

Tonix Pharmaceuticals

(TNXP-NASDAQ)

TNXP: Tonix Fundamentals Remain Strong As Pipeline Rolls Forward...

Current Recommendation	Buy
Prior Recommendation	Neutral
Date of Last Change	11/13/13
Current Price (08/11/14)	\$12.10
Target Price	\$16.00

We continue to be positive on shares of Tonix Pharmaceuticals. We believe the company's novel sublingual formulation of cyclobenzaprine has significant utility in the treatment of fibromyalgia and PTSD. We discuss the candidate for both indications below, as well as introduce TNX-201, the company's new candidate for tension headaches. We have conducted a sum-of-parts valuation for Tonix Pharmaceuticals that incorporates our three forecasts for sales of TNX-120SL in fibromyalgia and PTSD and TNX-201 in ETTH noted below.

We believe the shares are fairly-valued at \$16 per share, and recommend purchase at today's price.

SUMMARY DATA

52-Week High	\$18.67
52-Week Low	\$3.10
One-Year Return (%)	73.85
Beta	2.13
Average Daily Volume (sh)	87,641

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

Shares Outstanding (mil)	10
Market Capitalization (\$mil)	\$112
Short Interest Ratio (days)	1.52
Institutional Ownership (%)	31
Insider Ownership (%)	12

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 2014 Estimate	N/A
P/E using 2015 Estimate	N/A

ZACKS ESTIMATES

Revenue

(In millions of \$)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2013	0 A	0 A	0 A	0 A	0 A
2014	0 A	0 A	0 E	0 E	0 E
2015					0 E
2016					0 E

Earnings per Share

(EPS is operating earnings before non recurring items)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2013	-\$0.93 A	-\$0.95 A	-\$0.87 A	-\$0.74 A	-\$3.37 A
2014	-\$0.59 A	-\$0.61 A	-\$0.72 E	-\$0.79 E	-\$2.73 E
2015					-\$2.67 E
2016					-\$2.06 E

WHAT'S NEW

Financial Update – Solid Cash Level

On August 11, 2014, Tonix Pharmaceuticals (NASDAQ: TNXP) reported [financial results](#) for the second quarter for the period ending June 30, 2014. The company did not report any revenues during the quarter, in-line with expectations and our financial model. Net loss in the second quarter totaled \$6.0 million, or 61 cents per share. Loss was driven by \$4.1 million in R&D and \$2.0 million in G&A.

R&D expense has been tracking significantly higher over the past few quarters. For example, the \$4.1 million was \$3.2 million higher than in the second quarter 2013. The sizable increase in R&D is attributable to a number of circumstances. The primary driver was increased development work related to TNX-102 SL, including manufacturing, preclinical, and human efficacy studies in fibromyalgia (FM). We remind investors that the Phase 2b BESTFIT study with TNX-102 SL [completed enrollment](#) at 200 patients in May 2014, far ahead of expectations. Other events that are contributing to the higher R&D expense include preclinical work and preparations for moving TNX-102 SL into Phase 2 studies for post-traumatic stress disorder (PTSD). In this regard, Tonix received approval from the U.S. FDA on its [investigational new drug](#) (IND) application in June 2014. This 12-week study is expected to enroll approximately 220 patients with military-related PTSD at about 30 sites in the U.S. We expect the trial to commence enrollment here in the third quarter 2014. Finally, management is also planning to enter Phase 1 PK / bioequivalency study with TNX-201, a single isomer of isometheptene, in episodic tension-type headache (ETTH) during the first quarter of 2015. We have been impressed by management's aggressive efforts to expand the pipeline over the past year.

G&A expense of \$2.0 million remains under control for a growing organization. We note that the company expanding its senior management during the second quarter 2014. On June 3, 2014, Tonix appointed [Gregory M. Sullivan, MD](#), as Chief Medical Officer (CMO). A few weeks later, on June 26, 2014, Tonix appointed [Ronald R. Notvest, PhD](#) as Senior Vice President Commercial Planning and Development.

Tonix exited the second quarter 2014 with \$43.9 million in cash and investments. Operating burn in the second quarter totaled \$5.8 million. Burn for the first half of the year totaled \$9.9 million; however, Tonix cash position remains solid thanks to two equity offerings earlier in the year. In January 2014, the company raised approximately \$40.7 million through a [public offering](#) of 2.9 million shares at \$15.00 per share. Then, in July 2014, Tonix entered into a registered [direct offering](#) of 657,000 shares at \$11.90 per share, netting \$7.2 million in cash. Besides these offerings, Tonix has also received approximately \$4.9 million in warrant exercises during the first half of 2014.

