Zacks Small-Cap Research

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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: TNX-201 Development Stopped; Attention Turns to PTSD and Fibromyalgia…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	03/02/15
Current Price (02/16/16)	$4.04
Target Price	**$10.00**

On February 16, 2016, Tonix Pharmaceuticals announced topline results from the Phase 2 clinical trial of TNX-201 in episodic tension type headache (ETTH). The trial did not meet any of its primary endpoints and as a result the company has discontinued development of TNX-201.

The company still has two more programs in clinical trials: Tonmya™ in a Phase 3 trial for fibromyalgia and TNX-102SL in a Phase 2 trial for post traumatic stress disorder (PTSD). We anticipate results for TNX-102SL in PTSD in the second quarter of 2016 and for Tonmya™ in fibromyalgia in the third quarter of 2016.

We are maintaining a 'Buy' rating ahead of the data readouts later in 2016 and believe the current valuation offers an attractive opportunity for long-term investors.

SUMMARY DATA

52-Week High	**$10.50**
52-Week Low	**$3.77**
One-Year Return (%)	**-30.10**
Beta	**2.74**
Average Daily Volume (sh)	**112,679**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$76**
Short Interest Ratio (days)	**6.03**
Institutional Ownership (%)	**49**
Insider Ownership (%)	**9**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 A	0 A	0 A	0 E	0 E
2016					0 E
2017					0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.59 A	-$0.61 A	-$0.71 A	-$0.83 A	-$2.77 A
2015	-$0.71 A	-$0.73 A	-$0.72 A	-$0.56 E	-$2.71 E
2016					-$2.10 E
2017					-$1.91 E

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WHAT'S NEW

On February 16, 2016, Tonix Pharmaceutical Holdings Corp. (TNXP) announced topline results from the Phase 2 proof-of-concept clinical study of TNX-201 in episodic tension-type headache (ETTH). While TNX-201 was shown to be safe and very well tolerated with no serious adverse events reported, the study did not meet any of its primary endpoints, including achieving headache pain-free status at two hours after dosing. The company has discontinued all development of TNX-201 and is now fully focused on the development of Tonmya in fibromyalgia and TNX-102SL in post-traumatic stress disorder (PTSD).

TNX-201 Phase 2 Study

TNX-201 was an improved formulation of isometheptene (IMH), a compound that had been previously utilized in combination for the treatment of tension-type and migraine headaches. IMH is composed of two isomers, (R)-IMH and (S)-IMH, of which (R)-IMH (the active ingredient in TNX-201) was shown to be a potent agonist of the imidazoline-1-receptor (I_1-R) and significantly increased pain tolerance in multiple animal models.

Tonix initiated the Phase 2 study of TNX-201 in June 2015 (NCT02423408). The randomized, double blind, placebo controlled trial was designed to evaluate the efficacy of a single 140 mg dose of TNX-201 compared to placebo in 147 patients with ETTH. Both the TNX-201 (n=75) and placebo (n=72) groups were similar in demographics. The primary efficacy endpoint of headache pain-free at two hours post-dose was assessed on a four-point Numeric Rating Scale (NRS), a Visual Analog Scale (VAS), and a binary questionnaire for self-report of pain. The study also analyzed efficacy using the proportion of participants reported to be pain-free at various post-dose time intervals, the proportion of participants who utilized rescue medication during the 24-hour post dose period, and the change from baseline pain severity at several time intervals.

The company reported that the study did not meet the primary efficacy endpoint of achieving headache pain-free status at two hours. The study also failed to meet additional efficacy endpoints that included the proportion of participants with at least a 70% reduction in pain from baseline on the VAS at two hours after dosing, and an increase of the mean change from baseline to two hours post-dose in the VAS score. Based on these results, the company has decided to cease all further development of TNX-201.

Conclusion and Recommendation

While its disappointing that the development of TNX-201 has been halted due to the results of the Phase 2 trial, the company only spent approximately $7 million all-in on the development of the compound in order to get the proof-of-concept data. Now focus can shift to the ongoing clinical trials of Tonmya in fibromyalgia and TNX-102SL in post-traumatic stress disorder.

As a reminder, Tonix is currently conducting the Phase 3 AFFIRM trial (NCT02436096), which is a randomized, double-blind, placebo-controlled 12-week safety and efficacy study of approximately 500 fibromyalgia patients. The patients will be given either a 2.8 mg Tonmya™ tablet or placebo at bedtime in a 1:1 randomization. The trial is taking place at 35 sites in the U.S. We anticipate topline results in the third quarter of 2016. We also expect the company to initiate a second Phase 3 clinical trial of Tonmya™ in fibromyalgia in the second quarter of 2016. For a detailed examination of the data supporting the use of Tonmya in fibromyalgia, please see our previous report.

In addition, the company is conducting the Phase 2 AtEase study (NCT02277704), which is a randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of TNX-102SL in people with military-related PTSD and related conditions. The three-arm trial is expected to enroll approximately 220 participants, who will be randomized to receive either 2.8 mg or 5.6 mg of TNX-102SL or placebo taken sublingually at bedtime daily for 12 weeks. We anticipate results from this trial to be reported in the second quarter of 2016.

Due to the discontinuation of TNX-201 development we have completely removed it from our model, and as a result we have lowered our target price to $10. Thanks to raising approximately $20 million in July 2015, the company ended the third quarter of 2015 with approximately $55 million, which should be sufficient to fund operations into 2017. Based on the results of the Phase 2 trial of TNX-201, the stock is currently trading at approximately $2.60, which gives the company a market cap of only $50 million. We believe this is an over-reaction to the news about TNX-201, and we are maintaining a 'Buy' rating as the current setback represents a nice buying opportunity for long-term investors ahead of the two data readouts coming up in the second and third quarter of this year.

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PROJECTED FINANCIALS

Tonix Pharmaceuticals Holding Corp.
Income Statement

Tonix Pharmaceuticals	2014 A	Q1 A	Q2 A	Q3 A	Q4 E	2015 E	2016 E	2017 E
TNX-102SL (FM)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
TNX-102SL (PTSD)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
TNX-201 (ETTH)	$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
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$18.6	$6.8	$8.9	$10.3	$7.5	$33.5	$30.0	$30.0
SG&A	$9.0	$2.9	$2.9	$3.0	$3.0	$11.7	$12.0	$13.0
Operating Income	($27.7)	($9.7)	($11.8)	($13.3)	($10.5)	($45.3)	($42.0)	($43.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($27.6)	($9.7)	($11.8)	($13.3)	($10.5)	($45.3)	($42.0)	($43.0)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($27.6)	($9.7)	($11.8)	($13.3)	($10.5)	($45.3)	($42.0)	($43.0)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.77)**	**($0.71)**	**($0.73)**	**($0.72)**	**($0.56)**	**($2.71)**	**($2.10)**	**($1.91)**
YOY Growth	*-17.9%*	-	-	-	-	*-2.1%*	*-22.4%*	*-9.0%*
Weighted Shares Outstanding	10.0	13.7	16.1	18.4	18.6	16.7	20.0	22.5

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

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