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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: No AdCom Required for TNX-102 SL NDA…

Based on our probability adjusted DCF model that takes into account potential future revenues from the company's CNS, immunology, and biodefense programs, TNXP is valued at $50.00/share. This model is highly dependent upon continued clinical success of the company's assets and will be adjusted accordingly based upon future clinical results.

Current Price (04/03/25)	$17.39
Valuation	**$50.00**

OUTLOOK

On March 24, 2025, Tonix Pharmaceuticals Holding Corp. (TNXP) announced that the FDA will not require an Advisory Committee meeting regarding the New Drug Application (NDA) for TNX-102 SL for the management of fibromyalgia. An Advisory Committee meeting is scheduled when the FDA needs expert input regarding some or all aspects of the NDA. The fact that the FDA will not require Advisory Committee meeting is a indicative that the FDA has sufficient information to render a decision on TNX-102 SL. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of August 15, 2025 for a decision on the NDA. TNX-102 SL has the potential to become the first new treatment for fibromyalgia in more than 15 years.

SUMMARY DATA

52-Week High	**$634.18**
52-Week Low	**$7.38**
One-Year Return (%)	**-97.26**
Beta	**1.50**
Average Daily Volume (sh)	**2,532,527**
Shares Outstanding (mil)	**6**
Market Capitalization ($mil)	**$120**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**82**
Insider Ownership (%)	**0**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2025 Estimate	**-1.5**
P/E using 2026 Estimate	**-2.5**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	2.5 A	2.2 A	2.8 A	2.6 A	10.1 A
2025	2.5 E	2.5 E	2.5 E	3.6 E	11.1 E
2026					31.3 E
2027					131.5 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2024	-$591.06 A	-$1928.36 A	-$22.88 A	-$9.77 A	-$176.60 A
2025	-$3.37 E	-$12.49 E	-$4.49 E	-$5.03 E	-$16.43 E
2026					-$7.80 E
2027					-$0.53 E

WHAT'S NEW

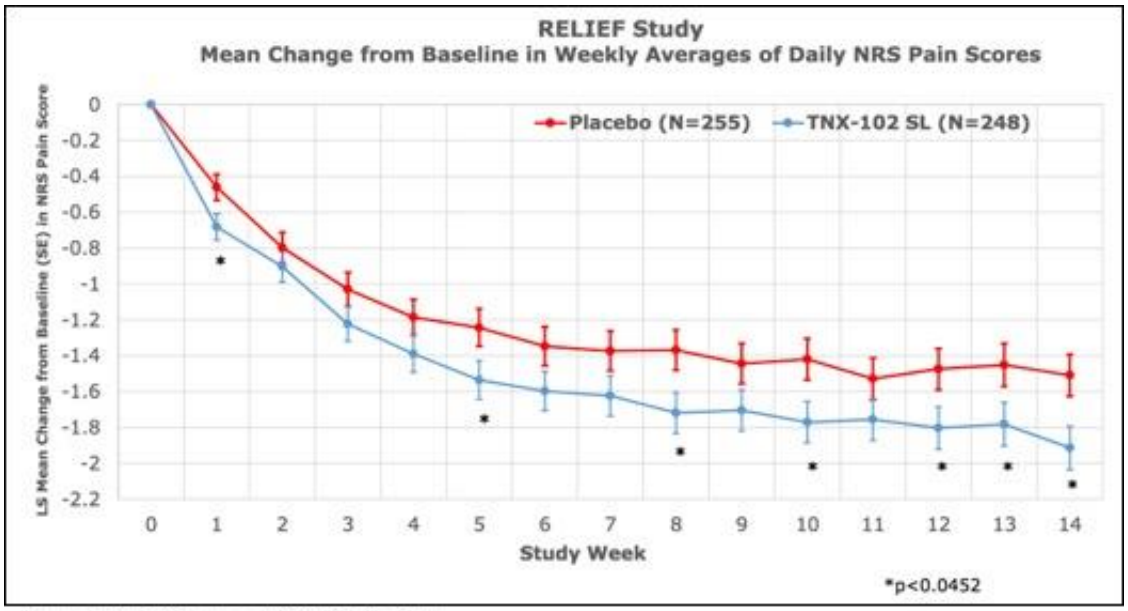
Business Update

No Advisory Committee Meeting for TNX-102 SL NDA

On March 24, 2025, Tonix Pharmaceuticals Corp. (TNXP) announced that the FDA will not require an Advisory Committee (AdCom) meeting regarding the New Drug Application (NDA) for TNX-102 SL for the management of fibromyalgia. An AdCom is typically convened by the agency when there are questions surrounding some or all of the aspects of an NDA, including data interpretation or statistical analysis. The fact that no AdCom will be taking place indicates that the FDA has all the information necessary for a determination on the NDA for TNX-102 SL and is another positive indicator as the PDUFA target date of August 15, 2025 gets closer.

