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September 26, 2023
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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Encouraging Topline Results for Long COVID Trial…

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 $8.00/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 (09/26/23)	$0.79
Valuation	**$8.00**

OUTLOOK

On August 10, 2023, Tonix Pharmaceuticals Holding Corp. (TNXP) announced financial results for the second quarter of 2023 and provided a business update. The company recently announced topline results for the proof-of-concept PREVAIL study of TNX-102 SL in Long COVID, which showed a robust effect size of 0.5 in PROMIS fatigue at Week 14. The company will have an 'End-of-Phase 2' meeting with the FDA in the 1Q24 to discuss a Phase 3 program in Long COVID. We continue to anticipate data from additional trials for fibromyalgia, chronic migraine, and depression in the 4Q23. The results for the Phase 3 RESILIENT trial in fibromyalgia, if successful, would be the final efficacy trial required to submit a New Drug Application (NDA) for TNX-102 SL. Recently, academic collaborators have initiated three Phase 2 investigator-initiated studies of TNX-1900 for the treatment of adolescent obesity, binge eating disorder, and social anxiety. The company also recently initiated a Phase 1 trial of TNX-1500 in healthy volunteers, which is designed to support a planned Phase 2 trial in prevention of kidney transplant rejection.

SUMMARY DATA

52-Week High	**$8.13**
52-Week Low	**$0.79**
One-Year Return (%)	**-76.15**
Beta	**2.20**
Average Daily Volume (sh)	**157,629**
Shares Outstanding (mil)	**18**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
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 2023 Estimate	**-0.1**
P/E using 2024 Estimate	**-0.2**

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)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 A	6 E	6 E	11 E
2024					23 E
2025					23 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$10.12 A	-$7.64 A	-$4.32 A	-$3.42 A	-$20.44 A
2023	-$3.26 A	-$2.68 A	-$1.66 E	-$1.62 E	-$8.53 E
2024					-$3.86 E
2025					-$3.07 E

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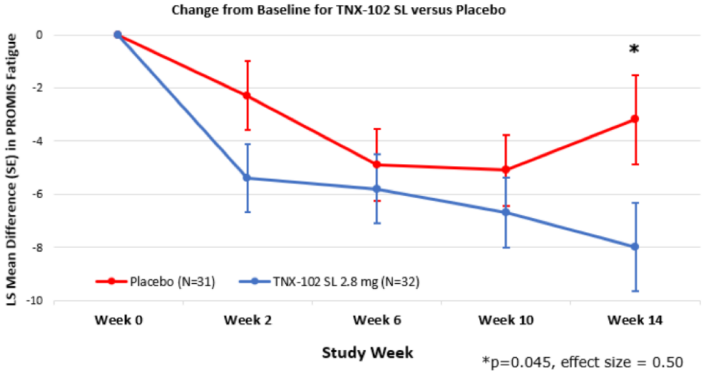
Business Update

Encouraging Topline Results for LONG Covid Study

On September 5, 2023, Tonix Pharmaceuticals Holding Corp. (TNXP) announced encouraging topline results for the proof-of-concept PREVAIL study of TNX-102 SL for the management of fibromyalgia-like Long COVID. The PREVAIL study was a randomized, double blind, placebo controlled, multi-site, proof-of-concept study of 63 participants with laboratory-confirmed COVID-19 infection preceding a diagnosis of Long COVID (NCT05472090).

While the trial did not meet the primary endpoint of multi-site pain reduction at week 14, there was a robust effect size of 0.5 in improving fatigue along with consistent activity across secondary measures of sleep quality, cognitive function, disability, and Patient Global Impression of Change (PGIC). The following graph shows the change from baseline in PROMIS Fatigue over the 14 weeks of the trial. These results are important as fatigue has been shown to be one of the main symptoms of Long COVID and is the symptom most closely related to functional impairment (Walker *et al.*, 2023).

