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December 3, 2024
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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: NDA Filed for 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 $2.50/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 (12/03/24)	$0.19
Valuation	**$2.50**

OUTLOOK

On October 16, 2024, Tonix Pharmaceuticals Holding Corp. (TNXP) announced that it submitted the New Drug Application (NDA) for TNX-102 SL for the treatment of fibromyalgia. The NDA is supported by the results of two Phase 3 clinical trials that reported statistically significant results on the primary endpoint of reducing widespread pain. The FDA typically has a 60-day filing review period to determine whether the submitted NDA is acceptable for review. If accepted for review, the FDA should assign a Prescription Drug User Fee Act (PDUFA) date for an approval decision in August 2025 for standard review or April 2025 if granted priority review.

SUMMARY DATA

52-Week High	**$21.25**
52-Week Low	**$0.13**
One-Year Return (%)	**-98.77**
Beta	**2.23**
Average Daily Volume (sh)	**56,180,852**
Shares Outstanding (mil)	**187**
Market Capitalization ($mil)	**$35**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**3**
Insider Ownership (%)	**2**
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 2024 Estimate	**0.0**
P/E using 2025 Estimate	**0.0**

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)
2023	0.0 A	0.0 A	4.0 A	3.8 A	7.8 A
2024	2.5 A	2.2 A	2.8 A	2.3 E	9.8 E
2025					9.5 E
2026					30.6 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$104.19 A	-$85.71 A	-$58.40 A	-$27.23 A	-$219.08 A
2024	-$5.91 A	-$19.28 A	-$0.23 A	-$0.13 E	-$1.16 E
2025					-$0.37 E
2026					-$0.27 E

WHAT'S NEW

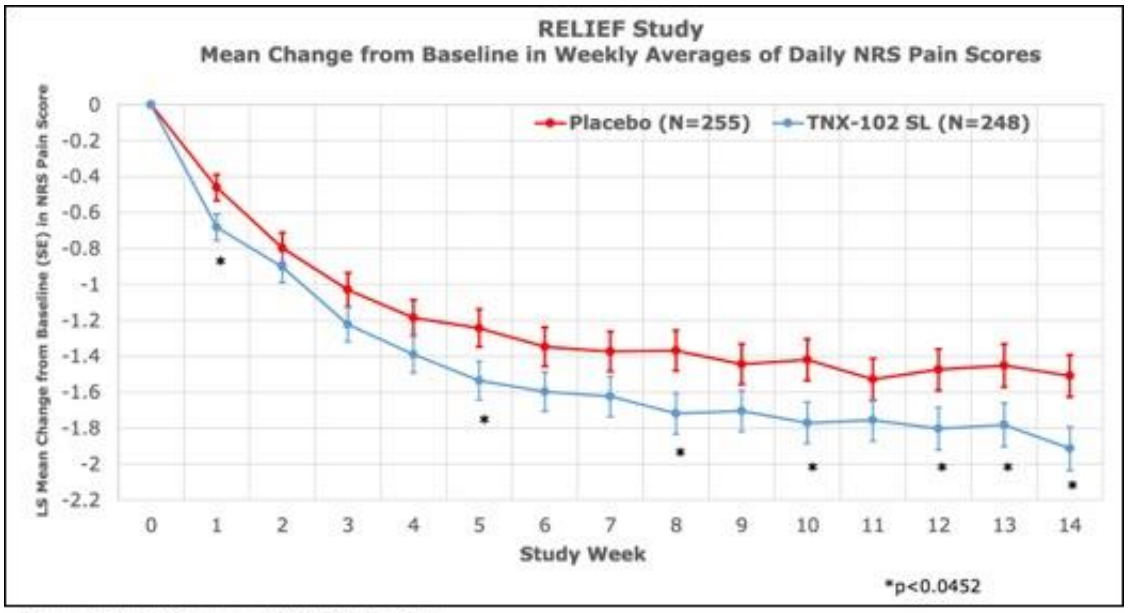
Business Update

NDA Filed for TNX-102 SL in Fibromyalgia

On October 16, 2024, Tonix Pharmaceuticals Holding Corp. (TNXP) announced that it had filed the New Drug Application (NDA) for TNX-102 SL for the treatment of fibromyalgia. The FDA typically has a 60-day window to determine if the submitted NDA is acceptable for review. If accepted, the FDA will issue a Prescription Drug User Fee Act (PDUFA) date for a decision on approval, which we anticipate being in August 2025 for a standard review or April 2025 for priority review. TNX-102 SL was previously granted Fast Track designation by the FDA in July 2024, making it eligible for priority review, however that is not determined by the FDA until acceptance of the NDA.

