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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Tonmya™ May Launch Alongside Another New Fibromyalgia Treatment…

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 $1.50/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 (03/12/24)	$0.36
Valuation	**$1.50**

OUTLOOK

Tonix Pharmaceuticals Holding Corp. (TNXP) will be filing a New Drug Application (NDA) for TNX-102 SL (cyclobenzaprine HCl) in the second half of 2024 based on positive results from the Phase 3 RELIEF and RESILIENT trials. The last fibromyalgia treatment was approved by the FDA in 2009, however along with TNX-102 SL there may be another NDA filed by Axsome Therapeutics for AXS14 (esreboxetine) for the treatment of fibromyalgia. Axsome in-licensed esreboxetine from Pfizer in 2020, including results from a positive Phase 3 and a positive Phase 2 trial. Tonix is currently preparing for a commercial launch of Tonmya™ (conditionally accepted trade name for TNX-102 SL in fibromyalgia) and pursuing regional commercialization deals.

SUMMARY DATA

52-Week High	**$4.41**
52-Week Low	**$0.27**
One-Year Return (%)	**-91.78**
Beta	**2.28**
Average Daily Volume (sh)	**1,223,995**
Shares Outstanding (mil)	**59**
Market Capitalization ($mil)	**$21**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
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 2024 Estimate	**-0.1**
P/E using 2025 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	4 A	4 E	8 E
2024					18 E
2025					19 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	-$1.83 A	-$1.64 E	-$8.80 E
2024					-$2.69 E
2025					-$1.91 E

WHAT'S NEW

Business Update

Two New FDA Approved Fibromyalgia Treatments Possible in 2025

In the second half of 2024, Tonix Pharmaceuticals Holding Corp. (TNXP) will be filing a new drug application (NDA) for TNX-102 SL (conditionally accepted trade name Tonmya™) for the treatment of fibromyalgia. The filing will be based in part on the positive results from the Phase 3 RESILIENT and RELIEF trials. For an overview of results from the RESILIENT trial see our previous report here and for an overview of the results from the RELIEF trial see our previous report here.

In addition to Tonix filing an NDA for TNX-102 SL for the treatment of fibromyalgia, we also anticipate Axsome Therapeutics (AXSM) filing an NDA for AXS-14 (esreboxetine) for the treatment of fibromyalgia in the first half of 2024. Esreboxetine is a highly selective norepinephrine reuptake inhibitor and the active enantiomer of reboxetine, which is an antidepressant sold in Europe. AXS-14 was in-licensed from Pfizer in 2020 and included results from a positive Phase 2 (Arnold *et al*., 2010) and a positive Phase 3 (Arnold *et al*., 2012) clinical trial of esreboxetine in fibromyalgia. In both trials, treatment with esreboxetine resulted in significantly greater improvement in the weekly mean pain score compared with the placebo group. The most common side effects included insomnia, constipation, dry mouth, nausea, and dizziness.

Axsome is filing for approval of AXS-14 under the 505(b)(1) pathway while Tonix is filing for approval of Tonmya under the 505(b)(2) pathway. We anticipate Axsome filing the NDA for AXS-14 in the first half of 2024 while Tonix will be filing the NDA for Tonmya in the second half of 2024. This puts both drugs on track to potentially be approved in 2025.

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 (many fibromyalgia patients skip doses or discontinue treatment in the first few months of therapy), has blockbuster potential. In addition, none of the currently approved therapies address the common symptoms of pain, poor sleep, and fatigue simultaneously.

Commercialization Plans for Tonmya

There are numerous examples of CNS-focused companies that have developed a drug through the NDA filing and gone on to commercialize those drugs on their own. As the following table shows, those companies each have market caps in excess of $1 billion, with Biohaven having been acquired for $12 billion following a successful commercial launch of Nurtec ODT that effectively de-risked the asset.

Company	Ticker	Market Cap ($B)	Product	Indication	2023 Sales ($M)
Axsome Therapeutics	AXSM	$3.9	Auvelity®	Depression	$130
Intracellular Therapies	INTC	$6.9	Caplyta®	Schizophrenia	$462
Supernus Pharmaceuticals	SUPN	$1.7	Oxtella-XR®	Seizures	$113
Neurocrine Biosciences	NBIX	$13.1	Ingrezza®	Tardive Dyskinesia	$1,836
Acadia Pharmaceuticals	ACAD	$4.0	Nuplazid®	Parkinsons's Psychosis	$549
Biohaven Ltd*	BHVN	$4.1	Nurtec®	Migraine	$928

Source: Zacks SCR; EvaluatePharma; Company reports

*Acquired by Pfizer for $12B in Oct 2022

Tonix has been developing a commercialization unit since the acquisition of the marketed products Zembrace and Tosymra, which are both indicated for the treatment of acute migraine in adults. Thus, Tonix will not be establishing commercial operations for Tonmya from scratch but will be building upon the infrastructure that already exists. Tonix has selected EVERSANA, a leading provider of commercialization services In addition, a substantial portion of drug marketing is done virtually now with fewer face to face interactions between sales representatives and physicians, thus limiting the size of the sales force that is necessary to successfully market a drug.

