Tonix Pharmaceuticals

Mar 25, 2025

Healthcare

TNXP

NCM

Rating

Outperform

Unchanged

Current Price

$30.51

Target Price

$70.00

Market Capitalization

196.33m

Shares Outstanding

6430000

Float

5530000

Institutional Holdings

2.36%

12-Month Low/High

$6.76/$1,146.01

Average 90-Day Volume

1790000

Fiscal Year End

2025-12-31

Revenues ($ MIL)

Period	2024A	2025A	2026E
Q1	2.5	2.6E	22.6E
Q2	2.2	2.8E	37.8E
Q3	2.8	2.8E	47.9E
Q4	2.6	2.9E	57.9 E
	10.1	11.1E	166.1 E

EPS ($)

Period	2024A	2025E	2026E
Q1	(18.47)	(3.09)E	(2.16)E
Q2	(93.24)	(2.68)E	(1.05)E
Q3	(22.88)	(2.99)E	(0.90)E
Q4	(35.55)	(3.12)E	(0.56)E
	(176.60)	(11.89)E	(4.670E

FDA Sends Positive Signal For Tonmya Approval With No Advisory Committee Meeting Needed

No Advisory Panel Required. Tonix has been informed that the FDA will not require an Advisory Committee Meeting to determine approvability of the NDA for Tonmya (TNX-102 SL). We see this as a sign that the NDA review has not raised questions about the clinical trial data, potential patient use, or other factors that would be answered by an Advisory Committee. Since the trial met its primary endpoint and all six secondary endpoints with high statistical significance, we interpret this to be a positive sign.

FDA Advisory Panel Hearings Evaluate and Provide Insight To Trial Data. As part of its NDA review process, the FDA may schedule an Advisory Committee hearing. The committee members each bring expertise in aspects of clinical practice, research, or statistical analysis. At a hearing, the company presents its analysis of the trial and the data, followed by the FDA's analysis. The Committee members then ask questions to make recommendations for or against NDA approval and/or product labeling. We see the review without an Advisory Committee as a sign that the FDA does not need additional information on efficacy or safety.

Approval Could Come By August 2025. Tonix conducted two Phase 3 trials in fibromyalgia, which met their primary and secondary endpoints. The data was highly statistically significant and we believe the data justifies approval. The TNX-102 SL NDA was submitted in October 2024 and has a PDUFA date of August 15, 2025. Since TNX-102 SL has received Fast Track Review designation, approval could come earlier.

Tonmya's Could Change The Treatment of Fibromyalgia. Symptoms of fibromyalgia include a variety of physical and cognitive symptoms, including chronic pain, insomnia, depression, fatigue, and cramps. Patients currently use a combination of pain medications, anti-depressants, insomnia drugs, and neurological drugs. Tonmya is the first drug to show strong efficacy on a broad range of fibromyalgia symptoms.

Conclusion. We continue to expect product approval on or before August 15, 2025 and expect the stock begin reflecting future sales of TNX-102 SL. We are reiterating our Outperform rating and $70 price target.

Equity Research

Robert LeBoyer, Senior Vice President, Equity Research Analyst, Biotechnology
(212) 896-4625, rleboyer@noblecapitalmarkets.com, Connect on LinkedIn

Noble Capital Markets, Inc.

Trading: (561) 998-5489 Sales: (561) 998-5491
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Refer to the last two pages for Analyst Certification & Disclosures

