Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

June 10, 2019
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Enrollment Continues for Phase 3 Trial of TNX-102 SL in PTSD…

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL PTSD, TNXP is valued at $10.00/share. This model is highly dependent upon continued clinical success of TNX-102 SL in PTSD and will be adjusted accordingly based upon future clinical results.

Current Price (06/10/19)	$1.59
Valuation	**$10.00**

OUTLOOK

In March 2019, Tonix Pharmaceuticals Holding Corp. (TNXP) announced that the first patient had been enrolled in the Phase 3 RECOVERY study of TNX-102 SL in patients with posttraumatic stress disorder (PTSD). The study will evaluate 5.6 mg TNX-102 SL in approximately 250 patients with civilian or military-related PTSD. Inclusion is limited to those with an index trauma within nine years of screening. The primary endpoint is the change from baseline in CAPS-5 at Week 4. We anticipate topline data in the first half of 2020.

The company also announced that following an encouraging FDA meeting, which included discussion of acceptable study design features, it will be expanding the 5.6 mg TNX-102 SL program to include its development for the treatment of fibromyalgia. A Phase 3 protocol is currently being finalized.

SUMMARY DATA

52-Week High	**$48.20**
52-Week Low	**$1.56**
One-Year Return (%)	**-96.44**
Beta	**1.90**
Average Daily Volume (sh)	**648,795**
Shares Outstanding (mil)	**6**
Market Capitalization ($mil)	**$10**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**4**
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	**-0.4**
P/E using 2019 Estimate	**-0.6**

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)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 A	0 E	0 E	0 E	0 E
2020					0 E
2021					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$8.83 A	-$7.25 A	-$5.72 A	-$6.10 A	-$26.81 A
2019	-$1.29 A	-$0.94 E	-$0.90 E	-$0.88 E	-$3.94 E
2020					-$2.37 E
2021					-$1.63 E

WHAT'S NEW

Business Update

Enrollment Continues in Phase 3 RECOVERY Trial

In March 2019, Tonix Pharmaceuticals Holding Corp. (TNXP) announced the first patient has been enrolled in the RECOVERY Phase 3 study of TNX-102 SL in patients with posttraumatic stress disorder (PTSD). The RECOVERY trial is a randomized, double blind, placebo controlled study of TNX-102 SL over 12 weeks with the primary endpoint being the Week 4 change in CAPS-5 score from baseline between TNX-102 SL and placebo-treated patients. The Week 12 change in CAPS-5 score will be a key secondary endpoint.

In addition to the primary endpoint being at Week 4 instead of Week 12, the RECOVERY trial incorporates other important changes compared to the Phase 3 HONOR trial that we think helps to increase the likelihood for success, including:

1) Inclusion will be limited to individuals with PTSD who experienced their trauma within the past nine years, while the HONOR trial included individuals who experienced a trauma from 2001 or later. A retrospective analysis showed a treatment effect in patients treated within nine years of trauma, while treated patients who were > nine years from their trauma failed to separate from placebo.
2) The study will include both civilian and military PTSD patients, while the HONOR trial had limited inclusion to only those with military-related PTSD.
3) The total number of study subjects is anticipated to be approximately 250, compared to approximately 550 subjects that were to be enrolled in the HONOR trial.

Management has indicated that thus far enrollment is going well and we believe that will continue to be the case. We anticipate topline results in the first half of 2020.

Update on CRADA with USAMMDA

On April 19, 2019, Tonix announced the receipt of a notice of termination, effective April 29, 2019, in which the U.S. Army Medical Material Development Activity (USAMMDA) intended to terminate without cause the Collaborative Research and Development Agreement (CRADA) that initiated on Dec. 4, 2015 between Tonix and USAMMDA. The CRADA related to the development of TNX-102 SL for the treatment of PTSD.

The termination of the CRADA has no financial consequences for Tonix nor does it affect the ongoing RECOVERY trial in any way. The purpose of the CRADA was for the USAMMDA to assist Tonix in recruiting active duty military personnel from military treatment facilities (MTFs) into the Phase 2 AtEase and the Phase 3 HONOR clinical trials in military-related PTSD. It is important to note that no patients were recruited by USAMMDA into either of those trials.

Another potential reason that the CRADA was terminated could stem from the changes in oversight of MTFs that is occurring. The National Defense Authorization Act of 2017 required that the Defense Health Agency (DHA) assume command for all MTFs. Army MTFs were under a command shared with the U.S. Army Medical Research and Material Command (MRMC). The CRADA was signed with the intention of USAMMDA recruiting patients from MTFs. Since the MTFs are now under the control of DHA the CRADA became no longer relevant to potentially recruiting patients.

