Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

May 28, 2025
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com 10 S. Riverside Plaza, Chicago, IL 60606

Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Preparations Continue for Potential Commercial Launch of TNX-102 SL in Fibromyalgia…

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 (05/28/25)	$36.99
Valuation	**$50.00**

OUTLOOK

On May 12, 2025, Tonix Pharmaceuticals Holding Corp. (TNXP) announced financial results for the first quarter of 2025 and provided a business update. The company is continuing pre-commercialization activities in preparation for the PDUFA date of August 15, 2025 for TNX-102 SL for the management of fibromyalgia. If approved, TNX-102 SL would be the first new treatment option for fibromyalgia in more than 15 years. The FDA has already announced that no Advisory Committee meeting will be necessary to discuss the TNX-102 SL New Drug Application (NDA) and we believe the two positive Phase 3 trials showing a statistically significant reduction in the chronic, widespread pain associated with fibromyalgia support its eventual approval.

SUMMARY DATA

52-Week High	**$560.70**
52-Week Low	**$7.38**
One-Year Return (%)	**-93.19**
Beta	**1.63**
Average Daily Volume (sh)	**1,177,163**
Shares Outstanding (mil)	**7**
Market Capitalization ($mil)	**$271**
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	**-2.0**
P/E using 2026 Estimate	**-5.9**

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	2.4 A	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	-$2.84 A	-$12.49 E	-$4.49 E	-$5.03 E	-$13.96 E
2026					-$7.80 E
2027					-$0.53 E

WHAT'S NEW

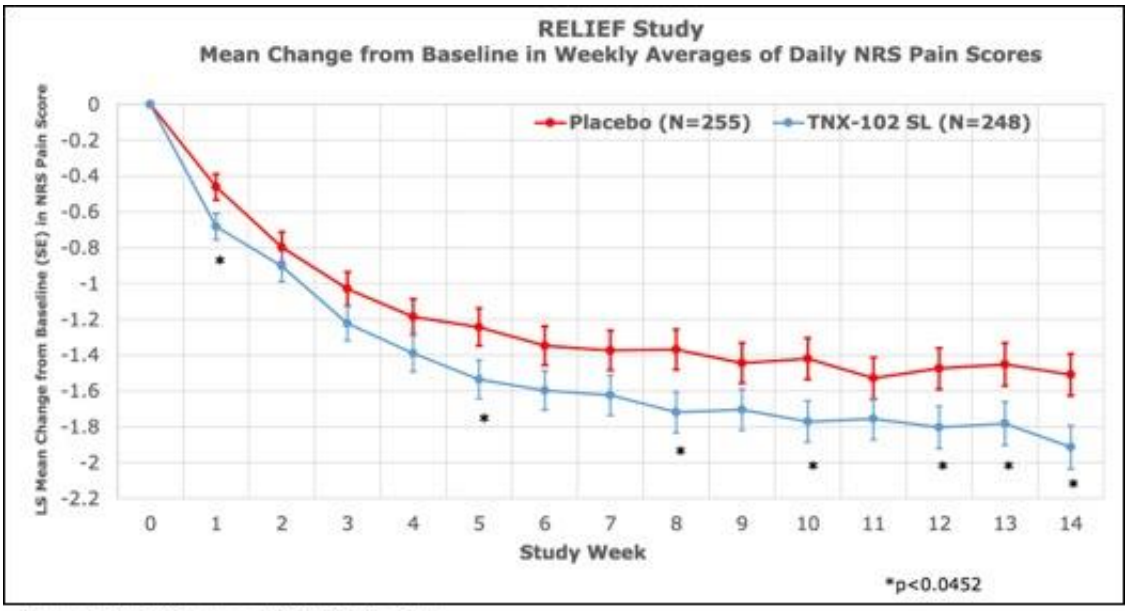
Business Update

Preparations Continue for Potential Commercialization of TNX-102 SL in Fibromyalgia

Tonix Pharmaceuticals Corp. (TNXP) is developing TNX-102 SL for the management of fibromyalgia. The company submitted a New Drug Application (NDA), which the U.S. Food and Drug Administration (FDA) accepted for review in December 2024 and assigned a Prescription Drug User Fee Act (PDUFA) date of August 15, 2025. In March 2025, Tonix announced that the FDA will not require an Advisory Committee (AdCom) meeting regarding the 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 date gets closer.

