

# INSTITUTIONAL RESEARCH

# **Biotechnology**COMPANY UPDATE

Member FINRA/SIPC

March 15, 2018

F2017A

\$0

F2018F

\$0

\$0.00/0.0%

## **Tonix Pharmaceuticals (Nasdaq/TNXP)**

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Focus on Tonmya for PTSD in 2018

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Tonix is developing innovative pharmaceutical products to address public health challenges

### **Investment Highlights**

**BUY** 

- 1) Tonix gave its fourth quarter financial results and 2017 corporate update earlier this month, with key news on Tonmya in PTSD and a new pipeline program in agitation in Alzheimer's patients. The Company's lead pipeline program, (Cyclobenzaprine HCI Sublingual Tablets) 5.6 mg in the treatment of military-related posttraumatic stress disorder, or PTSD, continues to make solid progress with several key milestones expected to be reached this year. Enrollment in the 550-patient Phase 3 HONOR trial is picking up after the addition of twelve new clinical sites last September, (out of 35-40 total) and Tonix now expects to announce reaching the 50% mark of efficacy-evaluable participants by the end of this month, with an unblended interim analysis potentially available sometime in Q3/2018 following review by the study's Independent Data Monitoring Committee. While the review and interim results are being completed, Tonix still expects to continue enrollment in the trial, and the timeline for compete enrollment and publication of top-line results could be as soon as the end of 2018.
- 2) In other pipeline-related developments, following a pre-NDA meeting with the FDA in November of last year, Tonix believes it has made sufficient progress to file a Phase 2 NDA on its TNX-102 SL for agitation in Alzheimer's disease before the end of Q1/2018. Although several recent pharma clinical programs to treat Alzheimer's have shown disappointing results, agitation in these patients is a leading cause of institutionalization (and the related high costs), and currently there are no treatments on the market for this major symptom. A number of pharma companies remain interested in any portion of the Alzheimer's market, and this could be a long-term positive factor for the Company. Tonix will most likely seek a partner for this indication, and indeed possibly for several indications of the drug, including PTSD and other preclinical candidates, perhaps later this year or next. The Company also continues preclinical development on its other compounds, including TNX-801 (synthesized horsepox) a

Current Price	\$3.41
Price Target	\$9.00

Revenues(\$000s)

Dividend / Yield

\$0

EPS	(\$15.41)	(\$3.17)	(\$2.85)
Stock Data			
52-Week Ran	ge	\$2	2.85-\$9.40
Shares Outsta	nding (mil.)		7.9
Market Capita	lization (mil.)		\$26.9
Enterprise Va	lue (mil.)		\$1.4
Debt to Capita	al (12/17)		0.0%
Book Value/S	hare (12/17)		\$3.12
Price/Book			1.1 x
Average Trad	ing Volume (3-Month)		67,000
Insider Owne	rship		3.1%
Institutional C	)wnership		26.5%
Short interest	-		354,000



<u>Price target and ratings changes over the past 3 yrs:</u>
Re- Initiate BUY rating with Price Target of \$9 - August 21, 2017



smallpox-preventing vaccine candidate, and TNX-601 (tianeptine oxalate oral formulation), a daytime treatment for PTSD, with acceleration of these programs dependent on additional funding or partnerships.

3) Tonix recently reported its fourth quarter 2017 results, including a reduced net loss of \$5.5 million or (\$0.71) per share, as compared to a net loss of \$7.5 million or (\$2.08) per share in Q4/16. The reduced net loss this year was due to both lower R&D costs and reduced general and administrative expenses, as the Company was involved in fewer product candidate programs following the September 2016 discontinuation of the TNX-102 SL fibromyalgia treatment program. For the full year 2017, net loss was \$21.1 million or (\$3.17) per share for Tonix, again a reduction from a loss of \$38.8 million or (\$15.41) per share in 2016, for similar reasons as in the fourth quarter. Operating cash burn was approximately \$19 million in 2017 for Tonix, and at the end of the year the Company had \$25.5 million in cash on hand. Tonix management has most recently estimated that the Company will have adequate financial resources available to complete its ongoing Phase 3 HONOR trial in PTSD and last into calendar 2019.

### **Conclusion/Stock Valuation**

With a solid balance sheet, a primary focus on a near-term Phase 3 clinical program for PTSD, and several other promising assets ready for clinical stage development, growth-oriented investors may find TNXP shares attractive. On the same hand, with a current market capitalization just slightly above cash on hand, value-oriented investors may also look with interest at TNXP shares. Our comparable group of seven neurology-targeted or new formulation oriented stocks currently trade at an average market capitalization well above the current market value of TNXP, and therefore we are maintaining our BUY rating on TNXP shares and 12-18 month price target of \$9 per share. (For our full stock valuation analysis on TNXP shares please see our Company Update report dated August 21, 2017)

### **Risk Factors**

In addition to normal economic and market risk factors that impact most equities and the common risks shared by Tonix with other companies in the industry, we believe an investment in TNXP involves the following risks:

- **Reliance on key management** At present, TNXP relies on several key members of its management team who either founded the Company or have been in key executive positions for an extended period of time. Should one or more of these key executives leave the Company, TNXP could find it difficult to replace their long-standing knowledge of operations and industry expertise.
- **Reliance on partnerships** To date, TNXP has not signed major development partnerships and/or agreements for its pharmaceutical technologies and products, but may do so in the future. Thus, in the future certain factors related to product commercialization and new product development may be determined by third parties and out of the control of Company management.
- **Limited stock liquidity** Trading volume in TNXP stock is comparatively light and these shares have a relatively limited history of trading on major US stock exchanges compared with other healthcare stocks. As such, news regarding TNXP, its target market, partners and/or competitors could lead to significant volatility in the stock price.
- Competitive Markets The Company competes in its target neurological product market with a number of companies, many of which are considerably larger than the Company. There can be no assurance that the Company will be able to successfully compete and launch new products into these competitive markets in the future.