Figure 4. PROMIS Fatigue

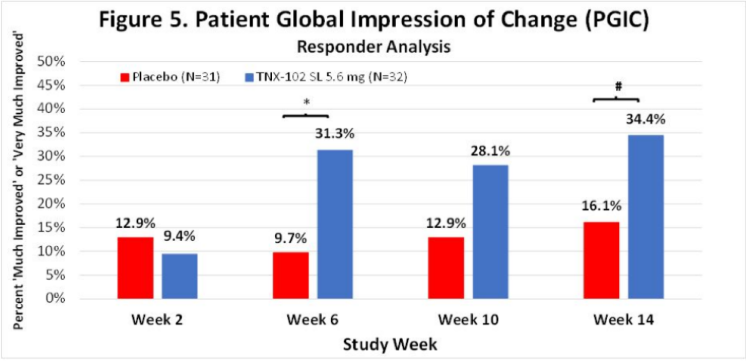


Abbreviations: LS, least squares; SE, standard error

Source: Tonix Pharmaceuticals Holding Corp.

In addition to showing an effect size of 0.5 in PROMIS fatigue, the following graph shows the PGIC over the course of the study. The percentage of patients who were "much improved" or "very much improved" at Week 14 was 34.4% for TNX-102 SL compared to 16.1% for placebo (*P*=0.096). There was also a statistically significant difference between the TNX-102 SL cohort and the placebo cohort at Week 6 (31.3% vs. 9.7%; *P*=0.034).

Figure 5. Patient Global Impression of Change (PGIC)



*p=0.034, #p=0.096

Source: Tonix Pharmaceuticals Holding Corp.

The company is planning to conduct an 'End-of-Phase 2' meeting with the FDA to discuss the results of the PREVAIL trial, which we anticipate occurring in the first quarter of 2024. At that meeting, Tonix will propose the use of PROMIS fatigue as a primary endpoint. Given how new Long COVID is, the FDA does not have a validated outcome to serve as a primary endpoint for a Phase 3 registration trial. However, given that fatigue is one of the most common symptoms of Long COVID, we believe the PROMIS fatigue scale is likely to be deemed acceptable as a primary endpoint for a Phase 3 trial. In support of this, PROMIS measures have demonstrated clinical validity across a range of chronic conditions (Cook *et al*., 2016).

Three Additional CNS Data Readouts in 2H23

Tonix is anticipating data readouts from clinical trials for three additional central nervous system (CNS) development products in the second half of 2023:

- In late December 2023, we anticipate topline results from the Phase 3 RESILIENT trial, which is a randomized, double blind, placebo controlled potentially pivotal study of TNX-102 SL 5.6 mg for the treatment of fibromyalgia. Tonix previously announced that it eliminated the interim analysis of the RESILIENT trial to ensure that topline data will be available in the fourth quarter of 2023. On August 1, 2023, the company announced enrollment was complete with a total of 457 participants.

  In December 2020, Tonix announced positive topline results for the Phase 3 RELIEF study of TNX-102 SL 5.6 mg (primary endpoint, *P*=0.010). Thus, since Tonix has already conducted one positive trial in fibromyalgia, positive results (a *P* value < 0.05) from the RESILIENT study could put the company in position to file a new drug application (NDA) for TNX-102 SL 5.6 mg for the management of fibromyalgia.

- In early November 2023, we anticipate topline results for the Phase 2 UPLIFT trial of TNX-601 ER for the treatment of major depressive disorder (MDD). In July 2023, Tonix announced that TNX-4300 (estianeptine), the single (S)-isomer of tianeptine, will be prioritized over TNX-601 ER, however TNX-601 ER will continue to be advanced if positive results are achieved in the UPLIFT trial. The threshold for achieving proof-of-concept is an effect size > 0.2 and the threshold for this being a potential registrational study is a *P* value < 0.05. The prioritization of TNX-4300 follows recent findings that showed estianeptine is able to improve memory and cognition *in vivo* as measured in the rat Novel Object Recognition (NOR) test along with the ability to restore neuroplasticity to neurons *in vitro*. Due to this, Tonix accelerated the completion of the Phase 2 UPLIFT trial to reallocate resources to the preclinical development of TNX-4300.

