NRx Pharmaceuticals, Inc. (NRXP)
Rating: Buy

Vernon Bernardino
646-975-6954
vbernardino@hcwresearch.com

Planning to File Two NDAs in 2024; Reiterate Buy With PT Adjusted to $19

Stock Data	8/1/2024
Price	$2.15
Exchange	NASDAQ
Price Target	$19.00
52-Week High	$7.33
52-Week Low	$1.90
Enterprise Value (M)	$29
Market Cap (M)	$23
Shares Outstanding (M)	10.7
3 Month Avg Volume	322,501
Short Interest (M)	0.30

Shares Outstanding (M): On April 2, 2024, a 1-for-10 reverse stock split came into effect. Therefore, we adjusted our historical and forward EPS figures.

Balance Sheet Metrics	
Cash (M)	$1.3
Total Debt (M)	$6.8
Total Cash/Share	$0.12
Book Value/Share	$0.25

Cash (M): On April 18, 2024, the company priced a public offering that raised aggregate gross proceeds of $2.0M.

EPS ($) Diluted			
Full Year - Dec	2023A	2024E	2025E
1Q	(1.64)	(0.74)A	--
2Q	(1.19)	(0.81)	--
3Q	(0.74)	(0.81)	--
4Q	(0.52)	(0.86)	--
FY	(3.98)	(3.25)	(0.95)

Revenue ($M)			
Full Year - Dec	2023A	2024E	2025E
1Q	0.0	0.0A	--
2Q	0.0	0.0	--
3Q	0.0	0.0	--
4Q	0.0	0.0	--
FY	0.0	0.0	40.0

Plans to file an NRX-100 (IV ketamine) NDA moving ahead. On July 29, NRx Pharmaceuticals announced alignment with the FDA on an initial pediatric study plan (IPSP) for NRX-100. This is positive news. Recall that on June 28, NRx announced that following advice from regulatory counsel, including former officials from the FDA, the company expects to be in position to file two New Drug Applications (NDAs) by year-end 2024: 1) an application for accelerated approval of NRX-101 as a treatment for bipolar depression (BD) in patients with akathisia; and notably, 2) an NDA for approval of NRX-100, NRx' proprietary intravenous formulation of ketamine (IVK) as a treatment for suicidal depression. With potential approval of NRX-100 and NRX-101 in 2025, potentially earlier for NRX-101, NRx could have two products in commercialization by year-end 2025, which we believe is underappreciated. We reiterate our Buy rating with a post-1-for-10 reverse stock split adjusted PT of $19 vs. our prior PT of $2.00.

Alignment on an IPSP was a gaiting requirement for filing an NDA. This was important as a precondition to filing an NDA as required by the Food and Drug Administration Safety and Innovation Act of 2012. As a result, NRx and Hope commit to conducting a clinical trial with NRX-100 in adolescents, aged 9-17, with suicidal depression, but will not be required to study the drug's effects in younger age groups. However, additional neurotoxicity studies will be conducted in juvenile animal subjects to support the safety of NRX-100. We are positive on this news as it positions use of NRX-100 for potential expansion into adolescents. According to CDC figures, 22% of high school students reported having seriously considered suicide, with 10% attempting suicide in the past year (CDC Youth Data and Trends, 2023).

