

December 31, 2024

NRx Pharmaceuticals Progresses NDA Filing for NRX-100 to Address Suicidal Depression

NRx Pharmaceuticals has filed the initial section of its New Drug Application (NDA) for NRX-100 (IV ketamine) with the U.S. FDA, targeting suicidal depression. This filing marks a critical step toward potentially becoming the first FDA-approved medication for this condition, which affects millions annually. Completion of the NDA submission is expected in Q1 2025, supported by robust clinical data from NIH and European government-funded trials. The move aligns with NRx's mission to address urgent unmet medical needs in central nervous system disorders.

Module 3: The submission of the manufacturing section (Module 3) is a strategic initiative by NRx to expedite FDA review while finalizing efficacy data and other sections. NRX-100 offers a differentiated formulation of ketamine, optimized for safety and traceability. The NDA builds on Fast Track Designation granted in 2017 for bipolar depression and expands its scope to include suicidal ideation across major depressive disorders. This regulatory milestone reflects the company's proactive engagement with the FDA and positions NRX-100 as a potential game-changer in addressing a significant public health crisis.

Sadly, It's a Big Market. Suicidal depression remains a critical unmet need, with over 13M Americans seriously considering suicide annually. Current treatment options, such as electroconvulsive therapy, are limited and often inaccessible. NRX-100 has shown promise as a fast-acting, effective treatment for acute suicidality, backed by data from rigorous clinical trials. NRx's efforts to secure FDA approval could enhance patient access and enable insurance reimbursement, unlocking a substantial \$3-5B market. This initiative aligns with broader goals to deliver innovative, lifesaving therapies to vulnerable populations, including veterans and individuals w/ treatment-resistant conditions.

Key milestones: We close the year with the start of the NDA filings for NRX-100 to treat suicidal ideation in depression. Next is NRX-101 for bipolar depression with suicidality or akathisia, leveraging Breakthrough Therapy Designation and Priority Review. HOPE Therapeutics is expected to continue building its clinic network, providing a foundation for future growth. These efforts position NRx to address critical unmet needs in mental health and suicide prevention while delivering shareholder value.

Valuation: Our \$31 PT 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), disc EPS (dEPS), and Sum-of-the-Parts (SOP). We use a 30% disc 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 co's, 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 PT.

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

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MARKET DATA

Rating	Buy
Price Target	\$31.00
Price	\$1.51
Average Daily Volume (000)	467
52-Week Range (\$)	\$1.10-\$7.33
Market Cap (M)	\$18
Enterprise Value (M)	\$22
Book Value	(1.42)
Dividend Yield	0.0%
Cash (M)	\$2
Qrtly Burn Rate (M)	\$(2)

ESTIMATES

	2023A	2024E	2025E
Revenue (M)	\$0.0	\$0.0	\$107.2
Total Expenses (M)	\$28	\$22	\$15
GAAP EPS	\$(0.28)	\$(1.86)	\$1.02

One Year Performance Chart



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Please see analyst certification and important disclosures on page 3 of this report.

NRx Pharmaceuticals: Income Statement																
000 : YE December 31	2023A	1Q24A	2Q24A	3Q24A	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	611	2,500	7,663	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	2,411	3,900	14,807	14,955	15,105	15,256	19,070	22,884	26,316	27,632	27,908	28,187	28,469
Total Operating Expenses	27,837	5,998	7,050	3,022	6,400	22,470	14,955	49,636	107,732	194,913	336,879	383,580	429,923	403,380	296,381	303,694
Loss from Operations	(27,837)	(5,998)	(7,050)	(3,022)	(6,400)	(22,470)	65,063	94,246	354,651	781,993	1,756,423	1,998,179	2,252,017	2,278,560	2,385,558	2,448,556
Other (income) Expenses																
Gain on extinguishment of debt	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Interest income	(494)	(27)	(7)	(6)	-	-	-	-	-	-	-	-	-	-	-	-
Interest expense - Convertible note	120	230	849	-	-	-	-	-	-	-	-	-	-	-	-	-
Change in fair value of warrant liability	2,707	318	23	(1,355)	-	-	-	-	-	-	-	-	-	-	-	-
Change in fair value of Earnout Cash liability	(20)	9	(18)	(38)	-	-	-	-	-	-	-	-	-	-	-	-
Total other (income) expense	530	847	(1,399)	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Loss	(30,150)	(6,528)	(7,897)	(1,623)	(6,400)	(22,470)	65,063	94,246	354,651	781,993	1,756,423	1,998,179	2,252,017	2,278,560	2,385,558	2,448,556
Deemed Dividend (& other)	(3)	-	-	-	-	-	-	4,712	28,372	78,199	316,156	479,563	630,565	683,568	739,523	808,024
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)	(1,626)	(6,400)	(22,451)	65,063	89,533	326,279	703,794	1,440,267	1,518,616	1,621,452	1,594,992	1,646,035	1,640,533
GAAP-EPS	(0.40)	(0.74)	(0.75)	(0.15)	(0.36)	(1.99)	(0.43)	1.81	6.57	14.12	28.77	30.22	32.14	31.48	32.41	32.22
GAAP EPS (dil)	(0.28)	(0.74)	(0.75)	(0.15)	(0.36)	(1.86)	1.02	1.12	4.06	8.71	17.76	18.65	32.14	31.48	32.41	32.22
Wgtd Avg Shrs (Bas) '000	75,762	8,852	10,517	10,973	18,000	12,086	41,180	49,457	49,655	49,854	50,054	50,255	50,456	50,658	50,785	50,912
Wgtd Avg Shrs (Dil) '000	109,406	8,852	10,517	10,973	18,000	12,086	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

Important Disclosures

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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

D. Boral

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent

BUY	48	97.96	13	27.08
HOLD	1	2.04	0	0.00
SELL	0	0.00	0	0.00

NRx Pharmaceuticals, Inc. Rating History as of 12/30/2024

