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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Retrospective Analyses from HONOR and AtEase Trials Presented…

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL PTSD, TNXP is valued at $3.00/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 (08/27/18)	$1.04
Valuation	**$3.00**

OUTLOOK

On August 21, 2018, Tonix Pharmaceuticals Holding Corp. (TNXP) announced the presentation of results from the recently discontinued Phase 3 HONOR trial of TNX-102 SL (cyclobenzaprine HCl sublingual tablet) in patients with posttraumatic stress disorder (PTSD) along with retrospective analyses from the HONOR trial and the Phase 2 AtEase trial. While the HONOR trial was stopped early due to not meeting a study continuation threshold on the primary outcome of improvement in CAPS-5 at Week 12, the retrospective analysis showed a treatment effect (as measured by the primary outcome) in patients who experienced trauma less than or equal to nine years prior to screening (*P* = 0.039). Thus, we believe Tonix will focus future studies on those individuals who have experienced more recent trauma.

SUMMARY DATA

52-Week High	**$4.83**
52-Week Low	**$1.02**
One-Year Return (%)	**-72.27**
Beta	**2.57**
Average Daily Volume (sh)	**1,275,756**
Shares Outstanding (mil)	**9.5**
Market Capitalization ($mil)	**$10**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**14**
Insider Ownership (%)	**4**
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	**-1.7**
P/E using 2019 Estimate	**-1.7**

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)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 A	0 A	0 E	0 E	0 E
2019					0 E
2020					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$1.27 A	-$0.65 A	-$0.77 A	-$0.70 A	-$3.17 A
2018	-$0.88 A	-$0.73 A	-$0.63 E	-$0.63 E	-$2.86 E
2019					-$1.98 E
2020					-$1.63 E

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WHAT'S NEW

Business Update

HONOR Data and Retrospective Analyses Presented

On August 21, 2018, Tonix Pharmaceuticals Holding Corp. (TNXP) announced a poster presentation at the 2018 Military Health System Research Symposium that included results from the Phase 3 HONOR trial and retrospective analyses from the HONOR trial and the Phase 2 AtEase trial of TNX-102 SL (cyclobenzaprine HCl sublingual tablet) in patients with posttraumatic stress disorder (PTSD).

In July 2018, the company announced that the HONOR trial was stopped early due to a lack of separation between the placebo group and treated group at the 12-week timepoint. The poster presentation reported that a treatment effect did exist in subjects that had experienced trauma less than or equal to nine years prior to screening, a group that included approximately 50% of the modified intent to treat (mITT) population. As can be seen in the following table comparing patient demographics in the Phase 2 AtEase trial (P201) and the Phase 3 HONOR trial (P301), the time since trauma in the P301 study was much higher than in the P201 study.

Table 2. Participant Demographics and Characteristics

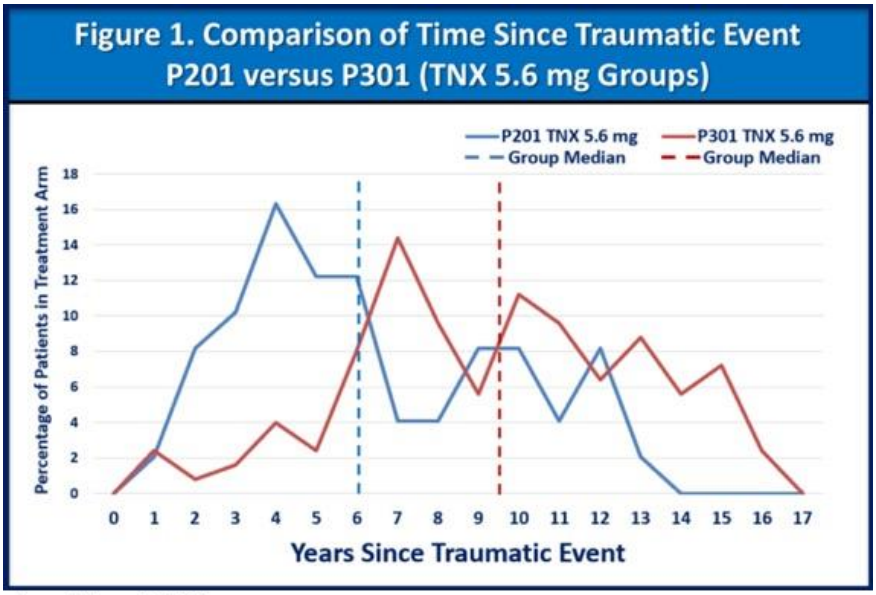
Variable	P201			P301	
	Placebo N=92	TNX 2.8 mg N=90	TNX 5.6 mg N=49	Placebo N=127	TNX 5.6 mg N=125
Females, %	6.50%	6.70%	8.20%	13.40%	8.00%
Age, yrs. (SD)	32.0	34.5	34.8	35.5	35.9
Body Mass Index, kg/m^2	28.9	29.0	29.0	29.3	29.9
Employment (current), %	58.7%	62.2%	67.3%	63.0%	55.2%
Unable to work due to PTSD, %	9.8%	11.1%	14.3%	12.6%	16.8%
Active Duty/Reservists/Veterans, No.	8/4/79	9/5/71	5/7/37	17/0/110	9/0/116
Time since trauma, mean years	7.1	7.3	6.2	9.2	9.2
Time since trauma, median years	7.0	7.2	6.0	9.3	9.5
Combat index trauma, %	80.4%	85.6%	93.8%	77.2%	83.2%
Number of deployments	2.2	2.3	2.6	3.0	2.6
Baseline CAPS-5 Scores	39.5	39.5	39.3	42.4	42.0
Baseline BDI-II Scores	NA	NA	NA	23.0	25.6
Baseline MADRS Scores	17.3	17.6	16.1	NA	NA

