Zacks Small-Cap Research

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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: A Closer Look at Data from the AtEase Trial of TNX-102 SL in Military-Related PTSD…

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 $12/share. This model is highly dependent upon continued clinical success of TNX-102 SL in both indications and will be adjusted accordingly based upon future clinical results.

Current Price (06/13/16)	$2.40
Valuation	**$12.00**

OUTLOOK

On May 31, 2016, Tonix Pharmaceuticals Holding Corp. (TNXP) presented data from the Phase 2 AtEase study for TNX-102 SL in PTSD at the American Society of Clinical Pharmacology Annual Meeting. The data confirm that the 5.6 mg dose of TNX-102 SL was effective at reducing the symptoms of military-related PTSD and was well tolerated. This report provides a detailed look at the data presented along with a comparison to a previous registration-quality PTSD study.

The company is hoping to meet with the FDA soon to map out the Phase 3 program for the 5.6 mg dose of TNX-102 SL. Two Phase 3 studies are likely to be needed, with the first potentially getting underway in the first half of 2017.

SUMMARY DATA

52-Week High	**$10.50**
52-Week Low	**$1.94**
One-Year Return (%)	**-72.79**
Beta	**2.62**
Average Daily Volume (sh)	**627,520**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$45**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**42**
Insider Ownership (%)	**10**
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 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**

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)
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 E	0 E	0 E	0 E
2017					0 E
2018					0 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.71 A	-$0.73 A	-$0.72 A	-$0.71 A	-$2.86 A
2016	-$0.74 A	-$0.57 E	-$0.52 E	-$0.47 E	-$2.30 E
2017					-$2.04 E
2018					-$2.00 E

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WHAT'S NEW

On May 31, 2016, Tonix Pharmaceuticals Holding Corp. (TNXP) presented data for TNX-102 SL from the Phase 2 AtEase study at the American Society of Clinical Pharmacology Annual Meeting. The data presented confirms that the 5.6 mg dose of TNX-102 SL was effective at reducing the symptoms of military-related Post Traumatic Stress Disorder (PTSD) and was well tolerated. Below we provide an overview of the data presented and provide context in relation to previous PTSD studies.

Overview of PTSD

PTSD is a psychiatric disorder that occurs from exposure to a wide variety of extreme stressors. One of the most common is war and combat. The Diagnostic and Statistical Manual of Mental Disorders (DSM) of the American Psychiatric Association (APA) most recent definition of PTSD was published in 2013 in DSM-5. Diagnosis of PTSD occurs when a patient meets a certain set of criteria related to exposure to a traumatic event, four sets of symptom clusters, two subtypes, the sufficient duration of symptoms, the impact on an individuals ability to function, and the lack of substance abuse and other medical illnesses that could account for the symptoms. It is estimated that approximately 8 million individuals in the U.S. suffer from PTSD.

Military personnel are at an increased risk of developing PTSD, with an estimated 14% of all veterans from Operation Iraqi Freedom and Operation Enduring Freedom (OIF/OEF) suffering from the condition. PTSD is now the third most common disability for which veterans receive disability benefits, behind tinnitus and hearing loss (McNally *et al.*, 2013). The number of veterans receiving PTSD-related disability benefits increased by 80% from 1999 to 2004 (Frueh *et al.*, 2007). For veterans receiving benefits for mental health disorders, 58% are for PTSD, with that percentage increasing to 75% for veterans of OIF/OEF. In 2012, the total number of veterans diagnosed with PTSD in the VA system was 638,451 (Bowe *et al.*, 2015).

Current treatment options for PTSD include both pharmacological and psychotherapeutic modalities. A number of different pharmacological treatments are utilized for PTSD (including alpha-adrenergic blockers, anticonvulsants, atypical antipsychotics, monoamine oxidase inhibitors, tricyclic antidepressants, and selective serotonin reuptake inhibitors), but only two are FDA-approved for the treatment of PTSD (sertraline and paroxetine) and they typically have undesirable side effects such as weight gain and sexual dysfunction.