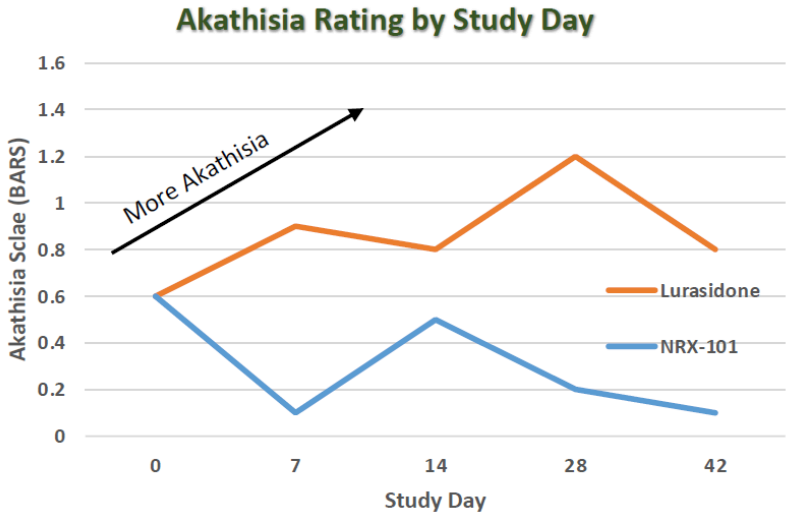
Launch of Hope could result in significant annual revenue streams. Recall also that in January 2024, NRx unveiled the company's plans to create Hope Therapeutics, a subsidiary focused on advancing a proprietary IVK formulation into commercialization. We believe Hope would position NRx to unlock value as NRX-100 is backed by strong data. More specifically, NRx has positive randomized, placebo-controlled clinical trial results that evaluated IVK's effects in 156 patients hospitalized for acute suicidality and depression. We note that while bipolar disorder (BD) affects about 1-5% of the total U.S. population, the rate of suicide among BD patients is approximately 10-30 times higher than the rate in the general population (Dome, P., et al. Medicina, 2019). In estimating NRX-100's market potential, we used Spravato, an intranasal S-ketamine marketed by J&J (JNJ; not rated) for treatment-resistant depression and depressive symptoms in adults with major depressive disorder with suicidal thoughts or actions, as a reference. Launched in 2019, J&J recorded $589M in Spravato sales in the U.S. in 2023 ($689M worldwide), or 80% yr/yr growth. Our initial modeling suggests NRX-100 could realize $19M in sales in 2025, and achieve up to $500M in peak annual sales by 2030, as a treatment for acutely suicidal patients with depression, representing up to $8/sh in untapped value in NRx' assets.

Poised to gain NRX-101 accelerated approval in bipolar depression with suicidality or akathisia. As we previously commented, we believe the company's data supporting NRX-101 is strong, and with the FDA determining suicidal bipolar depression as a life-threatening condition, there is regulatory support and recognition for the urgent need for treatment options. As a reminder, NRX-101 is NRx' patented combination of the NMDA antagonist, D-cycloserine, and lurasidone, a full antagonist of the dopamine D2 receptor, and serotonin receptors, 5-HT2A and 5-HT7. Recall also that in January 2024, the FDA awarded Breakthrough Therapy and Fast Track Designation to NRX-101. Lastly, the agency granted a Special Protocol Assessment to the NRX-101 Phase 2b/3 trial that as designed, could support accelerated approval for NRX-101's use in bipolar depression patients with akathisia if results are positive. Akathisia is a neuropsychiatric syndrome associated with psychomotor restlessness that usually involves the lower extremities, and an intense sensation of unease. Importantly, akathisia is the side effect observed in antidepressants most closely linked to suicide, resulting in FDA Black Box warnings on drug labels. We are positive on NRX-101's potential for approval in the initially narrow indication of bipolar depression with suicidality or akathisia. We believe NRX-101 could achieve more than $300M in annual sales by 2030. However, we believe initial approval creates potential for NRX-101's exploration as a primary treatment for bipolar depression patients who do not have active suicidality. As this condition affects more than 7M people in the U.S. (National Institute of Mental Health statistics, 2024), we believe there is upside potential for NRX-101 to realize almost $600M in annual sales if it is approved for use in the expanded bipolar depression patient population (not in our models).

