Zacks Small-Cap Research

January 26, 2015
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Ste 1600, Chicago, IL 60606

Tonix Pharmaceuticals (TNXP-NASDAQ)

TNXP: Clinical Programs Rolling Forward, Stock Looking Attractive For Second Half Of The Year Run…

Current Recommendation	**Neutral**
Prior Recommendation	Buy
Date of Last Change	09/29/14
Current Price (01/26/15)	$6.25
Target Price	**$10.00**

On January 15, 2015, we had a chance to sit down with the senior management team at Tonix Pharmaceuticals (TNXP) to receive an update on the company's three clinical programs. We discuss in detail below the path forward for TNX-102SL in both fibromyalgia and PTSD and TNX-201 in tension type headache. We believe Tonix shares are attractive for long-term investors, although near-term catalysts are limited. We think Tonix shares should be put on watch for a potential move in the second half of the year. We see $10 as a reasonable target for the shares.

SUMMARY DATA

52-Week High	**$17.86**
52-Week Low	**$5.41**
One-Year Return (%)	**-60.46**
Beta	**3.74**
Average Daily Volume (sh)	**82,800**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$67**
Short Interest Ratio (days)	**4.44**
Institutional Ownership (%)	**25**
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**

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)
2013	0 A	0 A	0 A	0 A	0 A
2014	0 A	0 A	0 A	0 E	0 E
2015					0 E
2016					0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.93 A	-$0.95 A	-$0.87 A	-$0.74 A	-$3.37 A
2014	-$0.59 A	-$0.61 A	-$0.71 A	-$0.61 E	-$2.52 E
2015					-$2.67 E
2016					-$2.06 E

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WHAT'S NEW

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TNX-102SL Phase 3 Fibromyalgia Study To Begin This Spring

In early 2015, Tonix provided a brief update to investors on the outcome of discussions with the U.S. FDA on the planned Phase 3 trial for TNX-102SL in the treatment of fibromyalgia. The results of these discussions were very positive, with the agency agreeing to allow Tonix to use a 30% responder analysis for the primary outcome measure in the pivotal study. This is the same primary outcome measure that Forest Labs/Cypress Biosciences used gain approval for Savella® (milnacipran HCl) for the treatment of fibromyalgia in January 2009. Based on our conversations with management, the Phase 3 trial is expected to start enrolling patients in May or June 2015.

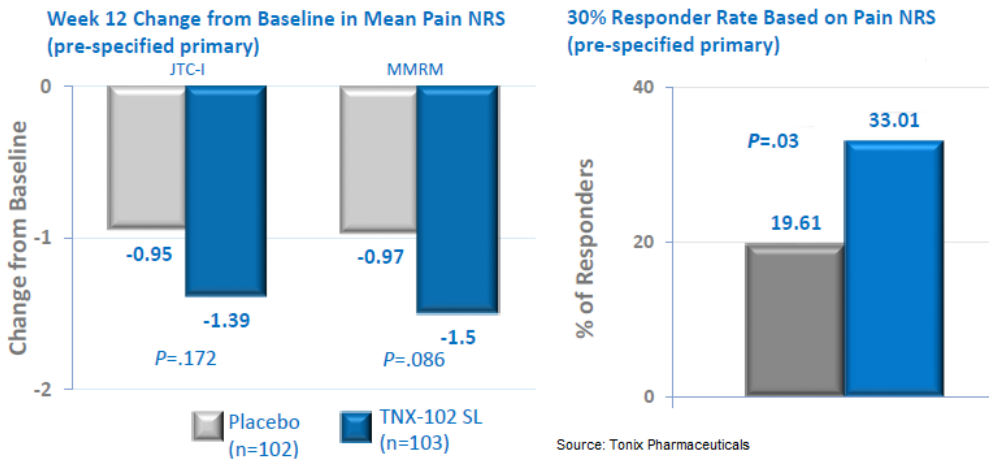
- ***What is 30% Responder Analysis?***

The 30% responder analysis is defined as an improvement in pain, as measured by the number of subjects who achieve at least a 30% improvement in their pain scores. A 30% improvement is considered moderate or clinically significant response. For example, if pain is rated on a numeric rating scale of 0 to 10, with 10 being the highest, a patient with a baseline pain score of 6 that is reduced to 4 at the end of the treatment period would have experienced a ~33% reduction in pain. This patient would count towards the primary endpoint. However, a patient with a baseline of 8 reduced to 6 at the end of the study would only have seen a 25% reduction in pain and thus not counted as a responder towards the primary endpoint.