Tonmya and AXS-14 Only Near-Term Potential Fibromyalgia Treatments

In January 2024, Vertex Pharmaceuticals (VRTX) announced positive results from a Phase 3 clinical trial of VX-548, a non-opioid NaV1.8 inhibitor, for the treatment of moderate-to-severe acute pain in both abdominoplasty and bunionectomy. Vertex is expected to file an NDA for VX-548 for the treatment of moderate-to-severe acute pain in mid-2024. While VX-548 appears to be effective as a treatment for acute pain, we don't believe the drug will have any impact in fibromyalgia patients due to its mechanism of action and thus should not be considered a competitor to Tonmya.

The NaV1.8 voltage-gated sodium channel is expressed in peripheral nociceptive neurons and plays a critical role in transmitting nociceptive pain (actual or threatened damage to non-neural tissue). In contrast, fibromyalgia is characterized by nociplastic pain, which is pain that arises from altered pain sensation despite no clear evidence of actual or threatened tissue damage or for disease or lesion of the somatosensory system. Thus, there is no reason to believe that VX-548 would be successful in treating fibromyalgia patients just as there is no reason to believe that Tonmya would be effective in treating moderate-to-severe acute pain since it is a centrally acting analgesic. What the two drugs do share in common is that they are both non-opioid analgesics, which is critically important at a time when the opioid epidemic continues in the U.S.

Additional Efficacy Data Presented for RESILIENT Trial

On March 11, 2024, Tonix announced the presentation of additional efficacy data from the Phase 3 RESILIENT study of Tonmya in patients with fibromyalgia. The company reported the effect sizes for the five continuous key secondary outcomes, which ranged from 0.3 to 0.5. In addition, treatment with Tonmya resulted in an improvement in cognitive dysfunction, or 'brain fog', as measured by the change in the Fibromyalgia Impact Questionnaire-Revies (FIQ-R) memory item. The FIQ-R cognitive item showed nominal improvement in Tonmya-treated patients compared to placebo with a *P*=0.001 and an effect size of 0.31. These results show the wide-ranging positive effects that Tonmya has in fibromyalgia patients.

Pursuing Regional Business Development Deals

In February 2024, Tonix announced positive results from a clinical pharmacokinetic (PK) bridging study of Tonmya in healthy adult male and female ethnic Japanese and Chinese volunteers. These data are expected to fulfill the requirement for a bridging study and to support regulatory filings in Japan and China where cyclobenzaprine is a new chemical entity. Tonix plans to file a Clinical Trial Notification (CTN) in Japan and Investigational New Drug (IND) application in China to support a registration-enabling Phase 3 study of Tonmya in fibromyalgia in Asia. We anticipate Tonix pursuing a commercialization partnership in Japan, China, Hong Kong, and Taiwan prior to a Phase 3 study initiating. In addition, we expect the company to pursue additional regional business development deals in other parts of the world.

