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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Six Phase 2 or 3 Studies for CNS Programs Expected in the Clinic by 1Q23…

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 $6.00/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 (12/05/22)	$0.39
Valuation	**$6.00**

OUTLOOK

On November 7, 2022, Tonix Pharmaceuticals Holding Corp. (TNXP) announced financial results for the third quarter of 2022. The company intends to have six Phase 2 or 3 studies for CNS programs to be in the clinic by the first quarter of 2023. In addition, Tonix expects the results of a preplanned interim analysis for the Phase 3 RESILIENT trial in fibromyalgia and the Phase 2 PREVAIL trial in Long COVID in the second quarter of 2023. Additional trials to initiate include a Phase 2 trial of TNX-102 SL in posttraumatic stress disorder (PTSD) in Kenya in 1Q23, a Phase 2 trial of TNX-1900 in chronic migraine in 1Q23, a Phase 2 trial of TNX-1300 in cocaine intoxication in 1Q23, and a Phase 2 trial of TNX-601 ER in 1Q23. Phase 1 trials of TNX-1500 in transplant rejection and TNX-801 in smallpox and monkeypox are expected to begin in the first half of 2023.

SUMMARY DATA

52-Week High	**$14.26**
52-Week Low	**$0.38**
One-Year Return (%)	**-97.03**
Beta	**1.61**
Average Daily Volume (sh)	**1,708,111**
Shares Outstanding (mil)	**58**
Market Capitalization ($mil)	**$23**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
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 2018 Estimate	**-0.1**
P/E using 2019 Estimate	**-0.2**

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)
2021	0 A	0 A	0 A	0 A	0 A
2022	0 A	0 A	0 A	0 E	0 E
2023					0 E
2024					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$2.25 A	-$2.28 A	-$1.62 A	-$2.09 A	-$8.20 A
2022	-$1.60 A	-$1.22 A	-$0.69 A	-$0.63 E	-$3.37 E
2023					-$1.60 E
2024					-$1.42 E

WHAT'S NEW

Business Update

Up to Six Phase 2 or 3 Studies for CNS Programs Expected in the Clinic by 1Q23

Tonix Pharmaceuticals Holding Corp. (TNXP) has built a diverse pipeline that includes development candidates for multiple central nervous system (CNS) diseases, biodefense, and immunology. The company could have up to six Phase 2 or 3 trials for CNS programs in the clinic by the first quarter of 2023. Five of the six studies are potentially pivotal studies.

Interim analysis for Phase 3 RESILIENT trial expected in 2Q23
In April 2022, Tonix initiated the RESILIENT study, a randomized, double blind, placebo controlled potentially pivotal Phase 3 trial of TNX-102 SL for the treatment of fibromyalgia. It is expected to enroll approximately 470 participants in the U.S. The results of a planned interim analysis are expected in the second quarter of 2023.

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 already has already conducted one positive trial in fibromyalgia, positive results from the RESILIENT study could put the company in position to file a new drug application (NDA) for TNX-102 SL for the treatment of fibromyalgia.

Interim analysis for Phase 2 PREVAIL trial expected in 2Q23
In August 2022, Tonix announced the initiation of the PREVAIL Phase 2 clinical trial of TNX-102 SL in patients with Long COVID (NCT05472090), a heterogeneous condition that involves nociplastic pain following infection with and recovery from SARS-CoV-2, the virus that causes COVID-19 (Bierle *et al*., 2021). It is a 14-week, double blind, randomized, multicenter, placebo controlled trial to evaluate the efficacy and safety of TNX-102 SL in patients with multi-site pain associated with post-acute SARS-CoV-2 infection (PASC). We anticipate approximately 470 patients being enrolled into the trial with the primary efficacy endpoint being the change from baseline in the weekly average of daily self-reported worst pain intensity scores at the Week 14 timepoint.

