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Tonix Pharmaceuticals (Nasdaq/TNXP)

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BUY
Tonmya Key for 2019

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Tonix is developing innovative pharmaceutical products to address public health challenges
Investment Highlights

1) **Tonix is back on track with its most advanced product candidate, Tonmya (Cyclobenzaprine HCl Sublingual Tablets) in the treatment of Post-Traumatic Stress Disorder (PTSD),** enrolling the first patient in a new Phase 3 study, named RECOVERY, in March. The RECOVERY study, whose innovative design was approved by the US FDA last fall, is expected to enroll approximately 250 patients, both civilian and military, across about 30 clinical sites in the US, administering Tonmya in a 5.6 mg dose over 12 weeks. Enrollment will be restricted to individuals with PTSD who experienced an index trauma within nine years of screening, a shorter time-frame than earlier trials. Tonix expects to report topline data from the DISCOVERY trial in the first half of next year. The Company further announced this week that its Breakthrough Therapy Designation for Tonmya for PTSD remains in effect and the Company will be meeting with the FDA in June to address an earlier “Intent to Rescind” Notice from the agency which was issued in December 2018 but recently withdrawn. The June meeting will allow the Company to present additional data to support continuing Breakthrough Therapy designation. The Company also recently revealed the receipt of a notice of termination (effective later this month) from the US Army Medical Materiel Development Activity (USAMMDA) to terminate without cause the Cooperative Research and Development Agreement (CRADA) from 2015 between Tonix and the agency, but since the new DISCOVERY trial is designed to also include civilian PTSD patients, this earlier collaboration had declined in importance for the Company.

2) **The Company is also enjoying a renaissance for its fibromyalgia (FM) clinical program,** recently holding a Clinical Guidance meeting with the FDA and obtaining support to advance the development of its TNX-102 SL in FM with a higher dose 5.6 mg tablet for a pivotal Phase 3 trial. Previously, the Company had used a 2.8 mg tablet in its Phase 2 and Phase 3 studies, but recent experience garnered in other trials (for PTSD, for example) with the higher 5.6 mg

Current Price \$2.34
Price Target \$6.00

Estimates	F2017A	F2018E	F2019E
Revenues(\$000s)	\$0	\$0	\$0
EPS	(\$31.69)	(\$26.81)	(\$4.60)

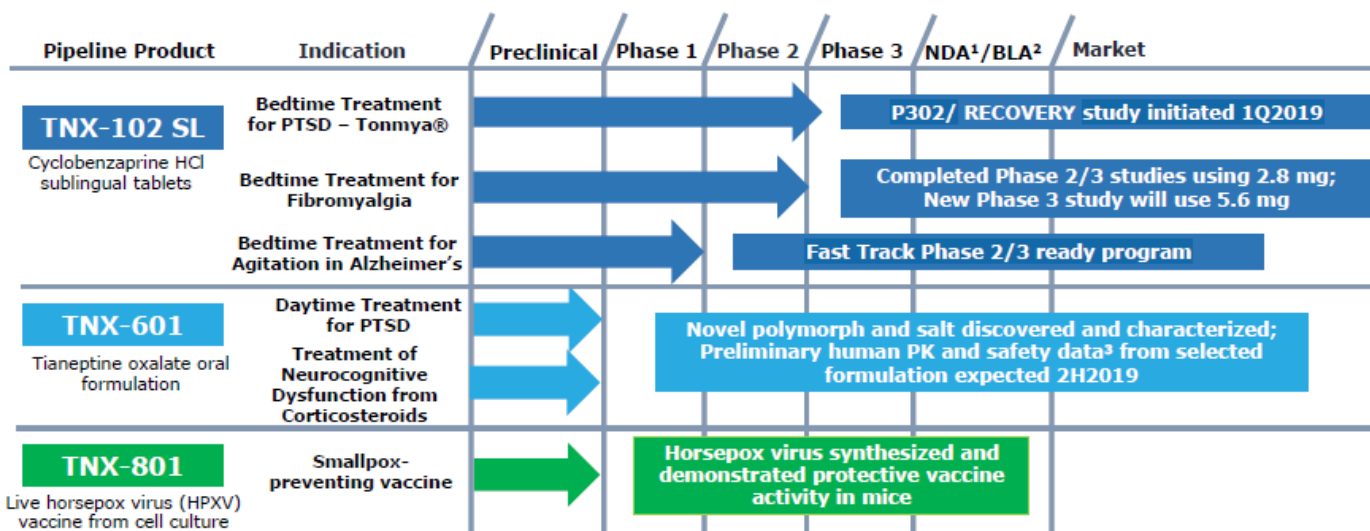
Stock Data	
52-Week Range	\$0.36-\$9.60
Shares Outstanding (mil.)	6.1
Market Capitalization (mil.)	\$14.3
Enterprise Value (mil.)	(\$10.8)
Debt to Capital (12/18)	0.0%
Book Value/Share (12/18)	\$3.88
Price/Book	0.6 x
Average Trading Volume (3-Month)(Mill)	1.6
Insider Ownership	1.8%
Institutional Ownership	10.0%
Short interest	330,000
Dividend / Yield	\$0.00/0.0%



Price target and ratings changes over the past 3 yrs:
 Re- Initiate BUY rating with Price Target of \$9 - August 21, 2017
 Update - BUY - Price Target \$3 - September 14, 2018
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Please find Important Disclosures beginning on Page 5.

