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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Tonmya® Launch Continues to Build Momentum; 37% QoQ Growth in Revenue

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 $56.00/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 (11/16/26)	$3.01
Valuation	**$56.00**

OUTLOOK

On November 9, 2026, Tonix Pharmaceuticals Holding Corp. (TNXP) announced financial results for the third quarter of 2026 and provided a business update. Tonix reported Tonmya® net sales of approximately $15.0 million, which represented a 37% increase compared to the second quarter of 2026. Prescriptions totaled 16,375 (28% QoQ growth) while new prescriptions and refills grew 17% and 56% QoQ, respectively. The company is continuing to enroll patients in the HORIZON study, a potentially pivotal 6-week, randomized, double blind, placebo controlled Phase 2 study of TNX-102 SL 5.6 mg as a first-line monotherapy in adults with major depressive disorder (MDD). In addition, Tonix is expected to initiate the ~500-person lead-in cohort for a Phase 2 field study of TNX-4800 for the prevention of Lyme disease in the first quarter of 2027, pending final FDA alignment on the protocol, with the remaining ~2,800 participants expected to be enrolled in the 2028 Lyme season. Lastly, a Phase 2 investigator-initiated study of TNX-1500 in five adults receiving new kidneys is expected to begin in 1Q27.

SUMMARY DATA

52-Week High	**$19.89**
52-Week Low	**$3.01**
One-Year Return (%)	**-81.07**
Beta	**1.90**
Average Daily Volume (sh)	**1,075,813**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$58**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**82**
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 2026 Estimate	**-0.3**
P/E using 2027 Estimate	**-0.5**

Risk Level	**Above Avg.**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025	2.4 A	2.0 A	3.3 A	5.4 A	13.1 A
2026	6.9 A	13.6 A	17.2 A	19.5 E	57.2 E
2027					96.5 E
2028					162.0 E

Earnings per Share*

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2025	-$2.84 A	-$3.86 A	-$3.59 A	-$3.95 A	-$14.57 A
2026	-$-2.93 A	-$2.43 A	-$2.89 A	-$2.73 E	-$10.97 E
2027					-$7.23 E
2028					$4.55 E

*Quarterly EPS may not sum due to changes in weighted-average shares outstanding

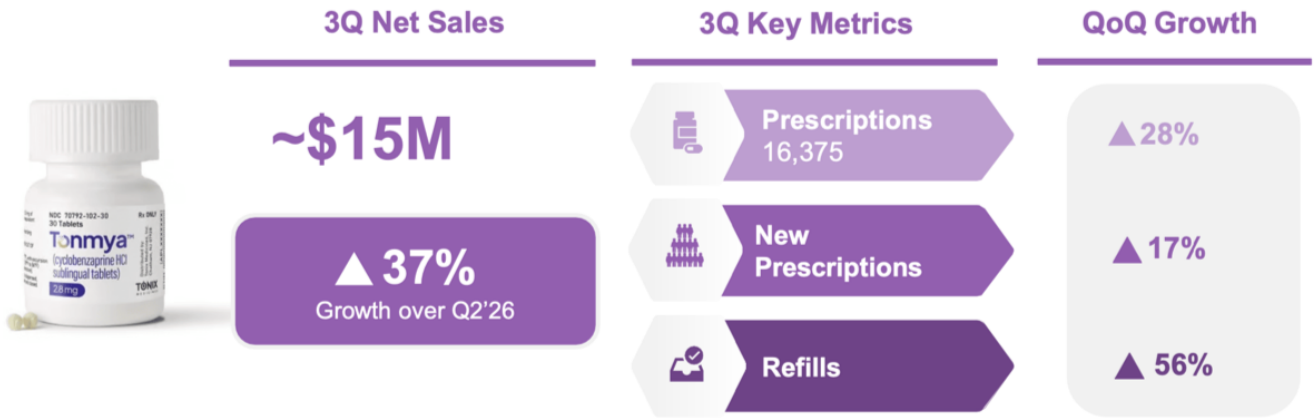
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WHAT'S NEW

Business Update

Tonmya® Launch Continues to Build Momentum; 37% QoQ Growth in Revenue

Tonix Pharmaceutical Holding Corp. (TNXP) reported another quarter of sequential growth for Tonmya, its FDA-approved sublingual cyclobenzaprine formulation for fibromyalgia, with 3Q26 net sales increasing 37% sequentially to approximately $15.0 million. Total prescriptions increased 28% QoQ to 16,375, including a 17% increase in new prescriptions and a 56% increase in refills. The stronger growth in refills relative to new prescriptions is encouraging, potentially reflecting improving patient persistence and a growing base of repeat users as the commercial launch continues.



Source: Tonix Pharmaceutical Holding Corp.

The company also continued expanding payer access, with coverage reaching approximately 166 million covered lives, or 53% of U.S. covered lives, following the addition of two managed Medicare agreements and expanded commercial and Medicaid access. Tonix completed its planned sales force expansion in September, bringing its commercial organization to approximately 150 representatives, and management believes the larger sales force is contributing to increased prescriber engagement and prescription growth.