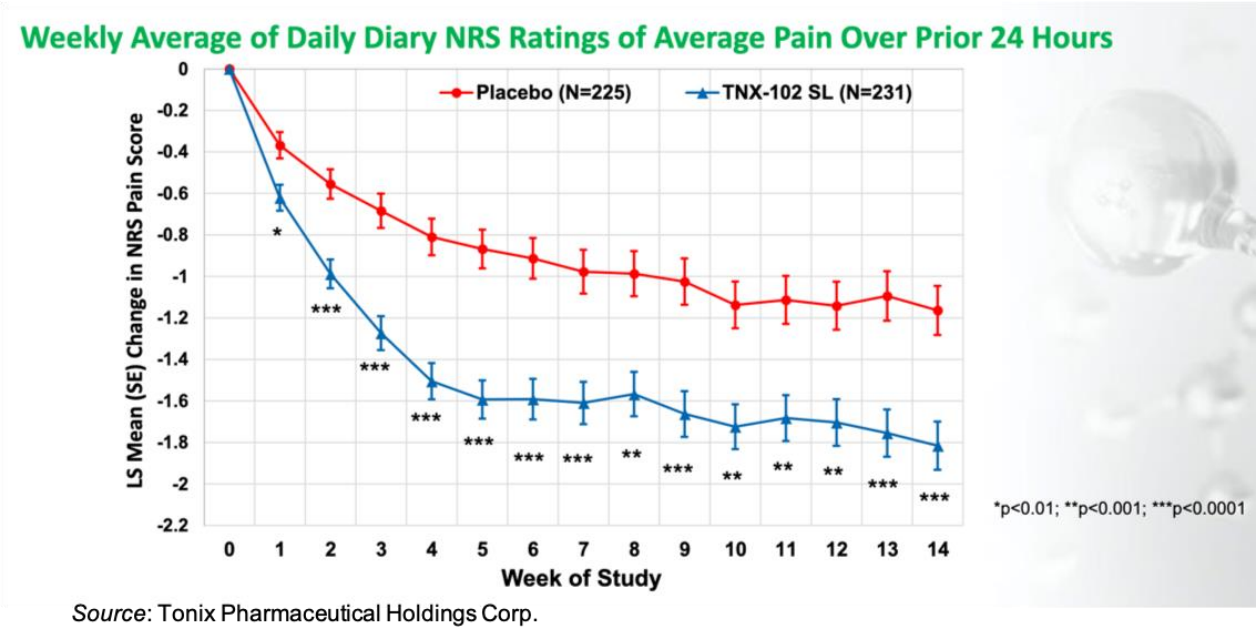
There has not been a new therapy approved for fibromyalgia by the FDA since 2009 (Savella), with Cymbalta (2008) and Lyrica (2007) approved previously. Lyrica generated revenues in excess of $1 billion in the treatment of fibromyalgia before going off patent and in 2022 generated revenues of approximately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

Update on TNX-801

On November 18, 2024, officials in California confirmed the first case of mpox clade Ib in the U.S. Other countries that have reported clade Ib include Sweden, Singapore, India, Germany, England, and Canada. Clade Ib is considered a more severe strain than clade IIb, which was primarily responsible for the global outbreak in 2022, and appears to spread through different contact routes in households than clade IIb, which was primarily spread through sexual contact. At this time there does not appear to be a high risk to the general population.

Tonix is developing TNX-801, a live form of the horsepox virus, as a vaccine to prevent mpox and smallpox. TNX-801 aligns with key elements of the World Health Organization's (WHO) preferred target product profile that includes single-dose, durable protection, administration without special equipment, and stability at ambient temperature.

The company previously presented data showing that nonhuman primates (NHPs) vaccinated with TNX-801 were fully protected with sterilizing immunity from an intra-tracheal challenge with mpox. In addition, the vaccinations were well tolerated as the animals had stable weights and body temperatures. Tonix recently presented new data showing there is no evidence of TNX-801 spreading to blood or tissues even at high doses in immunocompromised 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.

