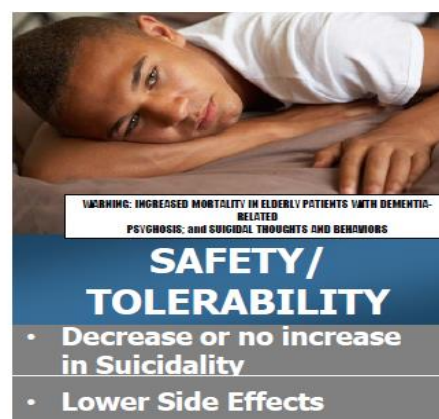
Source: Company reports.

Exhibit 5: Targeting Suicidal Bipolar Depression Risks

Why target Suicidal Bipolar Depression?

Suicide kills ~50,000 Americans annually* - suicide is particularly high in bipolar disorder

Selected Unmet Needs for New Antidepressants



Source: Company reports.

Exhibit 6: Bipolar Depression Suicide Market Opportunities

NRX-101 Market Opportunity in Bipolar Depression

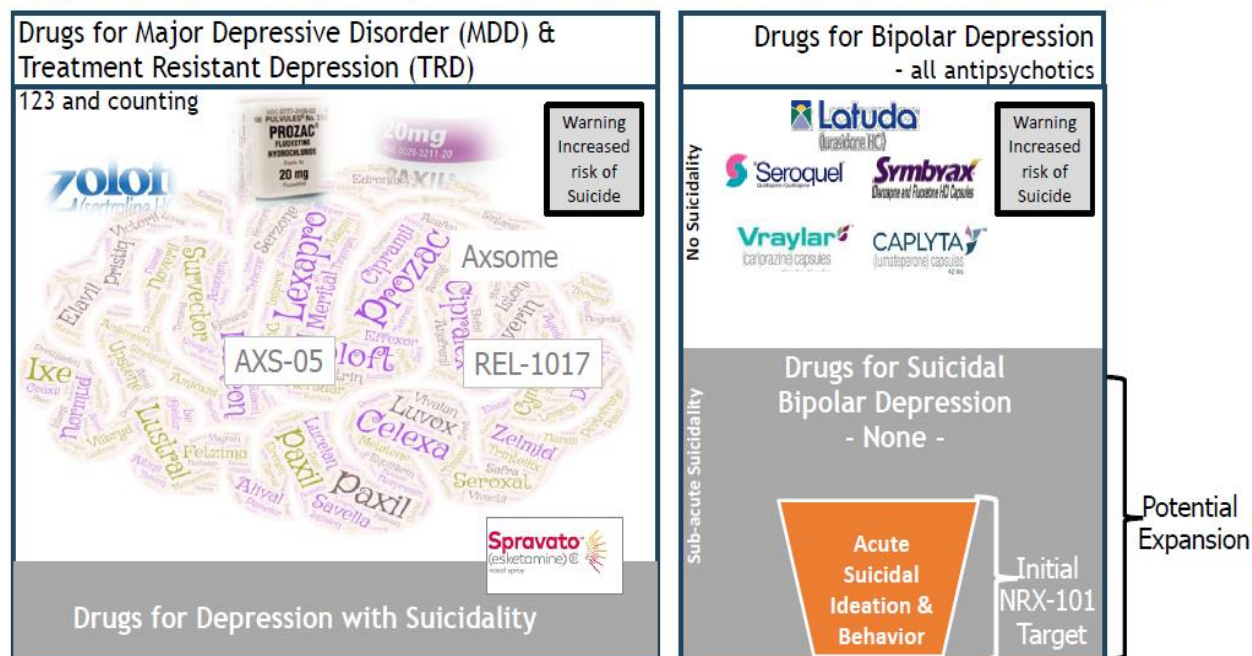
Patients in clinics and outpatient being treated for Bipolar Depression with Suicidality



Source: Company reports.

Exhibit 7: Unmet Need for Bipolar Depression Suicidality

Though numerous drugs have been approved for MDD and Bipolar Depression, faster, more robust response, and reduction of suicidality remain the unmet need



Source: Company reports.

Exhibit 8: Science of Depression and Suicidality

The Emerging Science of Depression and Suicidality

Depression and Suicidality – though overlapping is not the same

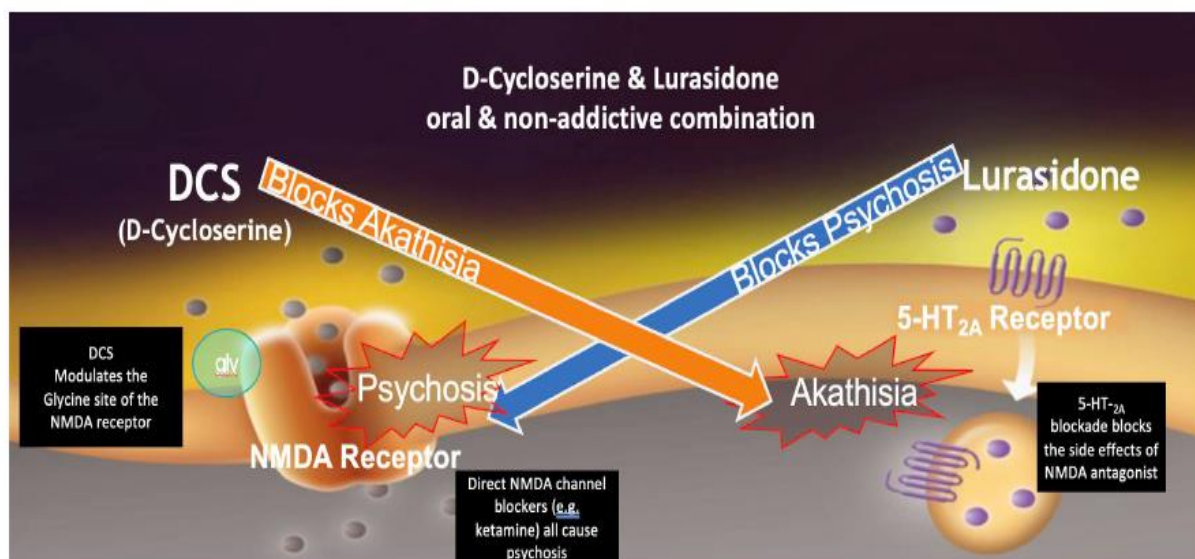
Depression with Suicidality	Implications for Bipolar Depression with Suicidality
<ul style="list-style-type: none"> Antidepressants (5HT2a / SSRIs) can increase suicidality – suicidality routinely an exclusion in depression studies NMDA antagonists (ketamine) can stabilize depression and suicidality – <ul style="list-style-type: none"> Suicidality improvement not strictly a function of improvements in depression Ketamine can create hallucinations, may be highly addictive, requires supervised administration 	<ul style="list-style-type: none"> Highest suicidality of depressive disorders ~ 50% attempt suicide Available drugs improve depression but can increase suicidality Drug abuse and overdose of great concern – addictive agents may require REMS
Development of Depression drugs has mostly avoided addressing Suicidality	