- In early December 2023, we anticipate topline results from the Phase 2 PREVENTION study of potentiated intranasal oxytocin (TNX-1900) for the prevention of migraine headaches in chronic migraineurs. It is a double blind, randomized, multicenter, placebo controlled study with three arms: two treatment regimens of TNX-1900 and one of placebo in a 1:1:1 ratio. After a four-week run-in phase to confirm chronic migraine criteria are met, the participants were treated for 12 weeks followed by a two-week safety follow up. The primary efficacy endpoint is the mean change in the number of migraine headache days between the 28-day run-in phase and the last 28-days of the treatment phase. The threshold for achieving proof-of-concept is an effect size > 0.2.

Background Info on TNX-1900

A migraine is a headache that can cause severe pain, can last up to 72 hours, has a pulsing quality, and may be associated with nausea, vomiting, phonophobia, or photophobia. Approximately one billion individuals in the world suffer from migraine headaches (GBD 2016 Headache Collaborators). In the U.S., migraines affect approximately 72 million individuals (Gooch *et al*., 2017). Chronic migraine, which is defined as having a headache at least 15 times a month for three months, eight of which are migraines, is less common (1-5% of migraine sufferers). While not a fatal condition, migraines still contribute to a significant decrease in quality of life and the total estimated cost of all migraine headaches is approximately $78 billion per year (Gooch *et al*., 2017).

Migraine treatments are classified as abortive (intended to stop a migraine once it begins) or prophylactic (decrease the frequency and/or severity of migraines). Abortive treatments include triptans and a ditan (which specifically target serotonin receptors), over the counter medications (that typically include some combination of a nonsteroidal anti-inflammatory drug (NSAID), acetaminophen, and/or caffeine), ergots, and calcitonin gene-related peptide (CGRP) antagonists. By 2028, the market for migraine treatments is estimated to be approximately $12 billion (EvalutePharma).

Tonix recently acquired two currently-marketed migraine products: Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg. Combined sales for the two products combined were approximately $23 million in 2022 (IQVIA). Recently, Tonix announced that GlaxoSmithKline (GSK) informed the U.S. FDA of its plan to discontinue Imitrex® nasal spray 5 mg and 20 mg products after January 2024. Tonix is preparing for potential increased demand for Tosymra, which is approved on the basis of bioequivalence to Imitrex injection 4 mg.

Treatments that target CGRP are forecast to be the market leaders in the next few years. Gepants are small molecule drugs that block the CGRP receptor and are effective at both relieving migraines and preventing them. There are four FDA approved gepants: Nurtec® (rimgepant), Ubrelvy® (ubrogepant), Qulipta® (atogepant), and Zavzpret® (zavegepant). Antibodies that target the CGRP pathway include Aimovig® (erenumab), which targets the CGRP receptor, and Ajovy® (fremanezumab), Emgality® (galcanezumab), and Vyepti® (eptinezumab), which each target CGRP. 2022 revenues and projected 2028 revenues for each of these medications is given below.

		Revenues ($mln)	
Product	**Company**	**2022**	**Projected 2028**
Nurtec	Pfizer	$211	$3,623
Ubrelvy	AbbVie	$680	$1,311
Qulipta	AbbVie	$158	$1,116
Zavzpret	Pfizer	-	$458
Aimovig	Amgen	$398	$470
Ajovy	Teva	$377	$635
Emgality	Eli Lilly	$486	$747
Vyepti	Lundbeck	$144	$500

Source: EvaluatePharma/Zacks SCR

Oxytocin in Migraine

While the exact cause of migraines remains to be elucidated, it appears to be associated with the hypothalamus and its connections with the spinal trigeminal nuclei and sensory trigeminovascular system, thus neuromodulators that target the trigeminal pathway could prove effective in migraines.

