Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

December 16, 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: TNX-102 SL P3 PTSD Trial Interim Readout in 1Q20; P3 Trial in Fibromyalgia Underway…

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL in fibromyalgia and PTSD, TNXP is valued at $5.00/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

Current Price (12/16/19)	$1.15
Valuation	**$5.00**

OUTLOOK

Tonix Pharmaceuticals Holding Corp. (TNXP) recently announced the primary endpoint in the Phase 3 clinical trial of TNX-102 SL in posttraumatic stress disorder (PTSD) has been changed to an analysis of the change in CAPS-5 from baseline to Week 12 instead of Week 4. In addition, the company has added an unblinded interim analysis that will allow for potential sample size re-estimation. We anticipate results of the interim analysis in the first quarter of 2020 and if the current projected full enrollment of 250 patients remains unchanged we anticipate topline results in the second quarter of 2020.

The company also recently initiated a Phase 3 trial of TNX-102 SL 5.6 mg in fibromyalgia. The RELIEF study is expected to enroll 470 patients with an interim analysis once the first 50% of patients enrolled are evaluable for efficacy.

SUMMARY DATA

52-Week High	**$33.70**
52-Week Low	**$0.90**
One-Year Return (%)	**-95.91**
Beta	**1.03**
Average Daily Volume (sh)	**3,112,280**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$10**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**9**
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 A	0 A	0 E	0 E
2020					0 E
2021					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$88.34 A	-$72.54 A	-$54.99 A	-$61.03 A	-$268.11 A
2019	-$12.86 A	-$9.47 A	-$5.69 A	-$1.23 E	-$14.01 E
2020					-$2.49 E
2021					-$2.33 E

© Copyright 2019, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Business Update

Phase 3 PTSD Trial Update

On November 26, 2019, Tonix Pharmaceuticals Holding Corp. (TNXP) announced receipt of the official minutes following a Breakthrough Therapy Type B Clinical Guidance Meeting with the FDA regarding the Phase 3 clinical trial of TNX-102 SL for the treatment of posttraumatic stress disorder (PTSD). The RECOVERY trial is a randomized, double blind, placebo controlled study of TNX-102 SL over 12 weeks that incorporates important changes compared to the Phase 3 HONOR trial that we think helps to increase the likelihood for success, including the inclusion of both civilian and military PTSD patients and limiting inclusion to individuals with PTSD who experienced their trauma within the past nine years, which is an inclusion criteria also being utilized by Otsuka Pharmaceuticals in the Phase 3 clinical trial of Brexpiprazole/Sertraline in adult PTSD patients (NCT04124614).

Based on its interactions with the FDA, Tonix has changed the primary endpoint in the RECOVERY trial from the change in CAPS-5 score from baseline to Week 4 to the change in CAPS-5 score from baseline to Week 12. In addition, the RECOVERY trial will include an unblinded interim analysis once 50% of patients are enrolled. It will be conducted by an independent Data Monitoring Committee and can have the following potential recommendations: 1) keep the current sample size and continue as planned; 2) increase the sample size up to a maximum of an additional 120 patients; or 3) stop the trial early for futility. Since more than 125 patients have already been enrolled in the trial we anticipate results from the interim analysis in the first quarter of 2020. If there is no recommendation to increase the number of participants, we anticipate topline data in the second quarter of 2020.

Phase 3 Trial in Fibromyalgia Initiated

On December 10, 2019, Tonix announced the first patient enrolled into the Phase 3 RELIEF trial, a pivotal study for TNX-102 SL 5.6 mg for the management of fibromyalgia (NCT04172831). It will be a randomized, double blind, placebo controlled trial and is expected to enroll approximately 470 patients at approximately 40 sites in the U.S. All patients assigned to TNX-102 SL will initiate on 2.8 mg daily for the first two weeks. Following that, the dosage will be increased to 5.6 mg daily for 12 weeks. The primary outcome measure is the change from baseline to Week 14 in the weekly average of the daily self-reported Numerical Rating Scale (NRS) pain severity scores. We expect an interim analysis to be performed once the first 50% of patients enrolled are eligible for efficacy, which we estimate will be in the second half of 2020.

Tonix previously tested TNX-102 SL 2.8 mg in the Phase 3 AFFIRM study in patients with fibromyalgia. This was a randomized, double blind, placebo controlled trial in which 519 patients were randomized 1:1 to receive TNX-102 SL 2.8 mg (n=262) or placebo (n=257) at bedtime and recorded average pain severity over the prior 24 hours in a daily diary. The primary endpoint was response defined as ≥ 30% improvement from baseline to Week 12 in the weekly average of the daily self-reported average NRS pain severity. Key secondary endpoints included Patient Global Impression of Change (PGIC) responder analysis at Week 12, Fibromyalgia Impact Questionnaire – Revised (FIQR) Symptom Domain score improvement at Week 12, Patient Reported Outcomes Measurement Information System (PROMIS) Short Form score for improvement in sleep disturbance at Week 12, and the improvement in the weekly average of the daily self-reported pain severity score at Week 12.

