

Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Multiple COVID Programs and Building Domestic Vaccine Research Infrastructure...

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL in fibromyalgia, TNX-1800, TNX-1900 and TNX-1300, TNXP is valued at \$3.00/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 (08/19/21) **\$0.67**
Valuation **\$3.00**

OUTLOOK

On August 9, 2021, Tonix Pharmaceuticals Holding Corp. (TNXP) announced financial results for the second quarter of 2021 and provided a business update. As the COVID-19 pandemic continues, Tonix has established a robust pipeline of COVID programs, with a clinical trial of TNX-2100 (a diagnostic skin test) set to initiate in 4Q21, along with building domestic vaccine research infrastructure to continue work related to the current and any future pandemics. In addition to its COVID programs, the company will be initiating multiple clinical trials in the second half of 2021 from its central nervous system (CNS) portfolio, including a Phase 2 trial of TNX-1300 for the treatment of cocaine overdose in the 3Q21, a Phase 2 trial of TNX-1900 for the treatment of chronic migraine in the 4Q21, and a Phase 3 trial of TNX-102 SL for the treatment of posttraumatic stress disorder (PTSD) in Kenya in the fourth quarter of 2021.

SUMMARY DATA

52-Week High **\$2.00**
52-Week Low **\$0.53**
One-Year Return (%) **-31.42**
Beta **1.29**
Average Daily Volume (sh) **11,266,200**

Shares Outstanding (mil) **358**
Market Capitalization (\$mil) **\$239**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **12**
Insider Ownership (%) **1**

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 **-2.7**
P/E using 2019 Estimate **-3.5**

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)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 A	0 A	0 E	0 E	0 E
2022					0 E
2023					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-\$0.37 A	-\$0.23 A	-\$0.09 A	-\$0.10 A	-\$0.55 A
2021	-\$0.07 A	-\$0.07 A	-\$0.07 E	-\$0.08 E	-\$0.30 E
2022					-\$0.19 E
2023					-\$0.17 E

WHAT'S NEW

Business Update

COVID-19 Pipeline Update

Tonix Pharmaceutical Holdings Corp. (TNXP) has multiple programs targeting the current COVID-19 pandemic and is expanding its R&D and manufacturing facilities to be able to work with greater efficiency in developing vaccines and other agents to battle COVID-19, variants of interest, and additional infectious diseases.

- **TNX-1800:** This is a live virus vaccine that utilizes the company's horsepox virus vector (TNX-800). It is designed to be a single dose COVID-19 vaccine to elicit T cell immunity targeting the Spike (S) protein of the virus. A Phase 1 clinical trial in humans is anticipated to start in the first half of 2022, pending IND clearance and availability of cGMP material. The company previously reported positive efficacy data from a preclinical study in non-human primates that were vaccinated with TNX-1800 and then challenged with SARS-CoV-2. The results showed that TNX-1800 induced protection against infection in both the upper and lower airways, suggesting it may prevent forward transmission of the disease, something that the current COVID-19 vaccines do not appear to do.
- **TNX-2100:** This is a diagnostic skin test as a means to test for a delayed-type hypersensitivity (DTH) reaction to SARS-CoV-2, the virus that causes COVID-19. It is modeled after the tuberculosis (TB) skin test (Tubersol®, Aplisol®, or the generic Mantoux test) that can determine if an individual has been exposed to the bacteria that causes tuberculosis, *Mycobacterium tuberculosis*. TNX-2100 is comprised of three different mixtures (TNX-2110, -2120, -2130) of synthetic peptides that correspond to different proteins of SARS-CoV-2. TNX-2110 represents multiple proteins from SARS-CoV-2, TNX-2120 represents only the spike protein of SARS-CoV-2, and TNX-2130 is representative of several proteins but not the spike protein. All three tests will be administered during the same procedure by application to three separate areas on the forearm in a similar manner to the TB skin test. They are designed for multiple potential applications: 1) As a biomarker for cellular immunity and protective immunity to SARS-CoV-2; 2) a method for stratifying participants in a COVID-19 vaccine trial by immune status; 3) an endpoint in COVID-19 vaccine trials; and 4) a biomarker of durability of vaccine protection. We anticipate a first-in-human clinical study to initiate in the fourth quarter of 2021.
- **TNX-102 SL:** In June 2021, Tonix announced a plan to develop TNX-102 SL as a treatment for Long COVID Syndrome, officially known as Post-Acute Sequelae of COVID-19 (PASC). The company anticipates receiving the meeting minutes from the FDA in the third quarter of 2021, with the design of a Phase 2 trial predicated on the feedback from the FDA. The company will provide an update on this program following receipt of the meeting minutes.
- **TNX-3500:** TNX-3500 (sangivamycin, formerly OYA1) is an antiviral compound being developed for the treatment of COVID-19 and possibly other viral diseases. Sangivamycin is a natural product that was originally isolated from *Streptomyces rimosus* and studied in the 1960's by the National Cancer Institute (NCI) as a potential cancer therapeutic. Due to lack of efficacy the drug did not advance as an anti-cancer therapy but it did show good safety and tolerability in those trials.