Oxytocin is a nine amino acid peptide hormone that is involved in a wide array of biological processes, including learning and memory, anxiety, addiction, feeding behavior, maternal behavior, and processing of social information (Cilz *et al*., 2019). A review of the available literature showed that in 29/33 animal studies oxytocin increased “pain” tolerance (Rash *et al*., 2014), which suggests it may act as an analgesic. Circumstantial evidence shows that oxytocin may be an effective migraine treatment based on the fact that increased oxytocin levels in pregnancy and during breastfeeding correlates with decreased migraine occurrence (Hoshiyama *et al*., 2012) and some women who suffer from migraines report that sex (which results in a surge in oxytocin levels) provides at least temporary relief from the condition (Hambach *et al*., 2013).

While the potential for oxytocin as a treatment for migraine headaches appears promising, getting oxytocin to the trigeminal system is challenging due to the fact that: 1) oxytocin is a small peptide that is broken down almost immediately in the gastrointestinal system; and 2) its half-life in the blood stream is very short (3-5 min) with only limited ability to cross the blood-brain barrier, thus eliminating the availability of oral or parenteral administration. But delivered intranasally, oxytocin permeates the nasal mucosa and is transported along the trigeminal nerve pathway to the trigeminal ganglion where it can inhibit release along trigeminal neurons that synapse within the lining of the dura mater and inhibit CGRP release. Additionally, the most direct way to bypass the blood brain barrier and gain access to the CNS could be nasal administration along olfactory and trigeminal pathways to the brain (Dhuria *et al*., 2010).

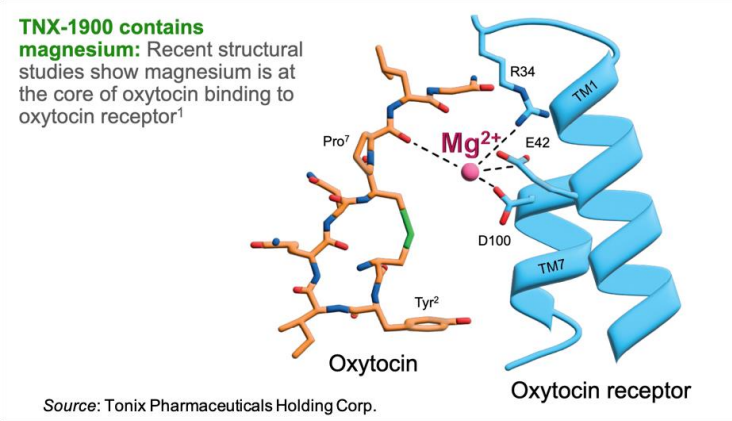
Multiple preclinical studies have examined the potential for oxytocin as a migraine treatment. Oxytocin receptors are present in rat trigeminal neurons, and the vast majority of neurons that express oxytocin receptors also express CGRP (Tzabazis *et al*., 2016). Intranasal administration of radiolabeled oxytocin in rats results in a very high concentration of oxytocin in all three branches of the trigeminal nerve and trigeminal ganglion (Tzabazis *et al*., 2017). Administration of nitroglycerin triggers migraine headaches in patients (Sances *et al*., 2004), thus intraperitoneal injection of nitroglycerin is utilized in a rat model of migraine (Ma *et al*., 2008). This model results in expression of *C-fos* in multiple trigeminal neurons (a marker for trigeminal nerve activation), however pre-treatment

with intranasal oxytocin markedly reduces the expression of *C-fos*, thus pointing to a potential role of oxytocin in preventing pain transmission.