The primary efficacy analysis of pain response (≥ 30% pain reduction) showed that 28.6% of TNX-102 SL-treated and 22.6% of placebo-treated patients met this criterion, which was not statistically significant (*P*=0.095). However, how missing data was treated had a large impact on the responder analysis. For the primary efficacy analysis, patients who left the study for any reason, prior to completion, were labeled as a non-responder regardless of their results up to that point. As the following table shows there was a large imbalance in 'withdrawal of consent' between the two treatment groups, which is usually the result of a person moving away from the site or starting school or a job that would preclude them from making additional study visits. This ultimately had a detrimental impact on the primary analysis.

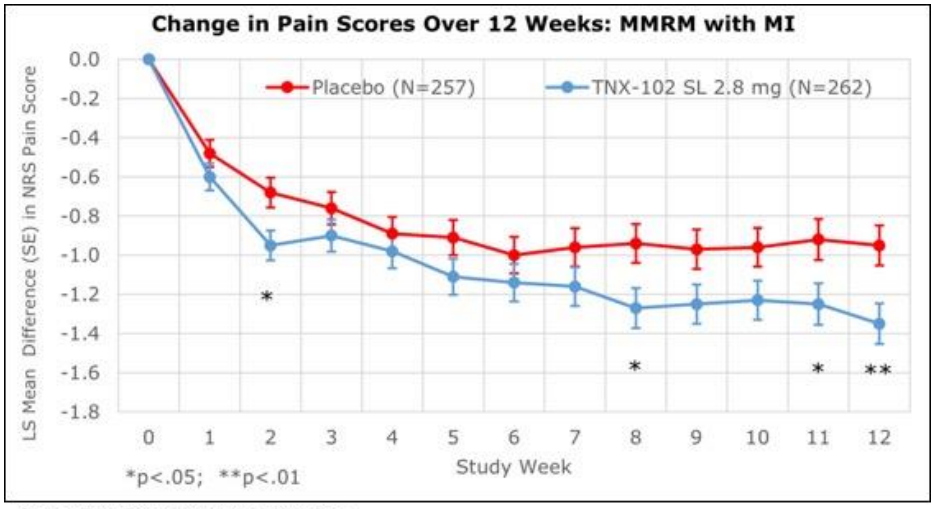
Discontinuation Reason	TNX-102 SL	Placebo
Occurrence of an AE	20 (7.6%)	11 (4.3%)
Withdrawal of Consent	**15 (5.7%)**	**3 (1.2%)**
Investigator Decision	6 (2.3%)	0 (0.0%)
Lack of Efficacy	6 (2.3%)	5 (1.9%)
Lost to Follow-up	11 (4.2%)	15 (5.8%)
Other	1 (0.4%)	1 (0.4%)
Total	59 (22.5%)	35 (13.6%)

Source: Tonix Pharmaceuticals Holding Corp.

Tonix performed two pre-specified sensitivity analyses to assess the impact of missing data on the primary efficacy outcome and show the effect of how discontinuations were analyzed.

1) The first analysis treated all discontinuations due to lack of efficacy (LOE) or adverse events (AEs) as non-responders while other discontinuations were treated as last observation carried forward (LOCF). This analysis showed the responder rate as 33.6% for TNX-102 SL patients and 23.7% for placebo patients (*P*=0.012). Thus, treating non-LOE/non-AE discontinuations as non-responders in the primary analysis reduced the response rate more for the TNX-102 SL group (~5%) than the placebo group (~1%), compared to LOCF.
2) The second analysis treated all discontinuations due to LOE or AEs as non-responders while all other discontinuations had values imputed using quadratic fit on within-subject observed pain scores. This analysis showed the responder rate as 39.3% for TNX-102 SL patients and 26.1% for placebo patients (*P*=0.001). Again, treating non-LOE/non-AE discontinuations as non-responders in the primary analysis reduced the response rate more for the TNX-102 SL group (~11%) than the placebo group (~4%), compared to within-subject quadratic fitting.

Further support for the RELIEF trial is shown in the following graph, which plots the change in pain scores over 12 weeks. The difference in least square mean score was -0.6 (*P*<0.001) and the separation from placebo was apparent as early as two weeks post dosing and the separation continued to increase out to 12 weeks. As a reminder, these results were obtained with a 2.8 mg dose of TNX-102 SL daily, while in the RELIEF trial patients will be administered 5.6 mg TNX-102 SL daily.