Positive Results for Anti-CD40L Drug Candidate in Lupus

On November 19, 2024, Biogen, Inc. (BIIB) presented results from the Phase 3 PHOENYCS GO study that tested dapirolizumab pegol (DZP), an Fc-free anti-CD40L drug candidate, and demonstrated significant clinical improvements in disease activity in those living with moderate-to-severe systemic lupus erythematosus (SLE). The trial met the primary endpoint of improvement of moderate-to-severe disease activity as assessed by achievement of British Isles Lupus Assessment Group (BILAG)-based Composite Lupus Assessment (BICLA) after 48 weeks of treatment. Clinical improvements were also noted in a number of secondary endpoints. The safety results were consistent with previous trials of DZP and in study participants with SLE receiving an immunomodulator.

DZP blocks CD40L signaling and is considered a “second generation” anti-CD40L development candidate. First generation anti-CD40L monoclonal antibodies Fc region interacted with FcγRIIA, which led to an increased risk of thrombosis (Robles-Carrillo *et al*., 2010). The second generation anti-CD40L proteins show markedly reduced binding to FcγRIIa.

Tonix is developing TNX-1500, a third-generation anti-CD40L monoclonal antibody for the prevention of allograft rejection, xenotransplantation, and the treatment of autoimmune disease. Preclinical results for TNX-1500 show that it consistently prevents kidney and heart rejection in allo-transplantation along with prevention of rejection in kidney xenograft transplantation in nonhuman primates. The company has completed enrollment and dosing in a Phase 1 trial of TNX-1500 in healthy volunteers to assess its safety, tolerability, and pharmacokinetics and pharmacodynamics. The results are intended to support dosing in a Phase 2 trial in kidney transplant recipients.

Financial Update

On November 12, 2024, Tonix announced financial results for the third quarter of 2024. Net product revenues for the third quarter of 2024 were approximately $2.8 million and the cost of sales was $1.6 million.

R&D expenses for the third quarter of 2024 were $9.1 million, compared to $21.0 million for the third quarter of 2023. The decrease was primarily due to decreased clinical, non-clinical, manufacturing expenses, and employee-related expenses. G&A expenses for the third quarter of 2024 were $7.7 million, compared to $8.7 million for the third quarter of 2023. The decrease was primarily due to lower employee-related expenses, a decrease in transactional services provided by Upsher Smith, and a decrease in sales and marketing partially offset by higher professional fees.

As of September 30, 2024, Tonix had approximately $28.2 million in cash and cash equivalents. Subsequent to the end of the quarter, the company raised approximately $5.1 million through the sale of 31.3 million shares under the At-the-Market agreement entered into in July 2024 with AGP. As of November 12, 2024, the company has approximately 186.9 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of 193.6 million.

