

NRx Pharmaceuticals, Inc. (NRXP)

COMPANY UPDATE

August 4, 2025

Regulatory Action - Citizens' Petition

NRx Pharmaceuticals has submitted a Citizen's Petition to the FDA requesting the removal of benzethonium chloride (BZT), a known toxic preservative, from all ketamine formulations currently marketed in the United States. NRx asserts that BZT poses unnecessary risks, especially for patients receiving repeated intravenous ketamine infusions for psychiatric conditions, and that safer, preservative-free alternatives are both viable and preferable.

The petition is supported by stability data from NRx's preservative-free formulation of ketamine, which has demonstrated sterility and room temperature stability for up to three years. This data underpins both a patent filing and an Abbreviated New Drug Application (ANDA) submitted by NRx in June. The company has initiated domestic high-volume manufacturing of its preservative-free version, potentially positioning itself as a safer, generic alternative to existing ketamine products. NRx's petition also aligns with ongoing regulatory efforts to eliminate toxic excipients from the U.S. pharmaceutical supply chain, referencing prior actions against BZT in topical and ophthalmic products.

If the FDA grants NRx Pharmaceuticals' Citizen Petition to remove benzethonium chloride (BZT) from ketamine products, it would require all manufacturers of BZT-containing ketamine to either reformulate or withdraw their products from the U.S. market. This would create an immediate competitive opening for NRx's preservative-free ketamine formulation, which has already demonstrated long-term sterility and room temperature stability and is the subject of an Abbreviated New Drug Application (ANDA). With high-volume domestic manufacturing already in place, NRx is well positioned to meet demand, especially in the growing psychiatric use case for ketamine in treatment-resistant depression and PTSD, where patients may receive repeated infusions and thus face higher cumulative exposure to preservatives.

While the Citizen Petition process does not have a mandated fixed timeline, the FDA is required to respond within 180 days. However, that response can be noncommittal or delayed if the agency deems further review necessary. In practice, a full resolution could take 6 to 24 months. Should the petition be granted within the next year, and if NRx receives approval for its preservative-free ANDA, the company could establish first-mover advantage in 2026. The combination of regulatory validation, manufacturing readiness, and alignment with public health priorities could position NRx to dominate the preservative-free ketamine space as existing products are either withdrawn or modified.

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), Discounted Earnings Per Share (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. The results of these three models are equal-weighted, averaged, and rounded to the nearest whole number to provide a 12-month PT of \$31.00.

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

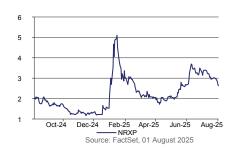
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MARKET DATA	
Rating	Buy
Price Target	\$31.00
Price	\$2.59
Average Daily Volume (000)	125
52-Week Range (\$)	\$1.10-\$6.01
Market Cap (M)	\$51
Enterprise Value (M)	\$45
Book Value	(1.42)
Dividend Yield	0.0%
Cash (M)	\$2
Qrtly Burn Rate (M)	\$(3)

ESTIMATES			
	2024A	2025E	2026E
Revenue (M)	\$0.0	\$107.2	\$180.3
Total Expenses (M)	\$19	\$26	\$61
GAAP EPS	\$(1.12)	\$(0.14)	\$1.54

One Year Performance Chart



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Important Disclosures

Analyst Certification

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Count Percent Count Percent



NRx Pharmaceuticals, Inc. Rating History as of 08/01/2025