AtEase Study of TNX-102 SL in PTSD

The AtEase study was a Phase 2 randomized, double blind, placebo controlled trial of TNX-102 SL in patients with military-related PTSD (NCT02277704). The three-arm trial enrolled 231 participants, who were randomized to receive either 2.8 mg of TNX-102 SL (n=90), 5.6 mg of TNX-102 SL (n=49), or placebo (n=92) taken sublingually at bedtime daily for 12 weeks. The primary endpoint of the trial was the week twelve mean change from baseline in the total CAPS-5 (Clinician-Administered PTSD Scale) score in participants who received TNX-102 SL as compared to those who received placebo. Safety was also evaluated. The CAPS is a structured interview designed to make a categorical PTSD diagnosis and provide a total PTSD symptom severity score, and is considered the "gold standard" in PTSD assessment and corresponds to the DSM-5 diagnosis for PTSD. The assessor combines information on frequency and intensity of an item into a single severity rating (0-4) for the 20 DSM-5 PTSD symptoms, thus patients are assigned a score with a maximum of 80 points possible. A higher score corresponds to more severe PTSD and patients are categorized as follows:

CAPS-5 Score	Category
0 – 10	asymptomatic/few symptoms
11 – 22	mild PTSD/subthreshold
23 – 34	moderate PTSD/threshold (moderate dx cutoff of 25 is a few points into the moderate range)
35 – 46	severe PTSD (stringent dx cutoff of 37 is a few points into the severe range)
47 +	extreme PTSD

AtEase Study Results

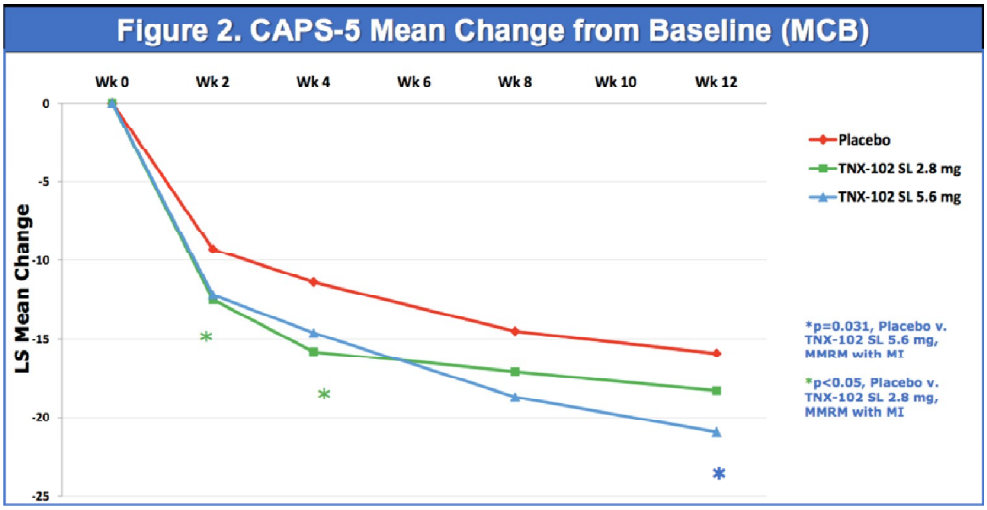
The following table gives patient demographics for the AtEase study. The study was very evenly distributed across the three treatment groups, particularly in regard to average CAPS score, which averaged 39.5, 39.5, and 39.3 for the placebo, 2.8 mg TNX-102 SL, and 5.6 mg TNX-102 SL groups, respectively.

Table 1. Patient Demographics and Characteristics				
Variable	Placebo N=92	TNX-102 SL 2.8 mg N=90	TNX-102 SL 5.6 mg N=49	Overall N=231
Females, no. (%)	6 (6.5%)	6 (6.7%)	4 (8.2%)	16 (6.9%)
Mean age, yrs (SD)	32.0 (6.5)	34.5 (8.3)	34.8 (9.0)	33.6 (7.8)
Weight, kg (SD)	91.6 (16.9)	90.9 (18.2)	90.8 (17.4)	91.1 (17.5)
BMI, kg/m2 (SD)	28.9 (4.4)	29.0 (5.2)	29.0 (4.7)	28.9 (4.8)
Education, some college or beyond	72 (78.2%)	80 (88.9%)	41 (83.7%)	193 (83.6%)
% currently employed	54 (58.7%)	56 (62.2%)	33 (67.3%)	143 (61.9%)
% in military service at time of index trauma	91 (98.9%)	85 (94.4%)	49 (100%)	225 (97.4%)
Number of: Active Duty/Reservists/Veterans	8/4/79	9/5/71	5/7/37	22/16/187
Number of: Law Enforcement Officers	1	5	0	6
Ave time since index trauma, yrs (SD)	7.1 (3.6)	7.3 (3.3)	6.2 (3.3)	7.0 (3.4)
Ave deployments, military/veterans (SD)	2.2 (1.84)	2.3 (2.15)	2.6 (2.1)	2.3 (2.00)
Baseline CAPS-5 Scores (SD)	39.5 (7.7)	39.5 (8.0)	39.3 (8.1)	39.5 (7.85)