- ***Why was this Selected?***

Tonix elected to use the 30% responder analysis for the planned Phase 3 trial because this endpoint demonstrated a statistically significant separation from the placebo group in the Phase 2b BESTFIT study. A 30% responder analysis was a pre-specified secondary outcome measure of BESTFIT.

As a reminder, in late September 2014, Tonix announced top-line results for the Phase 2b BESTFIT trial. The study did not achieve statistical significance in the primary efficacy endpoint of change in average daily pain score at week 12 (p=0.086 by mixed-effect model repeated measure analysis, p=0.172 by jump-to-control, multiple imputation analysis). However, there was a statistically significant effect on pain when examining the percentage of patients achieving a 30% or greater improvement (p=0.030).



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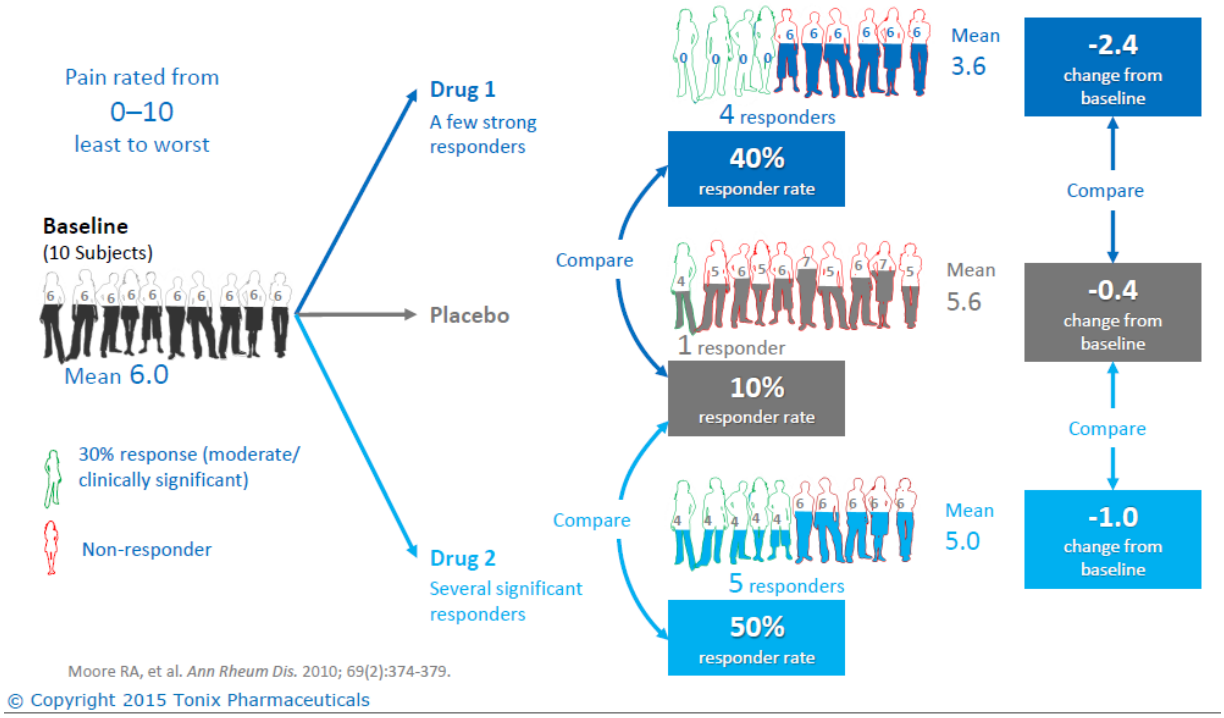
Investors may be confused by the fact that TNX-102SL did not reduce mean pain in the BESTFIT trial for the pooled patient data but did achieve separation based on a 30% reduction in pain using responder analysis. To help explain this seemingly contradictory data, Tonix has provided investors with a cartoon showing what they believe might have happened in BESTFIT:



Drug #1, for example, may be a drug like Lyrica® – a powerful drug that works exceptionally well for a small number of patients. Drug #2 may be a drug like Savella or TNX-102SL, a more broadly effective drug that reduces systemic pain to a more localized area. We note the results of BESTFIT are consistent in terms of placebo respond with what was seen in the Savella Phase 3 program. For example, the 30% responder rate for the placebo in BESTFIT was 19.6%. For the two Savella Phase 3 trials it was ~16% and ~19%. However, TNX-102SL was numerically superior to Savella in terms of 30% responder rate. TNX-102SL achieved a 33.0% 30% responder rate compared to only 25% and 27% for the two Savella Phase 3 trials. Savella had annual sales just north of $105 million in 2014.

➢ ***What else did we learn from BESTFIT?***

Besides encouraging data on the 30% responder rate, safety and tolerability were excellent for TNX-102SL in the Phase 2b BESTFIT trial. For example, 86.4% subjects randomized to TNX-102 SL finishing the trial. This was numerically superior to the placebo group at 83.3%. There were no reports of serious adverse events, only localized tongue numbness and abnormal taste were meaningfully different from the placebo group, which was to be expected for a sublingually administered drug. There were only three systemic adverse effects that occurred at a rate of 3.0% or greater in the overall trial population, which are indicated below.

Systemic	TNX-102 SL (N=103)		Placebo (N=101)		Total (N=204)	
Adverse Event	N	%	N	%	N	%
Somnolence	2	1.9	7	6.9	9	4.4
Dry Mouth	4	3.9	4	4.0	8	3.9
Back Pain	5	4.9	3	3.0	8	3.9

Source: Tonix Pharmaceuticals, Inc.

There were also a number of secondary analyses performed in BESTFIT where TNX-102SL did show statistical significance. These included outcomes in relation to pain, sleep, and fibromyalgia-related symptoms. The table below provides a summary of these analyses. As seen below, significant improvements in sleep and other fibromyalgia-related endpoints were demonstrated. Full data is expected at EULAR in June 2015.

Outcome Measure at Week 12	Intent-to-Treat Analysis	P value (1)
Pain		
Daily Pain Diary, NRS	Mean Change (2)	0.086 / 0.172 (JTC)
Daily Pain Diary, NRS	Proportion of Patients Achieving 30% Improvement (3)	0.030* (LR)
Clinic NRS 7-day pain recall	Mean Change	0.029*
FIQ-R Pain Item	Mean Change	0.004*
Sleep		
Daily Sleep Quality Diary, NRS	Mean Change	<0.001*
PROMIS Sleep Disturbance	T-score Change	0.003* / 0.004* (JTC)
FIQ-R Sleep Quality Item	Mean Change	<0.001*

Outcome Measure at Week 12	Intent-to-Treat Analysis	P value (1)
Fibromyalgia-Related		
Patient Global Impression of Change	Responder Analysis	0.025* (LR)
FIQ-R Total Score	Mean Change	0.014* / 0.015* (JTC)
FIQ-R Symptom Domain	Mean Change	0.004*
FIQ-R Function Domain	Mean Change	0.060
FIQ-R Anxiety Item	Mean Change	0.015*
FIQ-R Sensitivity Item	Mean Change	0.017*
FIQ-R Stiffness Item	Mean Change	0.039*

*JTC = Jump to Control, Multiple Imputation; LR = Logistic Regression; NRS = Numeric Rating Scale * p < 0.05*

(1) Analysis by Mixed-Effect Model Repeated Measure unless otherwise indicated.

(2) Primary endpoint for FDA approvals of Lyrica® and Cymbalta® in fibromyalgia.