Source: Tonix Pharmaceuticals Holding Corp.

Additional statistically significant results were shown on pain in two other endpoints, PGIC and FIQR, which assess global improvement and a range of fibromyalgia symptoms. Sleep quality was also improved, with separation from baseline occurring as early as Week 2. Treatment with TNX-102 SL also improved Global Physical Health, as assessed by PROMIS short form, with statistically significant effects during the last four weeks of treatment.

Lastly, TNX-102 SL was well-tolerated in the AFFIRM trial and the adverse event profile was similar to what was seen in other trials. There were three serious adverse events (SAEs) reported in the active group and four reported in the placebo group, however no new safety signals were observed with multiple causal factors being involved for each SAE. The most common adverse events are shown in the table below displaying all adverse events occurring at a rate greater than or equal to 3% in the TNX-102 SL group. Based on the safety of TNX-102 SL 5.6 mg observed in the HONOR trial we don't anticipate any additional safety signals emerging in the RELIEF trial.

Systemic Adverse Events	Placebo N=256	TNX-102 SL 2.8 mg N=262	Total N=518*
Fatigue	2.3%	5.7%	4.1%
Headache	3.9%	3.4%	3.7%
Somnolence	1.6%	3.1%	2.3%
Local Administration Site Reactions			
Hypoaesthesia oral#	0.8%	40.1%	20.7%
Glossodynia	1.6%	9.2%	5.4%
Paraesthesia oral	1.2%	7.6%	4.4%
Product taste abnormal	0.8%	6.1%	3.5%
Oral discomfort	0.0%	3.1%	1.5%

#Oral hypoaesthesia (tongue numbness) was most common AE, generally transient (<60 minutes), rated mild in 87% and moderate in 13% on TNX-102 SL, and rarely (0.8%) associated with discontinuation; *Safety Population (N=518)

Source: Tonix Pharmaceuticals Holding Corp.

Financial Update

On November 14, 2019, Tonix announced financial results for the third quarter of 2019. As expected, the company did not report any revenues for the third quarter of 2019. R&D expenses for the third quarter of 2019 totaled $5.1 million, compared to $3.3 million for the third quarter of 2018. The increase was primarily due to the timing of payments for the RECOVERY trial, work associated with TNX-601, and increased spending for the company's pipeline. G&A expenses totaled $2.8 million in the third quarter of 2019 compared to $2.3 million for the third quarter of 2018. The increase was due in part to increased patent expenses and higher insurance premiums. Net loss for the third quarter of 2019 was $7.8 million, or $5.69 per share, compared to a net loss of $5.5 million, or $54.99 per share, for the third quarter of 2018.

Tonix exited the third quarter of 2019 with approximately $10 million in cash and cash equivalents. On Nov. 20, 2019, the company announced the closing of a $9.0 million public offering, which has allowed the company to initiate the RELIEF trial. As of Dec. 12, 2019, there were approximately 8.5 million common shares outstanding, and when factoring in reasonably priced warrants the company has a fully diluted share count of approximately 13.7 million.

Conclusion

We are looking forward to the results of the interim analysis for the RECOVERY trial in the first quarter of 2020, and pending the outcome of that analysis, topline results in the second quarter of 2020. Based on the results of 2.8 mg TNX-102 SL in the AFFIRM trial, we believe there is a high likelihood of success for 5.6 mg TNX-102 SL in the RELIEF trial, and we anticipate updates regarding an interim analysis for that trial in 2020.

Now that the RELIEF trial is underway, we've added the potential for TNX-102 SL in fibromyalgia back into the model. For both fibromyalgia and PTSD, we model for Tonix to partner and receive a 15% royalty. We estimate for approval in 2024 for fibromyalgia and peak sales of $300 million. Using a 16% discount rate and a 40% probability of approval leads to a net present value of $32 million. For PTSD, we estimate for approval in 2021 and peak sales of approximately $500 million. Using a 15% discount rate and a 50% probability of approval leads to a net present value of $69 million. Combining the net present value for TNX-102 SL in each indication along with the company's current cash position and potential cash from reasonably priced warrants leads to a net present value of $127 million. Dividing by the fully diluted share count of approximately 13.7 million, with an additional 12 million shares added to account for future dilution, leads to a valuation of $5.00 per share.