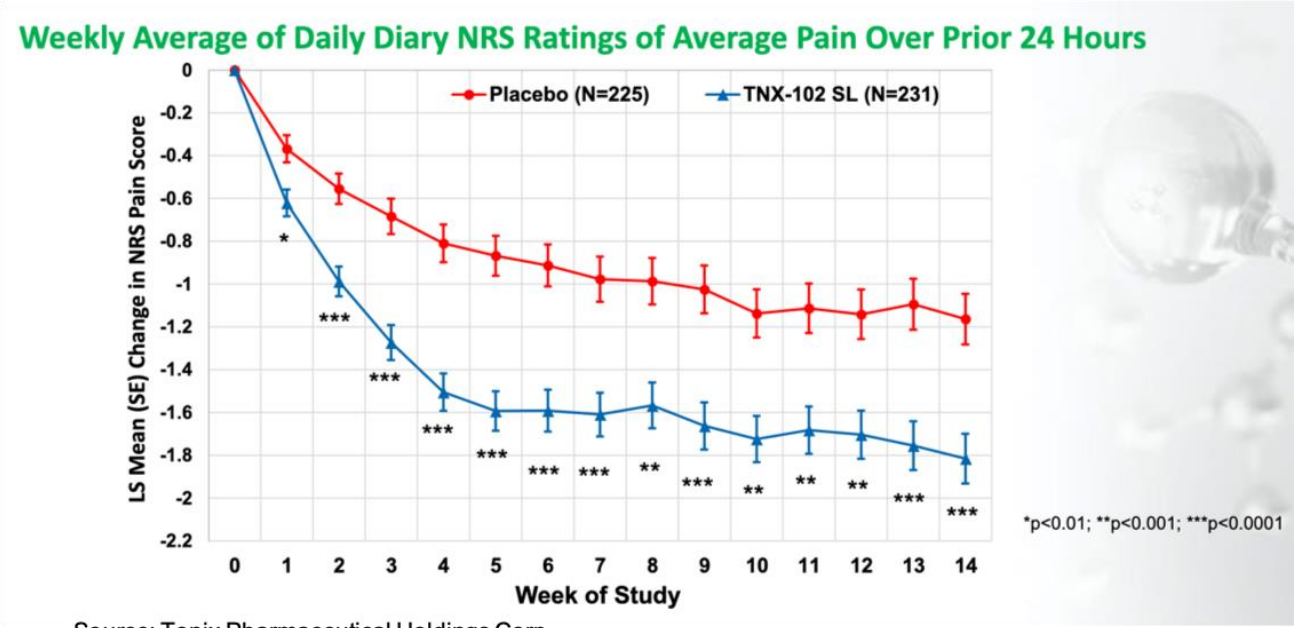
There has not been a new therapy approved for fibromyalgia by the FDA since 2009 (Savella), with Cymbalta (2008) and Lyrica (2007) approved previously. Lyrica generated revenues in excess of $1 billion in the treatment of fibromyalgia before going off patent and in 2022 generated revenues of approximately $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.

Multiple Recent Preclinical Data Presentations

- On April 24, 2025, Tonix announced it presented data on TNX-801 in an oral presentation at the World Vaccine Congress Washington 2025. The presentation highlighted positive preclinical efficacy data showing that TNX-801 provided protective immunity to animals in a single dose while being generally well tolerated, even in immunocompromised animals. Durable six-month protection was attained in these animals against a lethal challenge with rabbitpox virus and it protected immunocompromised animals against a lethal challenge with monkeypox clade IIa virus.