Conclusion

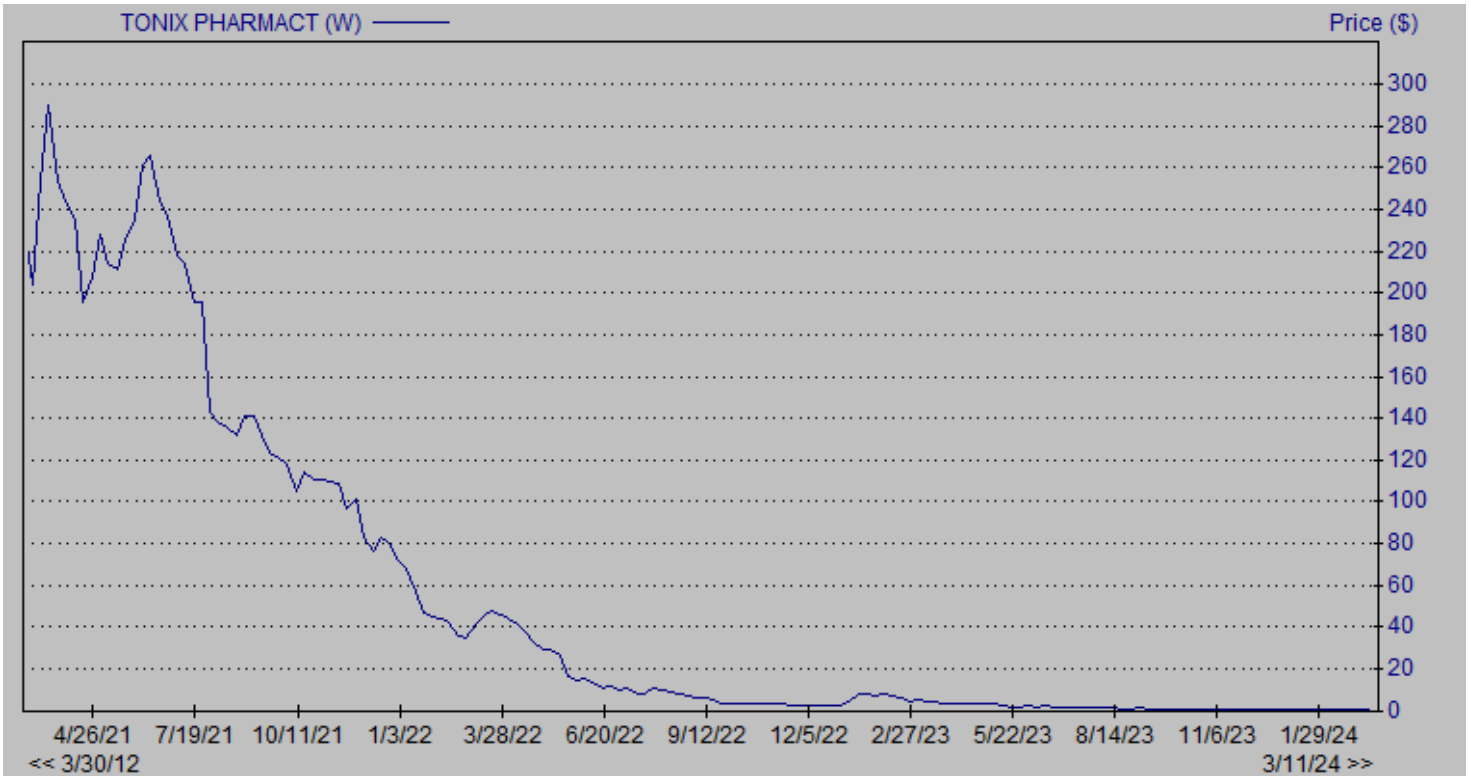
Tonix is fully focused on preparing the NDA for Tonmya, which we anticipate being filed in the second half of 2024, and building its commercialization footprint in anticipation of a potential approval in the second half of 2025. The possible approval of AXS-14 could expand the therapy options for patients, however we believe that Tonmya is fully differentiated from other treatments in the way it improves pain, sleep, and fatigue with a tolerable side effect profile. With no changes to our model our valuation remains at $1.50.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2022 A	Q1 A	Q2 A	Q3 A	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	$4	$4	$8	$18	$19
Research & Collaborations	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$4**	**$4**	**$8**	**$18**	**$19**
CoGS	$0.0	$0	$0	$2	$2	$4.8	$10.7	$11.4
Product Gross Margin	-	-	-	*40.5%*	*40.0%*	*40.2%*	*40.6%*	*40.0%*
R&D	$81.9	$26.5	$22.0	$21.1	$22.0	$91.5	$55.0	$50.0
SG&A	$30.2	$7.4	$7.0	$8.7	$10.0	$33.1	$35.0	$36.0
Operating Income	($112.1)	($33.9)	($29.0)	($28.1)	($30.4)	($121.5)	($82.7)	($78.4)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$1.9	$0.9	$0.6	$0.2	$0.8	$2.5	$2.0	$2.0
Pre-Tax Income	($110.2)	($33.0)	($28.4)	($28.0)	($29.6)	($118.9)	($80.7)	($76.4)
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)	($28.0)	($29.6)	($118.9)	($80.7)	($76.4)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($20.44)**	**($3.26)**	**($2.68)**	**($1.83)**	**($1.64)**	**($8.80)**	**($2.69)**	**($1.91)**
YOY Growth	*56.7%*	-	-	-	-	*-82.8%*	*-94.8%*	*-81.1%*
Weighted Shares Outstanding	5.7	10.1	10.6	15.3	18.0	13.5	30.0	40.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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