Clinical Evaluation of Oxytocin

A Phase 2 clinical trial of intranasal oxytocin was previously conducted by Trigemina, Inc., from which Tonix acquired TNX-1900 in June 2020. This was a double blind, placebo controlled trial in 218 mostly female migraine sufferers (143 on oxytocin; 75 on placebo) and was conducted in Chile, Australia, and New Zealand (NCT01839149). The trial consisted of a 28-day "run-in" period to establish a baseline of migraine days followed by 56 days of "as needed" dosing with either intranasal oxytocin or placebo. Results showed that while intranasal oxytocin was well tolerated, the study did not meet the primary endpoint of a reduction in migraine headache days from baseline. This was mostly due to an extremely high placebo response rate at the clinical sites in Chile, which was 74%, while subjects from New Zealand and Australia experienced a normal placebo response and showed a statistically significant difference between active and placebo groups (Tzabazis *et al*., 2017).

Based on results of preclinical studies demonstrating enhanced analgesic activity of oxytocin mediated by the oxytocin receptor in the presence of magnesium, Trigemina developed a proprietary, potentiated formulation of oxytocin containing magnesium. Tonix acquired the intellectual property for this formulation (TNX-1900). The following image shows how magnesium is involved in oxytocin binding to its receptor (Meyerowitz *et al*., 2022).



Source: Tonix Pharmaceuticals Holding Corp.

Additional lines of evidence exist that support the role of magnesium in migraine and its potentiation of oxytocin/oxytocin receptor binding. Serum magnesium levels are an independent risk factor for migraine headaches (Assarzadegan *et al*., 2016). In addition, magnesium has been used in migraine prophylaxis and treatment (Dolati *et al*., 2020). In an *in vivo* study, oxytocin supplemented with magnesium induced craniofacial analgesia on the withdrawal response time to noxious heat stimulation of the cheek of pre-inflamed rats (e.g., it increased their pain tolerance) (Bharadwaj *et al*., 2022).

Tonix has completed enrollment in the proof-of-concept Phase 2 PREVENTION study of TNX-1900 for the prevention of migraine headache in chronic migraineurs with a total of 88 subjects enrolled. We anticipate topline results from the study in the fourth quarter of 2023.

Additional Studies for TNX-1900

Tonix has recently announced three investigator-sponsored clinical trials and one research collaboration for TNX-1900:

- On July 10, 2023, Tonix announced the first patient was enrolled in the Phase 2 POWER trial of TNX-1900 for the treatment of pediatric obesity. The investigator-initiated study is being conducted at Massachusetts General Hospital that is expected to enroll approximately 75 participants 12-18 years old for the 12-week, double blind, placebo controlled trial.

- On July 17, 2023, Tonix announced the first patient was enrolled in the Phase 2 investigator-initiated, proof-of-concept study of TNX-1900 for the enhancing social safety learning in social anxiety disorder. The study is taking place at the University of Washington. A total of 100 subjects are expected to be enrolled 1:1 to receive TNX-1900 or placebo. The primary objective is to examine the potential role of TNX-1900 in enhancing vicarious extinction leaning in social anxiety disorder.

- On July 31, 2023, Tonix announced the first patient was enrolled in the investigator-initiated Phase 2 STROBE study of TNX-1900 for the treatment of binge eating disorder. The study is taking place at Massachusetts General Hospital. It is an 8-week trial that is expected to enroll approximately 60 subjects 18-45 years old with binge eating disorder. The primary endpoint is 8-week change from baseline in binge frequency.

- On May 22, 2023, Tonix announced a research collaboration with Erasmus University Medical Center to evaluate the effect of TNX-1900 on capsaicin- or electrical stimulation-induced forehead dermal blood flow in healthy human female volunteers.

Phase 1 Trial for TNX-1500 Underway

On August 16, 2023, Tonix announced the initiation of a Phase 1 single ascending dose trial of TNX-1500 in healthy volunteers. The trial is designed to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of intravenous (IV) TNX-1500. We anticipate approximately 36 participants being enrolled and evaluated regularly over a 120-day period after dosing. The results of the trial are intended to support a planned Phase 2 trial in kidney transplant recipients.