***Source*: Sullivan *et al.*, 2016**

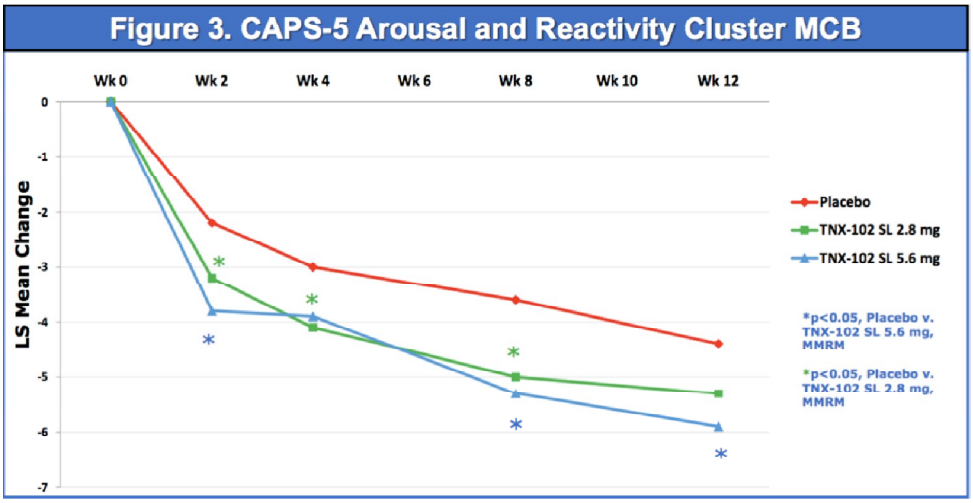
The following chart shows the mean change from baseline in CAPS-5 score through week 12 of the study. There was a rather sizeable placebo effect in the trial, however this was not unexpected. The reason for this is that as part of the trial, participants had to meet with and talk to clinicians every few weeks so that a CAPS-5 score could be determined at those time points. The act of meeting with a mental health clinician and discussing their symptoms can be thought of as a form of exposure psychotherapy for patients, which is known to help those with PTSD. However, even when accounting for the placebo response, there was still a statistically significant decrease in CAPS-5 score for patients that were treated with 5.6 mg TNX-102 SL (P=0.031; effect size=0.39). In addition, it appears there may have been a plateau reached at the 2.8 mg dose, but that does not appear to be the case for the 5.6 mg dose.

Figure 2. CAPS-5 Mean Change from Baseline (MCB)