Based on recent financing activity, we believe Tonix will exit the third quarter September 30, 2014 with approximately \$45.5 million in cash still on the books. We believe this is sufficient cash to fund operations for the foreseeable future. We view Tonix high cash balance as a significant reduction in risk for investors. For example, as of August 7, 2014, we calculate the (reasonable) fully-diluted share count as 12.2 million, meaning Tonix has approximately \$3.75 in current cash per share on hand. The strong financial position has recently allowed Tonix to improve its listing from the NASDAQ-Capital market to the [NASDAQ-Global market](#) on August 11, 2014.

Update On TNX-102 SL

Enrollment in the Phase 2b/3 [BESTFIT trial](#) recently [completed enrollment](#) on May 12, 2014. Enrollment occurred at a rate nearly twice as fast as we expected. In fact, enrollment took place with such efficiency that management made the decision to expand the study from 120 patients to 200 patients. We believe this is a testament to the size and under-served nature of fibromyalgia. BESTFIT is a randomized, double-blind, placebo-controlled 12-week safety and efficacy studies in fibromyalgia patients who will take either a TNX-102 SL (cyclobenzaprine HCl 2.8 mg) tablet or placebo at bedtime.

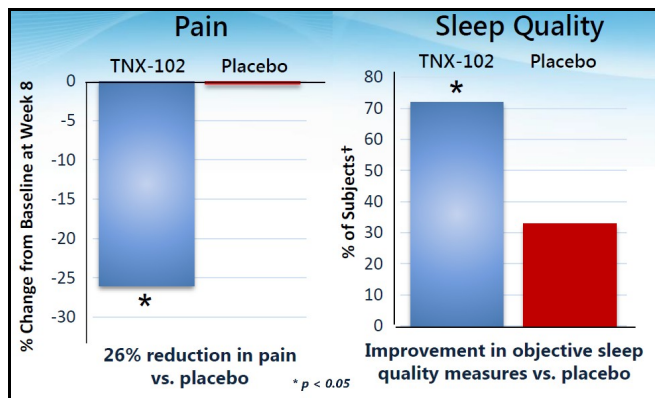
The primary endpoint of the trial is the change in pain from baseline to Week 12 as measured by the Numeric Rating Scale (NRS). We note the primary endpoint planned for this trial is similar to that utilized by Pfizer and Eli Lilly to gain approval for Lyrica and Cymbalta, respectively, for the treatment of fibromyalgia syndrome. Placebo response will be a key issue to watch. The study protocol included a 1-2 week wash-out period prior to randomization. We note the Pfizer Phase 3 study with Lyrica showed a placebo response rate of nearly 50%. The company will also collect information on secondary endpoints, including NRS scores at other time points during the 12 week study, the Fibromyalgia Impact Questionnaire (FIQ), and the Patient Global Impression of Change (PGIC). We expect top-line data early in the fourth quarter 2014.

In December 2013, Tonix announced that patients who have completed the BESTFIT trial will be eligible for enrollment in the [F203 study](#), a 12-month open-label long-term safety exposure study. The primary objective of F203 is to evaluate the long-term safety and tolerability of TNX-102 SL taken sublingually at bedtime once-daily in patients with fibromyalgia. The secondary objective is to evaluate the long-term efficacy of TNX-102 SL on the symptoms of fibromyalgia.

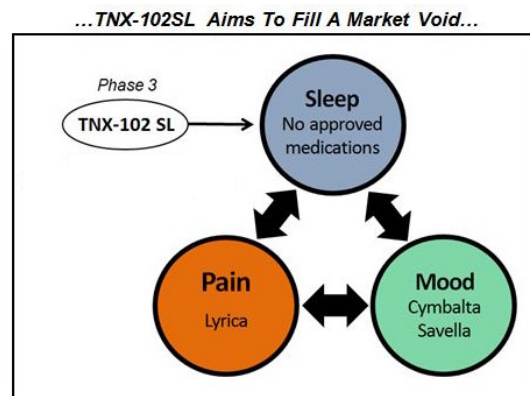
F203 has been accepted by the FDA as an abbreviated long-term safety exposure evaluation study is being conducted to support a 505(b)(2) new drug application for TNX-102 SL as a chronic medication for the management of fibromyalgia. We believe this is an important study with respect to the potential label for Tonix' drug because current generic formulations of cyclobenzaprine are limited to prescriptions lasting on "*up to two or three weeks*" based on the current [prescribing information](#). We expect Tonix can gain approval for chronic use of TNX-102 SL, thus providing another meaningful advantage of its candidate over generic substitutions.