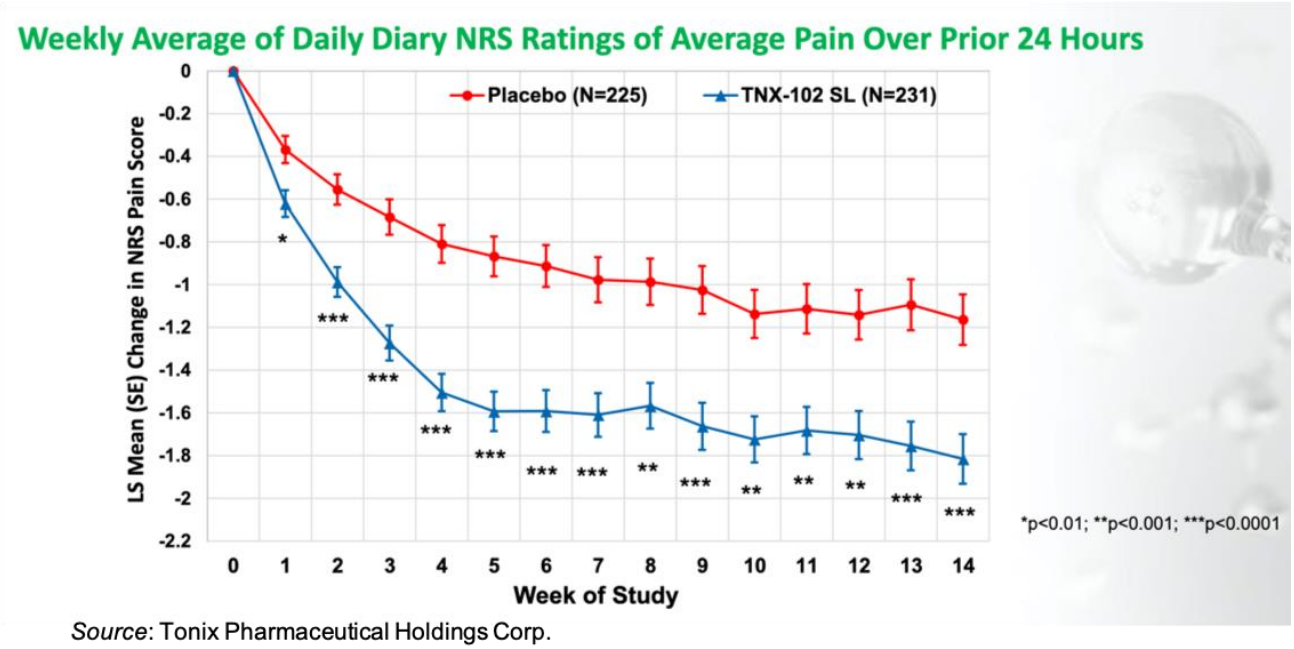
There has not been a new therapy approved for fibromyalgia by the FDA since 2009 (Savella), with Cymbalta (2008) and Lyrica (2007) approved previously. Lyrica generated revenues in excess of $1 billion in the treatment of fibromyalgia before going off patent and in 2022 generated revenues of approximately $624 million for the treatment of fibromyalgia (EvaluatePharma). Thus, an effective fibromyalgia therapy, particularly one that has an improved safety and tolerability profile compared to the currently approved medications, has blockbuster potential. In addition, none of the currently approved therapies address the common symptoms of pain, poor sleep, and fatigue simultaneously.

The NDA filing for TNX-102 SL in fibromyalgia is supported by the positive results from the Phase 3 RELIEF and RESILIENT trials. For a full overview of the results from the RELIEF trial see our previous report here. Briefly, the following graph shows the results for the primary efficacy endpoint of the trial, the mean change from baseline in weekly averages of the daily diary pain numerical rating scale (NRS) scores. At week 14, participants on TNX-102 SL had a LS mean change from baseline of -1.9 units compared to -1.5 units for participants on placebo (*P*=0.01). The graph shows separation between TNX-102 SL-treated and placebo-treated participants at Week 14 and shows separation (P<0.05) at Week 5, Week 8, and Week 10 and continues consistently from Week 12 to Week 14.



Source: Tonix Pharmaceuticals Holding Corp.

For a full overview of results from the RESILIENT trial see our previous report here. Briefly, the following graph shows the primary outcome measure of reduction in pain over the 14-weeks of the RESILIENT trial. TNX-102 SL showed a rapid onset of action and separated from placebo for each week of the study. It exhibited a robust effect size of 0.38. The Week 14 least square (LS) mean (SE) change from baseline for TNX-102 SL was -1.82 (0.12) and for placebo -1.16 (0.12), with a least square mean difference from placebo of -0.65 (0.16) (*P*=0.00005).