BDI-II=Beck Depression Inventory-II; CAPS-5=Clinician-Administered PTSD Scale for DSM-5; MADRS= Montgomery-Åsberg Depression Rating Scale; NA=not applicable – scale not administered in designated study

Source: Sullivan *et al.*, 2018

The difference in time since trauma between the two studies is also apparent when comparing the time since the traumatic event broken down by percentage of patients for each year since the trauma. The largest group of patients in the P201 study was clustered around the 4-year mark with a median time since trauma of 6.0 years, while the largest group of patients in the P301 study was clustered around the 7-year mark with a median time since trauma of 9.5 years. Since the P301 trial was a study of military veterans that took place approximately two years since the P201 trial (with no major troop deployments since that time) it was expected that there would likely be a two-year gap in the median time since trauma between the two trials, thus the three and a half year difference in median time since trauma (and the increase in patients that experienced trauma greater than nine years ago) is somewhat surprising and we are unsure why there was such an increase in patients who were further away from their trauma.

Figure 1. Comparison of Time Since Traumatic Event P201 versus P301 (TNX 5.6 mg Groups)



Source: Sullivan *et al.*, 2018

The interim results from the P301 study are shown in the following table. As can be seen, there was a statistically significant difference in the CAPS-5 score at Week 4 between the placebo group and the TNX-102 SL group (*P* = 0.019). However, this effect was not seen at either Week 8 or Week 12, owing mostly to the continued decrease in CAPS-5 for the placebo group and virtually no change in CAPS-5 for the TNX-102 SL group from Week 4 to Week 12.

Table 3. P301 Study Primary Analysis in mITT Population

	Placebo		TNX-102 SL 5.6 mg		
Visit	N=127		N=125		
Statistic	CAPS-5 Value	MCFB	CAPS-5 Value	MCFB	Difference
Week 4					
LS Mean (SE)	31.0 (1.62)	-11.2 (1.62)	27.5 (1.73)	-14.7 (1.73)	-3.6 (1.51)
95% CI	(27.8,34.2)	(-14.4,-8.0)	(24.1,30.9)	(-18.1,-11.4)	(-6.5,-0.6)
p-value					0.019
Week 8					
LS Mean (SE)	29.4 (1.76)	-12.8 (1.76)	27.6 (1.86)	-14.6 (1.86)	-1.8 (1.77)
95% CI	(25.9,32.8)	(-16.3,-9.4)	(24.0,31.3)	(-18.2,-10.9)	(-5.2,1.7)
p-value					0.321
Week 12					
LS Mean (SE)	28.0 (1.80)	-14.2 (1.80)	27.0 (1.90)	-15.2 (1.90)	-1.0 (1.88)
95% CI	(24.5,31.5)	(-17.7,-10.7)	(23.3,30.8)	(-18.9,-11.4)	(-4.7,2.7)
p-value					0.602

CAPS-5=Clinician-Administered PTSD Scale; LS=least squares; MCFB=mean change from baseline; SE=standard error

Source: Sullivan *et al.*, 2018

Based on the 9.5-year median time since trauma in the P301 study, Tonix examined whether there was a difference in treatment effect for those that had experienced a trauma equal to or earlier than nine years ago compared to those who experience a trauma greater than nine years ago. The following table shows that there was a clinically meaningful treatment effect for those that had experienced a trauma less than or equal to nine years ago, as judged by the change difference in the CAPS-5 score at Week 12 (*P* = 0.039). It should be noted that we calculated the mean time since trauma in the "≤ 9 years" group to be 6.4 years, which was almost identical to the mean time since trauma in the P201 TNX-102 SL 5.6 mg group of 6.2 years.