dosage have aided Tonix in its renewed efforts to address fibromyalgia, a chronic neurobiological disorder affecting 5-15 million in the US that is thought to result from amplified sensory and pain signaling. Tonix hopes to submit a final Phase 3 protocol and statistical analysis plan in the near future for TNX-102 SL in fibromyalgia. In addition, the Company expects to have preliminary human pharmacokinetic and safety data from a finalized formulation of its TNX-601 (tianeptine oxalate) by the second half of this year; TNX-601 is also a potential clinical candidate for PTSD but with a different mechanism of action than TNX-102 SL. Finally, the Company continues to be active in the development of its other clinical candidates, including smallpox-preventing vaccine TNX-801 and TNX-102 SL in the bedtime treatment for agitation in Alzheimer’s disease, albeit with lesser current emphasis than its later stage clinical programs due to funding restraints. The diagram below outlines Tonix’s clinical candidates in development:



Source: Tonix Pharma

3) Tonix recently reported results for its fourth quarter and full year 2018, including a net loss of \$7.6 million or (\$6.10) per share for Q4/18, as compared to a net loss of \$5.5 million or (\$7.07) per share in Q4/17, and a net loss of \$26.1 million or (\$26.81) per share for 2018 as a whole, compared to a net loss of \$21.1 million or (\$31.69) per share in 2017. Research and development expenses increased to \$17.6 million in 2018 from \$13.3 million the prior year due to increased clinical activity in the PTSD area, while general and administrative expenses grew less slowly for Tonix, to \$8.8 million from \$8.0 million in 2017. At the end of the year, following an equity placement in December 2018, the Company had \$25.0 million in cash on hand, as compared to \$25.5 million in cash at the start of the year. Cash used for operations for 2018 was \$24 million. For 2019E, we are projecting that the Company will post a loss of \$28.0 million or (\$4.60) per share, with an operating cash burn of approximately \$24 million, within the range of current cash on hand. The Company has not disclosed the net effect of the recent termination of the USAMMDA agreement, but it is not expected to significantly impact financial resources this year.

Conclusion/Stock Valuation

With a bolstered balance sheet, several key clinical milestones expected in the near-term, and other programs in their pipeline addressing large areas of medical need, both short-term and long-term investors have much to attract them to TNXP shares. Thus, we are maintaining our Buy rating on TNXP shares and adjusting our price target to reflect recent share issuances to \$6.00 per share based on the average market capitalization of a comparable group of neurology-focused biotechnology stocks. (For our full stock valuation analysis on TNXP shares please see our Initiation Report dated April 26, 2012 and 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	2011	2012	2013	2014	2015	2016	2017	2018	2019E
Revenues											
Licensing fees	\$0.0	\$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	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	0.0
Total revenues	<u>0.0</u>	<u>0.0</u>	<u>0.0</u>	<u>0.0</u>	<u>0.0</u>	<u>0.0</u>	<u>0.0</u>	<u>0.0</u>	<u>0.0</u>	<u>0.0</u>	<u>0.0</u>
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	17,558.0	19,000.0
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	3,500.0
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	3,800.0	4,000.0
General and administrative and other	26.0	316.2	573.9	812.8	1,108.9	1,964.0	2,587.0	2,036.0	1,649.0	1,664.0	1,800.0
Total operating expenses	<u>185.4</u>	<u>1,928.7</u>	<u>3,378.5</u>	<u>6,661.4</u>	<u>10,888.4</u>	<u>27,656.0</u>	<u>48,162.0</u>	<u>38,969.0</u>	<u>21,291.0</u>	<u>26,322.0</u>	<u>28,300.0</u>
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)	(26,322.0)	(28,300.0)
Interest expense, net	(43.3)	(35.8)	(91.6)	(1,613.0)	4.0	40.0	108.0	127.0	168.0	233.0	300.0
Other expense, net	7.9	0.0	0.0	(1,175.2)	0.0	0.0	0.0	0.0	0.0	0.0	(50.0)
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)	(26,089.0)	(28,050.0)
Cumulative dividends on preferred stock	32.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3,266.0	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)	(29,355.0)	(28,050.0)
Basic and diluted income (loss) per share	(\$737.18)	(\$351.58)	(\$323.92)	(\$558.02)	(\$336.84)	(\$276.56)	(\$286.19)	(\$154.07)	(\$31.69)	(\$26.81)	(\$4.60)
Basic and diluted shares outstanding	0.3	5.6	10.7	16.9	32.3	99.9	167.9	252.1	666.5	1,094.9	6,100.0
Key ratios:											
Cash Flow/share	(\$603.91)	(\$272.98)	(\$277.25)	(\$422.61)	(\$281.14)	(\$239.51)	(\$259.09)	(\$139.79)	(\$28.90)	(\$22.29)	(\$4.11)

Balance Sheets

(\$000s)

Assets:	12/31/17	12/31/18
Cash and equivalents	\$25,496	\$25,034
Restricted cash	0	0
Prepaid expenses and other	947	1,022
Total current	<u>26,443</u>	<u>26,056</u>
Property & equip., net	91	43
Restricted cash	89	100
Intangible assets and security deposits	131	120
TOTAL ASSETS	<u>\$26,754</u>	<u>\$26,319</u>
Liabilities:		
Accounts payable	\$1,296	\$1,404
Accrued expenses	830	1,251
Total current	<u>2,126</u>	<u>2,655</u>
Deferred rent payable	12	0
Stockholders' equity (deficiency)	24,616	23,664
TOTAL LIAB & EQ	<u>\$26,754</u>	<u>\$26,319</u>

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

Important Disclosures:

Price Chart:



Price target and ratings changes over the past 3 years:

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) **Neutral:** the analyst believes the price of the stock is fairly valued for the next 12-18 months;
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Ratings Distribution	Company Coverage		Investment Banking	
	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	37	86%	10	27%
Market Perform (Neutral)	6	14%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	43	100%	10	23%

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