Upon successful completion of the Phase 2b/3 BESTFIT trial, we expect Tonix will proceed with a second Phase 3 study in Fibromyalgia in 2015. If all goes well, we anticipate a U.S. new drug application (NDA) filing in 2016, with approval and launch in 2017. Averaging the data obtained from the NIH, AFSA, and NFA, we estimate there are approximately 8 million Americans living with fibromyalgia. Over 90% of these patients have sleep problems. Approximately 70% of these patients report difficulty in conducting normal daily tasks, such as light housework due to chronic fatigue. U.S. sales of prescription drugs specifically for the treatment of FM totaled \$1.2 billion in 2012. This figure includes sales of Cymbalta, Lyrica, and Savella of \$600 million, \$475 million, and \$110 million, respectively.

Despite the availability of FDA approved products, we believe the current treatment options for fibromyalgia continue to leave many patients dissatisfied. Existing approved fibromyalgia medications such as Lyrica and Cymbalta, which focus on reducing fibromyalgia-associated pain and mood disorder, respectively, do little to improve sleep quality. Insomnia medications such as Ambien and Lunesta improve total sleep time, but do little to improve the chronic fatigue associated with fibromyalgia.



Source: Tonix Pharmaceuticals Phase 2a data (Moldofsky et al, 2011)



If Tonix can gain approval for TNX-102 SL in fibromyalgia using standardized pain (NRS) endpoints in its Phase 2b and Phase 3 program, while also demonstrating improvement in symptoms of fatigue and sleep quality, we believe a meaningful market opportunity exists. Frost & Sullivan estimate that 48 million tablets of cyclobenzaprine were sold specifically for fibromyalgia in 2010. We believe at least a third of fibromyalgia patients would actively seek out prescription therapy, either as a monotherapy or an adjunctive therapy to Lyrica or Cymbalta, with their physicians support, and try a novel sublingual formulation of very low dose cyclobenzaprine.

Based on the generic market, the target population for Tonix with TNX-102 SL is over 2 million patients. We think that the sublingual formulation clearly contains meaningful advantages over the generic oral formulation. These include rapid absorption and minimal next-day residual effects ideal for a bedtime dose, and avoidance of first pass metabolism and build-up of norcyclobenzaprine ideal for chronic dosing. Of course, all this will need to be confirmed in clinical trials.

For the purpose of our model, we assume Tonix (and its partner) can capture 5% share – that's one out of every twenty patients currently on generic oral cyclobenzaprine for FM switching to TNX-102 SL. At a cost of \$10 per pill, with decent tier-2 and tier-3 coverage, we see TNX-102 SL as a \$650 million peak drug. We expect that by 2017, both Lyrica and Cymbalta will be generic, and that Tonix commercial partner will have one of the only (if not the only) branded prescription medications for fibromyalgia available.

We note our forecast above is for sales in FM only. In the third quarter 2014, Tonix plans to initiate a Phase 2 study with TNX-102 SL for the treatment of post-traumatic stress disorder. This is the same formulation of sublingual low-dose cyclobenzaprine being used in the company's Phase 2b/3 BESTFIT study. In June 2014, the company received [IND clearance](#) to begin this study. The Phase 2 study will be a randomized, double-blind, placebo-controlled clinical trial investigating the safety and efficacy of two doses of TNX-102 SL and placebo administered once daily at bedtime. This 12-week study is expected to enroll approximately 220 patients with military-related PTSD at about 30 sites in the U.S. The primary efficacy analysis will compare differences in mean scores on the Clinician-Administered PTSD Scale (CAPS).

As for PTSD, there is [enormous overlap](#) between fibromyalgia and PTSD. According to Tonix, 50% of the FM or PTSD patient population meets the criteria for the other disorder. Plus, the manifestations and treatment paradigms are similar, and include disturbed sleep and painkiller abuse and addiction. Roughly 3.5% of the U.S. adult population suffers from PTSD. The numbers are shockingly high for U.S. military service personnel, a population with high incidence of [suicide](#) and [opioid addiction](#). It's a sad and growing problem, and there have been no new approved medications for PTSD in over a decade. Tonix' Phase 2 program will focus specifically on PTSD associated with military / combat service. Although management has narrowed the PTSD population, eliminating things like car accidents and sexual assault, the homogenous population should lead to improved data collection. Plus, the growing attention of the U.S. government in this area should eventually lead to grants or additional funding in the future. It's an astute development plan in our view.