Source: Company reports.

Exhibit 9: NRx Discovery

The NRx Discovery

Simultaneous Blockade of NMDA and 5-HT_{2A}



D-Cycloserine acts as an NMDA antagonist above certain dosages

Studies have shown that DCS + 5HT2a increases the antidepressant response and reduces suicidality

Understanding the NMDA Receptor

The NMDA receptor is an ION Channel on the surface of Brain Cells

At high levels of NMDA activity (i.e. the channel is wide open) thoughts are slowed substantially, patients ruminate on negative, frequently suicidal thoughts. Brain cells stop making new connections to neighboring cells.

NMDA antagonists decrease symptoms of depression.

NMDA antagonists block the akathisia caused by SSRI antidepressants in nonclinical studies.

NMDA antagonists “rewire” the brain by stimulating new connections between brain cells.

NMDA RECEPTOR REGULATES SPEED OF THOUGHTS

TOO FAST and thoughts race uncontrollably (mania)

TOO SLOW and negative, self-destructive thoughts drive suicide

TURNING A DIMMER

Daily oral NRx-101 (a proprietary formulation of D-cycloserine and Lurasidone) modulates NMDA receptors at the glycine site.

FLIPPING THE SWITCH

A single infusion of injected Ketamine by pump initiates therapy; Blocks brain NMDA receptors at the “channel” site.

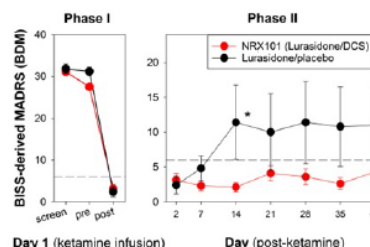
Source: Company reports.

Exhibit 10: Phase 2 Study of D-Cycloserine in Depression / Suicidality Conclusions

Phase 2 Success: 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 ($P=.14$)



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

Source: Company reports.

Exhibit 11: NRX-101 Phase 2b/3 Clinical Trial Program (SSIB & ASIB) Conclusions

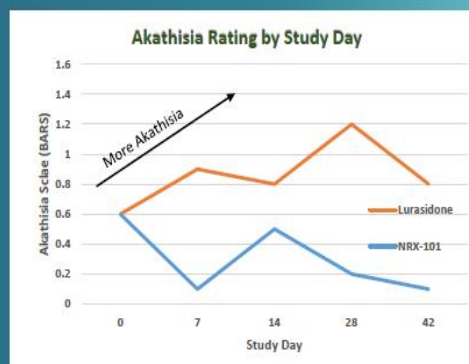
NRX-101 demonstrates reduced Akathisia and Time to Suicidality Remission in Suicidal Bipolar Depression: *No Ketamine Pre-treatment*

Phase 2b/3, randomized, double blind trial on NRX-101 vs Standard of Care (SoC) (lurasidone) in Suicidal Treatment Resistant Bipolar Depression (S-TRBD), $n=74$

- *Similar (50% reduction) in depression vs. SoC*
- *Significant reduction in akathisia vs. SoC, $p=0.03$*
- *Time to Sustained Remission from Suicidality (C-SSRS ≤ 3) vs. SoC, $p=0.05$*

➤ *We believe an antidepressant with Standard of Care level efficacy and a significant reduction in akathisia / suicidality vs SoC will become the new standard in bipolar depression*

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



Source: Company reports.

Exhibit 12: NRX-101 Advantages and Objectives

NRX-101 offers a differentiated profile for Suicidal Bipolar Depression with an FDA agreed upon path to NDA

Phase 3 with FDA Breakthrough Therapy designation

NMDA – A Validated Mechanism

- Depression & Suicidality
- Esketamine, NRX-101 Phase 2, etc.