Conclusion

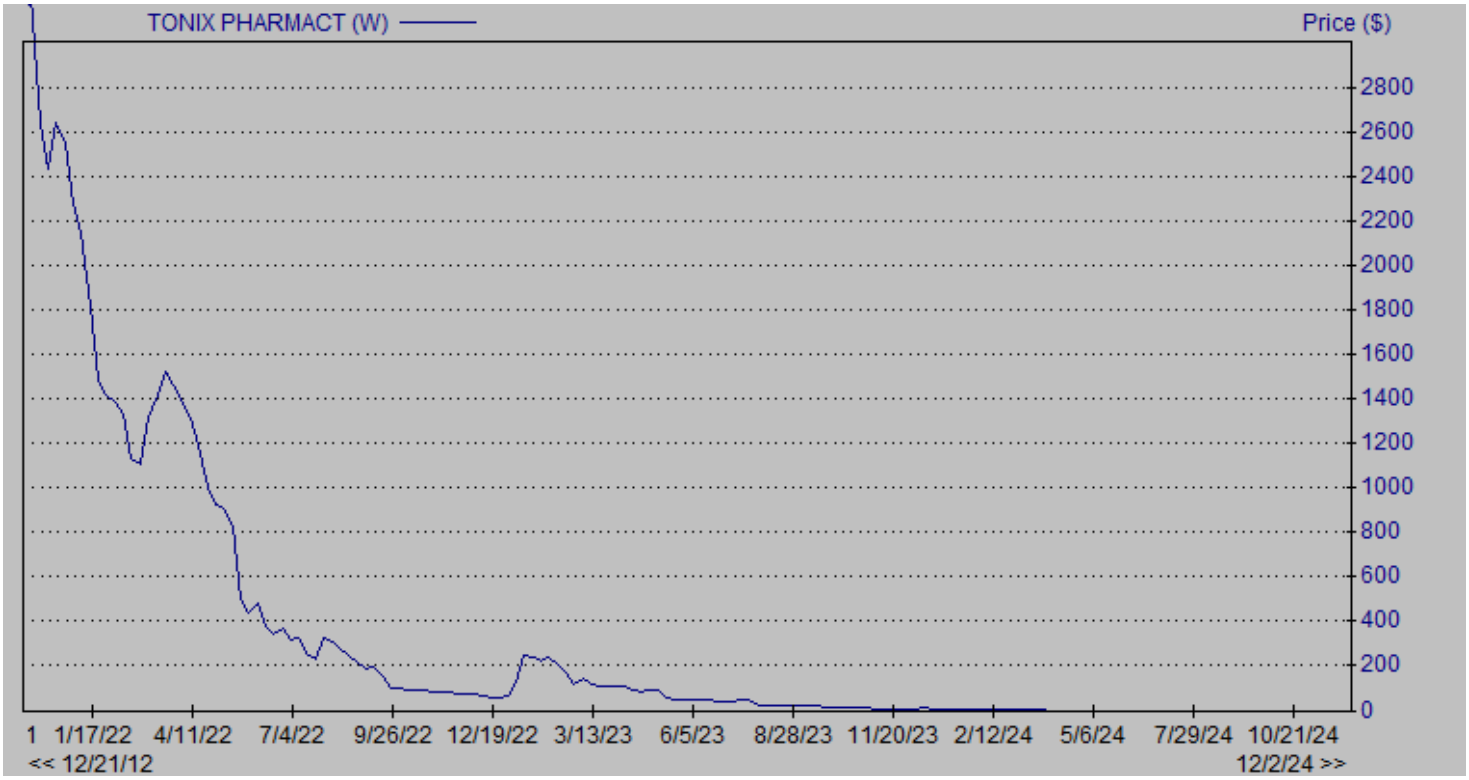
We look forward to the FDA’s decision whether to accept the TNX-102 SL NDA for review, which should occur in mid-December. If accepted, the PDUFA date will likely be either in August 2025 under a standard review or April 2025 for priority review. At the time the FDA determines whether the NDA is suitable for review it will also announce whether it will be a standard or priority review. TNX-102 SL was well tolerated in both of the positive Phase 3 trials, thus we anticipate the drug gaining approval in 2025. After incorporating the company’s recent financings into our model, our valuation is now at $2.50.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2023 A	Q1 A	Q2 A	Q3 A	Q4 E	2024 E	2025 E	2026 E
TNX-102 SL	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$21.0
Zembrace / Tosymra	$7.8	$2.5	$2.2	$2.8	$2.3	$9.8	$9.5	$9.6
Research & Collaborations	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$7.8**	**$2.5**	**$2.2**	**$2.8**	**$2.3**	**$9.8**	**$9.5**	**$30.6**
CoGS	$4.7	$1.7	$3.4	$1.6	$2.3	$8.9	$9.6	$13.0
Product Gross Margin	*39.0%*	*33.1%*	*-52.5%*	*44.9%*	*0.0%*	*9.5%*	*-1.1%*	*57.5%*
R&D	$86.7	$12.9	$9.7	$9.1	$13.1	$44.8	$55.0	$57.0
SG&A	$34.8	$9.3	$7.5	$7.7	$10.0	$34.5	$38.0	$55.0
Asset Impairment Charge	$0.0	$0.0	$59.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($118.4)	($21.4)	($77.3)	($15.6)	($23.1)	($78.4)	($93.1)	($94.4)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$1.7	$6.4	$1.5	$1.3	$0.1	$6.4	$0.5	$0.5
Pre-Tax Income	($116.7)	($14.9)	($78.8)	($14.2)	($23.0)	($72.0)	($92.6)	($93.9)
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	($116.7)	($14.9)	($78.8)	($14.2)	($23.0)	($72.0)	($92.6)	($93.9)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($219.08)**	**($5.91)**	**($19.28)**	**($0.23)**	**($0.13)**	**($1.16)**	**($0.37)**	**($0.27)**
YOY Growth	*-86.6%*	-	-	-	-	*-99.9%*	*-99.9%*	*-99.9%*
Weighted Shares Outstanding	0.5	2.5	4.1	62.1	180.0	62.2	250.0	350.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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