- On April 29, 2025, Tonix announced it presented data in a poster presentation on TNX-1700 (human TFF2-human serum albumin) at the American Association for Cancer Research (AACR) 2025 Annual Meeting. Human Trefoil Factor Family Member 2 (TFF2) is a secreted protein that is expressed in the gastrointestinal mucosa where it functions to protect and repair mucosa. In gastric cancer, TFF2 is epigenetically silenced, while in animal models TFF2 overexpression suppresses tumor growth. Data presented at AACR 2025 showed that TFF2-MSA (TFF2 fused to murine serum albumin) selectively reduced immunosuppressive neutrophils and cancer-driven granulopoiesis. In addition, treatment with TFF2-MSA in combination with an anti-PD1 antibody induced robust anti-tumor CD8+ T cell responses and inhibited tumor invasion.

Financial Update

On May 12, 2025, Tonix announced financial results for the first quarter of 2025. Net product revenues for the first quarter of 2025 were approximately $2.4 million compared to $2.5 million for the first quarter of 2024. Cost of sales in the first quarter of 2025 was approximately $0.9 million compared to $1.7 million for the same time period in 2024.

R&D expenses for the first quarter of 2025 were $7.4 million, compared to $12.9 million for the first quarter of 2024. The decrease was primarily due to decreased clinical, non-clinical, and manufacturing expenses. G&A expenses for the first quarter of 2025 were $10.1 million, compared to $9.3 million for the first quarter of 2024. The increase was primarily due to an increase in sales and marketing partially offset by a decrease in employee-related expenses.

As of March 31, 2025, Tonix had approximately $131.7 million in cash and cash equivalents. Subsequent to the end of the quarter, the company sold approximately 0.6 million shares of common stock for net proceeds of approximately $9.9 million. We estimate that the company's current cash position will finance operations into the second quarter of 2026 but not beyond. As of May 12, 2025, Tonix had approximately 7.3 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of 8.1 million.