In September 2022, Tonix announced the presentation of a retrospective observational study from approximately 75 million patients from a network of inpatient and outpatient electronic medical records from 48 U.S. healthcare organizations at the 2022 World Congress on Pain. The results showed that of 1 million patients diagnosed with COVID, approximately 52,000 had Long COVID symptoms that lasted between 3 and 6 months. In addition, of the patients with Long COVID, 41% had multi-site pain. These patients took a variety of medications, including benzodiazepines, opioids, and antidepressants. The rate of opioid use was 50% for patients that had multi-site pain and insomnia, with or without fatigue. This is especially concerning since approximately 25% of patients prescribed opioids long term will struggle with opioid addiction (U.S. Department of Labor). The results of this study clearly show that there is a large patient population suffering from Long COVID that need additional treatment options.

Phase 2 trial of TNX-102 SL in PTSD to initiate in Kenya in 1Q23
Tonix has previously reported positive Phase 2 data for TNX-102 SL in military personnel suffering from posttraumatic stress disorder (PTSD). The company will be initiating a Phase 2 clinical trial of TNX-102 SL in police officers in Kenya.

Phase 2 trial of TNX-1300 in cocaine intoxication to initiate in 1Q23
TNX-1300 is a recombinant enzyme derived from the *cocE* gene of a *Rhodococcus* species that utilizes cocaine as a sole source of carbon and nitrogen (Bresler *et al*., 2000). Results from a previous Phase 2 clinical trial showed that the recombinant CocE enzyme (then called RBP-8000, now TNX-1300) rapidly degraded plasma cocaine levels in volunteer cocaine users and was safe and well tolerated. Tonix will be initiating a new, potentially pivotal Phase 2 clinical trial of TNX-1300 for the treatment of cocaine intoxication in the first quarter of 2023, pending agreement with the U.S. FDA.

Phase 2 trial of TNX-1900 in migraine headache to initiate in 1Q23
TNX-1900 is a magnesium enhanced formulation of intranasal oxytocin to prevent migraines in chronic migraineurs. A Phase 2 clinical trial of intranasal oxytocin was previously conducted by Trigemina, Inc., from which Tonix acquired TNX-1900 in June 2020. 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. In addition, that trial was conducted with an oxytocin formulation that was not magnesium enhanced. To follow up on the results of the prior Phase 2 trial, we anticipate Tonix conducting a similarly designed Phase 2 trial of TNX-1900 for the prophylactic treatment of chronic migraine. We expect the trial to be similarly designed to the previous Phase 2 trial with a 28-day baseline period followed by 84 days of dosing. We anticipate the trial initiating in the first quarter of 2023.

Phase 2 trial of TNX-601 ER in major depressive disorder (MDD) to initiate in 1Q23
TNX-601 ER (tianeptine oxalate extended-release tablets) is a once daily formulation of tianeptine for major depressive disorder (MDD), posttraumatic stress disorder, and neurocognitive dysfunction associated with corticosteroid use. Tianeptine sodium immediate release tablets have been approved in Europe and many countries in Asia and Latin America for the treatment of MDD for over three decades, however no tianeptine-containing product has been approved by the FDA. TNX-601 ER is designed for once-daily dosing, which is in contrast to the three time per day dosing that is required for tianeptine sodium available in Europe and other jurisdictions, which should help to increase patient adherence. We anticipate Tonix initiating a Phase 2 trial of TNX-601 ER in the first quarter of 2023.

Immunology and Infectious Disease Candidates to Enter Clinic in 2023

In addition to the abovementioned trials that are expected to get underway for the company’s CNS programs, we anticipate two clinical trials initiating in the first half of 2023 for the company’s immunology and infectious disease programs.

Phase 1 trial of TNX-1500 in organ transplant rejection to initiate in 1H23
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. The CD40/CD40L signaling pathway is involved in the activation of both the innate and adaptive immune response. CD40 is predominantly expressed on antigen presenting cells (APCs) and delivers intracellular activating signals. CD40L, which does not contain any signaling capacity, is found on multiple cell types, including T cells, B cells, natural killer (NK) cells, macrophages, and platelets (Schönbeck *et al*., 2001). The CD40/CD40L pathway is essential for humoral immune responses to T cell-dependent antigens (Lederman *et al*., 1992), the production of proinflammatory cytokines (Cella *et al*., 1996), and generating effective cytotoxic T cell responses (Liu *et al*., 2013).

