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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Phase 3 Trial in PTSD Nearing 50% Enrollment; Interim Analysis in 3Q18…

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL PTSD, TNXP is valued at $13/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 (03/19/18)	$3.46
Valuation	**$13.00**

OUTLOOK

Tonix Pharmaceuticals Holding Corp. (TNXP) recently announced financial results for the fourth quarter and full year 2017 and provided a business update. We anticipate the Phase 3 study of TNX-102 SL in PTSD reaching 50% enrollment this quarter and the results of the interim analysis taking place in the third quarter of 2018. Topline results from the fully enrolled trial, if necessary, are expected in the fourth quarter of 2018. We also anticipate the company filing an IND such that it can initiate a Phase 2 study of TNX-102 SL in Alzheimer's agitation once additional funding is in place.

SUMMARY DATA

52-Week High	**$5.57**
52-Week Low	**$2.85**
One-Year Return (%)	**-8.90**
Beta	**2.87**
Average Daily Volume (sh)	**33,898**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$27**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**16**
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**

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 E	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	-$0.68 E	-$0.71 E	-$0.74 E	-$0.78 E	-$2.87 E
2019					-$2.15 E
2020					-$2.03 E

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WHAT'S NEW

Business Update

HONOR Study Nearing 50% Enrollment

In 2017, Tonix announced the first patient was enrolled in the Phase 3 HONOR study of TNX-102 SL 5.6 mg for the treatment of posttraumatic stress disorder (PTSD, NCT03062540). The HONOR trial is a 12-week, multicenter, randomized, double blind, placebo controlled, fixed dose study of 5.6 mg TNX-102 SL (2 x 2.8 mg tablets) taken at bedtime. Approximately 550 subjects who have served in the military and meet a diagnosis of PTSD according to the Clinician-Administered PTSD Scale (CAPS-5) for DSM-5 are eligible to enroll. There are approximately 40 clinical sites currently enrolling patients. The primary endpoint of the trial is change in CAPS-5 at Week 12 (CAPS-5 will also be scored at Week 4 and Week 8).

The CAPS is a structured interview designed to make a categorical PTSD diagnosis and provide a total PTSD symptom severity score. It 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

There is one unblinded interim analysis scheduled when the study has results from approximately 50% of randomized patients (~275 patients). We expect the trial to reach the 50% randomization level before the end of the first quarter of 2018. The interim analysis will be performed by an independent data monitoring committee. We anticipate this occurring in the third quarter of 2018. If the results of the interim analysis require continued enrollment, topline results from the 550 participants will likely be available in the fourth quarter of 2018.

Following the receipt of the final minutes from a meeting held with the FDA earlier this year, Tonix announced that the FDA indicated it might consider a single-study New Drug Application (NDA) for TNX-102 SL based on statistically persuasive topline data from the HONOR study. Typically, the FDA requires two positive Phase 3 clinical trials. In addition, since there is no recognized abuse liability with TNX-102 SL, the FDA agreed that studies assessing abuse potential of TNX-102 SL would not be required as part of an NDA filing.

In order to obtain the necessary safety data on TNX-102 SL required for registration, Tonix is performing an ongoing 12-week open-label extension study that is open to participants who completed the HONOR trial. In addition, the company plans to conduct registration-required open-label extension studies in order to obtain necessary 6- and 12-month safety exposure data since PTSD is a chronic psychiatric condition.

Outcomes Report for U.S. Army PTSD Summit

In June 2017, Tonix CEO Seth Lederman participated in the "Pathophysiology of Post-Traumatic Stress Disorder: Rethinking Drug Targets" summit sponsored by the Department of Defense. The outcomes of that meeting were recently published. During the meeting, a series of six questions were addressed by subject-matter experts, assigned to various working groups, to help move the field forward in identifying PTSD treatments. One of the questions dealt with desired attributes for drugs that target specific pathophysiological domains. The summary of responses for that question is shown below.

> *"Common themes for drug attributes included…highly effective with a durable response...safe with few side effects…easy to administer…low potential for abuse. To keep active military ready and alert it was deemed beneficial if some drugs had positive effects such as improved cognitive performance and fortifying sleep…"*

We believe that TNX-102 SL fits the above description quite well, as the Phase 2 results in PTSD showed the drug to have a durable response with limited side effects. In addition, it is easily administered prior to bedtime and it does not have any potential for abuse.

Another question dealt with the pathways potentially important to PTSD and which of those pathways should be explored. Seven of the 10 working groups identified circadian rhythms/sleep as a mechanism for having the potential for defining a new drug target. As a reminder, the proposed mechanism of action for TNX-102 SL in treating PTSD is through improved sleep.