TNX-1500 is a third-generation anti-CD40 ligand (CD40L) monoclonal antibody (mAb) that is being developed for the prevention of allograft rejection, xenotransplantation, and the treatment of autoimmune disease. Development of first-generation anti-CD40L mAbs had to be halted after multiple reports of thromboembolic complications (Kawai *et al*., 2000). This risk is thought to result from the IgG constant region interacting with FcγRIIA (Robles-Carrillo *et al*., 2010). Second- and third-generation anti-CD40L mAbs have been engineered to reduce binding to FcγRIIA, and while second-generation molecules have exhibited decreased efficacy, TNX-1500 is designed to preserve FcRn function and deliver efficacy without an increased safety risk.

Financial Update

On August 10, 2023, Tonix announced financial results for the second quarter of 2023. As expected, the company did not report any revenues for the second quarter of 2023. Net loss available to common shareholders for the second quarter of 2023 was $28.4 million, or $2.68 per share, compared to a net loss available to common shareholders of $27.4 million, or $7.64 per share for the second quarter of 2022. The weighted average common shares outstanding for the second quarter of 2023 were approximately 10.6 million compared to approximately 3.6 million in the second quarter of 2022.

R&D expenses for the second quarter of 2023 were $22.0 million, compared to $16.6 million for the second quarter of 2022. The increase was primarily due to increased clinical development expenses, employee-related expenses, lab supplies, building expenses, and professional fees. G&A expenses for the second quarter of 2023 were $7.0 million, compared to $6.8 million for the second quarter of 2022. The increase was primarily due to increased legal expenses partially offset by a decrease in employee-related expenses.

As of June 30, 2023, Tonix had approximately $25.6 million in cash and cash equivalents. Subsequent to the end of the quarter, Tonix raised gross proceeds of $7.0 million from a public offering of common stock. As of August 9, 2023, Tonix had approximately 17.8 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 26.2 million.

Conclusion

The results from the PREVAIL trial are encouraging and we look forward to the outcome of the 'End-of-Phase 2' meeting with the FDA in the first quarter of 2024, at which time we should get additional details regarding the Phase 3 program for TNX-102 SL in Long COVID. We anticipate data from three separate CNS trials between now and the end of 2023 in fibromyalgia, chronic migraine, and depression. Positive results from the Phase 3 trial in fibromyalgia could potentially lead to an NDA filing. We also anticipate the company initiating a Phase 2 clinical trial of TNX-1300 in the third quarter of 2023. After accounting for the recent financing our valuation is now $8.00 per share.

