Zacks Small-Cap Research

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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Potential for Only One Phase 3 Trial Needed for TNX-102 SL in PTSD…

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 (04/21/17)	$4.39
Valuation	**$13.00**

OUTLOOK

Tonix Pharmaceuticals Holding Corp. (TNXP) has had a number of positive recent events transpire. The company has initiated a Phase 3 clinical trial (the HONOR study) for TNX-102 SL in military-related posttraumatic stress disorder (PTSD). Following a meeting with the FDA in March, the agency indicated it might consider a single-study New Drug Application (NDA) approval based on statistically persuasive topline data from the HONOR study.

Following a 1-for-10 reverse stock split, the company raised net proceeds of approximately $8.3 million from the sale of 2.1 million shares of common stock. In addition, since Jan. 1, 2017, the company raised approximately $9.1 million in net proceeds through an ATM agreement. We estimate the company now has approximately $39 million in cash, cash equivalents, and marketable securities, which should be sufficient to fund operations through the end of the HONOR study.

SUMMARY DATA

52-Week High	**$29.00**
52-Week Low	**$3.49**
One-Year Return (%)	**-84.49**
Beta	**2.84**
Average Daily Volume (sh)	**2,606,199**
Shares Outstanding (mil)	**7**
Market Capitalization ($mil)	**$33**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**71**
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)
2016	0 A	0 A	0 A	0 A	0 A
2017	0 E	0 E	0 E	0 E	0 E
2018					0 E
2019					0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$7.41 A	-$4.97 A	-$2.90 A	-$2.08 A	-$15.41 A
2017	-$0.83 E	-$0.69 E	-$0.65 E	-$0.62 E	-$2.75 E
2018					-$2.39 E
2019					-$2.30 E

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WHAT'S NEW

Business Update

Tonix Pharmaceuticals Holding Corp. (TNXP) is a pharmaceutical company focused on the development of products for treating disorder of the central nervous system. The company's lead product, TNX-102 SL, is currently being developed as a treatment for posttraumatic stress disorder (PTSD). A Phase 3 clinical trial in military-related PTSD (the HONOR study) recently initiated, and we anticipate an unblinded interim analysis taking place in the first half of 2018. In addition, the company is pursuing development of TNX-801, a vaccine that potentially protects against smallpox, and TNX-601, a novel polymorph and salt of tianeptine for the treatment of PTSD.

TNX-102 SL

HONOR Study is Underway

On March 28, 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 PTSD (NCT03062540). HONOR 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. 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, 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

There is one unblinded interim analysis scheduled when the study has results from approximately 50% of efficacy-evaluable patients (~275 patients). The interim analysis will be performed by an independent data monitoring committee. We anticipate this occurring in the first half of 2018. If the results of the interim analysis require continued enrollment, topline results from the 550 participants will likely be available in the second half of 2018.

Potential for Only One Phase 3 Trial for Approval

On April 11, 2017, Tonix announced the receipt of the final minutes from a meeting held with the U.S. FDA to discuss the feasibility of accelerating the development and registration of TNX-102 SL for the treatment of PTSD. This meeting was scheduled due to Tonix receiving Breakthrough Therapy designation for TNX-102 SL for the treatment of PTSD in December 2016. During the meeting, the FDA indicated that it might consider a single-study New Drug Application (NDA) 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 evidence for potential abuse 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.

Intellectual Property Protection for TNX-102 SL to 2034

On March 14, 2017, Tonix announced that the U.S. Patent and Trademark Office issued a Notice of Allowance for U.S. Patent Application 14/214,433 titled "Eutectic Formulations of Cyclobenzaprine Hydrochloride and Amitriptyline Hydrochloride", which covers the proprietary sublingual formulation of TNX-102 SL. When issued, the patent will provide protection until 2034 in the U.S. for the allowed claims.

The claims cover the eutectic between cyclobenzaprine HCl and mannitol, which protects the acidic hydrochloride salt of cyclobenzaprine from molecular interactions with the basic excipient, potassium phosphate dibasic, which aids in trasmucosal absorption. This is an important differentiator from orally ingested forms of cyclobenzaprine, which are available as generic immediate-release tablets and branded extended-release capsules, and will prevent pharmacists from substituting orally ingested forms of cyclobenzaprine for TNX-102 SL, if approved.

Figure 2. Proprietary CBP-HCl Eutectic Mixture Stabilizes Tablet Formulation

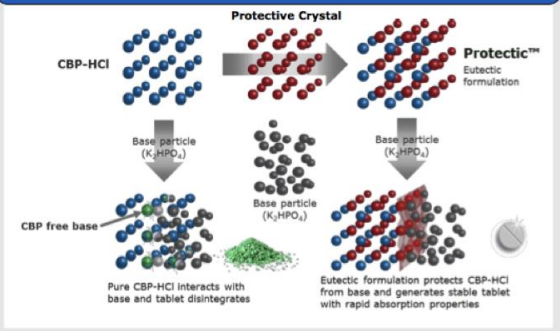
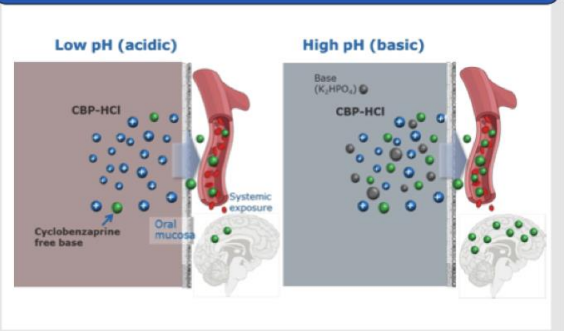


Figure 3. Formulation with Base Increases Systemic Absorption of Sublingual CBP



Source: Daugherty *et al.*, 2016

TNX-801

TNX-801 is a synthetic, live form of the horsepox virus developed using techniques broadly applicable to the field of 'synthetic biology'. Tonix has yet to disclose many details regarding the new horsepox virus vaccine that has been constructed, however the research has been submitted for peer review in a scientific publication, thus we anticipate learning additional details as soon as the paper is published.