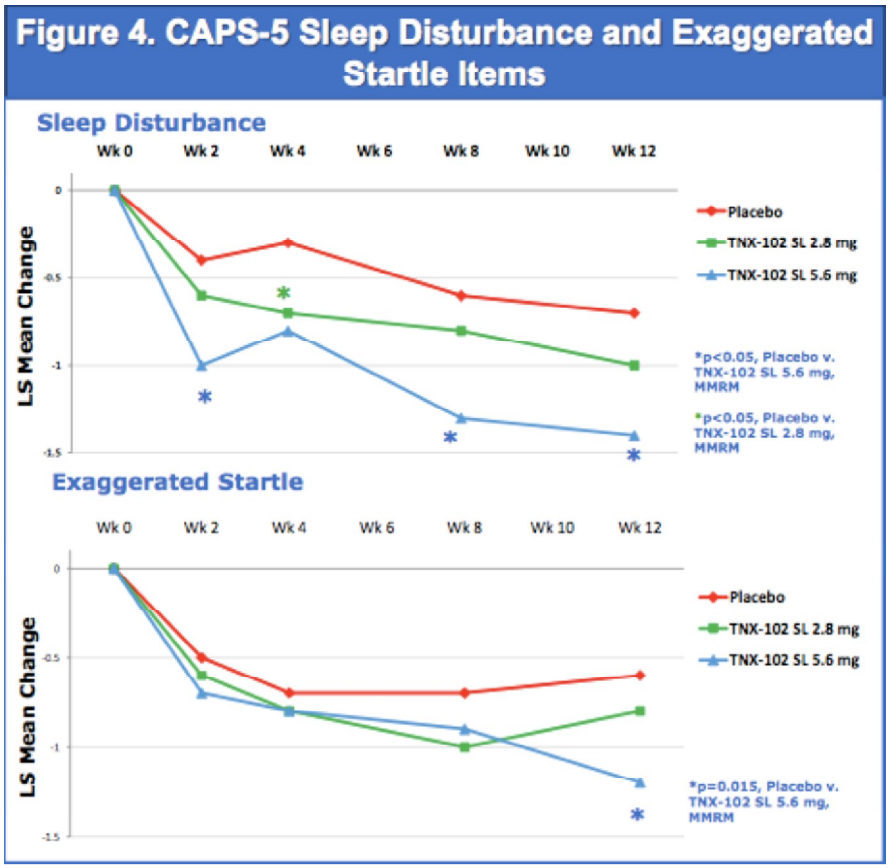
***Source*: Sullivan *et al.*, 2016**

As mentioned above, the CAPS-5 score is derived from assessing 20 symptoms of PTSD. These 20 symptoms are divided into “clusters”, one of which covers alterations in arousal and reactivity, which correspond to ways that the brain remains “on edge” and wary of additional threats. The arousal and reactivity cluster has been notoriously difficult to effectively treat in PTSD patients, however in the AtEase study the 5.6 mg dose of TNX-102 SL resulted in a statistically significant decrease compared to placebo, as shown in the following chart.



***Source*: Sullivan *et al.*, 2016**

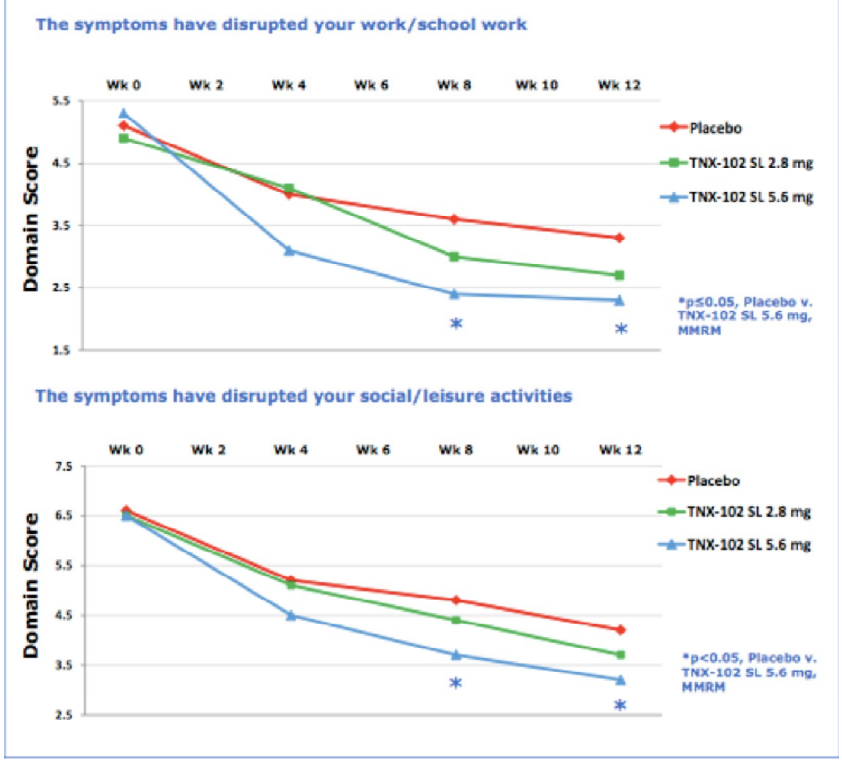
The following chart gives the results from two items of the arousal and reactivity cluster. The top chart shows the change in sleep disturbance, in which there appeared to be a dose effect with the 5.6 mg treated patients experiencing a statistically significant improvement in sleep, while the 2.8 mg treated patients were intermediate between placebo treated and 5.6 mg treated patients. The bottom chart shows the change in exaggerated startle, which is a "learned response" that occurs due to the traumatic event experienced by the patient. Since it is a learned response, a patient must "unlearn" the response, which would be expected to take time and is likely aided by restorative sleep, which is associated with cognitive restoration. The fact that the change in exaggerated startle became significant at 12 weeks fits with the data showing a significant decrease in sleep disturbance over time (likely resulting in more restorative sleep), thus contributing to the patients' ability to "unlearn" the exaggerated startle reflex. This data is particularly important, as exaggerated startle is another area that has proven very difficult to treat in patients with PTSD.