FDA Agreed Upon Regulatory Path

- Special Protocol Agreement, Breakthrough Therapy designation: Treatment of Severe Bipolar Depression in Patients with ASIB after initial stabilization with ketamine or other effective therapy

Addresses High Unmet Need

- Treats depression and suicidality (bipolar space)
- Oral, not addictive (not scheduled), avoids hallucinations
- Outpatient

Efficient Clinical Development Path to NDA

- Seeking to replicate P2 study
- NRX-100 (144 pts.) NRX-101 (~80 pts.) pivotal study (severely depressed and acutely suicidal) to start 2H22
- Path to NDA filing in 2023

Path
to
NDA

Composition of Matter Patent

- NRx has a composition of matter patent for NRX-101 and an array of NMDA+5HT2A compounds,
- Five patent families, 60+ applications, 30+ issued patents

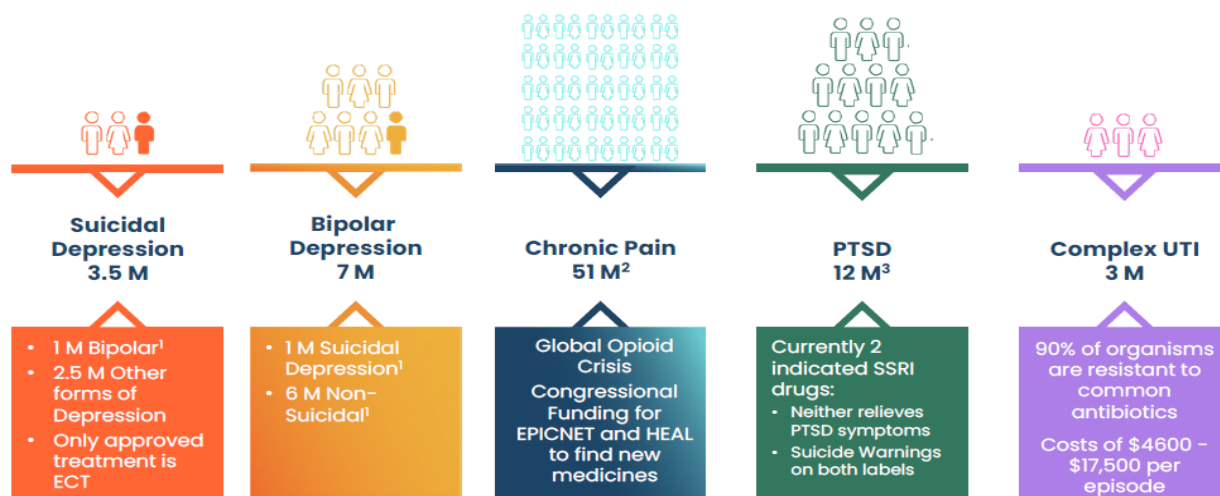
Exploring expansion in earlier population

- NRX-101 Phase 2 trial (Bipolar Depression in sub-acute suicidality) initiated 2Q 2022

Source: Company reports.

Exhibit 13: NRX-101 Market Opportunities

Potential to Reach 75 Million Lives



Source: Company reports.

Exhibit 14: Path to 2024 Accelerated Approval filing for NRX-101

Path to 2024 Accelerated Approval filing for NRX-101 in Patients with Bipolar Depression and Suicidality or Akathisia

- For long term approval, NRX-101 will require an additional clinical trial vs. placebo in future years for broad, first line indication. Beating placebo is highly likely, given that NRx demonstrated an antidepressant effect comparable to lurasidone, which has beaten placebo in multiple registration trials and NRX-101 demonstrated equivalence to lurasidone.
- Accelerated Approval allows for five years of market approval for drugs to treat a life-threatening condition in the absence of other approved therapy, when efficacy has been demonstrated on one or more intermediate clinical endpoints.
- FDA 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 from 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 benefit to patients.
- One path for confirmatory data is the PCORI program in Bipolar Depression that currently lacks a treatment arm for patients with suicidality and akathisia on standard medication

Source: Company reports.

Exhibit 15: HOPE 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 Ketamine and digital therapeutics
- 2 **Acquisition** of revenue generating Ketamine/interventional psychiatry clinics
- 3 **Insurance-reimbursable** Ketamine 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) – improved formulation
- 5 **Financing independent of NRXP:** equity and bond issuance

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**
Not reimbursed by Payers
Inconsistent in quality



Hope Therapeutics Near-Term Benefits to NRXP

- **NRXP to be majority shareholder after distribution**
additional investors would dilute HOPE, but not NRXP
 - Target \$45 million/yr run-rate
 - Opportunity Zone (tax-advantaged investment) focus
- **HOPE is an asset – adds to the NRXP Balance Sheet**
 - Increases NRXP Shareholder Equity
- **Potential dividends in 2025, if HOPE generates positive Cashflow**
 - Projected profitability in 2025

Source: Company reports.

Exhibit 16: Q2 2024 Results and Recent Business Highlights (as of August 14, 2024)

NRx Pharmaceuticals (NASDAQ:NRXP) Reports Second Quarter and Year to Date 2024 Financial Results and Provides Business Update

- *Company is now funded for and focused on New Drug Applications (NDAs) for NRX-100 (ketamine) and NRX-101*
- Audit of HOPE Therapeutics is now complete, SEC filing of spinout this quarter

Key Milestones

- Secured \$10.8 - \$16.3 million in convertible-debt funding from an institutional investor; funds targeted to support FDA New Drug Applications for NRX-100 (ketamine) and NRX-101. Replacement funding entails substantial reduction in interest rate, conversion discount, and other financial terms compared to prior debt
- Retirement of Streeterville debt and settlement of litigation at a substantial discount to litigation claims
- NRX-100 NDA for suicidal depression based on data from four clinical trials in nearly 1000 participants demonstrating highly significant efficacy compared to placebo, active comparator, and electroshock therapy
- Ketamine findings have just been confirmed in published 43,000 person cohort study¹
- Phase 2b/3 trial of NRX-101 in suicidal patients with bipolar depression demonstrated depression efficacy comparable to standard of care and significant reduction of akathisia ($P=0.025$) and time to sustained remission from suicidality ($P=.05$). Presented at the annual meeting of the American Society of Clinical Psychopharmacology. Profile demonstrates possible best in class bipolar depression medication
- Company plans to file a New Drug Application (NDA) for Accelerated Approval under Breakthrough Therapy Designation and Priority Review of NRX-101 in treatment of bipolar depression in people akathisia or suicidality, based on the Phase 2b/3 and STABIL-B data
- Stability data continues to mature on the three manufacturing lots required for the NRX-100 (IV ketamine) NDA filing and the Company announced alignment with FDA on its Pediatric Study Plan for NRX-100, also a requirement for filing an NDA
- HOPE Therapeutics, the Company's wholly owned subsidiary, is focused on developing a best-in-class network of clinics that currently offer ketamine and other lifesaving therapies to patients with suicidal depression and related disorders. HOPE is planned to be spun out as a separate company to be owned by NRx, current NRx shareholders, and new investors. This effort will be funded apart from NRx.
- Appointed Dr. Dennis McBride, a Neuroscience, Information Technology and Medical Technology Veteran, to its Board of Directors