The U.S. PTSD population is estimated at a similar 8 million in size. We believe approximately 25% of these cases are associated with military service, about half of which seek medical treatment for the disease. This puts the U.S. military-associated PTSD population at around 1 million. Assuming similar pricing and market penetration as noted above for fibromyalgia, we believe TNX-102 SL peak sales in PTSD are around \$300 million.

TNX-201 Ready for Clinical Development

On March 3, 2014 Tonix [announced](#) that they had recently held a pre-Investigational New Drug (pre-IND) meeting with the U.S. FDA to discuss the development of TNX-201, a single isomer isometheptene (IMH) for the relief of episodic tension-type headache (ETTH). Tension type headaches (TTH) are the most common type of headaches among adults and are also known as “stress headaches”. These headaches were previously known by a number of terms, however the term “tension-type headache” was chosen by the International Classification Headache Diagnosis I (ICHD) in 1988 and later retained by ICHD II in 2004. The terms “tension” and “type” refer to the unknown nature of the underlying etiology, however a number of clinical studies have been performed that underscore their neurobiological basis.

ICHD II classified tension type headaches as either episodic (ETTH) or chronic (CTTH). ETTH are further subdivided into infrequent (occurring less than 12 days per year) or frequent (more than 12 days per year but less than 180 days per year). CTTH are characterized by an occurrence of more than 180 days per year. The clinical symptoms for the three types of headache are all similar and are only differentiated based on their frequency. We note that these types of headaches are different from migraines and cluster headaches.

Approximately 20% of the world’s population suffers from tension type headaches. Women are slightly more affected than men and the peak incidence occurs between the ages of 30-39 and decreases with increasing age. A 1997 study showed that lost workdays from TTH are as much as three times greater than from migraine headaches. Despite numerous clinical studies, the exact cause of TTH remains elusive; however, there are certain things that seem to trigger them including: stress and anxiety, squinting, poor posture, dehydration, noise, bright sunlight, tiredness and certain smells.

Current treatment options for ETTH include over-the-counter analgesics such as ibuprofen, naproxen, acetaminophen, and aspirin, all of which have been shown to be more effective than placebo in controlled trials. Studies have shown that non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and naproxen are most likely more effective than aspirin or acetaminophen, but these results are not unequivocal. Caffeine, codeine, sedatives, or tranquilizers are often combined with NSAIDs to increase their efficacy; however, this can lead to the risk for dependency, abuse, and chronification of the headache.

The only currently FDA approved medications for the treatment of ETTH are fioricet and fiorinal, both of which contain butalbital, a barbiturate that can lead to dependency. These compounds have also been linked to Medication Overuse Headaches (MOH), also known as rebound headaches. These headaches occur through the overuse of pain medications to relieve primary headaches. They can occur frequently, can be very painful and are the third most common cause of headache. Regular use of over-the-counter medications such as ibuprofen and acetaminophen have also been linked to MOH, thus doctors typically advise limiting their use to not more than two days weekly. In addition to MOH, the overuse of acetaminophen has been linked to liver damage while the overuse of NSAID can cause gastrointestinal bleeding.

...A New Treatment Option...

Isometheptene, 6-methylamino-2-methylheptene, is a compound that has been utilized to treat headaches for greater than 50 years. It is composed of two isomers, one believed to provide efficacy while the other only contributes to side-effects. It was first introduced into the clinic for the treatment of spasmodic conditions of the biliary and urinary tracts but quickly became utilized in the treatment of migraine headaches. It is an indirect-acting agent and is thought to elicit an anti-headache action through a sympathomimetic effect leading to constriction of blood vessels in the head. It targets both the Alpha-1A adrenergic receptor and the synaptic vesicular amine transporter. Interaction with these cell surface targets elicits smooth muscle activation leading to vasoconstriction.

Tonix has developed a method for purifying a single isomer of isometheptene that the company believes can potentially reduce the toxicity associated with the racemic mixture (a mixture of the two isomeric forms). Isometheptene falls under the category of drugs where one isomer is believed to confer the anti-headache effect while the other isomer is responsible for the unwanted side effects. Tonix will need to prove this in clinical trials. However, assuming that the clinical trials go according to plan, we foresee TNX-201 clinical trials finishing in 2017 with an NDA filing in 2018 and approval in 2019.