***Source*: Sullivan *et al.*, 2016**

The Sheehan Disability Scale is a self-administered test designed to assess the impact of a patient's PTSD symptoms on three major areas of life. The patient rates how his or her 1) work/school life, 2) social life/leisure activities, and 3) family life or home responsibilities are impacted by their symptoms. The scale is widely used in clinical trials testing pharmacological agents for various psychiatric conditions. The following charts show how the 5.6 mg dose of TNX-102 SL produced a statistically significant decrease in disruption in patients work life and social life. This data shows how treatment with TNX-102 SL has a real-world affect that positively impacts a patient's life.

Figure 5. Sheehan Disability Scale Work/School and Social/Leisure Domain Scores



***Source:* Sullivan *et al.*, 2016**

Importantly, these positive results were seen at the 5.6 mg dose of TNX-102 SL with a relatively benign adverse event profile. The following table lists all adverse events that were seen in ≥5% of patients in any group. The most common side effect for those administered TNX-102 SL was tongue or mouth numbness (hypoaesthesia oral). This side effect has been seen previously in clinical trials involving TNX-102 SL, is usually transient, and often resolves within 30-45 minutes after administration. The low rate of adverse events may have also contributed to the fact that patients taking 5.6 mg TNX-102 SL had the highest retention rate (83.7%) compared to those taking 2.8 mg TNX-102 SL (78.9%) or placebo (72.8%).

Table 4. Adverse Events (≥ 5% rate in any group)

Preferred Term	Placebo N=94	TNX-102 SL 2.8 mg N=93	TNX-102 SL 5.6 mg N=50	Overall N=237
Local Administration Site Reactions				
Hypoaesthesia oral	2 (2.1%)	36 (38.7%)	18 (36.0%)	54 (37.8%)
Paraesthesia oral	3 (3.2%)	15 (16.1%)	2 (4.0%)	17 (11.9%)
Glossodynia	1 (1.1%)	3 (3.2%)	3 (6.0%)	6 (4.2%)
Systemic Adverse Events				
Somnolence	6 (6.4%)	11 (11.8%)	8 (16.0%)	19 (13.3%)
Dry mouth	10 (10.6%)	4 (4.3%)	8 (16.0%)	12 (8.4%)
Headache	4 (4.3%)	5 (5.4%)	6 (12.0%)	11 (7.7%)
Insomnia	8 (8.5%)	7 (7.5%)	3 (6.0%)	10 (7.0%)
Sedation	1 (1.1%)	2 (2.2%)	6 (12.0%)	8 (5.6%)
Upper respiratory tract infection	5 (5.3%)	3 (3.2%)	2 (4.0%)	5 (3.5%)
Abnormal dreams	5 (5.3%)	1 (1.1%)	1 (2.0%)	2 (1.4%)
Weight increased	5 (5.3%)	1 (1.1%)	1 (2.0%)	2 (1.4%)