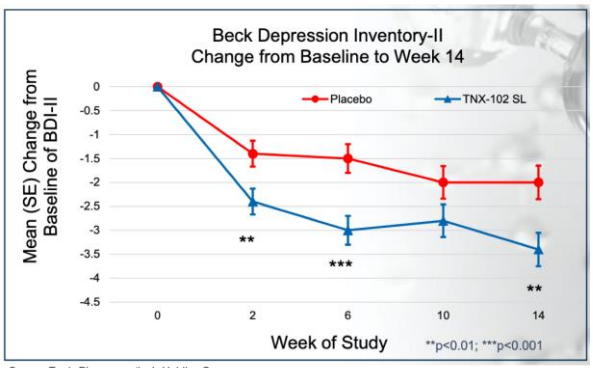
During the quarterly conference call, management highlighted several encouraging trends. The company indicated that gross-to-net was more favorable than expected during 3Q26, although it continues to expect fluctuations as the launch progresses. In addition, management made note of increasing prescription approval rates, continued strong prior authorization rates, and a declining percentage of prescriptions originating through the bridge program, with a favorable conversion rate from bridge to commercially reimbursed prescriptions. These trends suggest that expanded payer coverage is beginning to translate into improved access and monetization. Management also cited growing physician awareness, with >80% of healthcare providers surveyed recognizing Tonmya when prompted.

HORIZON Trial in MDD Continues

In June 2026, Tonix announced that the first patient was enrolled into the HORIZON trial. It is a randomized, double blind, placebo controlled Phase 2 study that is evaluating TNX-102 SL 5.6 mg as a first-line monotherapy in adults with major depressive disorder (MDD). Approximately 360 patients are expected to be enrolled across approximately 30 U.S. sites. The primary endpoint is the change from baseline in the Montgomery-Asberg Depression Rating Scale (MADRS) total score at Week 6. Tonix has positioned this study as "potentially pivotal", thus instead of functioning as an exploratory proof-of-concept study, the trial is designed to generate data that could potentially support a regulatory pathway with fewer additional clinical steps if the results are sufficiently robust and the FDA agrees with the development strategy.

The support for evaluating TNX-102 SL as a treatment for depression stems from results of TNX-102 SL in fibromyalgia and post-traumatic stress disorder (PTSD) clinical trials. For example, in the RESILIENT Phase 3 trial,

there was a greater reduction in the total Beck Depression Inventory-II score in the TNX-102 SL cohort compared to placebo at Week 14 with an effect size of 0.27, as shown in the following figure.



Source: Tonix Pharmaceuticals Holding Corp.

Update on TNX-4800

Tonix is developing TNX-4800 (formerly 2217LS), a long-acting, human monoclonal antibody (mAb) prophylactic treatment for the prevention of Lyme disease. It is being developed for annual seasonal use in the spring to protect against Lyme disease through the entire tick season in the U.S. There are currently no FDA-approved vaccines or prophylactics to protect against Lyme disease.

The company recently conducted a Type C meeting with the FDA early in the third quarter of 2026 with the final meeting minutes showing agency support for an adaptive Phase 2 field study in 1Q27, subject to final FDA review and agreement on the study protocol. It will be a randomized, double blind, placebo controlled, adaptive Phase 2 field study to evaluate the efficacy of a two-dose subcutaneous regiment of TNX-4800 in preventing the first occurrence of confirmed Lyme disease during the primary efficacy surveillance period (Day 3 through Month 6 following administration). Each fixed dose is expected to provide exposures comparable to the 5 mg/kg dose evaluated in the Phase 1 trial. The first dose will be administered in the Spring and the second booster dose will be administered three months later. Eligible participants will be adults 18 years of age and older in Lyme-endemic areas in the U.S. The primary endpoint will be the prevention of Lyme disease for six months (comparison of TNX-4800 group and placebo group) from the initial dose. A key secondary endpoint will be protection through three months.

The study will be conducted over (at least) two years. The lead-in cohort will be focused on safety, while also capturing efficacy, and will enroll approximately 500 participants in 2027. Enrollment is expected to initiate in the first quarter of 2027, will include a Data Safety Monitoring Board (DSMB) review after the second dose, and the results will contribute to the final efficacy analysis. The second cohort, focused on efficacy, is expected to begin in 2028 (following DSMB clearance) and enroll approximately 2,800 additional participants, with a third cohort possible in 2029 depending on Lyme disease incidence. The participants being targeted for the study are those involved in occupational or outdoor activities, who reside, work, or travel to Lyme-endemic regions, and who are interested in preventative medicine.