Large effect size but long-term approval would require an additional trial. In 2018, results were announced from STABIL-B, a Phase 2 trial in which patients received one infusion of IVK or placebo, then received either NRX-101 or lurasidone alone. NRX-101 demonstrated superiority to lurasidone in reducing depression after IVK pretreatment (mean 7.7-point benefit in severity per the Montgomery-Asberg Depression Rating Scale (MADRS), $p = 0.03$ at Day 28, and $p = 0.04$ at Day 42). This positioned NRX-101 to be the first antidepressant to demonstrate clinically meaningful reduction in akathisia and suicidality. NRX-101 also demonstrated positive results in secondary EPs with a 1.5-point advantage on the Columbia Suicide Severity Rating Scale (C-SSR, $p = 0.02$), as well as positive effects on relapse (no relapse with NRX-101 vs. 40% in the control group, $p = 0.07$), and decreased akathisia (Barnes Akathisia Rating Scale (BARS, $p = 0.14$). With its antidepressant effect comparable to lurasidone, the current standard of care, and in the absence of another therapeutic option, we believe NRX-101 has high probability of gaining accelerated approval for bipolar depression with suicidality or akathisia in the next 6-12 months. However, as results with NRX-101 were demonstrated in relatively small studies, we believe the FDA will require NRx commit to conducting a much larger, well-designed, controlled, randomized confirmatory post-marketing Phase 3 trial to achieve full approval.

Valuation and risks. Our $19 PT was derived by using a weighted-average cost of capital of 15% for NRx shares to discount free cash flows we project 2024 through 2033 (vs. our prior 2023 through 2031), and dividing them by our projected number of shares for each year to account for the effects of share dilution, and then ascribing a 2% terminal growth rate and 60% probability of success. Risks to our investment thesis include failure of clinical trials, regulatory requirements for additional clinical studies, commercialization strategy and product launch, failure of products to show sufficient competitive differentiation in targeted product indications, intellectual property expiry or invalidation, and potential to raise additional funds under poor market conditions.

Exhibit 1. Reduction in Akathisia With NRX-101 Observed in the STABIL-B Phase 2 Trial.



Source: Company reports.

Exhibit 2. NRX-101 STABIL-B Trial Results.

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

Source: Company reports.

Financial Statements

Exhibit 1. Income Statement, Quarterly Fiscal 2023A-2024E

Income Statement (*Fiscal year ends December 31*)												
(in $MM, except per share data)	**2022A**	**1QA**	**2QA**	**3QA**	**4QA**	**2023A**	**1QA**	**2QE**	**3QE**	**4QE**	**2024E**	**2025E**
Product Sales	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**40.0**
NRX-101 (ASIB & SSIB)	-	-	-	-	-	-	-	-	-	-	-	20.9
NRX-100/HTX-100 (Suicidal Depression)	-	-	-	-	-	-	-	-	-	-	-	19.1
Royalties and Licensing Revenue	-	-	-	-	-	-	-	-	-	-	-	-
Other Revenue	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**40.0**
Cost of Sales	-	-	-	-	-	-	-	-	-	-	-	7.0
Gross Profit	-	-	-	-	-	-	-	-	-	-	-	33.0
R&D Expense	17.0	3.7	3.9	3.3	2.5	13.4	1.7	2.5	2.8	3.1	10.1	11.3
SG&A Expense	27.3	5.8	4.1	2.5	1.9	14.2	4.3	6.5	8.2	11.2	30.1	33.6
Royalty payment to shareholders	-	-	-	-	-	-	-	-	-	-	-	0.2
Other Operating Expense	-	-	0.3	-	-	0.3	-	-	-	-	-	-
Operating Expense	44.3	9.4	8.2	5.8	4.4	27.8	6.0	9.0	11.0	14.3	40.3	45.0
Operating Income (Loss)	**(44.3)**	**(9.4)**	**(8.2)**	**(5.8)**	**(4.4)**	**(27.8)**	**(6.0)**	**(9.0)**	**(11.0)**	**(14.3)**	**(40.3)**	**(12.0)**
Interest and other income	0.2	0.2	0.1	0.1	0.1	0.5	0.0	-	-	-	0.0	-
Interest expense and other finance costs	-	-	-	(0.0)	(0.1)	(0.1)	(0.2)	(0.2)	(0.1)	-	(0.5)	-
Other income (expenses)	4.3	(1.8)	(0.7)	(0.3)	0.1	(2.7)	(0.3)	-	-	-	(0.3)	-
Pre-tax Income (Loss)	**(39.8)**	**(11.0)**	**(8.7)**	**(6.1)**	**(4.3)**	**(30.2)**	**(6.5)**	**(9.2)**	**(11.1)**	**(14.3)**	**(41.0)**	**(12.0)**
Tax (Benefit) Expense and others	-	-	-	-	-	-	-	-	-	-	-	1.9
Net Income (Loss)	**(39.8)**	**(11.0)**	**(8.7)**	**(6.1)**	**(4.3)**	**(30.2)**	**(6.5)**	**(9.2)**	**(11.1)**	**(14.3)**	**(41.0)**	**(13.9)**
Deemed dividend - Warrants	-	-	-	-	0.0	0.0	-	-	-	-	-	-
Deemed dividend - Earnout Shares	-	-	-	-	-	-	-	-	-	-	-	-
Income/loss attributable to non-controlling shareholders	-	-	-	-	-	-	-	(0.9)	(1.0)	(1.1)	(3.1)	2.9
Net loss attributable to common stockholders	**(39.8)**	**(11.0)**	**(8.7)**	**(6.1)**	**(4.3)**	**(30.2)**	**(6.5)**	**(8.2)**	**(10.1)**	**(13.1)**	**(38.0)**	**(16.8)**
EPS (diluted)	**($6.05)**	**($1.64)**	**($1.19)**	**($0.74)**	**($0.52)**	**($3.98)**	**($0.74)**	**($0.81)**	**($0.81)**	**($0.86)**	**($3.25)**	**($0.95)**
Weighted Average Shares	6.6	6.7	7.3	8.2	8.4	7.6	8.9	10.2	12.4	15.3	11.7	17.8