Conclusion

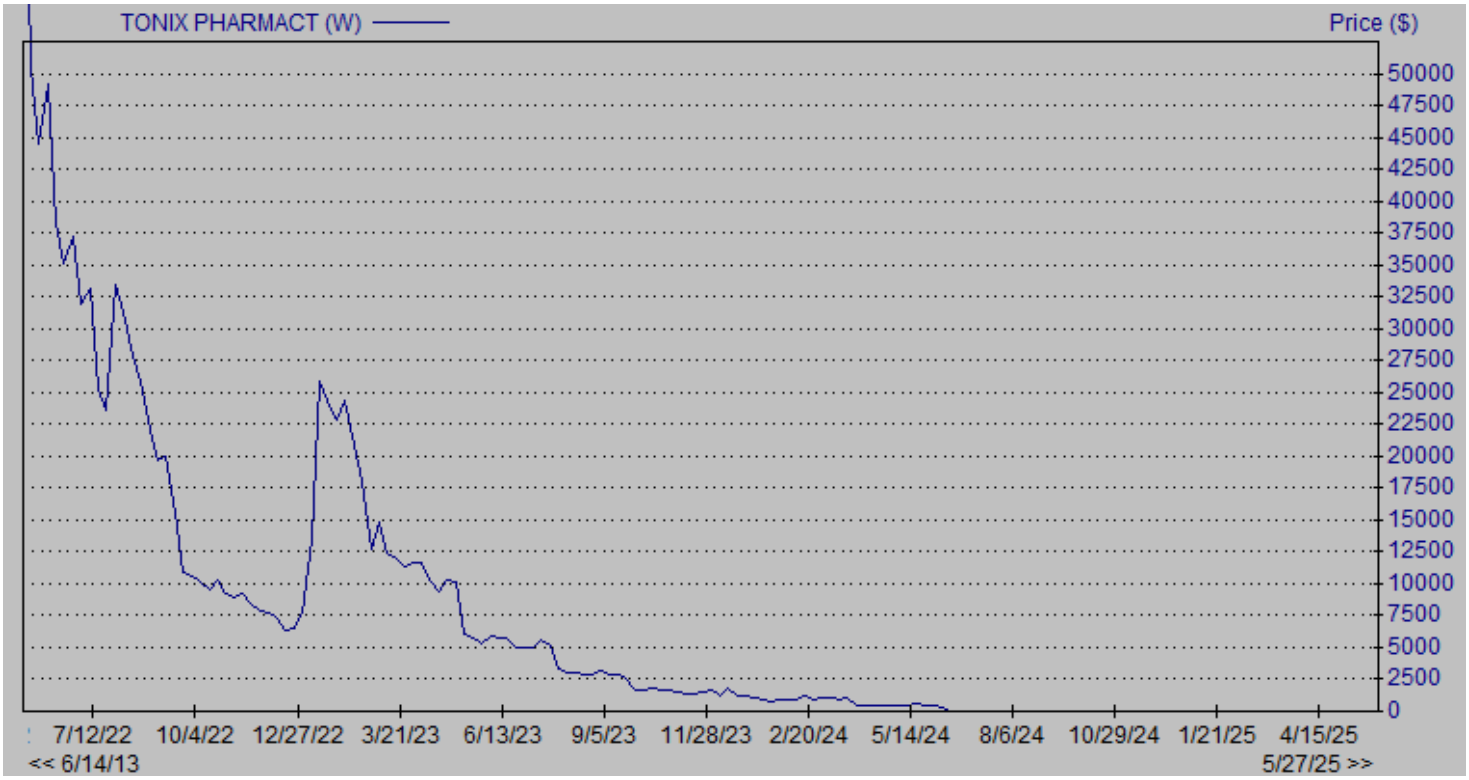
We're excited for the final countdown to the August 15, 2025 PDUFA date for TNX-102 SL for the management of fibromyalgia. We are confident that the data compiled in the NDA will support approval and that, if approved, Tonix will be able to execute a successful commercial launch, particularly given the company's healthy balance sheet. As we await the FDA's decision we have made no changes to our model and our valuation remains at $50 per share.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2024 A	Q1 A	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	$2.4	$2.5	$2.5	$2.6	$10.0	$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**	**$2.4**	**$2.5**	**$2.5**	**$3.6**	**$11.0**	**$31.3**	**$131.5**
CoGS	$7.8	$0.9	$1.0	$1.0	$1.8	$4.7	$6.0	$16.0
Product Gross Margin	*23.1%*	*61.2%*	*60.0%*	*60.0%*	*50.0%*	*57.0%*	*80.8%*	*87.8%*
R&D	$40.0	$7.4	$10.0	$10.0	$12.0	$39.4	$43.0	$45.0
SG&A	$40.1	$10.1	$13.0	$20.0	$25.0	$68.1	$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)	($16.1)	($80.5)	($28.5)	($35.2)	($101.3)	($89.7)	($4.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$6.7	$0.8	$0.0	$0.0	$0.0	($0.8)	$0.0	$0.0
Pre-Tax Income	($130.0)	($16.8)	($80.5)	($28.5)	($35.2)	($102.0)	($89.7)	($4.5)
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)	($16.8)	($80.5)	($28.5)	($35.2)	($102.0)	($89.7)	($4.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($176.60)**	**($2.84)**	**($10.73)**	**($3.65)**	**($4.40)**	**($13.96)**	**($7.48)**	**($0.30)**
YOY Growth	*-99.9%*	-	-	-	-	*-100.0%*	*-100.0%*	*-100.0%*
Weighted Shares Outstanding	0.7	5.9	7.5	7.8	8.0	7.3	12.0	15.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.