- **FDA and regulatory risks** TNXP is subject to regulatory review for its ongoing research and development activities, principally the US Food and Drug Administration's application processes. In addition, the quality assurance and manufacture of the Company's pharmaceutical products are subject to ongoing oversight and regulation, and any negative correspondence from the FDA or other regulatory agencies could have an adverse effect on the ongoing operations of the Company.
- Lack of historic profitability TNXP has not achieved operating profitability on an annual basis for several years, and according to our forecasts may not be expected to do so in the near future. Although the Company maintains adequate cash reserves at the present time, there can be no assurance the Company will not need to raise additional working capital in the future should operating losses continue.
- Need to defend patents and other intellectual property TNXP currently holds a number of US and International patents on its products and related technologies, some of which expire in the near future. The Company may be required to defend its patents in the US and overseas in the future, and there can be no assurance these defenses will be successful.



# Tonix Pharmaceuticals, Inc. Consolidated Statements of Income (in \$000s, except EPS)

Robert M. Wasserman

FYE December	<u>2009</u>	2010	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015</u>	<u>2016</u>	<u>2017</u>	<u>2018E</u>
Revenues	1					1				
Licensing fees	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Grants and other funding					0.0	0.0	0.0	0.0	0.0	0.0
Product sales and royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Expenses										
Research and development	32.5	584.3	1,158.2	2,583.3	4,649.8	18,617.0	35,504.0	28,533.0	13,342.0	14,500.0
Payroll costs	0.0	414.0	731.3	1,820.9	3,247.7	4,511.0	5,824.0	5,200.0	3,300.0	3,400.0
Professional services	126.9	614.3	915.2	1,444.5	1,882.1	2,564.0	4,247.0	3,200.0	3,000.0	3,100.0
General and administrative and other	<u>26.0</u>	316.2	<u>573.9</u>	812.8	1,108.9	1,964.0	2,587.0	2,036.0	1,649.0	1,800.0
Total operating expenses	185.4	1,928.7	3,378.5	6,661.4	10,888.4	27,656.0	48,162.0	38,969.0	21,291.0	22,800.0
Loss from operations	(185.4)	(1,928.7)	(3,378.5)	(6,661.4)	(10,888.4)	(27,656.0)	(48,162.0)	(38,969.0)	(21,291.0)	(22,800.0)
Interest expense, net	(43.3)	(35.8)	(91.6)	(1,613.0)	4.0	40.0	108.0	127.0	168.0	250.0
Other expense, net	<u>7.9</u>	0.0	0.0	(1,175.2)	0.0	0.0	0.0	0.0	0.0	0.0
Net income (loss)	(220.8)	(1,964.5)	(3,470.1)	(9,449.6)	(10,884.4)	(27,616.0)	(48,054.0)	(38,842.0)	(21,123.0)	(22,550.0)
Cumulative dividends on preferred stock	32.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net income (loss) attributable to common stock	(252.8)	(1,964.5)	(3,470.1)	(9,449.6)	(10.884.4)	(27,616.0)	(48,054.0)	(38,842.0)	(21,123.0)	(22,550.0)
Basic and diluted income (loss) per share	(\$73.72)	(\$35.16)	(\$32.39)	(\$55.80)	(\$33.68)	(\$27.66)	(\$28.62)	(\$15.41)	(\$3.17)	(\$2.85)
Basic and diluted shares outstanding	3.4	55.9	107.1	169.3	323.1	998.6	1,679.1	2,521.0	6,665.1	7,900.0
Key ratios:										
Cash Flow/share	(\$60.39)	(\$27.30)	(\$27.72)	(\$42.26)	(\$28.11)	(\$23.95)	(\$25.91)	(\$13.98)	(\$2.89)	(\$2.58)

Balance Sheets
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	(\$000s)	
Assets:	12/31/16	12/31/17
Cash and equivalents	\$18,941	\$25,496
Marketable securities	7,180	0
Prepaid expenses and other	1,019	947
Total current	27,140	26,443
Property & equip., net	150	91
Restricted cash	89	89
Intangible assets and security deposits	<u>131</u>	<u>131</u>
TOTAL ASSETS	\$27,510	\$26,754
Liabilities:		
Accounts payable	\$872	\$1,296
Accrued expenses	2,116	830
Total current	2,988	2,126
Deferred rent payable	33	12
Stockholders' equity (deficiency)	25,361	24,616
TOTAL LIAB & EQ	\$28,382	\$26,754

Source: Dawson James Securities, Inc. estimates; Company documents



### **Important Disclosures:**

### **Price Chart:**



<u>Price target and ratings changes over the past 3 years:</u>
Re-Initiated with BUY rating and Price target of \$9 - August 21, 2017

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- 1) **Buy**: the analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) Neutral: the analyst believes the price of the stock is fairly valued for the next 12-18 months:
- 3) **Sel**I: the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

	Company Co	verage	Investment Banking		
<b>Ratings Distribution</b>	# of Companies	% of Total # of Companies 9		% of Totals	
Market Outperform (Buy)	15	88%	5	33%	
Market Perform (Neutral)	2	12%	0	0%	
Market Underperform (Sell)	0	0%	0	0%	
Total	17	100%	5	29%	

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