Source: Company reports and H.C. Wainwright & Co. estimates.

Important Disclaimers

This material is confidential and intended for use by Institutional Accounts as defined in FINRA Rule 4512(c). It may also be privileged or otherwise protected by work product immunity or other legal rules. If you have received it by mistake, please let us know by e-mail reply to unsubscribe@hcwresearch.com and delete it from your system; you may not copy this message or disclose its contents to anyone. The integrity and security of this message cannot be guaranteed on the Internet.

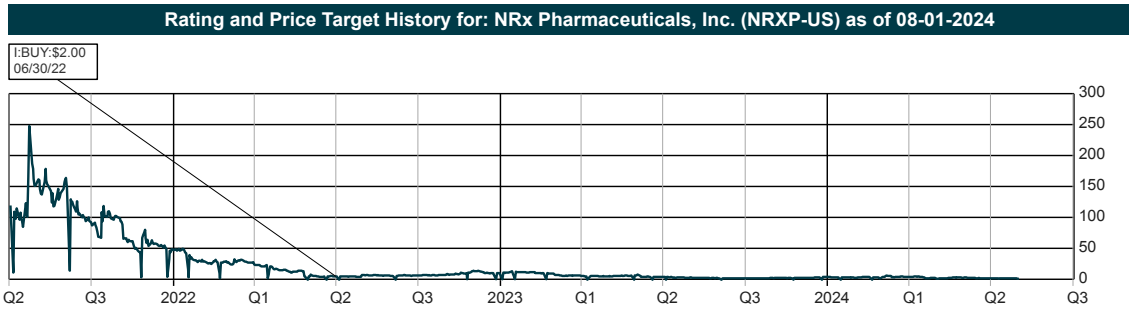
H.C. WAINWRIGHT & CO, LLC RATING SYSTEM: H.C. Wainwright employs a three tier rating system for evaluating both the potential return and risk associated with owning common equity shares of rated firms. The expected return of any given equity is measured on a RELATIVE basis of other companies in the same sector. The price objective is calculated to estimate the potential movements in price that a given equity could reach provided certain targets are met over a defined time horizon. Price objectives are subject to external factors including industry events and market volatility.

RETURN ASSESSMENT

Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

Market Perform (Neutral): The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector.