(3) Primary endpoint for FDA approval of Savella® in fibromyalgia.

Source: Tonix Pharmaceuticals, Inc.

- ***What will the Phase 3 look like?***

We are expecting Tonix to start enrolling patients in the Phase 3 trial in May 2015. To get a sense of what we expect for the Phase program, let's quickly review the key components of BESTFIT. BESTFIT was a randomized, double-blind, placebo-controlled 12-week safety and efficacy study in fibromyalgia patients who were given either a 2.8 mg TNX-102SL tablet or placebo at bedtime. A total of 205 patients were enrolled at 17 centers in the U.S., with the final randomization as follows: TNX-102 SL (n=103), placebo (n=102). BESTFIT cost Tonix roughly $5 million to complete.

We are expecting the Phase 3 trial will look very similar, only larger. The Phase 3 is expected to be a double-blind, placebo-controlled 12-week safety and efficacy study in approximately 500 fibromyalgia patients given either a 2.8 mg TNX-102SL tablet or placebo at bedtime at 1:1 randomization. We expect the trial to take place at 30-35 sites in the U.S., with some overlap to the highest performing 17 BESTFIT sites. BESTFIT took roughly a year to enroll. The Phase 3 trial will be twice the size, yet at twice as many sites. So we are expecting enrollment will take between 12 to 14 months. We are estimating the cost at around $12 million. If the study begins in May 2015, enrollment should complete late summer 2016, with data expected early in the fourth quarter 2016. Tonix is hoping that with strong results from the Phase 3 trial (p-value < 0.025) the company can package an application to the U.S. FDA using both BESTFIT and the new data in early 2017. Assuming a standard review, the best case scenario would be that TNX-102SL receives FDA approval in early 2018.

- ***How big is TNX-102SL?***

Based on the generic market, the target population for Tonix with TNX-102 SL is over 2 million patients. There were some 50 million prescriptions for cyclobenzaprine in 2013. We think that the sublingual formulation clearly contains meaningful advantages over the generic oral formulation of low dose cyclobenzaprine. 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.

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 fibromyalgia switching to TNX-102SL. At a cost of $15 per pill (comparable to Lyrica and Cymbalta®), with decent tier-2 and tier-3 coverage, we see TNX-102SL as a $600 million peak drug in the U.S. We expect that by 2018, both Lyrica and Cymbalta will be generic, and that Tonix will have one of the only branded prescription medications for fibromyalgia available.

Military-Related PTSD Study Just Underway

On January 15, 2015, Tonix announced the Phase 2 AtEase study had enrolled its first patient. The AtEase study is a Phase 2 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. More information on AtEase can be found on the website announcing the study or on ClinicalTrials.gov (NCT02277704).

The primary endpoint of the trial is the week eight mean change from baseline in the total CAPS-5 (Clinician-Administered PTSD Scale) score in participants who received 2.8 mg of TNX-102 SL as compared to those who received placebo only. Safety will also be evaluated. The trial is expected to be conducted at approximately 25 U.S. sites. Management plans to use print and radio media to spark military interest in the study, and then hope peer-networking speeds enrollment throughout 2015. We are anticipating data in 2016.

- ***Why 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 addition. 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 ($15 per day) and market penetration (roughly 5%) as noted above for fibromyalgia, we believe TNX-102SL peak sales in PTSD are around $400 million.

TNX-201 – A New Option For Headache

In late October 2014, Tonix received FDA clearance on an IND to begin Phase 1 clinical studies with TNX-201 for the treatment of episodic tension-type headache (ETTH). Earlier in the year, management announced that they have completed the Phase 1 safety, tolerability, and pharmacokinetic study of TNX-201 with encouraging results. Data from the 45-patient study shows a dose-related increase in TNX-201 plasma levels (Cmax, AUC), with no evidence of isomer inter-conversion and only mild adverse events, none of which were considered drug-related or serious enough to discontinue treatment.