Company Profile

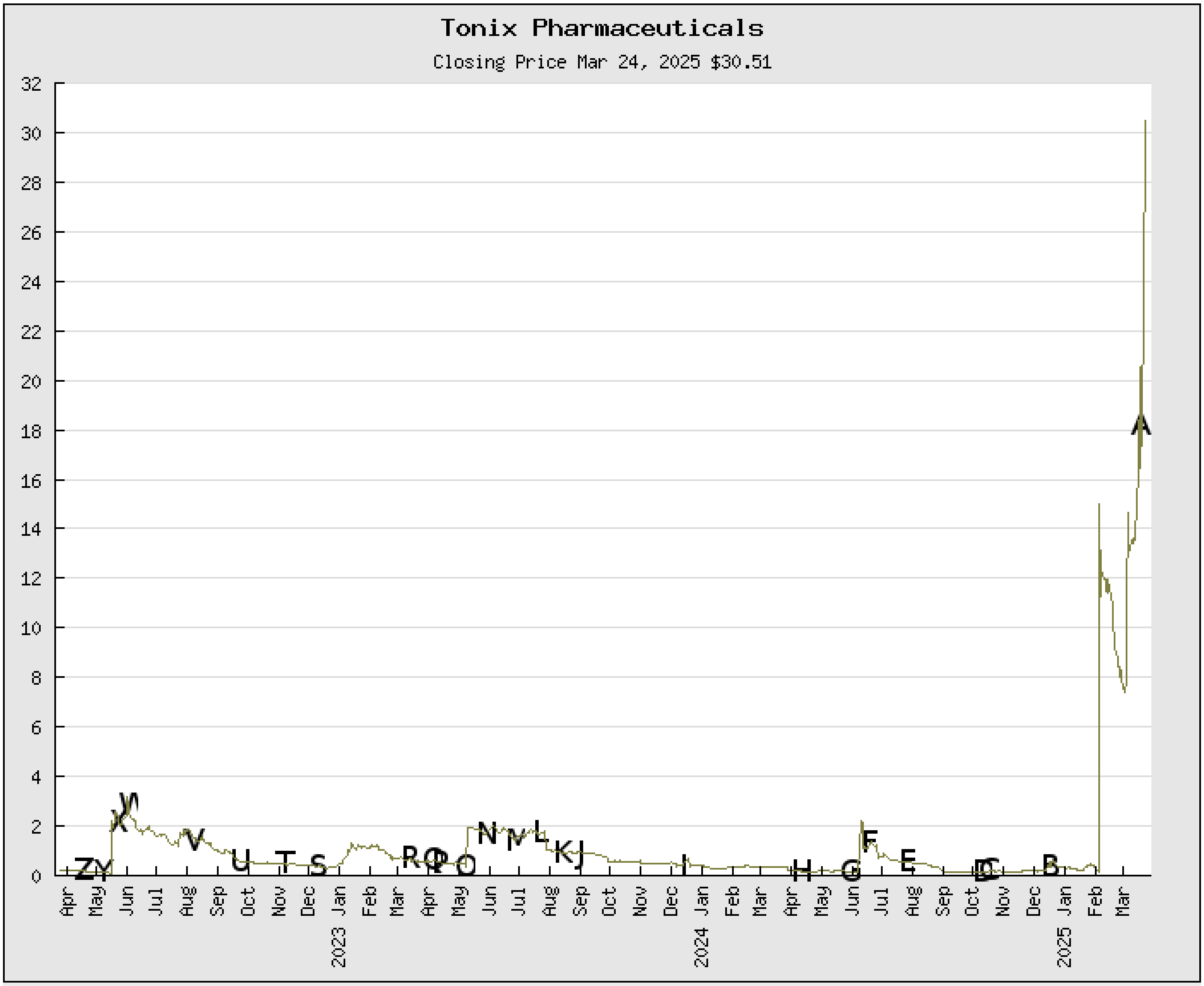
Tonix is a biopharmaceutical company developing therapeutics in immunology, infectious diseases, and central nervous system (CNS) disorders. Its products are for conditions with immunological and/or neurological components in several disease areas. These products have been based on both its internal research and in-licensing for development. Its most advanced product, TNX-102 SL is in a Phase 3 clinical trial for fibromyalgia. Other programs are in COVID-19, infectious disease, transplantation, cancer, and biodefense.

Fundamental Analysis; 4.0/5.0 Checks

Based on our analysis, we give TNXP 4.0 out of 5.0 checks. This falls in our "above average" range of 3.5 to 4.0 checks. The company's executives, advisors, and collaborators at research institutions are accomplished scientists with experience in drug development to guide the products through clinical trials to the market. For a further explanation of our fundamental analysis, please refer to the disclosures at the end of this report.

Valuation Summary

TNXP is currently trading at a market capitalization of about $92 million. Its balance sheet as of December 31, 2023 had $98.8 million or $15.35 in cash. We value the company based on potential revenues from Tonmya, a novel drug for fibromyalgia. Based on our estimate of product sales, we assign a multiple of 5X to our estimated revenue for a target market valuation of $450 million. Our price target is $70 per share.