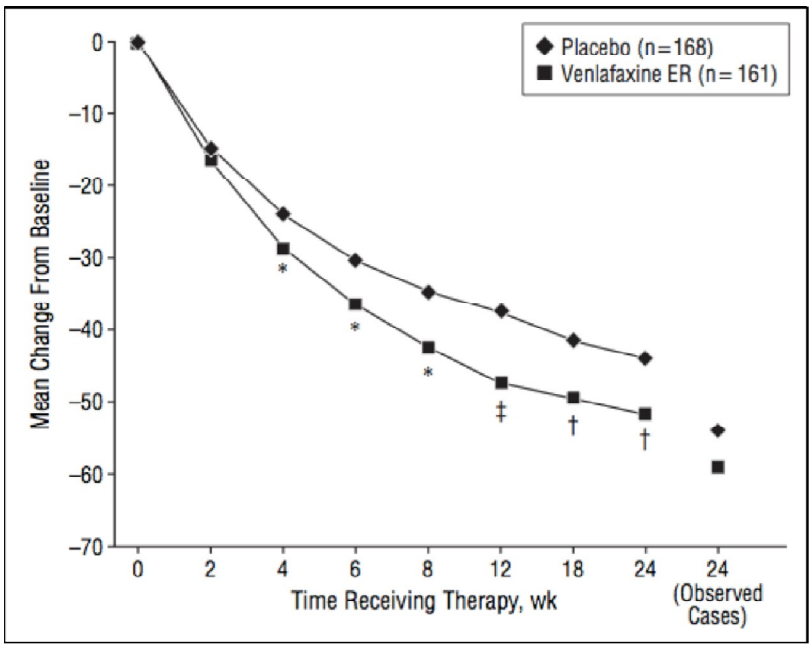
***Source:* Sullivan *et al.*, 2016**

Putting the Data Into Context

We identified a clinical trial from 2006 that examined venlafaxine extended release (ER) in a mostly civilian PTSD population to help investors get a feel for what type of results are seen in other well-designed, registration quality, multi-center trials (Davidson *et al*., 2006). Since no two clinical trials are the same, it's important to point out the major differences between the venlafaxine ER trial and the AtEase trial.

1) The venlafaxine ER trial was composed of a mostly civilian population as only 12% of participants had combat experience. This is in contrast to the AtEase study where close to 100% of participants experienced their trauma during military service.
2) The patient population in the venlafaxine ER trial was 54% female compared only 7% female in the AtEase trial.
3) The venlafaxine ER trial had 168 subjects taking placebo and 161 subjects taking venlafaxine ER, while the AtEase study had 92 subjects taking placebo and 49 subjects taking 5.6 mg TNX-102 SL.
4) The primary outcome was at six months in the venlafaxine ER trial, thus treatment was twice as long as in the AtEase trial.

The following figure shows the change in baseline in CAPS-SX_{17}, which assessed the 17 PTSD symptoms in DSM-IV (DSM-5 was not published until 2013). Just as with the AtEase results, there is a very large placebo effect, thus showing this is a common outcome in PTSD trials.



***Source*: Davidson *et al*., 2006**

The following table shows the *P* values and effect size for the total CAPS-SX_{17} and the three different clusters. Treatment with venlafaxine ER resulted in a statistically significant difference in the total CAPS-SX_{17} score (*P*=0.006) as well as for cluster B (*P*=0.008) and cluster C (*P*=0.006), however cluster D was not statistically significant (*P*=0.06). Cluster D is the arousal and reactivity cluster, and the results with venlafaxine ER are in contrast to what was seen in the AtEase trial, where treatment with 5.6 mg TNX-102SL resulted in a statistically significant decrease in the arousal and reactivity cluster. In addition, as the following table shows, the effect size for overall CAPS-SX_{17} score in the venlafaxine ER trial was 0.31, while the effect size seen with 5.6 mg TNX-102SL for the CAPS-5 score was 0.39, showing that TNX-102SL resulted in a greater treatment effect than venlafaxine ER.

Outcome Measure Score	Venlafaxine ER Mean (SD), (n = 161)	Placebo Mean (SD), (n = 168)	Mean Difference	Effect Size	*P* Value
CAPS-SX_{17} total	29.2 (26.09)	38.1 (29.11)	−8.9	0.31	.006
CAPS-SX_{17} cluster B	8.0 (8.5)	10.6 (9.97)	8	0.26	.008
CAPS-SX_{17} cluster C	11.5 (11.41)	15.2 (11.82)	11.5	0.31	.006
CAPS-SX_{17} cluster D	9.8 (8.83)	12.2 (9.73)	9.8	0.25	.06

***Source*: Davidson *et al*., 2006**

Lastly, the following table shows the mean Sheehan Disability Scale scores and differences between venlafaxine ER and placebo treated patients. While there was a 0.6-point separation between active and control patients for the work/school and social life domains in the venlafaxine ER trial, in the AtEase study the separation for those two domains was 1.0 point for each (shown in Figure 5) above.