Source: Tonix Pharmaceutical Holdings Corp.

Pre-commercialization activities are currently underway. Tonix's commercialization unit currently markets Zembrace and Tosymra, which are both indicated for the treatment of acute migraine in adults. Thus, Tonix will not be establishing commercial operations for TNX-102 SL from scratch but will be building upon the infrastructure that already exists. Tonix also had a market opportunity analysis conducted by EVERSANA. Overall, the analysis found a high level of interest in TNX-102 SL among physicians who treat fibromyalgia patients that included a substantial dissatisfaction rate with the currently FDA approved therapies for fibromyalgia.

Grant for Development of TNX-801

On March 10, 2025, Tonix announced that it was awarded a grant from the Medical CBRN Defense Consortium (MCDC) to support the development of TNX-801, a live form of the horsepox virus, for the prevention of smallpox and mpox. MCDC is a consortium of industrial, academic, and non-profit entities that support the U.S. government in meeting military requirements for medical products to protect against chemical, biological, radiological, and nuclear (CBRN) threats.

In January 2020, Tonix announced preclinical results showing TNX-801 protected non-human primates from a challenge with clade I mpox virus. No animals developed lesions, signifying sterilizing immunity. TNX-801 administration was safe and well tolerated as there were no changes in body weights or body temperatures in the treated animals.

Tonix has entered into a sponsored research agreement with the Kenya Medial Research Institute (KEMRI) to design, plan, and seek regulatory approval for a Phase 1 clinical trial of TNX-801 in Kenya. Tonix will sponsor the study and KEMRI will lead the execution of the trial.

Financial Update

On March 18, 2025, Tonix announced financial results for the fourth quarter and full year 2024. Net product revenues for the fourth quarter of 2024 were approximately $2.6 million, compared to $3.8 million for the fourth quarter of 2023. Cost of sales for the fourth quarter of 2024 and 2023 were $1.2 million and $2.4 million, respectively.

R&D expenses for the fourth quarter of 2024 were $8.3 million, compared to $17.1 million for the fourth quarter of 2023. The decrease was primarily due to decreased clinical expenses resulting from fewer clinical trials. G&A expenses for the fourth quarter of 2024 were $15.6 million, compared to $11.6 million for the fourth quarter of 2023. The increase was primarily due to an increase in financial reporting expenses, sales and marketing, and professional fees associated with TNX-102 SL's NDA submission.

For 2024, net product revenues were approximately $10.1 million and the cost of sales for 2024 were approximately $7.8 million. R&D expenses in 2024 were $40.0 million, compared to $86.7 million for 2023. The decrease was primarily due to fewer clinical trials and pipeline prioritization, which further decreased non-clinical, manufacturing, employee-related, and professional expenses. G&A expenses for 2024 were $40.1 million, compared to $34.8 million for 2023. The increase was primarily due to increased financial reporting expenses, sales and marketing expenses associated with the recently acquired marketed products, and professional fees associated with TNX-102 SL's NDA submission.

As of December 31, 2024, Tonix had approximately $98.8 million in cash and cash equivalents. Subsequent to the end of the year, the company raised $46.3 million in net proceeds from the sale of common stock under an at-the-market (ATM) facility. We estimate this will be sufficient to fund operations into the first quarter of 2026 but not beyond. As of March 17, 2025, Tonix has approximately 6.9 million shares outstanding and, when including outstanding options and warrants, a fully diluted share count of approximately 7.6 million.