Source: Company reports.

Exhibit 17: Positive Phase 2b/3 Clinical Trial (May 6, 2024)

Safety Combined with Similar Efficacy in the Trial of NRX-101 Compared to Lurasidone in Suicidal Bipolar Depression



- Both drugs demonstrated > 50% response for treating depression. NRX-101 demonstrated a mean 76% reduction in symptoms of akathisia compared to lurasidone that was sustained over 42 days (Effect Size .37; $P=0.025$), using prespecified analytic methodology memorialized in FDA Special Protocol Agreement. Levels of akathisia with NRX-101 were essentially zero at day 42
- This safety advantage was previously reported in the Company's published STABIL-B trial
- Akathisia is identified as a life-threatening side effect of nearly all antidepressants, reported in 10-15% of treated patients and is closely linked to suicide in FDA black box warning
- Akathisia was seen in 2% of participants treated with NRX-101 vs. 11% treated with lurasidone
- Company plans to seek accelerated approval of NRX-101 for use in patients with bipolar depression at risk of akathisia while continuing to broaden the indication to all patients with bipolar depression and perhaps schizophrenia
- Study will be presented at the American Society of Clinical Psychopharmacology (ASCP) meeting May 28-31, 2024 (Miami) together with study investigators, accompanied by a broadcast scientific presentation on akathisia and antidepressant safety, and investor Q&A

Commonly heard

"But the recent trial did not meet its primary endpoint..."

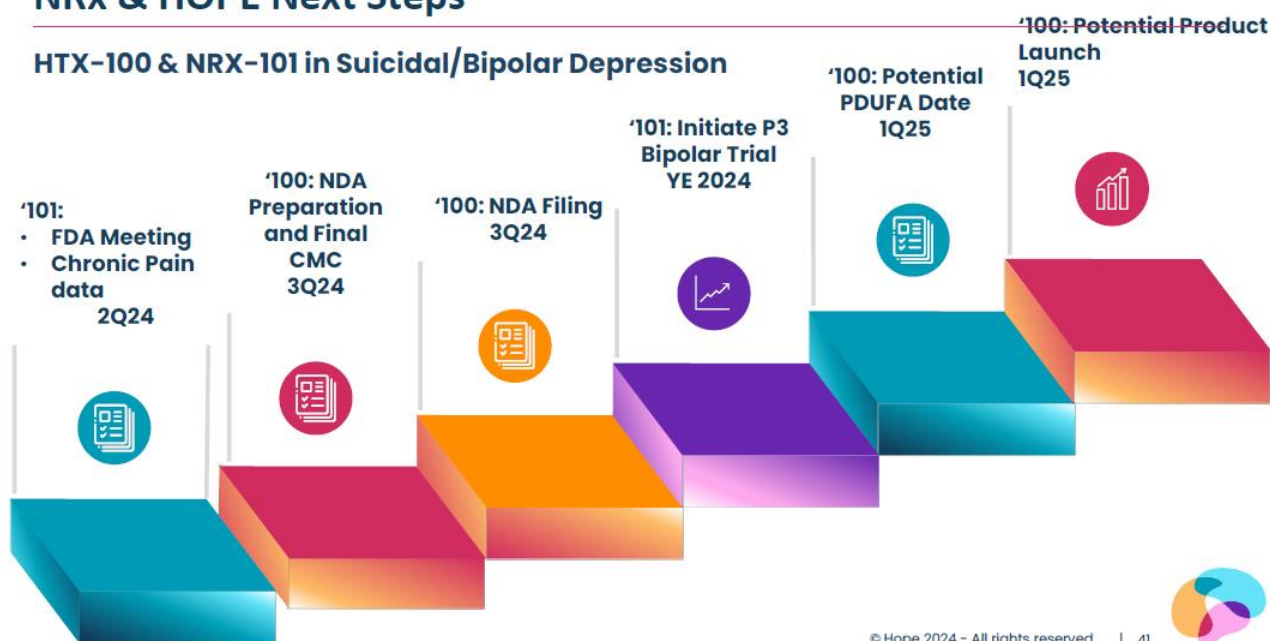
- The trial did not demonstrate a superior antidepressant effect vs. a leading antidepressant (i.e. the declared primary efficacy endpoint)
- The trial did meet both primary (suicidality) and secondary (akathisia) pre-declared safety endpoints at a statistically-significant level and confirms the findings of two prior trials in this regard
- This provides a basis to file for time-limited (5 year) accelerated approval for patients who have no therapeutic alternative. During that period, the sponsor is required to provide confirmatory evidence of sustained benefit

Source: Company reports.