Outcome Measure Score	Venlafaxine ER Mean (SD), (n = 161)	Placebo Mean (SD), (n = 168)	Mean Difference	Effect Size	*P* Value
SDS total‡	9.2 (8.84)	11.2 (8.67)	−2	0.23	.03
SDS work/school	3.1 (3.20)	3.7 (3.07)	−0.6	0.20	.05
SDS social life	3.2 (3.07)	3.8 (2.94)	−0.6	0.20	.08
SDS family life/home responsibilities	2.8 (2.99)	3.6 (3.09)	−0.8	0.26	.01

***Source*: Davidson *et al*., 2006**

Next Steps in PTSD

Tonix has requested a meeting with the FDA to map out a Phase 3 program for the 5.6 mg dose of TNX-102 SL in PTSD. It will likely involve two clinical trials. The first clinical trial will likely be in military-related PTSD and could begin as soon as the first quarter of 2017 and will probably enroll approximately twice as many patients as the AtEase study. Now that Tonix knows how to recruit for a study such as that, we expect enrollment to take approximately one year, with topline data under this scenario being available in the first half of 2018.

The second Phase 3 study would likely involve individuals with any type of PTSD, not just military-related. The reason for this is because recruiting for two studies in military-related PTSD would likely prove difficult, as there are many more civilian patients with PTSD than military-related. In addition, civilians with PTSD tend to be more amenable to medication treatment for PTSD and have been more responsive to medication in prior trials. For example, the FDA approved sertraline for the treatment of PTSD based on studies involving only civilians. However, a multi-center clinical trial of sertraline for military-related PTSD was unsuccessful. It is unclear at this point whether this second trial would be run concurrently with the first trial or not.

Based on the fact that PTSD is such a serious issue, particularly in the military, as exemplified by the fact that the suicide rate among military veterans is quite high, with as many as five to eight thousand suicides a year (2012 VA Suicide Data Report), it is conceivable that strong results in one Phase 3 clinical trial in PTSD could form the basis for a regulatory filing along with the data from the AtEase trial. This would depend on FDA review and the Phase 3 results being highly statistically significant, and at this point we only mention it as a possibility. We may get more clarity on this possibility after Tonix is able to meet with the FDA regarding the Phase 3 program.

Conclusion and Valuation

The data set for the AtEase trial presented by Tonix shows that at 5.6 mg TNX-102SL was effective in a difficult to treat population (mostly males with military-related PTSD), effectively treated difficult aspects of PTSD (arousal and reactivity symptoms), and was well tolerated. Up to this point, there was essentially no effective pharmacological treatment option with established efficacy for military-related PTSD, and the AtEase results could be looked at as a real scientific breakthrough. We will be interested to hear more about the company's plan for a Phase 3 program once management has had a chance to meet with the FDA.

In terms of timeline, we anticipate the first Phase 3 trial for PTSD initiating in the first quarter of 2017, with results from that trial most likely by the first half of 2018. We will await further guidance on whether the second Phase 3 trial will be run concurrently with the first Phase 3 trial or not. We model for peak sales of TNX-102SL in PTSD of approximately $650 million, but this number is highly contingent upon successful results in a Phase 3 program in both a military and civilian population.

Based on our model, we value TNXP at $12/share. The stock currently trades a large discount to this valuation, and positive data from the AFFIRM trial, which will be released in the third quarter of 2016, could move the stock closer to our target.

PROJECTED FINANCIALS

Tonix Pharmaceuticals Holding Corp.
Income Statement

Tonix Pharmaceuticals	2015 A	Q1 A	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E
TNX-102 SL (FM)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
TNX-102 SL (PTSD)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Research & Collaborations	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
CoGS	$0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$35.5	$10.7	$8.0	$7.0	$6.0	$31.7	$34.0	$37.0
SG&A	$12.7	$3.3	$2.9	$3.0	$3.0	$12.2	$13.0	$15.0
Operating Income	($48.2)	($14.0)	($10.9)	($10.0)	($9.0)	($43.9)	($47.0)	($52.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($48.1)	($14.0)	($10.9)	($9.9)	($9.0)	($43.9)	($47.0)	($52.0)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($48.1)	($14.0)	($10.9)	($9.9)	($9.0)	($43.9)	($47.0)	($52.0)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.86)**	**($0.74)**	**($0.57)**	**($0.52)**	**($0.47)**	**($2.30)**	**($2.04)**	**($2.00)**
YOY Growth	*3.5%*	-	-	-	-	*-19.8%*	*-11.0%*	*-2.1%*
Weighted Shares Outstanding	16.8	18.9	19.1	19.2	19.3	19.1	23.0	26.0