TNX-801 was constructed by Professor David Evans, Ph.D. and research associate Ryan Noyce, Ph.D. at the University of Alberta. Tonix wholly owns the synthesized horsepox virus stock and related sequences and the company has initiated manufacturing activities for additional preclinical testing. In order to gain approval, Tonix would need to show safety in a healthy adult population along with efficacy in two animal models, one of which would be non-human primates. Those studies would likely not initiate until 2018.

In addition to potentially selling TNX-801 to the U.S. government to be included in the national stockpile, approval of TNX-801 could include the issuance of a priority review voucher, which allows the holder of the voucher to receive an expedited six-month review from the FDA for a NDA or biologics license application (BLA) instead of the usual ten-month review. The 21st Century Cures Act created a priority review voucher for medical countermeasures, which are drugs or vaccines intended to treat biological, chemical, radiological, or nuclear agents that present a national security threat. A vaccine to protect against smallpox would almost certainly fall into that category. Priority review vouchers are also awarded for the development of treatments for certain tropical diseases and rare pediatric diseases.

Priority review vouchers are fully transferrable, and a number of companies that have been issued the vouchers in the past have sold them, including one that was sold to AbbVie (ABBV) in August 2015 for $350 million and most recently one that was sold to Gilead (GILD) for $125 million in February 2017.

TNX-601

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 though 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 treatment for depression 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.

Financial Update

On April 17, 2017, Tonix announced financial results for the fourth quarter and full year 2016. As expected, the company did not report any revenues during the fourth quarter or the full year 2016. Net loss for the fourth quarter of 2016 was $7.5 million, or $2.08 per share. For the fourth quarter of 2016, including non-cash expenditures, R&D expenses totaled $4.9 million, compared to $9.5 million for the fourth quarter of 2015, while G&A expenses totaled $2.6 million, compared to $3.9 million for the corresponding time period of 2015.

Net loss for the year ending December 31, 2016 was $38.8 million, or $15.41 per share, and, including non-cash expenditures, consisted of $28.5 million in R&D expenses and $10.4 million in G&A expenses. This compares with a net loss for the year ending December 31, 2015 of $48.1 million, consisting of $35.5 million in R&D expenses and $12.7 million in G&A expenses for the year ending December 31, 2015. The decrease in R&D expenses was primarily due to decreased development work related to TNX-201 for episodic tension-type headache and TNX-102 SL for fibromyalgia. The decrease in G&A expenses was primarily due to a reduction in activities related to compensation-related expenses and professional services.

The company reported $26.1 million in cash, cash equivalents, and short-term investments as of December 31, 2016. Subsequent to the end of the year, the company raised net proceeds of $9.1 million through an at-the-market (ATM) sales agreement with Cowen and Company that was entered into in April 2016. The ATM agreement allowed for Tonix to sell up to $15 million of common stock, and since all $15 million worth of shares have been sold the agreement has been terminated. In March 2017, Tonix sold 1.8 million shares of common stock through an underwriting agreement with Aegis Capital Corp., which raised net proceeds of approximately $7.2 million. Following the full exercise of the over-allotment option by the underwriters, the total net proceeds raised were approximately $8.3 million. We currently estimate Tonix has approximately $39 million in cash, cash equivalents, and short-term investments, which will be sufficient to fund operations through the announcement of results for the HONOR study.

Following a 1-for-10 reverse stock split in March 2017, Tonix now has approximately 7.5 million shares of common stock outstanding. When factoring in the warrants with exercise prices of $6.30 and $6.88, the company has a fully diluted share count of approximately 8.1 million.

Conclusion

Tonix has had a number of positive developments over the past few months, including the initiation of the HONOR study and raising sufficient capital to fund operations past the release of results from the HONOR study, even if all 550 patients will be required. The first interim analysis is likely to take place in the first half of 2018, and if the trial continues at that time, results from all 550 patients will be available in the second half 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 $67 million. Combined with the company's current cash position and dividing by a reasonable fully diluted share count of 8.1 million shares leads to a valuation of $13 per share.

PROJECTED FINANCIALS

Tonix Pharmaceuticals Holding Corp.
Income Statement

Tonix Pharmaceuticals	2016 A	Q1 E	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
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	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$28.5	$3.0	$3.2	$3.2	$3.3	$12.7	$13.0	$14.0
SG&A	$10.4	$2.0	$2.0	$2.0	$2.0	$8.0	$8.5	$9.0
Operating Income	($39.0)	($5.0)	($5.2)	($5.2)	($5.3)	($20.7)	($21.5)	($23.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.1	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	($38.8)	($5.0)	($5.2)	($5.2)	($5.3)	($20.6)	($21.4)	($22.9)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($38.8)	($5.0)	($5.2)	($5.2)	($5.3)	($20.6)	($21.4)	($22.9)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($15.41)**	**($0.83)**	**($0.69)**	**($0.65)**	**($0.62)**	**($2.75)**	**($2.14)**	**($1.76)**
YOY Growth	*-46.2%*	-	-	-	-	*-82.2%*	*-22.1%*	*-17.7%*
Weighted Shares Outstanding	2.5	6.0	7.5	8.0	8.5	7.5	10.0	13.0

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

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