Exhibit 18: Near Term Catalysts and Outlook

NRx & HOPE Next Steps

HTX-100 & NRX-101 in Suicidal/Bipolar Depression



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

National Library of Medicine
National Center for Biotechnology Information

ClinicalTrials.gov
ACTIVE, NOT RECRUITING

D-cycloserine for the Treatment of Chronic, Refractory Low Back Pain
ClinicalTrials.gov ID: NCT03535688
Sponsor: Northwestern University
Information provided by: Thomas J. Schnitzer, Northwestern University (Responsible Party)
Last Update Posted: 2023-10-31

Study Overview

Brief Summary

The purpose of this study is to evaluate the efficacy and safety of **D-cycloserine** versus placebo in relieving the signs and symptoms of patients with chronic **lower back pain**.

Detailed Description

This is a 26-week, double-blind, randomized, placebo-controlled two-arm parallel-group trial of d-cycloserine, a pharmacological treatment selected based on positive results from previous preclinical and clinical studies, for the treatment of chronic, refractory low back pain (CRBP). After a 2-week screening period, individuals will be randomized to receive either 12 weeks of d-cycloserine or placebo and then followed for an additional 12 weeks to evaluate persistence of benefit at study endpoint, 24 weeks after randomization. During the 12-week treatment period, participants will undergo evaluation at baseline and at clinic visits on weeks 2, 6 and 12 after randomization to assess pain, proper treatment...

[+ Show more](#)

Source: Company reports.

Exhibit 19: NRx Pharmaceuticals, Inc. Stock Price (5-Years)

SPAC (Big Rock Partners Acquisition Corp.) IPO - 11/20/17

SPAC Merger Announcement (with NeuroRx, Inc.) - 12/14/20

SPAC Merger Completion (to form NRx Pharmaceuticals, Inc.) - 5/25/21



*Reflects a 1:10 reverse stock split in April 2024

Source: <https://bigcharts.marketwatch.com/>

Exhibit 20: Consensus Expectations (as of August 14, 2024)

	Revenue (mils)			EPS	
	<u>2024E</u>	<u>2025E</u>		<u>2024E</u>	<u>2025E</u>
Q1 Mar	\$0A		Q1 Mar	\$(0.74)A	
Q2 Jun	\$0E		Q2 Jun	\$(0.58)E	
Q3 Sep	\$0E		Q3 Sep	\$(0.57)E	
Q4 Dec			Q4 Dec		
Total	\$0E	\$0E	Total	\$(3.21)E	\$(1.85)E

*Quarterly estimates may not add to annual estimates due to variations in contributing estimates and rounding

*Reflects a 1:10 reverse stock split in April 2024

Source: Company report, LSEG, and Ascendant Capital Markets estimates

FINANCIAL MODEL

NRx Pharmaceuticals, Inc.

Income Statement (\$ mils)	Mar-22	Jun-22	Sep-22	Dec-22	2022	Mar-23	Jun-23	Sep-23	Dec-23	2023	Mar-24	Jun-24	Sep-24	Dec-24	2024	Mar-25	Jun-25	Sep-25	Dec-25	2025
Fiscal Year End: December 31	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E
Total Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Cost of Revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Gross Profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Research & development	5.5	3.0	4.1	4.5	17.0	3.7	3.9	3.3	2.5	13.4	1.7	2.8	3.0	3.0	10.6	2.0	2.0	2.0	2.0	8.0
General and administrative	10.2	6.6	5.0	5.5	27.4	5.8	4.1	2.5	1.9	14.2	4.3	4.2	4.0	4.0	16.5	4.0	4.0	4.0	4.0	16.0
Restructuring and other					0.0		0.3			0.3					0.0					0.0
Total operating expenses	15.7	9.6	9.1	10.0	44.4	9.4	8.2	5.8	4.4	27.8	6.0	7.1	7.0	7.0	27.0	6.0	6.0	6.0	6.0	24.0
Operating income (loss)	(15.7)	(9.6)	(9.1)	(10.0)	(44.4)	(9.4)	(8.2)	(5.8)	(4.4)	(27.8)	(6.0)	(7.1)	(7.0)	(7.0)	(27.0)	(6.0)	(6.0)	(6.0)	(6.0)	(24.0)
Interest income (expense)	(0.0)	0.0	0.1	0.1	0.2	0.2	0.1	0.1	(0.0)	0.4	(0.2)	0.0	(0.3)	(0.7)	(1.2)	(0.8)	(0.8)	(0.8)	(0.8)	(3.1)
Other income (expense)	2.3	2.6	(0.0)	(0.5)	4.3	(1.8)	(0.7)	(0.3)	0.1	(2.7)	(0.3)	(0.9)	0.0	0.0	(1.2)	0.0	0.0	0.0	0.0	0.0
Income before income taxes	(13.4)	(7.0)	(9.1)	(10.3)	(39.8)	(11.0)	(8.7)	(6.1)	(4.3)	(30.2)	(6.5)	(7.9)	(7.3)	(7.7)	(29.4)	(6.8)	(6.8)	(6.8)	(6.8)	(27.1)
Income taxes					0.0					0.0			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net income (loss)	(13.4)	(7.0)	(9.1)	(10.3)	(39.8)	(11.0)	(8.7)	(6.1)	(4.3)	(30.2)	(6.5)	(7.9)	(7.3)	(7.7)	(29.4)	(6.8)	(6.8)	(6.8)	(6.8)	(27.1)
Nonrecurring/noncash adjustments					0.0					0.0					0.0					0.0
Net income (pro forma)	(13.4)	(7.0)	(9.1)	(10.3)	(39.8)	(11.0)	(8.7)	(6.1)	(4.3)	(30.2)	(6.5)	(7.9)	(7.3)	(7.7)	(29.4)	(6.8)	(6.8)	(6.8)	(6.8)	(27.1)
EBITDA																				
Shares, Basic	6.4	6.6	6.6	6.8	6.6	6.7	7.3	8.2	8.2	7.6	8.9	10.5	11.0	11.1	10.4	11.2	11.3	11.4	11.5	11.4
Shares, Diluted	6.4	6.6	6.6	6.8	6.6	6.7	7.3	8.2	8.2	7.6	8.9	10.5	11.0	11.1	10.4	11.2	11.3	11.4	11.5	11.4
EPS Basic (pro forma)	(\$2.11)	(\$1.06)	(\$1.37)	(\$1.53)	(\$6.05)	(\$1.64)	(\$1.19)	(\$0.74)	(\$0.53)	(\$3.98)	(\$0.74)	(\$0.75)	(\$0.66)	(\$0.69)	(\$2.84)	(\$0.60)	(\$0.60)	(\$0.59)	(\$0.59)	(\$2.39)
EPS Diluted (pro forma)	(\$2.11)	(\$1.06)	(\$1.37)	(\$1.53)	(\$6.05)	(\$1.64)	(\$1.19)	(\$0.74)	(\$0.53)	(\$3.98)	(\$0.74)	(\$0.75)	(\$0.66)	(\$0.69)	(\$2.84)	(\$0.60)	(\$0.60)	(\$0.59)	(\$0.59)	(\$2.39)
Margins																				
Gross margin																				
Research & development																				
General and administrative																				
Operating margin																				
Tax rate, GAAP																				
Net margin																				
Y/Y % change																				
Total Revenue																				
Gross margin																				
Research & development	88%	-37%	-34%	-31%	-16%	-33%	31%	-20%	-43%	-21%	-52%	-28%	-9%	18%	-21%	14%	-29%	-33%	-33%	-24%
General and administrative	387%	-47%	-64%	-88%	-63%	-43%	-39%	-50%	-66%	-48%	-27%	4%	60%	114%	16%	-6%	-6%	0%	0%	-3%
Operating income (loss)	-39%	-44%	-55%	-81%	-62%	-40%	-15%	-36%	-56%	-37%	-36%	-14%	21%	59%	-3%	0%	-15%	-14%	-14%	-11%
Net income (loss)	-47%	-97%	-56%	-78%	-89%	-18%	25%	-33%	-58%	-24%	-41%	-9%	20%	77%	-2%	4%	-14%	-7%	-12%	-8%
EPS Diluted (pro forma)	-70%	-98%	-66%	-81%	-92%	-23%	12%	-46%	-65%	-34%	-55%	-37%	-10%	31%	-29%	-18%	-20%	-11%	-15%	-16%