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

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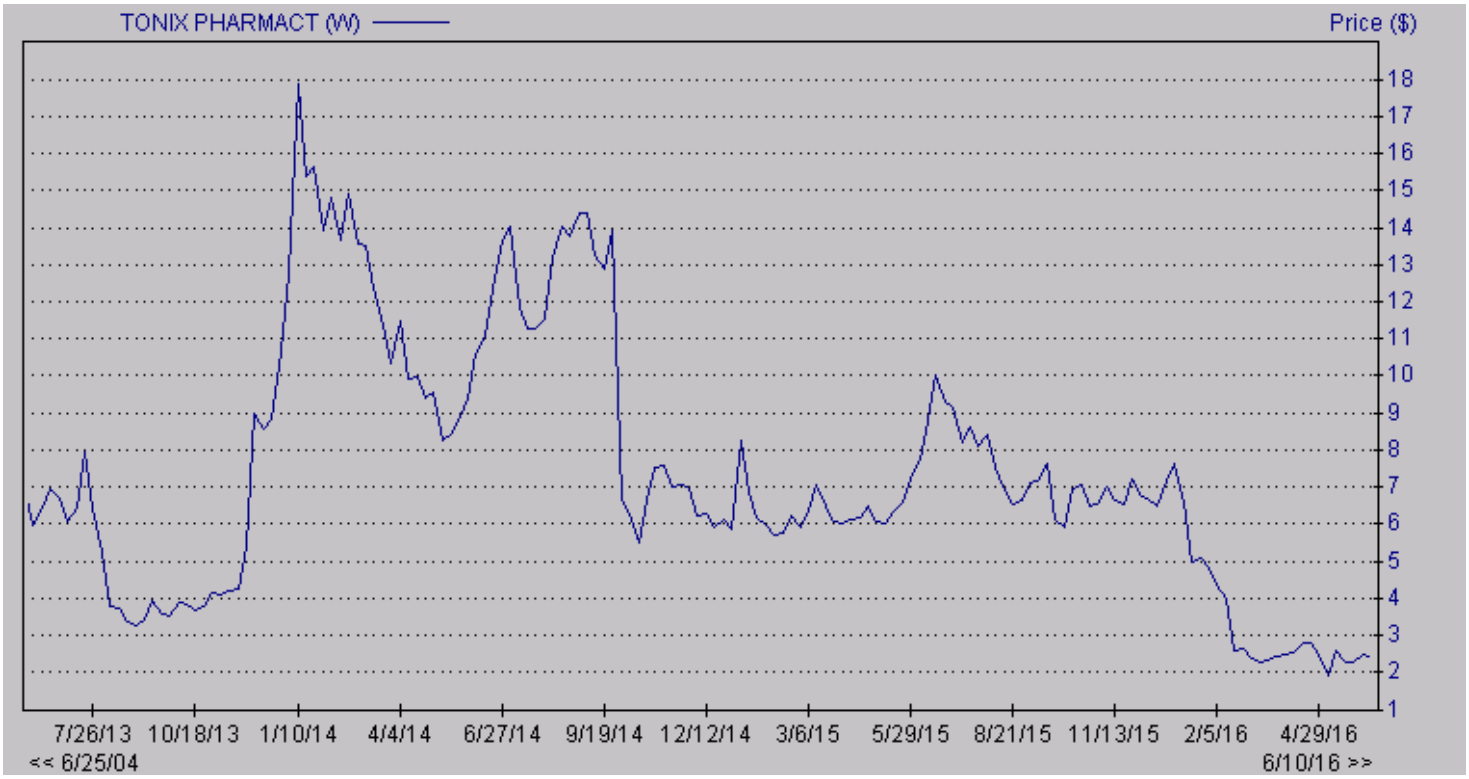
HISTORICAL STOCK PRICE



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