Table 4. P301 Study Subsamples on CAPS-5 - ≤9 & >9 Years Since Trauma										
	Time Since Index Trauma ≤9 Years					Time Since Index Trauma >9 Years				
	Placebo (N=60)		TNX 5.6 mg (N=61)			Placebo (N=67)		TNX 5.6 mg (N=64)		
Visit Statistic	Value	MCFB	Value	MCFB	Diff	Value	MCFB	Value	MCFB	Diff
Week 4										
LS Mean	34.2	-7.8	27.3	-14.7	-6.9	33.1	-9.3	30.7	-11.7	-2.4
p-value					0.004					0.300
Week 8										
LS Mean	32.4	-9.6	27.2	-14.8	-5.2	31.5	-10.9	31.3	-11.1	-0.2
p-value					0.069					0.940
Week 12										
LS Mean	33.2	-8.8	27.3	-14.7	-5.9	28.3	-14.1	30.1	-12.3	1.8
p-value					0.039					0.509

CAPS-5=Clinician-Administered PTSD Scale; Diff=least squares mean difference; LS=least squares; MCFB=mean change from baseline

Source: Sullivan *et al.*, 2018

Epidemiological data suggests that approximately 1/3rd of PTSD patients remit during the first year ("rapid remitters"), another 1/3rd remit over the next four to five years ("slow remitters"), and in the last 1/3rd PTSD lasts for a long time ("non-remitters") (Kessler *et al.*, 1995). These data are similar to what is seen in military veterans (Armenta *et al.*, 2018). Based on the results from the P201 and P301 studies, it appears that there is a treatment effect based on time since trauma, indicating that the TNX-treatment responsive patients are likely those in the "rapid" and "slow" remitter phase. Thus, future development of TNX-102 should focus on those patients that are ≤ 9 years removed from their trauma. The data also point to a need to diagnose PTSD, particularly military-related PTSD, in a timely fashion in order to increase the chance for successful treatment.

Financial Update

On August 13, 2018, Tonix announced financial results for the second quarter of 2018. As expected, the company did not report any revenues. Net loss for the second quarter of 2018 was $6.1 million, or $0.73 per share, compared to a net loss of $4.8 million, or $0.65 per share, in the second quarter of 2017. R&D expenses were $4.1 million in the second quarter of 2018 compared to $2.8 million in the second quarter of 2017. The increase was predominantly due to the clinical development work associated with the PTSD program. G&A expenses were $2.1 million in the second quarter of 2018 compared to $2.0 million in the second quarter of 2017. The increase was primarily due to increased professional fees partially offset by lower compensation expenses as a result of fewer personnel.

Tonix exited the second quarter of 2018 with approximately $16.7 million in cash and cash equivalents. Cash burn for the second quarter of 2018 was approximately $5.5 million. We estimate the company currently has sufficient capital to fund operations through the second quarter of 2019, and additional funds will need to be raised to conduct an additional Phase 3 trial of TNX-102 SL in PTSD. As of August 9, 2018, Tonix had approximately 9.5 million shares outstanding and when factoring in options and reasonably priced warrants a fully diluted share count of approximately 11.5 million.

Conclusion

The company will be meeting with the FDA soon in order to map out the next step in the development of TNX-102 SL in PTSD, and we believe the company will put forth the idea of studying patients less than nine years since trauma. In addition, the next trial will likely include all individuals with PTSD and not be limited to military-related trauma. Lastly, the company will seed guidance on the possibility of using a four-week timepoint for the primary outcome, as there was a clinically meaningful separation in CAPS-5 between the treated group and placebo group in the HONOR trial. We look forward to the company releasing the minutes from the FDA meeting and refining its plans for a Phase 3 study in 2019.

Based on stopping of the HONOR study we have made significant changes to our valuation, including lowering the probability of approval to 33% and lowering the estimated peak sales for TNX-102 SL in PTSD to approximately $500 million. This leads to a net present value for TNX-102 SL in PTSD of $39 million. When combined with the company's current cash position and dividing by the fully diluted share count (with additional shares to account for expected dilution) it leads to a valuation of $3.00.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2017 A	Q1 A	Q2 A	Q3 E	Q4 E	2018 E	2019 E	2020 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	$13.3	$5.2	$4.1	$3.5	$3.5	$16.2	$14.4	$16.5
SG&A	$7.9	$1.8	$2.1	$1.9	$1.9	$7.7	$7.5	$8.0
Operating Income	($21.3)	($7.0)	($6.1)	($5.4)	($5.4)	($23.9)	($21.9)	($24.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.2	$0.1	$0.1	$0.0	$0.0	$0.2	$0.1	$0.1
Pre-Tax Income	($21.1)	($6.9)	($6.1)	($5.4)	($5.4)	($23.8)	($21.8)	($24.4)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($21.1)	($6.9)	($6.1)	($5.4)	($5.4)	($23.8)	($21.8)	($24.4)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($3.17)**	**($0.88)**	**($0.73)**	**($0.63)**	**($0.63)**	**($2.86)**	**($1.98)**	**($1.63)**
YOY Growth	*-79.4%*	-	-	-	-	*-9.8%*	*-30.7%*	*-17.9%*
Weighted Shares Outstanding	6.7	7.9	8.4	8.5	8.5	8.3	11.0	15.0

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

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