Dr. Reddy's Laboratories Files Paragraph IV ANDA

Dr. Reddy's Laboratories has filed an Abbreviated New Drug Application (ANDA) containing a Paragraph IV patent certification with the U.S. FDA for a generic version of Tonmya. The Paragraph IV patent certification was made with respect to U.S. Patent Nos. 9,636,408, 9,956,188, 10,117,936, and 10,864,175 listed in the FDA's "Orange Book". A Paragraph IV patent certification is a certification by a generic applicant that, in the opinion of the applicant, the patent(s) listed in the Orange Book for a branded product is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the generic product.

On November 13, 2026, Tonix filed a complaint for patent infringement against Dr. Reddy's in the U.S. District Court for the District of New Jersey. The complaint alleges that by filing the ANDA, Dr. Reddy's has infringed certain of Tonix's patents in the Orange Book and seeks an order that the effective date of FDA approval of the ANDA should be no earlier than the expiration of the last to expire of the asserted patents. The complaint filing triggers a statutory stay of final FDA approval of Dr. Reddy's ANDA for up to 30 months, subject to applicable exceptions and court orders.

Financial Update

On November 9, 2026, Tonix announced financial results for the third quarter of 2026. Net product revenues for the third quarter of 2026 were approximately $17.2 million compared to $3.3 million for the third quarter of 2025. Net revenue from sales of Tonmya for the third quarter was approximately $15.0 million while net revenue from sales of Zembrace and Tosymra was approximately $2.2 million. Cost of sales in the third quarter of 2026 was approximately $1.3 million compared to $1.4 million for the same time period in 2025. The decrease in the cost of sales was primarily due to a change in product mix.

R&D expenses for the third quarter of 2026 were $25.8 million, compared to $9.3 million for the third quarter of 2025. The increase was primarily due to higher manufacturing and clinical trial costs associated with advancing the company's prioritized pipeline programs along with increased employee-related costs reflecting increased headcount. G&A expenses for the third quarter of 2026 were $45.6 million, compared to $25.7 million for the third quarter of 2025. The increase was primarily due to spending on sales and marketing related to Tonmya along with increased employee-related and professional expenses.

As of September 30, 2026, Tonix had approximately $162.8 million in cash and cash equivalents. Subsequent to the end of the quarter, the company raised approximately $1.5 million in proceeds utilizing its at-the-market (ATM) facility. We estimate that the company's current cash position will finance operations into early third quarter of 2027 but not beyond. As of November 6, 2026, Tonix had approximately 19.4 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of 22.3 million.

Conclusion

Tonmya's launch continues to demonstrate encouraging prescription and revenue growth, supported by expanding payer access, improving refill activity, and a larger commercial organization. We remain encouraged by the commercial trajectory and are confident that the company will be able to translate prescription growth into sustained revenue expansion. At the same time, we're encouraged by the continued advancement of the pipeline, with the HORIZON study in MDD continuing to enroll patients and the expected initiation of the Phase 2 study of TNX-4800 in the first quarter of 2027. With a cash runway into the third quarter of 2027, we've added the need for additional financings into our model, which has decreased our valuation to $56.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2025 A	Q1 A	Q2 A	Q3 A	Q4 E	2026 E	2027 E	2028 E
Tonmya	$1.4	$3.7	$11.0	$15.0	$17.0	$46.7	$85.0	$150.0
Zembrace / Tosymra	$11.7	$3.1	$2.6	$2.2	$2.5	$10.4	$11.5	$12.0
Research & Collaborations	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$13.1**	**$6.9**	**$13.6**	**$17.2**	**$19.5**	**$57.2**	**$96.5**	**$162.0**
CoGS	$6.6	$1.6	$0.7	$1.3	$1.1	$4.6	$8.3	$15.8
Product Gross Margin	*49.3%*	*77.1%*	*94.8%*	*92.7%*	*94.4%*	*91.9%*	*91.4%*	*90.2%*
R&D	$44.5	$18.2	$19.4	$25.8	$27.0	$90.5	$120.0	$133.0
SG&A	$87.7	$28.6	$36.0	$45.6	$48.0	$158.2	$190.0	$200.0
Asset Impairment Charge	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($125.7)	($41.5)	($42.5)	($55.4)	($56.6)	($196.1)	($221.8)	($186.8)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$1.7	$1.3	$2.0	$2.1	$2.0	$7.4	$5.0	$5.0
Pre-Tax Income	($124.0)	($40.2)	($40.5)	($53.3)	($54.6)	($188.7)	($216.8)	($181.8)
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%*	*100%*
Net Income	($124.0)	($40.2)	($40.5)	($53.3)	($54.6)	($188.7)	($216.8)	($181.8)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($14.57)**	**($2.93)**	**($2.44)**	**($2.89)**	**($2.73)**	**($10.97)**	**($7.23)**	**($4.55)**
YOY Growth	*-100.0%*	-	-	-	-	*-100.0%*	*-99.9%*	*-100.0%*
Weighted Shares Outstanding	8.5	13.7	16.6	18.4	20.0	17.2	30.0	40.0

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

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