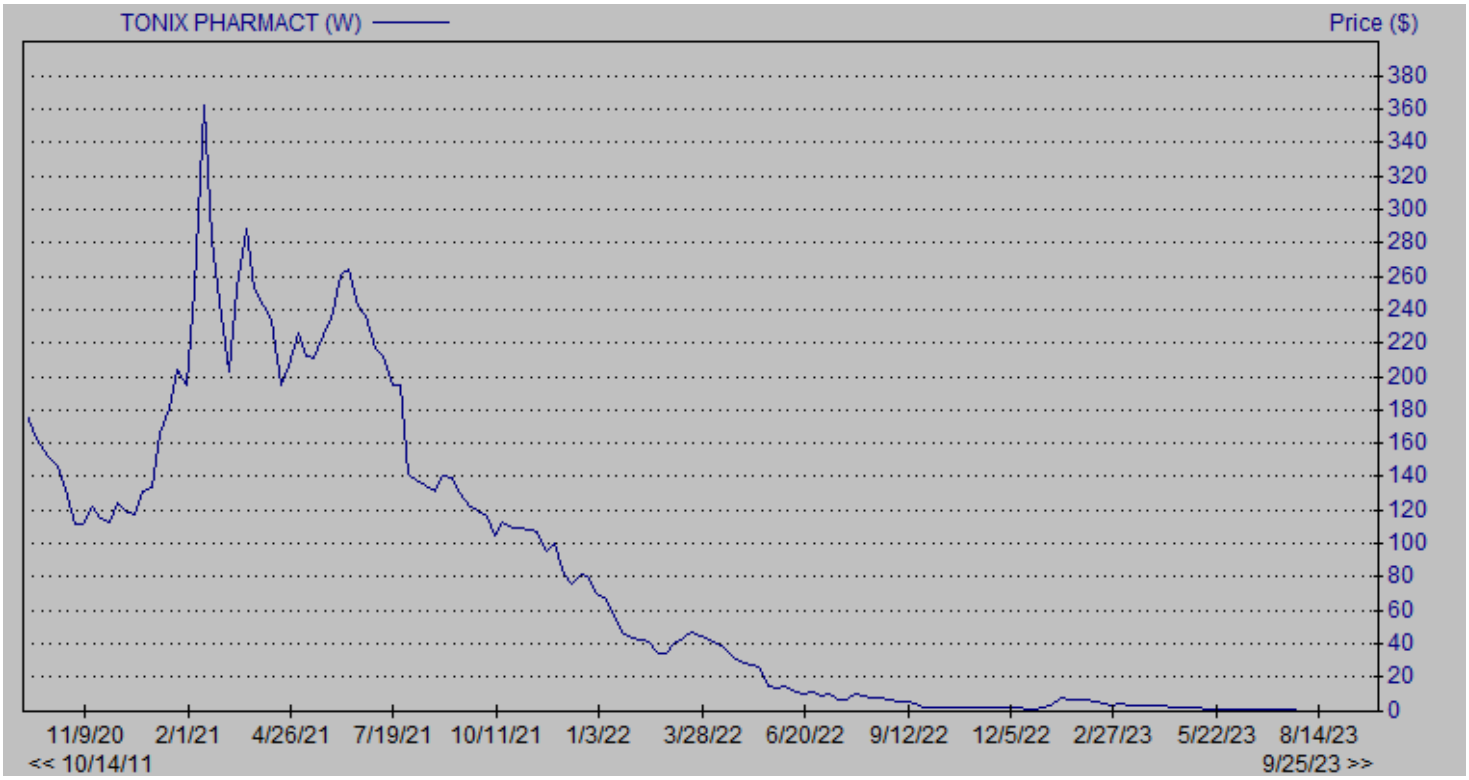
PROJECTED FINANCIALS

Tonix Pharmaceuticals	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
TNX-102 SL (FM)	$0	$0	$0	$0	$0	$0	$0	$0
Zembrace / Tosymra	$0	$0	$0	$6	$6	$11	$23	$23
Research & Collaborations	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$6**	**$6**	**$11**	**$23**	**$23**
CoGS	$0.0	$0	$0	$1	$1	$2.8	$5.7	$5.7
Product Gross Margin	-	-	-	*74.5%*	*74.5%*	*74.5%*	*75.2%*	*75.2%*
R&D	$81.9	$26.5	$22.0	$23.0	$24.0	$95.5	$95.0	$100.0
SG&A	$30.2	$7.4	$7.0	$10.0	$10.0	$34.4	$40.0	$42.0
Operating Income	($112.1)	($33.9)	($29.0)	($28.9)	($29.9)	($121.7)	($117.7)	($124.7)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$1.9	$0.9	$0.6	$0.6	$0.8	$2.9	$2.0	$2.0
Pre-Tax Income	($110.2)	($33.0)	($28.4)	($28.3)	($29.1)	($118.8)	($115.7)	($122.7)
Preferred Stock Deemed Dividend	$6.7	$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	($116.9)	($33.0)	($28.4)	($28.3)	($29.1)	($118.8)	($115.7)	($122.7)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($20.44)**	**($3.26)**	**($2.68)**	**($1.66)**	**($1.62)**	**($8.53)**	**($3.86)**	**($3.07)**
YOY Growth	*56.7%*	-	-	-	-	*-83.4%*	*-92.5%*	*-69.7%*
Weighted Shares Outstanding	5.7	10.1	10.6	17.0	18.0	13.9	30.0	40.0

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

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HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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