Source: Company reports and Ascendant Capital Markets estimates.

*Reflects a 1-for-10 Reverse Stock Split in April 2024

NRx Pharmaceuticals, Inc.

Balance Sheet (\$ mils)	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25	Dec-25
Fiscal Year End: December 31	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Assets																
Cash and cash equivalents	40.2	24.5	18.2	20.1	16.5	15.0	8.9	4.6	1.3	1.9	6.1	0.5	1.2	(5.5)	(12.1)	(18.8)
Short term investments											0.0	0.0	0.0	0.0	0.0	0.0
Account receivable																
Deferred income taxes											0.0	0.0	0.0	0.0	0.0	0.0
Prepaid expenses and other	3.4	7.9	6.6	5.7	5.3	4.8	4.2	2.3	2.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0
Total current assets	43.6	32.4	24.8	25.8	21.8	19.8	13.1	6.9	3.3	4.9	9.1	3.5	4.2	(2.5)	(9.2)	(15.8)
Property and equipment, net											(0.0)	0.0	0.0	0.0	0.0	0.0
Intangibles, net											0.0	0.0	0.0	0.0	0.0	0.0
Deferred income tax											0.0	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.4	0.4	0.4	0.4	0.0	0.0	0.0	0.0
Total assets	43.6	32.4	24.8	25.8	21.8	19.8	13.1	7.3	3.8	5.3	9.5	3.9	4.2	(2.5)	(9.2)	(15.8)
Liabilities and stockholders' equity																
Accounts payable	4.3	3.1	2.2	2.1	3.8	2.2	3.6	4.6	6.3	5.0	5.0	5.0	5.0	5.0	5.0	5.0
Accrued expenses	4.5	4.0	5.8	5.8	6.1	6.9	5.3	5.2	5.8	10.0	10.0	10.0	10.0	10.0	10.0	10.0
Deferred income tax											0.0	0.0	0.0	0.0	0.0	0.0
Warrant liabilities	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other	2.5					0.8	0.3				0.0	0.0	0.0	0.0	0.0	0.0
Short term debt	0.5			8.7	12.2	12.7	10.1	9.2	6.8	8.6	20.0	22.0	22.0	22.0	22.0	22.0
Total current liabilities	11.9	7.1	8.0	16.6	22.1	22.6	19.3	19.0	18.9	23.7	35.1	37.1	37.1	37.1	37.1	37.1
Deferred income taxes											0.0	0.0	0.0	0.0	0.0	0.0
Warrant liabilities											0.0	0.0	0.0	0.0	0.0	0.0
Other long term liabilities											0.0	0.0	7.0	7.0	7.0	7.0
Long term debt				1.8							0.0	0.0	0.0	0.0	0.0	0.0
Total other liabilities	0.0	0.0	0.0	1.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	7.0	7.0	7.0	7.0
Preferred stock							0.0	0.0			0.0	0.0	0.0	0.0	0.0	0.0
Common stock	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.0	0.1	0.2	0.3	0.4	0.5	0.6
Additional paid-in capital	228.3	229.0	229.5	230.4	233.6	239.9	242.5	241.3	244.6	249.2	249.2	249.2	249.2	249.2	249.2	249.2
Retained earnings	(196.7)	(203.7)	(212.8)	(223.1)	(234.0)	(242.8)	(248.8)	(253.1)	(259.7)	(267.6)	(274.9)	(282.6)	(289.3)	(296.1)	(302.9)	(309.7)
Other											0.0	0.0	0.0	0.0	0.0	0.0
Accumulated other comprehensive income					0.1	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
Total stockholders' equity	31.7	25.4	16.8	7.4	(0.3)	(2.8)	(6.2)	(11.7)	(15.1)	(18.4)	(25.6)	(33.2)	(39.9)	(46.5)	(53.2)	(59.9)
Total stockholders' equity and liabilities	43.6	32.4	24.8	25.8	21.8	19.8	13.1	7.3	3.8	5.3	9.5	3.9	4.2	(2.5)	(9.2)	(15.8)