Tonix has an extensive patent portfolio for TNX-201. The intellectual property relates to isometheptene isomers and includes patent applications directed to a purified isomer of isometheptene, pharmaceutical compositions containing isometheptene, isometheptene formulations, methods for modulating headache and other CNS conditions and

treating CNS conditions utilizing isometheptene isomers, and methods of manufacturing isometheptene isomers. The Isometheptene Technology patent portfolio includes U.S. patent applications such as U.S. Provisional Patent Application Nos. 61/754,281, 61/793,456, and 61/814,664. If U.S. and non-U.S. patents claiming priority from those applications issue, those patents would expire in 2034, excluding any patent term adjustments or extensions.

TNX-201 clearly targets a large market. Various sources range the number of Americans suffering from TTH between 35 and 45 million. Approximately 80% of these are episodic in nature, with roughly 10% not adequately controlled by OTC NSAIDs or aspirin. Of these approximate 3.2 million individuals, we suspect that 50% will seek medical Rx to treat their TTH. The average sufferer has about one episode per week. Assuming Tonix prices TNX-201 comparable to migraine drugs Cambia® (\$33 per pill) and Treximet® (\$28 per pill), with 10% market share of the active medical Rx seekers, TNX-201 looks to be around a \$300 million drug.

Conclusion

We have conducted a sum-of-parts valuation for Tonix Pharmaceuticals that incorporates our three forecasts for sales of TNX-120 SL in fibromyalgia, in PTSD, and for TNX-201 in episodic tension-type headache noted in our report. We believe investors are dramatically under-estimating the market size and potential adoption of TNX-102 SL in fibromyalgia. Through our research we found that this is a market meaningfully under-served by existing medications and there is a significant willingness for patients, physicians, and payers to try new medications. As a result, many fibromyalgia patients bounce around between existing approved and off-label therapies, one of which is cyclobenzaprine.

The economic / societal burden of fibromyalgia is significant, with a high number of patients on either disability or unemployment. Prescription drugs costs average over \$10,000 per year, and the average out-of-pocket expense can range between \$1,500 and \$3,000 per year. We believe a low-dose, sublingual formulation of cyclobenzaprine specifically optimized for long-term, chronic bedtime use by the fibromyalgia patient can capture 5% market share of the existing generic cyclobenzaprine market.

Although generic competition is a concern, we believe Tonix and its commercial partner will employ aggressive pricing measures to reduce the average out-of-pocket expense for TNX-102 SL, thus leveling the playing field in the eyes of the patient and physician. Additional upside to the Tonix story comes from the development of TNX-102 SL in PTSD and TNX-201 in ETTH.

At the current market value of roughly \$100 million, Tonix valuation is supported by \$45+ million in cash on the books, a fully-enrolled Phase 2b program with data roughly two months away, and two new programs to start in the next several months. We believe the shares are fairly valued at \$16.