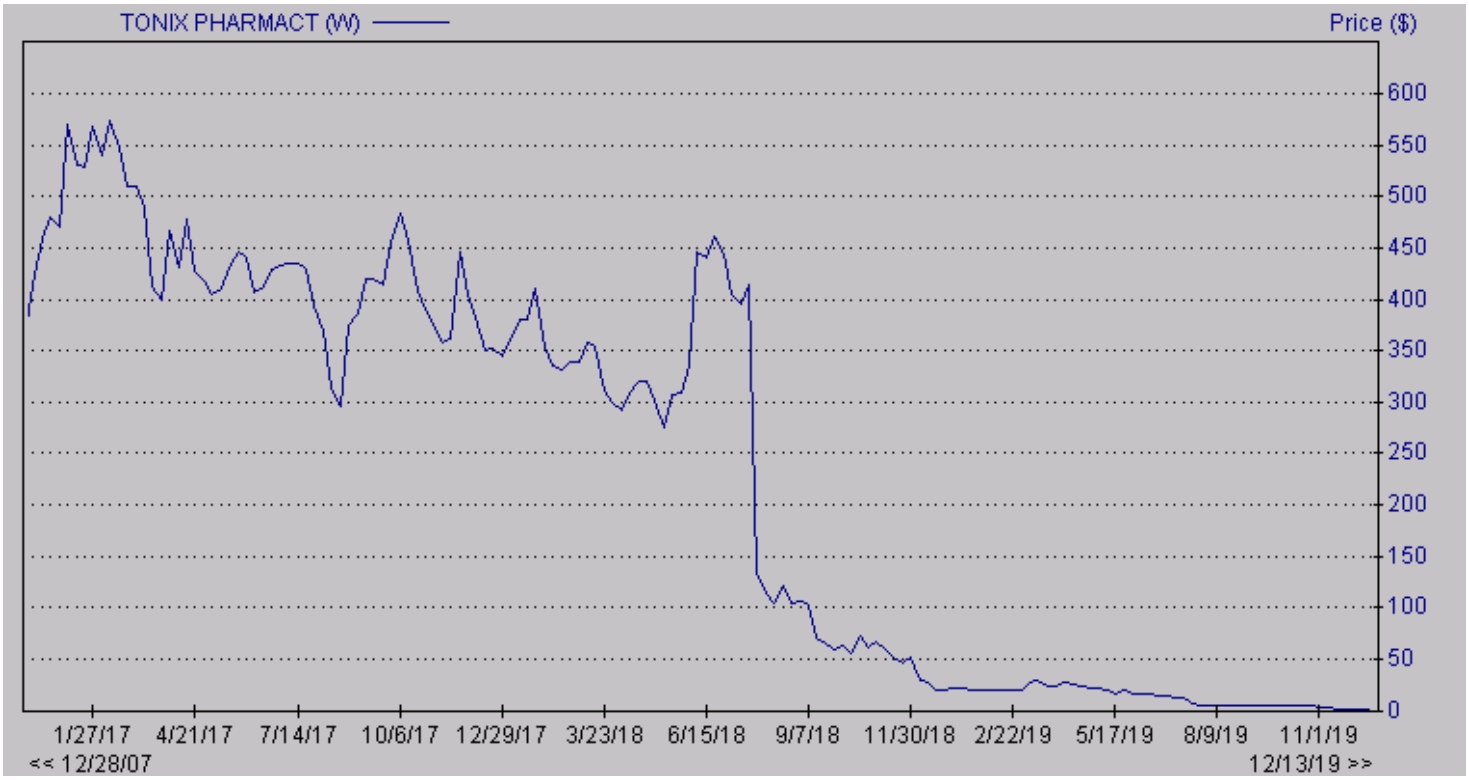
PROJECTED FINANCIALS

Tonix Pharmaceuticals	2018 A	Q1 A	Q2 A	Q3 A	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	$3.6	$5.1	$4.1	$16.6	$20.0	$23.0
SG&A	$8.8	$2.4	$2.4	$2.8	$2.1	$9.7	$10.0	$12.0
Operating Income	($26.3)	($6.3)	($5.9)	($7.9)	($6.2)	($26.3)	($30.0)	($35.0)
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)	($5.8)	($7.8)	($6.2)	($26.2)	($29.9)	($34.9)
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)	($5.8)	($7.8)	($6.2)	($26.2)	($29.9)	($34.9)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($268.11)**	**($12.86)**	**($9.47)**	**($5.69)**	**($1.23)**	**($14.01)**	**($2.49)**	**($2.33)**
YOY Growth	*-15.4%*	-	-	-	-	*-94.8%*	*-82.2%*	*-6.6%*
Weighted Shares Outstanding	0.1	0.5	0.6	1.4	5.0	1.9	12.0	15.0

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

© Copyright 2019, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2019, Zacks Investment Research. All Rights Reserved.

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.

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.