The next step with TNX-201 is a Phase 2, double-blind, randomized, multicenter, placebo-controlled study to evaluate the efficacy and safety of TNX-201 for the treatment of a single episodic tension-type headache. We anticipate approximately 150 subjects will be randomized 1:1 to either 140 mg of TNX-201 or placebo, with the primary endpoint being the number of subjects who report "pain free" at two hours following one dose of study medication (upon first ETTH episode experienced). Enrollment is expected to take place at 10 centers in the U.S. and commence in the second quarter of 2015. We believe this will be a relatively quick study with the potential to offer top-line data before the end of the year.

- ***What is TNX-201?***

The active ingredient in TNX-201 is (R)-isometheptene mucate, a single isomer of isometheptene mucate. Isometheptene is a racemic mixture of both the (R) and (S) isomers. The drug has been widely used as a single-agent prescription medicine and as a component of combination drug products (e.g. Midrin® and Prodrin®) for many decades in the U.S. for various indications including tension-type headache. Isometheptene mucate was introduced as a pharmaceutical prior to 1962, and no products containing isometheptene mucate are currently approved by the U.S. FDA for any indication. Isometheptene prescriptions peaked at roughly 2.5 million per year in the late 1990s.

Tonix believes that (R)-isometheptene has strong analgesic effects with an improved safety profile over both (S)-isometheptene and the racemic compound. Tonix preclinical data shows significantly less effect on diastolic arterial blood pressure with use of (R)-iso vs. (S)-iso and the racemic mixture, while maintaining strong efficacy in mouse studies (Zhang L et al, 2013). Previous research has shown isometheptene to have high affinity for the imidazole I_1 receptor (I_1–R) with no α_1/α_2 agonism that has been proven to induce smooth muscle and blood vessel constriction like other I_1 receptor binders such as clonidine, rilmenidine, moxonidine, and dexmedetomidine (Khan ZP et al, 1999). TNX-201 is protected by a composition-of-matter patent that does not

expire until 2033.

- ***What is ETTH?***

Tension type headaches (TTH) are the most common type of headaches among adults and are also known as "stress headaches". The episode can last as short as 30 minutes, or in extreme cases as long as several days. Patients can experience one episode a month (infrequent TTH), to several a month (frequent TTH), or in the most severe cases in excess of 15 a month (>180 a year for chronic TTH). Unlike migraine headaches, the pain from a tension headache occurs on both sides of the head. It is not a pulsating pain like a migraine; instead it is more of a pressure/tightening pain. Often, migraine headaches are brought on by light or sound. Tension type headaches are more idiopathic in nature. A review of 107 publications on the epidemiology of headache conducted by Stovner L, et al, 2007, found that approximately 38% of the population will experience an ETTH over the course of a year compared to 10% for migraine headaches. In the U.S., that equates to roughly 75 million Americans that may suffer from frequent ETTH. The majority of the sufferers (>70%) are female.

- ***Why is TNX-201 Better?***

Treatment of headache in the U.S. is a significant market opportunity for pharmaceutical companies. For example, according to the IMS National Disease and Therapeutics Index, non-migraine headaches lead to 9.2 million emergency room or office visits each year. The vast majority of patients choose over-the-count medications to treat ETTH, with NSAIDs such as ibuprofen/naproxen and acetaminophen the most commonly used. However, beyond OTC medication, there were still roughly 10 million total prescriptions for headache in the U.S. in 2013, with butalibitals, opioids, and triptans the leading prescription choices after NSAIDs. According to IMS Health, butalbital combination products accounted for approximately 3.5 million prescriptions in 2013.

The U.S. FDA has placed a warning on butalbital products noting the risk of potential abuse and addiction. As a result, long-term use of these products is discouraged. The drug is Schedule III by the DEA. The market leading butalbital combination product was Fioricet (butalbital, acetaminophen, and caffeine). Combination butalbital and opioid products also exist but market share is low due to the compounded potential for abuse and addiction.