A recent study identified sangivamycin as an inhibitor of Ebola virus replication, and surprisingly it also inhibited the replication of Marburg virus, Lassa virus, cowpox virus, and vaccinia virus ([Bennett et al., 2020](#)). OyaGen followed up these results with a collaborative research project with the National Institutes of Allergy and Infectious Diseases Integrated Research Facility (NIAID-IRF) to study the effect of sangivamycin on the replication of SARS-CoV-2. Unpublished results show that the compound has strong dose-dependent antiviral activity against SARS-CoV-2 and was approximately 65 times more potent than remdesivir (Veklury®). In addition, combination treatment with sangivamycin and remdesivir show additive activity against SARS-CoV-2.

Tonix is currently conducting multiple preclinical studies to test the safety and efficacy of sangivamycin as a treatment for COVID-19 and we anticipate an update on this program later this year.

Over the past year, Tonix has vastly expanded its R&D and manufacturing facilities to include both basic research facilities all the way up to commercial scale manufacturing.

- In July 2021, Tonix announced an agreement to purchase an infectious disease research facility in Frederick, MD. This facility is being acquired from Southern Research, which is collaborating with Tonix on development of TNX-1800 and TNX-801. Tonix is set to take ownership of the facility on October 1, 2021 and it should be operational shortly thereafter.
- In August 2021, Tonix announced a groundbreaking ceremony for the company's 45,000 square foot clinical scale manufacturing facility in the New Bedford Business Park in Massachusetts. Once completed, the facility will house Tonix's Advanced Development Center (ADC) for R&D and analytical activities along with the ability to produce clinical trial quality vaccines. The facility should be operational in the first half of 2022.
- In June 2021, Tonix announced plans were advancing to construct a commercial-scale manufacturing facility in Hamilton, MT. Tonix entered into a public/private sector collaboration between Ravalli County and the company to bring high-tech bioscience jobs to the Bitterroot Valley.

One of the major issues that became readily apparent during the COVID-19 pandemic is the lack of U.S. domestic vaccine development and manufacturing capabilities. The facilities purchased by Tonix will help to ensure that sufficient resources are available domestically to develop vaccines for various infectious agents. In addition, the U.S. government is likely going to have a sustained interest in pandemic preparedness, which these facilities could also be utilized for.

Multiple CNS Clinical Trials to Initiate 2H21; RALLY Trial Topline Results in 4Q21

Tonix has established a robust pipeline of clinical stage assets focused on the treatment of central nervous system (CNS) and immunological diseases. In addition, the company continues to have a strong balance sheet, with \$165.7 million in cash and cash equivalents reported as of June 30, 2021, along with no debt, no preferred shares, and a very limited number of warrants.

