

Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Additional Details Revealed for Phase 3 Trial of TNX-102 SL in PTSD Starting in 1Q19...

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL PTSD, TNXP is valued at \$10.00/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 (01/03/19) **\$2.24**
Valuation **\$10.00**

OUTLOOK

On November 29, 2018, Tonix Pharmaceutical Holding Corp. (TNXP) announced additional details regarding the upcoming Phase 3 RECOVERY trial of TNX-102 SL in posttraumatic stress disorder (PTSD), which we expect to initiate in the first quarter of 2019. Following receipt of the meeting minutes from the FDA, the company announced that the trial will enroll approximately 250 individuals with PTSD, including those with civilian as well as military-related traumas. The primary outcome of the trial will be the change in CAPS-5 score at 4 weeks and enrollment will be limited to those who experienced a trauma within the last nine years. Topline results are expected in the first half of 2020.

The company recently completed a \$15 million financing to fund the RECOVERY trial following enactment of a 1:10 reverse split.

SUMMARY DATA

52-Week High **\$48.20**
52-Week Low **\$1.83**
One-Year Return (%) **-93.79**
Beta **1.71**
Average Daily Volume (sh) **526,601**

Shares Outstanding (mil) **2**
Market Capitalization (\$mil) **\$3**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **6**
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 A	0 E	0 E
2019					0 E
2020					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-\$12.71 A	-\$6.52 A	-\$7.71 A	-\$7.01 A	-\$31.69 A
2018	-\$8.83 A	-\$7.25 A	-\$5.72 A	-\$3.84 E	-\$23.97 E
2019					-\$10.90 E
2020					-\$9.76 E

WHAT'S NEW

Business Update

New Phase 3 Trial for TNX-102 SL to Initiate in 1Q19

On November 29, 2018, Tonix Pharmaceuticals Holding Corp. (TNXP) [announced](#) receipt of the meeting minutes from the recently completed Breakthrough Therapy Type B Clinical Guidance meeting with the U.S. FDA concerning the upcoming Phase 3 trial of TNX-102 SL in posttraumatic stress disorder (PTSD). We anticipate the trial initiating in the first quarter of 2019, and it will incorporate several important changes in comparison to the Phase 3 HONOR trial, including:

- 1) The primary endpoint will be the change from baseline in CAPS-5 score at 4 weeks. The primary outcome of the HONOR trial was the change from baseline in CAPS-5 score at 12 weeks. The HONOR trial was stopped early due to lack of separation between treated and control subjects at 12 weeks, however there was a clinically meaningful separation at 4 weeks ($P=0.019$).
- 2) Inclusion will be limited to individuals with PTSD who experienced their trauma within the past nine years, while the HONOR trial included individuals who experienced a trauma from 2001 or later. A retrospective analysis showed a treatment effect in those patients, while no treatment effect was seen in patients who were > nine years removed from their trauma.
- 3) The study will include both civilian and military PTSD patients, while the HONOR trial had limited inclusion to only those with military-related PTSD.
- 4) The total number of study subjects is anticipated to be approximately 250, compared to approximately 550 subjects that were to be enrolled in the HONOR trial.

The new trial will be a randomized, double blind, placebo controlled study of TNX-102 SL over 12 weeks with the primary endpoint being the Week 4 mean change in CAPS-5 score from baseline between TNX-102 SL and placebo-treated patients. The Week 12 mean change in CAPS-5 score will be a key secondary endpoint. We anticipate topline results being available in the first half of 2020.

Otsuka/Lundbeck Positive Phase 2 PTSD Data

On Nov. 30, 2018, H. Lundbeck A/S and Otsuka Pharmaceuticals Co., Ltd. [announced](#) positive results in a Phase 2 clinical trial of brexpiprazole (Rexulti®) and sertraline (Zoloft®) in patients with PTSD. While the companies did not disclose many details of the trial, it was announced that the combination of brexpiprazole and sertraline showed a statistically significant change in CAPS-5 compared to placebo ($P<0.01$) while the use of either compound alone did not demonstrate a clinically meaningful difference from placebo.

We view the potential for Otsuka and Lundbeck to enter the PTSD market as a positive since approximately 80% of PTSD patients are not treated, thus the increased awareness and activity brought about by those companies may help to increase diagnosis and thus expand the addressable PTSD market. In addition, if both TNX-102 SL and brexpiprazole/sertraline were approved for PTSD, it is conceivable that they could be used by the same patients as TNX-102 SL is taken at bedtime while brexpiprazole and sertraline are generally used during the day. Lastly, brexpiprazole costs approximately \$37/day (Goodrx.com) and thus helps to establish a price threshold for patented PTSD products.

Financial Update

On Dec. 7, 2018, Tonix [announced](#) the pricing of a \$15 million public offering in which the company sold Class A units (consisting of one share of common stock and one warrant to purchase a share of common stock at \$3.50) and Class B Units (consisting of one share of Series A Convertible Preferred Stock that is convertible into 286 shares of common stock) with the aggregate number of shares of common stock issued being 4,285,714. The warrants have a call feature if the company's stock price closes at or above \$10.50 for 10 consecutive days. The company also granted the underwriters a 45-day option to purchase an additional 642,857 shares of common stock and warrants to purchase 642,857 shares of common stock. We estimate that the company will exit 2018 with approximately \$25 million, which we expect will be enough to fund the upcoming Phase 3 PTSD clinical trial.

In Nov. 2018, the company enacted a 1:10 reverse split and thus, following the financing, we estimate the company has approximately 5.8 million shares of common stock outstanding (which includes potential conversion of Series A Convertible Preferred Stock) and when factoring in the warrants a fully diluted share count of approximately 10.1 million.

Conclusion

We are glad to see the company has completed a financing that is expected to fund the upcoming Phase 3 clinical trial, thus addressing the 'financing overhang' affecting the stock price. Tonix will be initiating the Phase 3 trial in the first quarter of 2019, and with an expected enrollment of only 250 individuals that includes both civilians and military personnel, we anticipate data in the first half of 2020. Due to the financing and reverse split we have adjusted our valuation to \$10.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2017 A	Q1 A	Q2 A	Q3 A	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	\$3.3	\$3.5	\$16.0	\$14.4	\$16.5
SG&A	\$7.9	\$1.8	\$2.1	\$2.3	\$1.9	\$8.1	\$7.5	\$8.0
Operating Income	(\$21.3)	(\$7.0)	(\$6.1)	(\$5.6)	(\$5.4)	(\$24.1)	(\$21.9)	(\$24.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	\$0.2	\$0.1	\$0.1	\$0.1	\$0.0	\$0.2	\$0.1	\$0.1
Pre-Tax Income	(\$21.1)	(\$6.9)	(\$6.1)	(\$5.5)	(\$5.4)	(\$23.9)	(\$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)	(\$6.1)	(\$5.5)	(\$5.4)	(\$23.9)	(\$21.8)	(\$24.4)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	(\$31.69)	(\$8.83)	(\$7.25)	(\$5.72)	(\$3.84)	(\$23.97)	(\$10.90)	(\$9.76)
YOY Growth	-79.4%	-	-	-	-	-24.4%	-54.5%	-10.5%
Weighted Shares Outstanding	0.7	0.8	0.8	1.0	1.4	1.0	2.0	2.5

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

HISTORICAL STOCK PRICE



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