Fibromyalgia Program

On April 4, 2019, Tonix announced the expansion of the 5.6 mg TNX-102 SL program to include the treatment of fibromyalgia. The company received the FDA meeting minutes following a recent clinical guidance meeting which indicated the agency supports the advancement of TNX-102 SL as a centrally acting non-opioid analgesic for the management of fibromyalgia. Two positive Phase 3 trials will support the registration of 5.6 mg TNX-102 SL in fibromyalgia along with long-term safety exposure data from the PTSD program.

Tonix previously tested 2.8 mg TNX-102 SL in fibromyalgia in the Phase 3 AFFIRM trial, a 12-week, randomized, double blind, placebo controlled trial of 519 patients who were administered either 2.8 mg TNX-102 SL or placebo at bedtime in a 1:1 randomization. The trial did not achieve statistical significance in the primary efficacy endpoint of

the proportion of patients who reported a 30% or greater decrease in pain from baseline (*P*=0.095). The pre-specified statistical method utilized for the primary efficacy analysis counted all patients who withdrew from the study as non-responders, even if the reason for leaving the study had nothing to do with efficacy or tolerability. Another standard statistical method that takes into account the reasons for discontinuation showed statistical significance in the 30% responder analysis (*P*=0.012). Additionally, the same pain data analyzed by mean pain, an FDA accepted pain endpoint, demonstrated significant separation from placebo by mixed model repeated measures (MMRM) analysis (*P*<0.001).

While the AFFIRM trial did not meet the primary efficacy endpoint, 2.8 mg TNX-102 SL did show statistically significant effects on two other key secondary endpoints, Patient Global Impression of Change (PGIC) and Fibromyalgia Impact Questionnaire-Revised (FIQ-R) function and symptom domain scores, which assess global improvement, a range of fibromyalgia symptoms, and functional improvement.

New approaches to treat fibromyalgia are needed, as approximately one-third of patients are on chronic opiates. Given that 2.8 mg TNX-102 SL showed clinical benefit in a number of different outcomes, we believe that increasing the dose to 5.6 mg is likely to provide evidence to support its approval in the management of fibromyalgia. The company will need to secure additional funding to advance the fibromyalgia program as well as finalize and submit a new Phase 3 protocol and statistical analysis plan for FDA acceptance.

Financial Update

On May 13, 2019, Tonix announced financial results for the first quarter of 2019. As expected, the company did not report any revenues for the first quarter of 2019. R&D expenses in the first quarter of 2019 were $3.9 million compared to $5.2 million for the first quarter of 2018. The decrease was primarily due to the pharmacokinetic bridging study of TNX-102 SL that was performed in the first quarter of 2018 partially offset by an increase in manufacturing costs due to TNX-601 formulation work. G&A expenses in the first quarter of 2019 were $2.4 million compared to $1.8 million in the first quarter of 2018. The increase was primarily due to increased investor relations costs and insurance expenses. Net loss for the first quarter of 2019 was $6.2 million, or $1.29 per share, compared to a net loss of $6.9 million, or $8.80 per share, in the first quarter of 2018.

Tonix exited the first quarter of 2019 with approximately $16.4 million in cash and cash equivalents, which we believe will be sufficient to fund operations through the end of 2019. As of May 9, 2019, the company had approximately 6.1 million shares outstanding and when factoring in warrants with strike prices of $3.50 the company has a fully diluted share count of approximately 11.0 million.