A - 03/20/2025 Outperform Target $70.00 Current $18.19
B - 12/18/2024 Outperform Target $4.00 Current $0.36
C - 10/17/2024 Outperform Target $4.00 Current $0.18
D - 10/11/2024 Outperform Target $1.50 Current $0.15
E - 07/29/2024 Outperform Target $1.50 Current $0.57
F - 06/21/2024 Outperform Target $1.50 Current $1.30
G - 05/31/2024 Outperform Target $1.50 Current $0.16
H - 04/11/2024 Outperform Target $1.50 Current $0.17
I - 12/21/2023 Outperform Target $10.00 Current $0.38
J - 09/06/2023 Outperform Target $10.00 Current $0.92
K - 08/14/2023 Outperform Target $10.00 Current $0.93
L - 07/25/2023 Outperform Target $6.50 Current $1.72
M - 06/27/2023 Outperform Target $10.00 Current $1.41
N - 05/30/2023 Outperform Target $6.50 Current $1.63
O - 05/09/2023 Outperform Target $6.50 Current $0.35
P - 04/14/2023 Outperform Target $6.50 Current $0.51
Q - 04/05/2023 Outperform Target $6.50 Current $0.59
R - 03/14/2023 Outperform Target $6.50 Current $0.68
S - 12/13/2022 Outperform Target $6.50 Current $0.37
T - 11/08/2022 Outperform Target $6.50 Current $0.46
U - 09/23/2022 Outperform Target $6.50 Current $0.55
V - 08/09/2022 Outperform Target $10.00 Current $1.40
W - 06/02/2022 Outperform Target $10.00 Current $2.80
X - 05/24/2022 Outperform Target $10.00 Current $2.13
Y - 05/10/2022 Outperform Target $0.60 Current $0.14
Z - 04/18/2022 Outperform Target $0.60 Current $0.17

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The fundamental assessment rating system is designed to provide insights on the company's fundamentals both on a macro level, which incorporates a company's market opportunity and competitive position, and on a micro/company specific level. The micro/company specific attributes include operating & financial leverage, and corporate governance/management. The number of check marks that a company receives is designed to provide a quick reference and easy determination of the company's fundamentals based upon the following five attributes of the company (weighting reflects the importance of each attribute in the overall scoring of company's fundamental analysis):

Attribute	Weighting
Corporate Governance/Management	20%
Market Opportunity Analysis	20%
Competitive Position	20%
Operating Leverage	20%
Financial Leverage	20%

For each attribute, the analysts score the company from a low of zero to a high of ten based upon the analysis described below. The final rating and resulting check marks is a result of dividing the overall score (out of 100%) by ten.

Rating	Score	Checks
Superior	9.1 to 10	Five Checks
Superior	8.1 to 9	Four & A Half Checks
Above Average	7.1 to 8	Four Checks
Above Average	6.1 to 7	Three & A Half Checks
Average	5.1 to 6	Three Checks
Average	4 to 5	Two & A Half Checks
Below Average	3 to 3.9	Two Checks
Below Average	2 to 2.9	One & A Half Checks
Low Quality	0 to 1.9	One Check

While these are the attributes currently used for the analyst's fundamental analysis, the attributes and weighting may be reviewed, updated with additional attributes, and/or changed in the future based on discussions with the analysts and recommendations from the Director of Research.

Following is the description of each attribute in the fundamental analysis.

Corporate Governance/Management

We believe that a review of corporate governance and assessment of the senior management are important tools to determine investment merit. Good corporate governance aligns management with the interests of stakeholders. As such, analysts are to rank the company on the basis of good corporate governance principles that may include rules and procedures, board composition and staggered term limits, rights and responsibilities, corporate objectives, monitoring of actions and policies, and accountability. In addition, analysts will assess issues with controlling shareholders and whether decisions have been made in the past that were in the interests of all shareholders. In addition, management will be assessed based on industry experience, expertise, and/or track record.

High ranking example: Board and management that is aligned with the interests of shareholders with incentives based on stock price appreciation and with an experienced management team known for exceptional shareholder returns.

Low ranking example: Concentrated ownership without independent directors that do not necessarily align with all shareholders' interests.

The Market Opportunity Analysis

In this review, the analyst assesses the company's macro environment as a measure of understanding the industry. Factors considered include the size and growth potential of the industry under various economic conditions, the emerging demands in the market, technological benefits/disruptions, competition, geographical opportunities, and customer demands/needs, and an assessment of supply and distribution channels. In addition, the analyst will review legal and regulatory trends, as well as potential shifts in consumer or social behavior and natural environment changes.