In regards to the CNS portfolio, Tonix is planning to initiate three clinical trials during the second half of 2021:

- **TNX-102 SL:** The company will be initiating a Phase 3 trial of TNX-102 SL for the treatment of posttraumatic stress disorder (PTSD) in the fourth quarter of 2021. The trial will be enrolling police officers and is taking place in Kenya.
- **TNX-1300:** The company will be initiating a Phase 2 clinical trial of TNX-1300 for the treatment of cocaine overdose in the third quarter of 2021. 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.
- **TNX-1900:** The company will be initiating a Phase 2 clinical trial of TNX-1900 for the treatment of chronic migraine in the fourth quarter of 2021. A previous single dose, placebo controlled, double blind Phase 2 study that included 40 chronic migraine patients that were currently experiencing a migraine showed that at four hours post dose 64% of those administered intranasal oxytocin (then called TI-001) reported a reduction in pain by two categories (severe, moderate, mild, none) compared to only 27% of patients who received placebo. It should be noted that those results were obtained with a formulation that did not contain magnesium, which TNX-1900 contains. Preclinical studies indicate that magnesium enhances the analgesic activity of oxytocin mediated by the oxytocin receptor.

In July 2021, Tonix announced that the RALLY trial, the second Phase 3 clinical trial of TNX-102 SL 5.6 mg for the treatment of fibromyalgia, stopped enrolling patients following a pre-planned interim analysis by the Independent Data Monitoring Committee (IDMC). Based on interim analysis results of the first 50% of patients (n=337), the IDMC recommended stopping the trial for futility as TNX-102 SL 5.6 mg was unlikely to demonstrate a statistically significant improvement in the primary endpoint. The company remains blinded to the data and is allowing participants already enrolled in the study to complete the trial and will then evaluate the full data set before deciding on next steps for the program. Topline results are expected in the fourth quarter of 2021.

Financial Update

On August 9, 2021, Tonix announced financial results for the second quarter of 2021. As expected, the company did not report any revenues for the second quarter of 2021. Net loss available to common shareholders for the second quarter of 2021 was \$23.6 million, or \$0.07 per share, compared to a net loss available to common shareholders of \$14.2 million, or \$0.23 per share, for the second quarter of 2020. The weighted average common shares outstanding for the second quarter of 2021 were approximately 331.3 million compared to approximately 62.4 million in the second quarter of 2020.

R&D expenses for the second quarter of 2021 were \$18.1 million, compared to \$10.6 million for the second quarter of 2020. The increase was primarily due to increased non-clinical expenses, manufacturing expenses, employee-related expenses, and regulatory/legal expenses. G&A expenses for the second quarter of 2021 were \$5.4 million, compared to \$3.6 million for the second quarter of 2020. The increase was primarily due to increased employee-related expenses, increased investor relations expenses, increased financial reporting expenses, and increased insurance premiums.

As of June 30, 2021, Tonix had approximately \$165.7 million in cash and cash equivalents. As of August 9, 2021, Tonix had approximately 357.5 million common shares outstanding and, when factoring in stock options and reasonably priced warrants, a fully diluted share count of approximately 382.6 million.