Conclusion

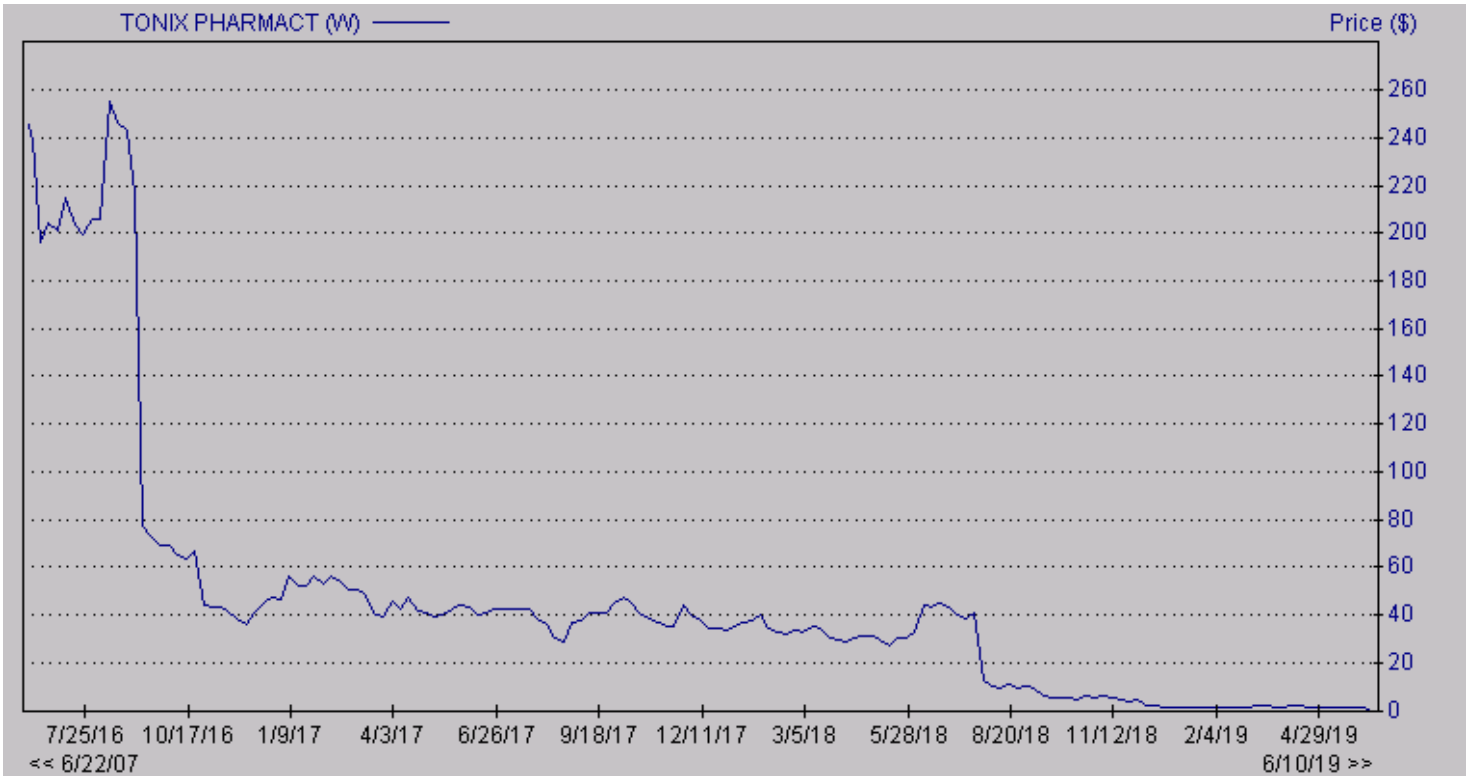
We're glad to hear that enrollment is progressing nicely in the RECOVERY trial, and we believe that the changes incorporated into that trial increase the probability for success. In addition, we don't see the termination of the CRADA as an issue that will affect the company or the RECOVERY trial. We look forward to evaluating the topline data in the first half of 2020. The fibromyalgia program for 5.6 mg TNX-102 SL is a nice complement to the PTSD program and could lead to a welcome treatment option for those patients. Our valuation remains at $10 per share.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2018 A	Q1 A	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 E
TNX-102 SL (PTSD)	$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	$17.6	$3.9	$4.0	$4.0	$4.1	$16.0	$16.0	$16.3
SG&A	$8.8	$2.4	$1.8	$1.9	$2.1	$8.2	$7.8	$8.2
Operating Income	($26.3)	($6.3)	($5.8)	($5.9)	($6.2)	($24.2)	($23.8)	($24.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.2	$0.1	$0.1	$0.1	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($26.1)	($6.2)	($5.7)	($5.8)	($6.2)	($24.1)	($23.7)	($24.4)
Preferred Stock Deemed Dividend	$3.3	$0	$0	$0	$0	$0	$0	$0
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($29.4)	($6.2)	($5.7)	($5.8)	($6.2)	($24.1)	($23.7)	($24.4)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($26.81)**	**($1.29)**	**($0.94)**	**($0.90)**	**($0.88)**	**($3.94)**	**($2.37)**	**($1.63)**
YOY Growth	*-15.4%*	-	-	-	-	*-85.3%*	*-39.9%*	*-31.4%*
Weighted Shares Outstanding	1.1	4.8	6.1	6.5	7.0	6.1	10.0	15.0

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

HISTORICAL STOCK PRICE



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 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.