

INSTITUTIONAL RESEARCH

Biotechnology COMPANY UPDATE

Member FINRA/SIPC

September 14, 2018

F2017A

\$0

\$0

\$0.00/0.0%

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Tonix Pharmaceuticals (Nasdaq/TNXP)

BUY

Tonmya Re-wind for 2018

Tonix is developing innovative pharmaceutical products to address public health challenges

Investment Highlights

- 1) Tonix has announced a revised strategy for its most advanced product candidate, Tonmya (Cyclobenzaprine HCI Sublingual Tablets) in PTSD, centering around an upcoming October 2018 meeting with the FDA to discuss a potential trial protocol for a new Phase 3 study for this bedtime treatment for PTSD. The Company is targeting a sub-group of patients from its earlier Phase 3 HONOR trial which was discontinued earlier this year (after 275 of a possible 550 patients had been treated) - those with traumatic events nine years or less from trial screening, and also with a greater emphasis on nonmilitary PTSD sufferers. If the FDA meeting is conclusive, Tonix hopes to agree on a new Phase 3 trial for Tonmya by the end of this year and begin enrollment as soon as Q1/2019. Since announcing the disappointing interim results for HONOR in July, the Company has been busy presenting results and retrospective analyses of Tonmya at medical conferences, as there still remains a large market for new treatments for the disease as well as interest from other pharma companies.
- 2) The Company is also making progress with its other pipeline programs, including TNX-601 (tianeptine Oxalate) for daytime dosing of PTSD and TNX-801, a smallpox-preventing vaccine candidate. Active ingredient tianeptine sodium has already been approved in the EU and other geographies for depression, and Tonix was recently awarded a US patent on its novel oxalate salt polymorph with improved pharma properties suitable for reformulation. Next step for the Company related to TNX-601 will be to release preliminary human pharmacokinetic and safety data of different formulations of the new compound in H1/2019, in anticipation of filing an IND for a Phase 2 trial to begin potentially in 2020. For TNX-801 (synthesized horsepox) a smallpox-preventing vaccine candidate, the Company is currently developing a viral production process for the purpose of establishing Good Manufacturing Practice (GMP) operations for the vaccine, and Tonix intends to meet with the FDA in the near future to

Current Price	\$0.74
Price Target	\$3.00

Revenues(\$000s)

Dividend / Yield

\$0

EPS	(\$15.41)	(\$3.17)	(\$2.80)
Stock Data			
52-Week Ran	ige	\$(0.89-\$5.11
Shares Outsta	anding (mil.)		9.5
Market Capita	alization (mil.)		\$7.0
Enterprise Va	alue (mil.)		(\$9.6)
Debt to Capit	al (6/18)		0.0%
Book Value/S	Share (6/18)		\$1.67
Price/Book			0.4 x
Average Trac	ling Volume (3-Month)		700,000
Insider Owne	rship		3.4%
Institutional (Ownership		26.7%
Short interes	t		200,000



<u>Price target and ratings changes over the past 3 yrs:</u>
Re- Initiate BUY rating with Price Target of \$9 - August 21, 2017
Update - BUY - Price Target \$3 - September 14, 2018



determine clinical study protocols. And relating to its TNX-102 SL product candidate for treatment of agitation in Alzheimer's disease, following the receipt of Fast Track designation from the FDA in July, the Company is awaiting additional funding (possibly through a development partnership) before initiating a Phase 2/3 study for the drug, perhaps as soon as early next year.

3) Tonix recently reported its second quarter 2018 results, including a net loss of \$6.1 million or (\$0.73) per share, as compared to a net loss of \$4.8 million or (\$0.65) per share in Q2/17. The larger net loss this year was primarily due to increased R&D spending related to the PTSD programs, at \$4.1 million as compared to \$2.8 million one year ago, while general and administrative expenses were essentially flat for the two periods, at \$2.1 million versus \$2.0 million for the same period one year ago. Cash used in operations for the second quarter was approximately \$5.5 million, and at the end of the second quarter Tonix had \$16.7 million in cash and equivalents on its balance sheet. This cash balance has been increased by roughly \$3 million since the end of the second quarter by the Company through the employment of part of its at-the-market equity facility. Company management has stated that they believe quarterly operating expenses will be lower for the last two quarters of this year following the discontinuation of the HONOR study and prior to initiation of any new clinical trials next year, and they estimated there are adequate financial resources available to fund operations through mid-2019.

Conclusion/Stock Valuation

Despite a recent clinical setback, Tonix still maintains a deep product pipeline focusing on several large areas of clinical need, bolstered by a solid balance sheet with plenty of financial resources to move its pipeline forward. Currently, TNXP shares trade at a valuation well below cash on hand, and well below average market capitalization of our comparable group of seven neurology-targeted or new formulation oriented stocks. Therefore, we are maintaining our BUY rating on TNXP shares but reducing our 12-18 month price target to \$3 per share, due to recent timeline delays and adjusted market size in the Company's product pipeline. (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	2009	2010	<u>2011</u>	<u>2012</u>	2013	2014	<u>2015</u>	<u>2016</u>	<u>2017</u>	2018E
Revenues	1					1	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	17,500.0
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	3,300.0
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	2,900.0
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	1,700.0
Total operating expenses	<u>185.4</u>	1,928.7	3,378.5	6,661.4	10,888.4	27,656.0	48,162.0	38,969.0	21,291.0	25,400.0
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)	(25,400.0)
Interest expense, net	(43.3)	(35.8)	(91.6)	(1,613.0)	4.0	40.0	108.0	127.0	168.0	200.0
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)	(25,200.0)
Cumulative dividends on preferred stock	<u>32.0</u>	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)	(25,200.0)
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)	(\$2.80)
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	9,000.0
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)

	Dalance Sne	ets
	(\$000s)	
Assets:	12/31/17	6/30/18
Cash and equivalents	\$25,496	\$16,679
Restricted cash	0	89
Prepaid expenses and other	<u>947</u>	1,391
Total current	26,443	18,159
Property & equip., net	91	65
Restricted cash	89	
Intangible assets and security deposits	<u>131</u>	<u>131</u>
TOTAL ASSETS	\$26,754	\$18,355
Liabilities:		
Accounts payable	\$1,296	\$1,640
Accrued expenses	<u>830</u>	872
Total current	2 126	2 512

Deferred rent payable

TOTAL LIAB & EQ

Stockholders' equity (deficiency)

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

12

24,616

\$26,754

15,842

Balance Sheete



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
Update - BUY - Price Target \$3 - September 14, 2018

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- 2) **Neutra**l: 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.

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	Company Co	verage	Investment Banking		
Ratings Distribution	on # of Companies % of Total # of Companie		# of Companies	% of Totals	
Market Outperform (Buy)	n (Buy) 26 90%		8	31%	
Market Perform (Neutral)	3	10%	0	0%	
Market Underperform (Sell)	0	0%	0	0%	
Total	29	100%	8	28%	

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