Conclusion

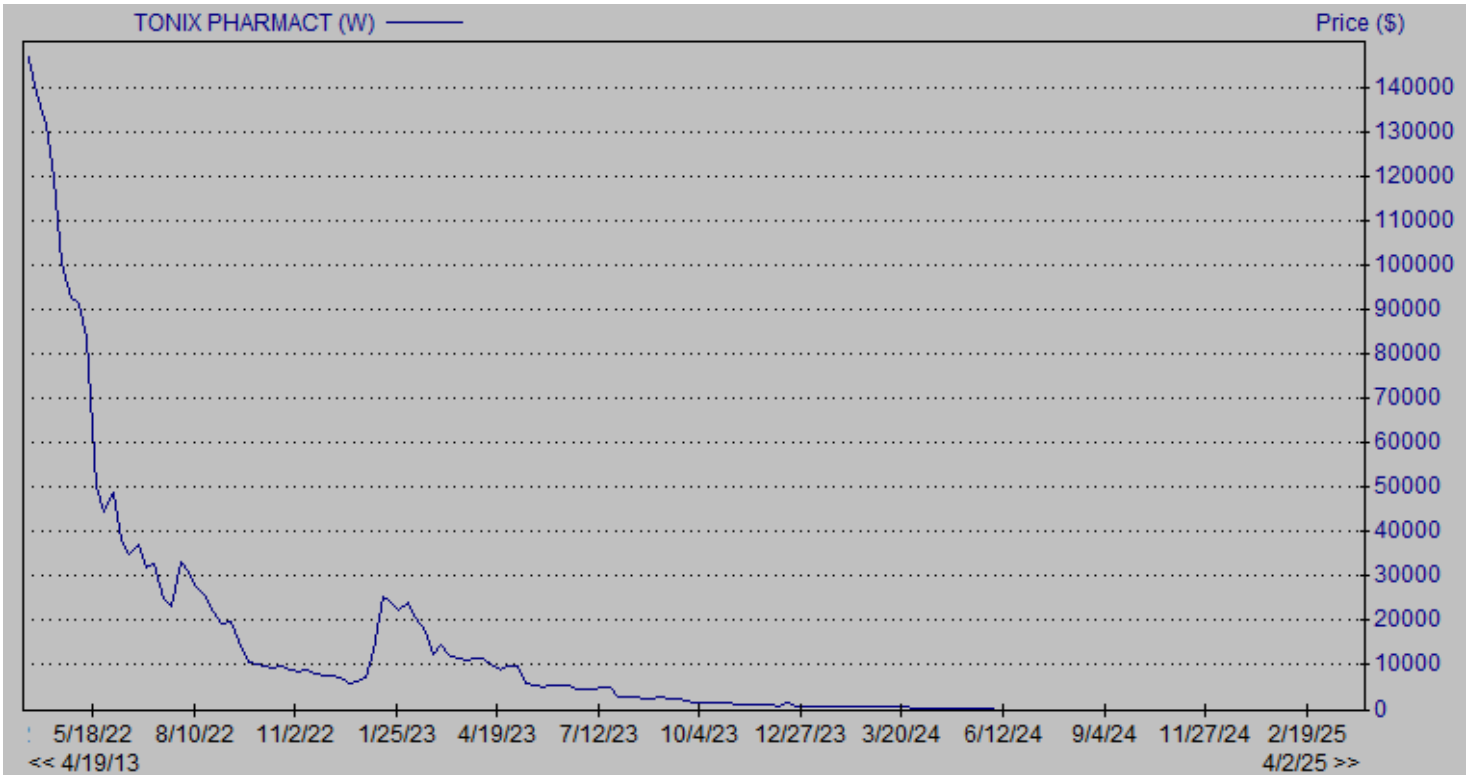
We believe the fact that the FDA does not need to convene an AdCom to discuss the NDA for TNX-102 SL in fibromyalgia is a positive sign that the agency as all the information it needs to reach a decision on whether or not to approve the drug. We look forward to the FDA's decision on or before August 15, 2025 and anticipate the drug gaining approval based on the positive Phase 3 trials and its tolerability. With no changes to our model our valuation remains at $50 per share.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2024 A	Q1 E	Q2 E	Q3 E	Q4 E	2025 E	2026 E	2027 E
TNX-102 SL	$0.0	$0.0	$0.0	$0.0	$1.0	$1.0	$21.0	$121.0
Zembrace / Tosymra	$10.1	$2.5	$2.5	$2.5	$2.6	$10.1	$10.3	$10.5
Research & Collaborations	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$10.1**	**$2.5**	**$2.5**	**$2.5**	**$3.6**	**$11.1**	**$31.3**	**$131.5**
CoGS	$7.8	$1.7	$1.7	$1.7	$1.8	$6.9	$9.9	$19.5
Product Gross Margin	*23.1%*	*31.5%*	*32.0%*	*32.0%*	*50.0%*	*37.7%*	*68.4%*	*85.2%*
R&D	$40.0	$9.0	$10.0	$10.0	$12.0	$41.0	$43.0	$45.0
SG&A	$40.1	$12.0	$13.0	$20.0	$25.0	$70.0	$72.0	$75.0
Asset Impairment Charge	$59.0	$0.0	$59.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($136.7)	($20.2)	($81.2)	($29.2)	($35.2)	($106.8)	($93.6)	($8.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$6.7	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($130.0)	($20.2)	($81.2)	($29.2)	($35.2)	($106.8)	($93.6)	($8.0)
Preferred Stock Deemed Dividend	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Warrant Deemed Dividend	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($130.0)	($20.2)	($81.2)	($29.2)	($35.2)	($106.8)	($93.6)	($8.0)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($176.60)**	**($3.37)**	**($12.49)**	**($4.49)**	**($5.03)**	**($16.43)**	**($7.80)**	**($0.53)**
YOY Growth	*-99.9%*	-	-	-	-	*-99.9%*	*-100.0%*	*-100.0%*
Weighted Shares Outstanding	0.7	6.0	6.5	6.5	7.0	6.5	12.0	15.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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