

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

Jason Kolbert

jkolbert@dboralcapital.com

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



Please see analyst certification and important disclosures on page 2 of this report.

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.

Company-Specific Disclosures

D. Boral Capital, or its affiliates have received compensation from NRx Pharmaceuticals, Inc. for investment banking services within the past 12 months.

D. Boral Capital, or its affiliates will seek compensation from NRx Pharmaceuticals, Inc. for investment banking services within three months following publication of this research report.

General Disclosures

The information contained in Research Reports or other Research products produced by D. Boral Capital LLC is for informational purposes only and does not constitute solicitation of the sale or purchase of securities or other investments. The information in such products is derived from sources that are believed to be reliable. Prices, numbers, and similar data include past results, estimates, and forecasts, all of which may differ from actual data. These prices, numbers, and similar data may also change without prior notification.

D. Boral Capital holds the copyright on this research report. Any unauthorized use or transmission of any part of this research report for any reason, whether by digital, mechanical, or any other means, is prohibited. If you have any questions, please contact your sales representative. Additional information is available upon request.

Certain company names, product and/or service names that appear in this research report are trademarks or registered trademarks of D. Boral Capital or other companies mentioned in the report.

Copyright 2025 D. Boral Capital LLC.

D. Boral Capital rating definitions are expressed as the total return relative to the expected performance of S&P 500 over a 12-month period.

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

D. Boral

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

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