PROJECTED FINANCIALS

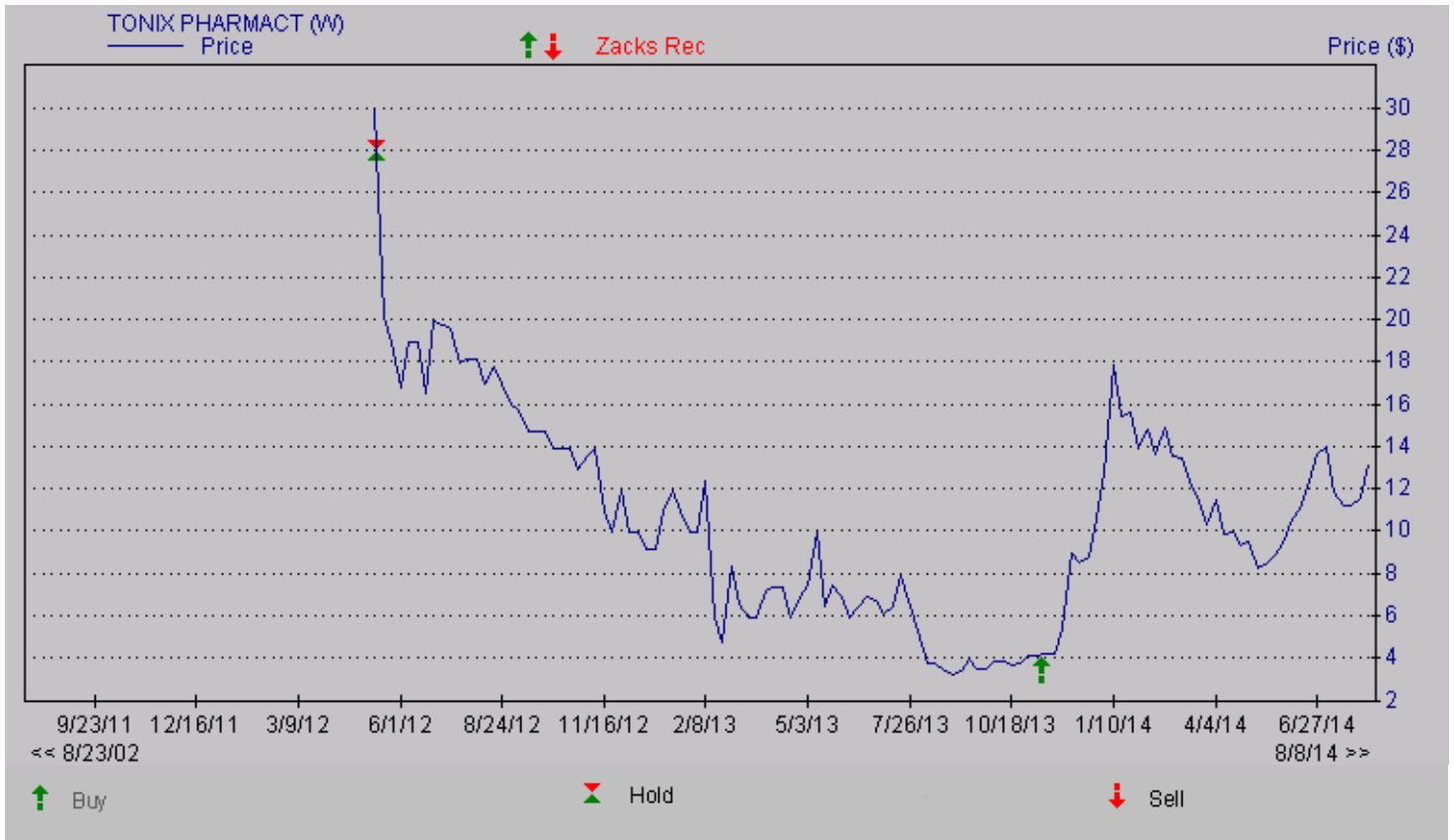
Tonix Pharma Income Statement

Tonix Pharmaceuticals	2013 A	Q1 A	Q2 A	Q3 E	Q4 E	2014 E	2015 E	2016 E
TNX-102SL (FM)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
TNX-102SL (PTSD)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
TNX-201 (ETTH)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Research & Collaborations	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Total Revenues	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
CoGS	\$0	\$0	\$0	\$0	\$0	\$0	\$0.0	\$0.0
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
R&D	\$4.7	\$3.6	\$4.1	\$5.5	\$6.5	\$19.6	\$25.0	\$22.0
<i>% R&D</i>	-	-	-	-	-	-	-	-
SG&A	\$6.2	\$1.6	\$2.0	\$2.1	\$2.1	\$7.8	\$8.5	\$9.0
<i>% SG&A</i>	-	-	-	-	-	-	-	-
Operating Income	(\$10.9)	(\$5.2)	(\$6.0)	(\$7.6)	(\$8.6)	(\$27.4)	(\$33.5)	(\$31.0)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Interest & Other Income	\$0.0	\$0.0	\$0.0	\$0.0	\$0.1	\$0.1	\$0.1	\$0.1
Pre-Tax Income	(\$10.9)	(\$5.2)	(\$6.0)	(\$7.6)	(\$8.5)	(\$27.3)	(\$33.4)	(\$30.9)
Taxes & Other	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$10.9)	(\$5.2)	(\$6.0)	(\$7.6)	(\$8.5)	(\$27.3)	(\$33.4)	(\$30.9)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$3.37)	(\$0.59)	(\$0.61)	(\$0.72)	(\$0.79)	(\$2.73)	(\$2.67)	(\$2.06)
<i>YOY Growth</i>	-39.6%	-	-	-	-	-18.8%	-2.3%	-22.9%
Weighted Shares Outstanding	3.2	8.7	9.9	10.6	10.7	10.0	12.5	15.0

Source: Zacks Investment Research, Inc.

Jason Napodano, CFA

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The current distribution is as follows: Buy/Outperform- 16.8%, Hold/Neutral- 75.9%, Sell/Underperform – 6.4%. Data is as of midnight on the business day immediately prior to this publication.