High rank example: A company in an industry that is growing revenues well above GDP rates (which are on average 2% plus) and/or may have unmet or under-served needs in a rapidly growing market opportunity.

Low rank example: A mature industry that is in secular decline and likely to grow below GDP rates.

Competitive Position
The evaluation of the company's competitive position is another macro environment attribute designed to measure the relevance, market share, position and value proposition, and sustainable differentiations of the company and its products/services within its industry. Ease of entry into the industry and the ability of other well-funded players to potentially enter the market would be determined. As such, the assessment would consider the company's strengths and advantages of its products/services against weaknesses and limitations. This may include the company's current brand awareness, pricing and cost structure, current market strategies and geographic penetration that may affect demand for its products/services. In addition, the company's competitors would be evaluated.

High rank example: An analyst would consider the company's product to be superior to its competitors and that should allow the company to gain market share.

Low rank example: A company with a "me-too" product that does not have any significant technology advantages in an industry that has low barriers to entry.

Operating Leverage
Simplistically, operating leverage is determined by the operating income relative to changes in revenue. The analyst will calculate the impact on sensitivity on gross margins and variable costs to determine operating leverage. The analyst will take into account the ability of the company to cut fixed and variable costs in a challenged revenue environment and technological changes that may impact operating expenses. In addition, the analyst is to assess corporate strategies that include capital investment, which may be required for sustainable revenue growth, marketing expenses, and the company's ability to attract and retain talent and/or employees. The analyst should focus on the revenue opportunity and determine the price elasticity of demand for the company's products or services. In other words, the analyst is to rank the company based on improved operating margins going forward on an absolute and relative basis.

High rank example: A company that has improving margins for the foreseeable future, with significant price elasticity.

Low rank example: A company that is in a challenged revenue environment with a fixed cost structure and limited ability to cut costs, indicating an outlook for declining margins.

Financial Leverage
A strict definition of financial leverage is total debt divided by total shareholder's equity. Financial leverage analysis is to determine the company's ability to improve shareholder value by means of utilizing its balance sheet to grow organically or to acquire assets. Analysts may look at the company's debt to cash flow leverage ratio, interest coverage ratios, or debt to equity ratios. In addition, the interest rate environment and the outlook for interest rates are a factor in determining the company's ability to manage financial leverage. Finally, the analyst is expected to determine the ability to service the debt given the industry and/or company profile, such as cyclicality, barriers to entry, history of bankruptcy, consistency in revenue and profit growth, or predictability in sales and profits and large cash reserves. The analyst is expected to take into account capital intensity of the company and the anticipated of capital allocation decisions.

High rank example: A company with predictable and growing revenue and cash flow with modest debt levels. This may indicate that the company could improve shareholder value through growth investments, including acquisitions, using debt financing.

Low rank example: A company in a cyclical industry in a late stage economic cycle that has above average debt leverage and is in an industry that has a history of financial challenges, including bankruptcies.

ANALYST CREDENTIALS, PROFESSIONAL DESIGNATIONS, AND EXPERIENCE
Senior Equity Research Analyst focusing on the Biotechnology and Specialty Pharmaceuticals industry. 16 years of industry experience. BA in Economics from Tulane University and an MBA from Columbia Business School. FINRA licenses 7, 24, 63, 86, 87

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NOBLE RATINGS DEFINITIONS	% OF SECURITIES COVERED	% IB CLIENTS
Outperform: potential return is >15% above the current price	88%	16%
Market Perform: potential return is -15% to 15% of the current price	12%	6%
Underperform: potential return is >15% below the current price	0%	0%

NOTE: On August 20, 2018, Noble Capital Markets, Inc. changed the terminology of its ratings (as shown above) from "Buy" to "Outperform", from "Hold" to "Market Perform" and from "Sell" to "Underperform." The percentage relationships, as compared to current price (definitions), have remained the same.

Additional information is available upon request. The recipient of this report who wishes further information regarding the subject company or the disclosure information mentioned herein, should contact by mail or phone.

Noble Capital Markets, Inc.
150 E Palmetto Park Rd, Suite 110
Boca Raton, FL 33432
561-994-1191

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