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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: HONOR Trial Stopped Early Following Interim Analysis…

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 (08/09/18)	$1.14
Valuation	**$3.00**

OUTLOOK

On July 27, 2018, Tonix Pharmaceuticals Holding Corp. (TNXP) announced that the HONOR study of TNX-102 SL (cyclobenzaprine HCl sublingual tablet) is being stopped early due to a lack of separation between the placebo group and treated group at 12 weeks. The company did state that there was a clinically meaningful separation between the placebo group and treated group at 4 weeks in both CAPS-5 and in the Clinical Global Impression – Improvement scale. Tonix will be meeting with the FDA to propose using the 4-week timepoint as the primary analysis in the next pivotal study. We believe this meeting will take place in 4Q18. At this point we are uncertain as to whether the FDA will agree with the company's proposal, however we will get a clearer picture following release of the meeting minutes.

SUMMARY DATA

52-Week High	**$4.83**
52-Week Low	**$1.10**
One-Year Return (%)	**-66.57**
Beta	**2.57**
Average Daily Volume (sh)	**724,690**
Shares Outstanding (mil)	**8.5**
Market Capitalization ($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 E	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	-$0.63 E	-$0.63 E	-$0.63 E	-$2.77 E
2019					-$1.98 E
2020					-$2.03 E

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WHAT'S NEW

Business Update

HONOR Trial Stopped Early Following Interim Analysis

On July 27, 2018, Tonix Pharmaceuticals Holding Corp. (TNXP) announced that the Phase 3 HONOR trial of TNX-102 SL (cyclobenzaprine HCl sublingual tablet) in patients with posttraumatic stress disorder (PTSD) has been stopped early due to a lack of separation between the placebo group and treated group at the 12-week timepoint. We were surprised and disappointed in this outcome, as we had previously laid out a number of reasons that we believed the trial would succeed. However, these results point to the difficulty in treating PTSD patients.

On the bright side, the company announced that the results at the 4-week timepoint showed a clinically meaningful separation between the placebo group and treated group as determined by both the CAPS-5 (*P*=0.019) and the Clinical Global Impression – Improvement (CGI-I; *P*=0.015), which was a key secondary endpoint. The company is planning to meet with the FDA (which we believe will take place during 4Q18) and will propose using the 4-week timepoint as the primary outcome measure for the next pivotal trial. Until the company presents the full topline data we are unable to determine whether the FDA will agree to the company's proposal, however we will get greater clarity on the issue following release of the meeting minutes, which should be approximately 30 days following the meeting. One of the advantages of TNX-102 SL having Breakthrough Therapy Designation is that the company is able to proactively meet with the FDA to get clarity on the next steps in the drugs development. The company will not move forward with a new clinical trial without the FDA being on board.

In addition to the data at the 4-week timepoint, other encouraging items from the study included the fact that preliminary safety data did not show any serious and unexpected adverse events and the decision to stop the study did not have anything to do with any safety issues or concerns.

TNX-601 a Potential Daytime PTSD Treatment

In addition to TNX-102 SL, Tonix is also developing TNX-601 for the daytime treatment of PTSD (as opposed to TNX-102 SL, which is administered at bed time). TNX-601 is a novel formulation of tianeptine, a tricyclic antidepressant (TCA) molecule that has different pharmacological properties than other TCA's such as amitriptyline and imipramine. It is thought to exert its antidepressant effects through indirect action on glutamate receptors (both AMPA and NMDA) that causes release of brain-derived neurotrophic factor (BDNF) (McEwen *et al*., 2010).

Tianeptine is currently available as a depression treatment in the E.U., Asia, and Latin America, but is not approved in the U.S. or U.K. Tonix has discovered a novel salt and polymorph of tianeptine that could lead to improved stability, consistency, and manufacturing. The company plans on developing TNX-601 as a daytime treatment for PTSD, and due to its reported pro-cognitive and anxiolytic effects it may treat PTSD by a different mechanism of action compared to TNX-102 SL.

Conclusion

The company will be meeting with the FDA to propose the use of the 4-week timepoint as a primary outcome in the next pivotal trial for TNX-102 SL in PTSD, however until the meeting minutes are released we are unsure if the FDA will agree to that proposal. One thing that may work in the company's favor is that Sage Therapeutics is using a four-week timepoint for SAGE-217 for the treatment of major depressive disorder (MDD), which like PTSD can be a chronic psychological disorder. However, whether the use of a four-week timepoint for PTSD is accepted by the FDA as it was for MDD awaits to be seen.

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. As of March 31, 2018, the company had approximately $19 million in cash and cash equivalents, which means the company will need to raise more capital to conduct an additional trial for TNX-102 SL in PTSD and for the company to pursue the compound in Alzheimer's agitation. The company currently has approximately 8.5 million shares outstanding and we estimate an additional 9 million shares will be sold for financing future studies, which leads to a current valuation of $3.00.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2017 A	Q1 A	Q2 E	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	$3.5	$3.5	$3.5	$15.7	$14.4	$16.5
SG&A	$7.9	$1.8	$1.8	$1.9	$1.9	$7.4	$7.5	$8.0
Operating Income	($21.3)	($7.0)	($5.3)	($5.4)	($5.4)	($23.1)	($21.9)	($24.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.2	$0.1	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($21.1)	($6.9)	($5.3)	($5.4)	($5.4)	($22.9)	($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)	($5.3)	($5.4)	($5.4)	($22.9)	($21.8)	($24.4)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($3.17)**	**($0.88)**	**($0.63)**	**($0.63)**	**($0.63)**	**($2.77)**	**($1.98)**	**($2.03)**
YOY Growth	*-79.4%*	-	-	-	-	*-12.6%*	*-28.4%*	*2.6%*
Weighted Shares Outstanding	6.7	7.9	8.3	8.5	8.5	8.3	11.0	12.0

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

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