Conclusion

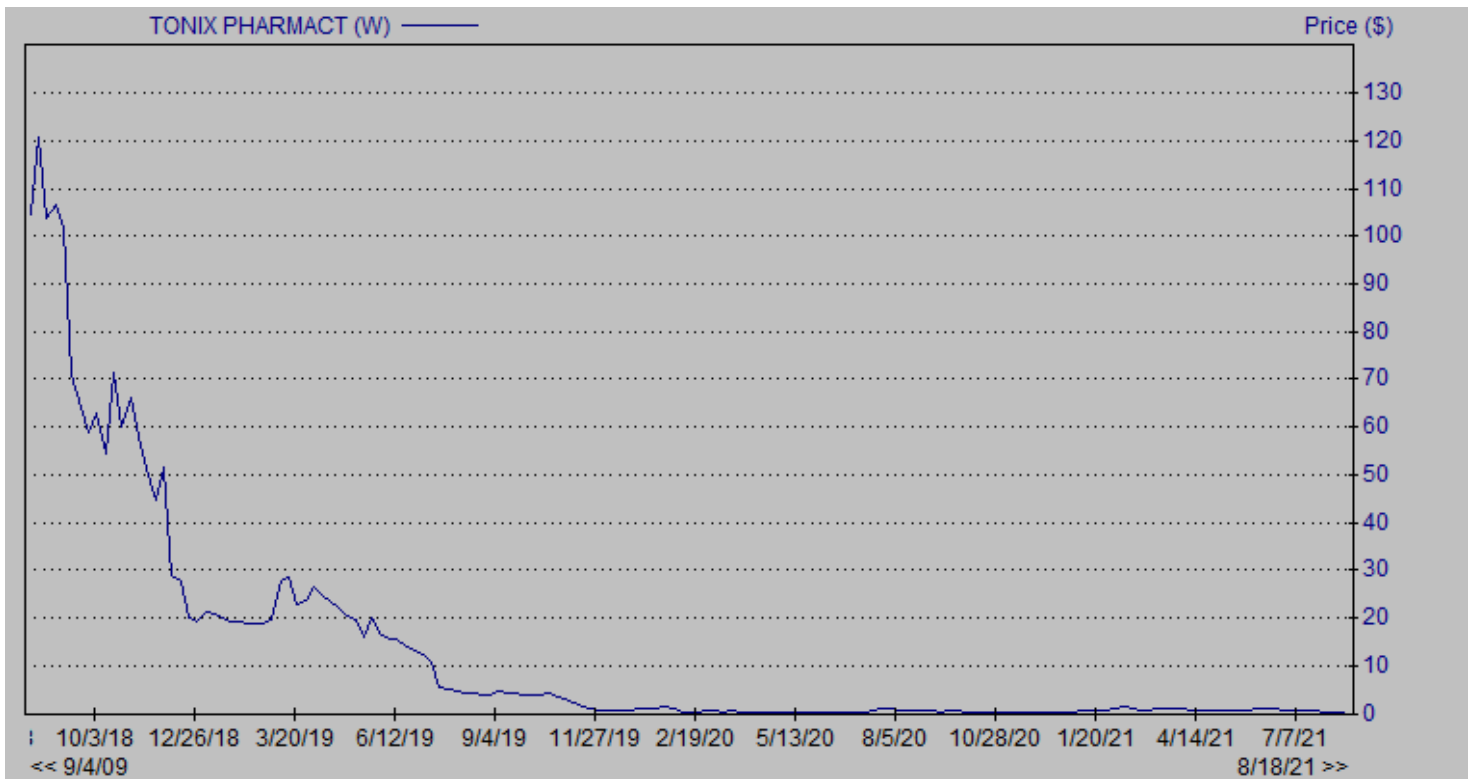
We're glad to see Tonix is continuing to advance its pipeline with four clinical trials planned to initiate in the second half of 2021. The news that the RALLY trial is not likely to hit the primary endpoint was disappointing, however trial failures in CNS indications are not uncommon. We will be interested to see what the company decides to do with the fibromyalgia program once the topline data from the RALLY trial is announced, which we expect in the fourth quarter of 2021, keeping in mind that the company has completed one successful Phase 3 trial in fibromyalgia. Given the uncertainty surrounding TNX-102 SL in fibromyalgia we have decreased its probability of approval in that indication to 25%, which coupled with the increase in shares outstanding has decreased our valuation to \$3.00 per share.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 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	\$36.2	\$15.3	\$18.1	\$21.0	\$24.0	\$78.5	\$80.0	\$90.0
SG&A	\$14.4	\$5.4	\$5.4	\$5.7	\$6.0	\$22.5	\$13.5	\$14.0
Operating Income	(\$50.5)	(\$20.7)	(\$23.6)	(\$26.7)	(\$30.0)	(\$101.0)	(\$93.5)	(\$104.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	\$0.0	\$0.1	\$0.0	\$0.0	\$0.0	\$0.2	\$0.2	\$0.2
Pre-Tax Income	(\$50.5)	(\$20.7)	(\$23.6)	(\$26.7)	(\$30.0)	(\$100.8)	(\$93.3)	(\$103.8)
Preferred Stock Deemed Dividend	\$1.3	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Warrant Deemed Dividend	\$0.5	\$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	(\$52.2)	(\$20.7)	(\$23.6)	(\$26.7)	(\$30.0)	(\$100.8)	(\$93.3)	(\$103.8)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	(\$0.55)	(\$0.07)	(\$0.07)	(\$0.07)	(\$0.08)	(\$0.30)	(\$0.19)	(\$0.17)
YOY Growth	-97.1%	-	-	-	-	-45.6%	127.3%	-42.3%
Weighted Shares Outstanding	94.6	290.1	331.3	358.0	365.0	336.1	500.0	600.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.

Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.

SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover.

SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.