Balance Sheet Drivers

	Mar-22	Jun-22	Sep-22	Dec-22	Mar-23	Jun-23	Sep-23	Dec-23	Mar-24	Jun-24	Sep-24	Dec-24	Mar-25	Jun-25	Sep-25	Dec-25
	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3A	Q4A	Q1A	Q2A	Q3E	Q4E	Q1E	Q2E	Q3E	Q4E
Book & Cash Value (per share)																
Book Value per Share (diluted)	\$4.98	\$3.86	\$2.53	\$1.10	(\$0.04)	(\$0.38)	(\$0.76)	(\$1.43)	(\$1.70)	(\$1.75)	(\$2.33)	(\$2.99)	(\$3.56)	(\$4.12)	(\$4.67)	(\$5.21)
Cash per Share (diluted)	\$6.31	\$3.73	\$2.75	\$2.97	\$2.45	\$2.04	\$1.09	\$0.56	\$0.15	\$0.18	\$0.55	\$0.04	\$0.11	(\$0.48)	(\$1.07)	(\$1.64)
Net cash per Share (diluted)	\$6.23	\$3.73	\$2.75	\$1.41	\$0.64	\$0.31	(\$0.14)	(\$0.56)	(\$0.62)	(\$0.64)	(\$1.26)	(\$1.94)	(\$1.86)	(\$2.43)	(\$2.99)	(\$3.55)

Source: Company reports and Ascendant Capital Markets estimates

NRx Pharmaceuticals, Inc.