Lastly, one of the questions dealt with how the Department of Defense can facilitate partnerships between academia, industry and government. Multiple participants mentioned that:

> *"…the government might consider partnering with small pharmaceutical companies to repurpose current drugs."*

We believe this would be an important step forward for the field and Tonix would be a logical choice for a potential government partner since the company already has positive Phase 2 data and is in the midst of an ongoing Phase 3 clinical trial in PTSD.

Board of Directors Strengthened

On Feb. 15, 2018, Tonix announced the appointment of David L. Grange, a retired U.S. Army Brigadier General, to the Board of Directors. Gen Grange is currently CEO of Pharm-Olam International, Ltd. Prior to Pharm-Olam, he was President of Osprey Global Solutions, LLC and CEO of Pharmaceutical Product Development, Inc. (PPD). Gen Grange served 30 years in the U.S. Army as a Ranger, Green Beret, Aviator, Infantryman, and a member of special operations units. We believe both his military and business experience will be important attributes for Tonix as it continues development of TNX-102 SL in military-related PTSD.

Financial Update

On March 12, 2018, Tonix announced financial results for the fourth quarter and full year 2017. As expected, the company did not report any revenues for the fourth quarter of 2017 or the full year 2017. Net loss for the fourth quarter of 2017 was $5.5 million, or $0.71 per share, compared to a net loss of $7.5 million, or $2.08 per share, for the fourth quarter of 2016. Non-cash expenditures for the fourth quarter of 2017 totaled $0.3 million compared to non-cash expenditures of $1.1 million in the fourth quarter of 2016. For the fourth quarter of 2017, R&D expenses totaled $3.6 million, compared to $4.8 million for the fourth quarter of 2016, including non-cash expenditures, while G&A expenses totaled $2.0 million, compared to $2.6 million for the corresponding time period of 2016, including non-cash expenditures.

Net loss for the year ending Dec. 31, 2017 was $21.1 million, or $3.17 per share, compared to a net loss of $38.8 million, or $15.41 per share, for the year ending Dec. 31, 2016. R&D expenses for the full year 2017 and 2016 were $13.3 million and $28.5 million, respectively, including non-cash expenditures. The decrease was predominantly due to the discontinuation of the episodic tension-type headache and fibromyalgia programs. G&A expenses for the full year 2017 and 2016 were $8.0 and $10.4 million, respectively, including non-cash expenditures. The decrease was primarily due to a reduction in personnel and professional services.

The company reported $25.5 million in cash and cash equivalents as of Dec. 31, 2017, which we believe will be sufficient to fund operations through the end of 2018. As of Mar. 1, 2018, the company had approximately 7.8 million shares outstanding and when factoring in warrants with strike prices of $6.30 and $6.88 the company has a fully diluted share count of approximately 8.4 million.

Conclusion

We look forward to learning about the HONOR study hitting the 50% enrollment mark such that the interim analysis can be conducted. We anticipate learning more about the potential outcomes for the interim analysis as we get closer to its release, which we believe will be early in the third quarter. If required, we anticipate results from all 550 patients to be available later in the fourth quarter of 2018.

Our valuation for Tonix is derived from a probability adjusted discounted cash flow model that takes into account potential future revenues from the sale of TNX-102 SL in PTSD. Of the approximately 8 million individuals in the

U.S. who suffer from PTSD, it's estimated that approximately 20% seek treatment. With a peak market share of only 6%, we currently estimate that peak sales of $650 million are possible. Using a discount rate of 18% and a 50% probability of approval leads to a net present value for the PTSD program of $83 million. Combined with the company's current cash position and dividing by a reasonable fully diluted share count of 8.4 million shares leads to a valuation of approximately $13 per share.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2017 A	Q1 E	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	$3.5	$3.8	$4.0	$4.2	$15.5	$16.0	$16.5
SG&A	$7.9	$1.8	$1.8	$1.9	$2.1	$7.6	$7.8	$8.0
Operating Income	($21.3)	($5.3)	($5.6)	($5.9)	($6.3)	($23.1)	($23.8)	($24.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.2	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($21.1)	($5.3)	($5.6)	($5.9)	($6.3)	($23.0)	($23.7)	($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)	($5.3)	($5.6)	($5.9)	($6.3)	($23.0)	($23.7)	($24.4)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($3.17)**	**($0.68)**	**($0.71)**	**($0.74)**	**($0.78)**	**($2.87)**	**($2.15)**	**($2.03)**
YOY Growth	*-79.4%*	-	-	-	-	*-9.4%*	*-25.0%*	*-5.6%*
Weighted Shares Outstanding	6.7	7.8	7.9	7.9	8.0	8.0	11.0	12.0

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

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