- ***How big is TNX-201?***

TNX-201 clearly targets a large market. Above we noted some 75 million Americans that suffer from tension type headaches each year. Although the majority may be treated with OTC medications, there were still roughly 10 million prescriptions for headache medications in the U.S in 2013. We believe approximately 70% of these are for ETTH in nature. We suspect the 3.5 million prescriptions for butalbital combination products is the initial low-hanging fruit for Tonix, with opportunity to take away market from prescription NSAID and Triptan products offering significant upside. At peak, isometheptene was doing 2.5 million prescriptions per year in the late 1990s.

If we assume the average headache sufferer has about one episode per week, and we price TNX-201 comparable to migraine drugs Cambia® ($35 per pill) and Treximet® ($40 per pill), with 10% market share of the active medical Rx seekers, TNX-201 looks to be around a $500 million drug.

What is Tonix Worth?

Above we have outlined our assumptions for the sales and market opportunity for each of the company's three clinical programs. For TNX-102SL in fibromyalgia, we assume approval and launch in early 2018, with the drug costing approximately $15 per day. We are assuming Tonix (or its partner) can capture 5% of the market by 2023, with peak sales of $650 million. If we apply a 25% discount rate and 25% probability of success to the asset, we arrive at a net present value (NPV) for TNX-102SL in fibromyalgia of approximately $70 million.

For PTSD, a slightly smaller peak sales opportunity of $400 million exists. We believe approval of TNX-102SL in PTSD is approximately one year behind the timelines noted above for fibromyalgia. Thus, our NPV analysis for TNX-102SL in PTSD yields a fair value valuation of approximately $30 million. We believe there is potential for Tonix to receive partial funding of the AtEase study from the U.S. Department of Defense (DOD) not currently factored into our model. Nevertheless, together, we believe TNX-102SL in PTSD and fibromyalgia are worth roughly $100 million in NPV. We remind investors that TNX-102SL is protected by a pharmacokinetic patent that does not expire until 2033 and a composition-of-matter patent that does not expire until 2034.

For TNX-201, we place slightly lower odds of success in our NPV model simply due to the earlier-stage nature of the candidate. However, even with applying as low as a 10% chance of success, we still believe this candidate is worth $25 million in NPV based on peak sales of approximately $500 million in 2023.