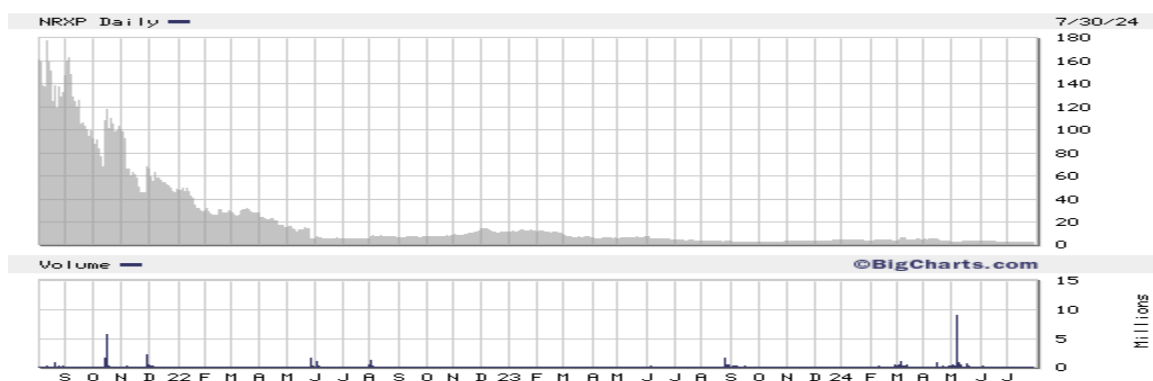
Cash Flow Statement (\$ mils)	Mar-22	Jun-22	Sep-22	Dec-22	2022	Mar-23	Jun-23	Sep-23	Dec-23	2023	Mar-24	Jun-24	Sep-24	Dec-24	2024	Mar-25	Jun-25	Sep-25	Dec-25	2025
Fiscal Year End: December 31	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3A	Q4A	FY-A	Q1A	Q2A	Q3E	Q4E	FY-E	Q1E	Q2E	Q3E	Q4E	FY-E
Cash flow from operating activities																				
Net income	(13.4)	(7.0)	(9.1)	(10.2)	(39.8)	(11.0)	(8.7)	(6.1)	(4.3)	(30.2)	(6.5)	(7.9)	(7.3)	(7.7)	(29.4)	(6.8)	(6.8)	(6.8)	(6.8)	(27.1)
Depreciation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Amortization					0.0					0.0					0.0					0.0
Debt related amortization expen	0.0	(0.0)	0.0	0.0	0.0					0.0					0.0					0.0
Stock comp	1.3	1.0	0.5	0.8	3.6	0.7	0.5	0.4	(1.2)	0.4	0.2	0.1	0.1	0.1	0.5	0.1	0.1	0.1	0.1	0.4
Deferred income taxes					0.0					0.0					0.0					0.0
Change in fair value of warrant l	(0.2)	(0.1)	0.0	0.5	0.3	1.8	0.7	0.3	(0.1)	2.7	0.3	2.2			2.5					0.0
Change in fair value of earnout c	(2.1)	(2.5)			(4.6)					0.0					0.0					0.0
Writedowns and impairments					0.0					0.0					0.0					0.0
Other gains/losses					0.0		0.3			0.3					0.0					0.0
Other					0.0					0.0					0.0					0.0
Changes in operating assets and liabilities:																				
Accounts receivable					0.0					0.0					0.0					0.0
Prepaid expenses & other curre	1.7	(4.5)	1.3	0.8	(0.6)	0.5	0.4	0.6	1.5	3.0	0.3	(0.9)			(0.6)					0.0
Income tax					0.0					0.0					0.0					0.0
Other assets					0.0					0.0					0.0	0.4	0.0	0.0	0.0	0.4
Accounts payable	0.6	(1.2)	(0.9)	(0.1)	(1.6)	1.7	(1.6)	1.5	1.0	2.7	2.1	2.1			4.2					0.0
Accrued expenses	1.6	(0.5)	1.8	(0.0)	2.9	0.3	0.6	(1.3)	(0.1)	(0.5)	(0.1)	0.9			0.8					0.0
Other liabilities					0.0					0.0		0.9	0.0	0.0	0.9	7.0	0.0	0.0	0.0	7.0
Net cash (used in) provided by	(10.4)	(14.8)	(6.3)	(8.3)	(39.8)	(6.1)	(7.8)	(4.6)	(3.2)	(21.7)	(3.7)	(2.6)	(7.2)	(7.6)	(21.0)	0.7	(6.7)	(6.7)	(6.7)	(19.3)
Cash flow from investing activities																				
Purchases of property and equi	(0.0)	(0.0)	(0.0)	0.0	(0.0)	(0.0)	0.0	(0.0)	0.0	(0.0)			0.0	(0.0)	(0.0)	0.0	0.0	(0.0)	(0.0)	(0.0)
Purchases of short-term investments					0.0					0.0					0.0					0.0
Acquisitions					0.0					0.0					0.0					0.0
Other					0.0					0.0					0.0					0.0
Net cash used in investing activ	(0.0)	(0.0)	(0.0)	0.0	(0.0)	(0.0)	0.0	(0.0)	0.0	(0.0)	0.0	0.0	0.0	(0.0)	(0.0)	0.0	0.0	(0.0)	(0.0)	(0.0)
Cash flow from financing activities																				
Issuance of debt				10.0	10.0		0.8		0.4	1.2			11.4	2.0	13.4	0.0	0.0	0.0	0.0	0.0
Repayment of debt		(0.5)			(0.5)		(0.1)	(2.7)	(0.3)	(3.1)	(2.2)	(0.0)			(2.2)					0.0
Issuance of stock	23.0	(0.3)	(0.0)	0.1	22.7	2.5	5.6	1.2	(1.2)	8.1	2.6	3.1	0.0	0.0	5.7	0.0	0.0	0.0	0.0	0.0
Proceeds from stock option exercises				0.0	0.0					0.0					0.0					0.0
Other					0.0					0.0					0.0					0.0
Dividends and distributions					0.0					0.0					0.0					0.0
Cash provided by (used in) fina	23.0	(0.9)	(0.0)	10.1	32.2	2.5	6.3	(1.5)	(1.1)	6.2	0.4	3.1	11.4	2.0	16.9	0.0	0.0	0.0	0.0	0.0
Effect of exchange rate on cash					0.0					0.0					0.0					0.0
Net increase (decrease) in cash	12.6	(15.7)	(6.3)	1.8	(7.6)	(3.5)	(1.5)	(6.1)	(4.3)	(15.5)	(3.3)	0.6	4.2	(5.6)	(4.1)	0.7	(6.7)	(6.7)	(6.7)	(19.3)
Beginning cash and equivalents	27.6	40.2	24.5	18.2	27.6	20.1	16.5	15.0	8.9	20.1	4.6	1.3	1.9	6.1	4.6	0.5	1.2	(5.5)	(12.1)	0.5
Ending cash and equivalents	40.2	24.5	18.2	20.1	20.1	16.5	15.0	8.9	4.6	4.6	1.3	1.9	6.1	0.5	0.5	1.2	(5.5)	(12.1)	(18.8)	(18.8)

Source: Company reports and Ascendant Capital Markets estimates

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NRx Pharmaceuticals, Inc.



*Reflects a 1:10 reverse stock split in April 2024

Source: <https://bigcharts.marketwatch.com/>

	Report Date		Price
Report	Date	Rating	Target
1	11/9/2022	B	40.00
2	11/18/2022	B	45.00
3	4/5/2023	B	47.50
4	5/23/2023	B	50.00
5	9/6/2023	B	52.50
6	12/22/2023	B	55.00
7	5/4/2024	B	50.00
8	6/6/2024	B	43.00

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Risks & Considerations

Risks to attainment of our share price target include balance sheet/liquidity risks, failure of product candidates to demonstrate safety and efficacy in clinical trials, failure to gain regulatory approvals, ability to commercialize product, failure to obtain suitable reimbursement, competition, changing macroeconomic factors, investor sentiment for investing in biotech stocks, and changes in consumer or government priorities for healthcare.

Ascendant Capital Markets, LLC Rating System

BUY: We expect the stock to provide a total return of 15% or more within a 12-month period.

HOLD: We expect the stock to provide a total return of negative 15% to positive 15% within a 12-month period.

SELL: We expect the stock to have a negative total return of more than 15% within a 12-month period.

Total return is defined as price appreciation plus dividend yield.

Ascendant Capital Markets, LLC Distribution of Investment Ratings (as of July 12, 2024)

Rating	Count	Percent	Investment Banking Services Past 12 months	
			Count	Percent
Buy	58	98%	21	36%
Hold	0	0%	0	0%
Sell	1	2%	0	0%
Total	59	100%	21	36%

Other Important Disclosures

Our analysts use various valuation methodologies including discounted cash flow, price/earnings (P/E), enterprise value/EBITDAS, and P/E to growth rate, among others. Risks to our price targets include failure to achieve financial results, product risk, regulatory risk, general market conditions, and the risk of a change in economic conditions.

Dissemination of Research

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