Market Underperform (Sell): The common stock of the company is expected to underperform a passive index comprised of all the common stock of companies within the same sector.



Investment Banking Services include, but are not limited to, acting as a manager/co-manager in the underwriting or placement of securities, acting as financial advisor, and/or providing corporate finance or capital markets-related services to a company or one of its affiliates or subsidiaries within the past 12 months.

Distribution of Ratings Table as of August 1, 2024

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	559	88.03%	132	23.61%
Neutral	69	10.87%	4	5.80%
Sell	1	0.16%	0	0.00%
Under Review	6	0.94%	1	16.67%

H.C. Wainwright & Co, LLC (the “Firm”) is a member of FINRA and SIPC and a registered U.S. Broker-Dealer.

I, Vernon Bernardino , certify that 1) all of the views expressed in this report accurately reflect my personal views about any and all subject securities or issuers discussed; and 2) no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report; and 3) neither myself nor any members of my household is an officer, director or advisory board member of these companies.

None of the research analysts or the research analyst’s household has a financial interest in the securities of NRx Pharmaceuticals, Inc. (including, without limitation, any option, right, warrant, future, long or short position).

As of June 30, 2024 neither the Firm nor its affiliates beneficially own 1% or more of any class of common equity securities of NRx Pharmaceuticals, Inc..

Neither the research analyst nor the Firm knows or has reason to know of any other material conflict of interest at the time of publication of this research report.

The research analyst principally responsible for preparation of the report does not receive compensation that is based upon any specific investment banking services or transaction but is compensated based on factors including total revenue and profitability of the Firm, a substantial portion of which is derived from investment banking services.

The firm or its affiliates received compensation from NRx Pharmaceuticals, Inc. for non-investment banking services in the previous 12 months.

The Firm or its affiliates did receive compensation from NRx Pharmaceuticals, Inc. for investment banking services within twelve months before, and will seek compensation from the companies mentioned in this report for investment banking services within three months following publication of the research report.

H.C. Wainwright & Co., LLC managed or co-managed a public offering of securities for NRx Pharmaceuticals, Inc. during the past 12 months.

The Firm does not make a market in NRx Pharmaceuticals, Inc. as of the date of this research report.

The securities of the company discussed in this report may be unsuitable for investors depending on their specific investment objectives and financial position. Past performance is no guarantee of future results. This report is offered for informational purposes only, and does not constitute an offer or solicitation to buy or sell any securities discussed herein in any jurisdiction where such would be prohibited. This research report is not intended to provide tax advice or to be used to provide tax advice to any person. Electronic versions of H.C. Wainwright & Co., LLC research reports are made available to all clients simultaneously. No part of this report may be reproduced in any form without the expressed permission of H.C. Wainwright & Co., LLC. Additional information available upon request.

H.C. Wainwright & Co., LLC does not provide individually tailored investment advice in research reports. This research report is not intended to provide personal investment advice and it does not take into account the specific investment objectives, financial situation and the particular needs of any specific person. Investors should seek financial advice regarding the appropriateness of investing in financial instruments and implementing investment strategies discussed or recommended in this research report.

H.C. Wainwright & Co., LLC's and its affiliates' salespeople, traders, and other professionals may provide oral or written market commentary or trading strategies that reflect opinions that are contrary to the opinions expressed in this research report.

H.C. Wainwright & Co., LLC and its affiliates, officers, directors, and employees, excluding its analysts, will from time to time have long or short positions in, act as principal in, and buy or sell, the securities or derivatives (including options and warrants) thereof of covered companies referred to in this research report.

The information contained herein is based on sources which we believe to be reliable but is not guaranteed by us as being accurate and does not purport to be a complete statement or summary of the available data on the company, industry or security discussed in the report. All opinions and estimates included in this report constitute the analyst's judgment as of the date of this report and are subject to change without notice.

Securities and other financial instruments discussed in this research report: may lose value; are not insured by the Federal Deposit Insurance Corporation; and are subject to investment risks, including possible loss of the principal amount invested.