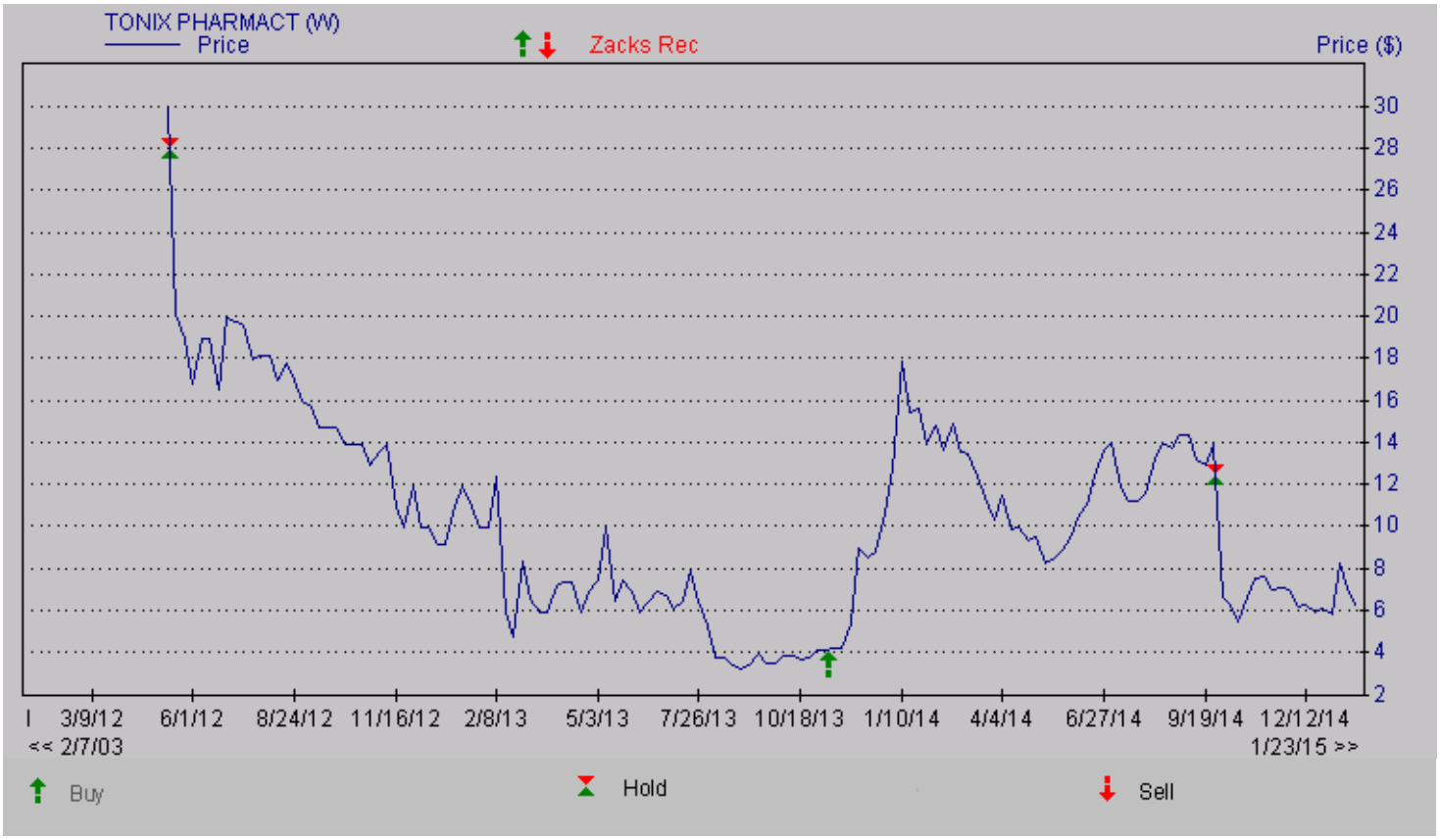
Summing up our NPV calculations we arrive at a total firm value of approximately $125 million. Based on the fully-diluted share count of approximately 12.2 million, we see fair-value at $10 per share. We remind investors that Tonix exited the third quarter 2014 (ended September 30, 2014) with $46.2 million in cash and investments. We suspect the number at the end of December 2014 was roughly $40 million. Operating burn in the third quarter totaled $5.0 million. We believe the current cash position is sufficient cash to fund operations for the foreseeable future. We view Tonix high cash balance as a significant reduction in risk for investors, and the soon-to-be three active clinical programs are sure to draw significant investor attention to the name later in the year. As such, we believe Tonix Pharmaceuticals is attractive for long-term investors today.

Tonix Pharma
Income Statement

Tonix Pharmaceuticals	2013 A	Q1 A	Q2 A	Q3 A	Q4 E	2014 E	2015 E	2016 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	$4.7	$3.6	$4.1	$5.2	$4.5	$17.3	$25.0	$22.0
% R&D	-	-	-	-	-	-	-	-
SG&A	$6.2	$1.6	$2.0	$2.2	$2.1	$7.9	$8.5	$9.0
% SG&A	-	-	-	-	-	-	-	-
Operating Income	($10.9)	($5.2)	($6.0)	($7.4)	($6.6)	($25.3)	($33.5)	($31.0)
Operating Margin	-	-	-	-	-	-	-	-
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)	($7.4)	($6.5)	($25.1)	($33.4)	($30.9)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($10.9)	($5.2)	($6.0)	($7.4)	($6.5)	($25.1)	($33.4)	($30.9)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($3.37)**	**($0.59)**	**($0.61)**	**($0.71)**	**($0.61)**	**($2.52)**	**($2.67)**	**($2.06)**
YOY Growth	*-39.6%*	-	-	-	-	*-25.1%*	*5.9%*	*-22.9%*
Weighted Shares Outstanding	3.2	8.7	9.9	10.5	10.7	10.0	12.5	15.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

HISTORICAL ZACKS RECOMMENDATIONS



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Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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.