Preclinical data for TNX-1500 was recently presented at the 29th International Congress of The Transplantation Society by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital. The data showed that TNX-1500 prevented organ rejection and was well tolerated in non-human primates in an allograft model. In addition, TNX-1500 prevented xenograft kidney rejection and was well tolerated in non-human primates.

We anticipate a Phase 1 clinical trial of TNX-1500 initiating in the first half of 2023.

Phase 1 trial of TNX-801 for prevention of smallpox and monkeypox to initiate in first half of 2023
Tonix is working with the Kenya Medical Research Institute to plan, seek approval for, and conduct a Phase 1 clinical trial in Kenya for TNX-801 as a vaccine to protect against smallpox and monkeypox. The company previously presented data showing that TNX-801 protected non-human primates with sterilizing immunity from a challenge with intra-tracheal monkeypox. The results also showed that TNX-801 was well tolerated.

We anticipate a Phase 1 clinical trial of TNX-801 initiating in the first half of 2023.

Financial Update

On November 7, 2022, Tonix announced financial results for the third quarter of 2022. As expected, the company did not report any revenues for the third quarter of 2022. Net loss available to common shareholders for the third quarter of 2022 was $29.0 million, or $0.69 per share, compared to a net loss available to common shareholders of $18.5 million, or $1.60 per share, for the third quarter of 2021. The weighted average common shares outstanding for the third quarter of 2022 were approximately 41.9 million compared to approximately 11.6 million in the third quarter of 2021.

R&D expenses for the third quarter of 2022 were $22.2 million, compared to $13.1 million for the third quarter of 2021. The increase was primarily due to increased clinical, manufacturing, non-clinical, employee-related, and

laboratory expenses. G&A expenses for the third quarter of 2022 were $7.4 million, compared to $5.5 million for the third quarter of 2021. The increase was primarily due to employee-related and financial reporting expenses.

As of September 30, 2022, Tonix had approximately $140.0 million in cash and cash equivalents. As of November 4, 2022, the company had approximately 57.5 million common shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 60.0 million.

Conclusion

Tonix has multiple inflection points coming up over the next few quarters, with the pre-specified interim analyses expected for both the Phase 3 RESILIENT and Phase 2 PREVAIL trials in the second quarter of 2023. In addition, Tonix is continuing to build out its pipeline with up to four additional clinical trials set to get underway by the end of the first quarter of 2023 for CNS indications and another two trials set to initiate in immunology and infectious disease by the end of the first half of 2023. After accounting for the company's capital raises this quarter, our valuation now stands at $6 per share.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2021 A	Q1 A	Q2 A	Q3 A	Q4 E	2022 E	2023 E	2024 E
TNX-102 SL (FM)	$0	$0	$0	$0	$0	$0	$0	$0
Research & Collaborations	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
CoGS	$0.0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$68.8	$18.4	$16.6	$22.2	$24.0	$81.2	$90.0	$95.0
SG&A	$23.5	$8.0	$6.8	$7.4	$7.5	$29.7	$30.0	$33.0
Operating Income	($92.3)	($26.4)	($23.3)	($29.6)	($31.5)	($110.9)	($120.0)	($128.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.0	$0.0	$0.2	$0.6	$0.0	$0.8	$0.1	$0.1
Pre-Tax Income	($92.3)	($26.4)	($23.1)	($29.0)	($31.5)	($110.0)	($119.9)	($127.9)
Preferred Stock Deemed Dividend	$0.0	$0.0	$4.3	$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	($92.3)	($26.4)	($27.4)	($29.0)	($31.5)	($110.0)	($119.9)	($127.9)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($8.20)**	**($1.60)**	**($1.22)**	**($0.69)**	**($0.63)**	**($3.37)**	**($1.60)**	**($1.42)**
YOY Growth	*-53.6%*	-	-	-	-	*61.4%*	*-80.5%*	*-82.7%*
Weighted Shares Outstanding	11.3	16.3	22.4	41.9	50.0	32.7	75.0	90.0

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

HISTORICAL STOCK PRICE

Source: Zacks Small Cap Research

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