Zacks Small-Cap Research

August 16, 2013
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Tonix Pharmaceuticals

(TNXP-NASDAQ)

TNXP: Tonix Completes Secondary Offering, Uplists to NASDAQ, Initiation of Phase 2/3 Trial Imminent…

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	07/23/2012
Current Price (08/16/13)	$3.80
Target Price	**$7.00**

UPDATE

After a one-for-20 reverse stock split on May 1, 2013, Tonix completed its secondary offering on August 14, raising gross proceeds of $10 million in cash in through an offering of 2.68 million units of one share and one warrant per unit at $4.25 per unit. This offering provides the necessary funding for the planned phase 2/3 trial in fibromyalgia and additionally provided sufficient shareholder equity for the company to execute on its planned up-listing to NASDAQ.

We are pleased to see Tonix take two major steps forward in August 2013. The uplisting to the NASDAQ and the $10 million financing show testament to the hard work management has put in over the past year. We have made several adjustments to our financial model, and now see $7.00 as fair-value for the shares.

SUMMARY DATA

52-Week High	**$17.80**
52-Week Low	**$2.50**
One-Year Return (%)	**-78.43**
Beta	**0.05**
Average Daily Volume (sh)	**40,349**
Shares Outstanding (mil)	**2**
Market Capitalization ($mil)	**$8**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
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 2013 Estimate	**N/A**
P/E using 2014 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)
2012	0 A	0 A	0 A	0 A	0 A
2013	0 A	0 A	0 E	0 E	0 E
2014					0 E
2015					10 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$1.27 A	-$1.79 A	-$1.01 A	-$1.49 A	-$5.58 A
2013	-$0.93 A	-$0.95 A	-$0.49 E	-$0.56 E	-$2.08 E
2014					-$2.08 E
2015					-$0.15 E

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WHAT'S NEW

On May 1, 2013, Tonix Pharmaceuticals announced a 1-for-20 reverse split of its issued and outstanding common stock, thereby reducing the number of outstanding shares from 43.95 million to 2.197 million.

Tonix Reports Closing of Secondary Offering

On August 14, 2013, Tonix announced closure of the previously announced secondary offering. The fully subscribed offering included 2,680,000 units at an offering price of $4.25 per unit. Each unit included

- One share of common stock, and
- One warrant to purchase one share of common stock. The warrants, which will be exercisable on a cashless basis under certain circumstances, feature a strike price of $4.25 and expire on the fifth anniversary of the date of issue. The exercise price and number of shares of common stock issuable upon exercise of the warrants will be adjustable under certain circumstances, including stock splits, stock dividends, reorganization, and similar transactions.

An additional 107,200 warrants were issued to the underwriters.

Net proceeds to the company were approximately $10 million. Shares outstanding increased from 2.16 million at the end of the second quarter to 4.88 million on August 14. Outstanding warrants to purchase company shares increased from 1.23 million at the end of the quarter to 4.39 million. At the end of the second quarter employee options totaled 0.38 million, giving a fully diluted share count on August 14 of approximately 9.67 million.

Second Quarter Financial Results

Research and development expenses for the three months ended June 30, 2013 were $943,995, an increase of $116,207, or 14%, from $827,788 for the three months ended June 30, 2012. The increase in clinical and non-clinical cost and activities is primarily due to additional development work related to TNX-102-SL, including manufacturing and clinical development, offset by decreases in regulatory and market research expenses.

General and administrative expenses for the three months ended June 30, 2013 were $1,141,694, an increase of $118,544, or 12%, from $1,023,150 incurred in the three months ended June 30, 2012. Payroll-related expenses for the three months ended June 30, 2013 include non-cash compensation associated with options granted in 2012 and 2013 of $441,571, as compared to $228,532 for the same period last year.

Net loss decreased from $3.07 million in the second quarter of 2012 to $2.09 million in the second quarter of 2013. Much of the difference is attributable to non-cash charges of $1.22 million in the second quarter of 2012 related to the expiration of reset provisions on certain previously issued warrants.

Cash on hand at the beginning of the second quarter of 2013 was $0.42 million. Cash used in operations was $0.76 million compared to $1.13 million in the second quarter of 2012. Cash flow from investing activities was -$0.02 million vs. -$0.33 million in the corresponding quarter of 2012. Financing transactions, including a $0.2 million related party interest-free loan, $0.31 million from the exercise of warrants, and -$0.10 million in deferred offering costs provided a net cash flow of $0.41 million. Based on the disclosed $0.07 million cash on hand on June 30, 2013, an estimated cash burn rate of $0.26 million per month, the August 14th financing event, and a $0.08 million dollar interest free loan obtained from a related party on August 1st, we estimate current cash on hand to be around $9.77 million. As noted below, we anticipate the company initiating the phase 2b/3 trial with TNX-102-SL here in the third quarter. We assume some upfront costs associated with the initiation of this program, so burn rate should increase relative to the second quarter 2013. As such, we forecast cash on hand as of September 30, 2013 will be reported at around $8.75 million. We find this to be sufficient to fund operations until late 2014.

INVESTMENT THESIS

Plans For TNX-102-SL

Tonix held an End-of Phase 2/Pre-Phase 3 meeting with the FDA to discuss its proposed NDA plan for TNX-102 SL in February this year. Official FDA meeting minutes indicate FDA acceptance of the clinical program and provide clear direction to achieve a successful NDA filing of TNX-102-SL in fibromyalgia.

...Registrational Trials…

The registrational clinical trials will consist of two 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 both trials will be the change in pain from baseline to Week 12 as measured by the Numeric Rating Scale (NRS). The Company plans to conduct these trials in sequence, and expects to begin dosing in the first trial here in the third quarter of 2013. This trial will enroll 100 to 200 fibromyalgia patients, and top-line data are anticipated to become available in late 2014.

We note the primary endpoint planned for these trials 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. Tonix plans to include 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 suspect that the trial will take about 12 months to enroll and report top-line data, at an all-in cost of around $3-4 million.

…Pharmacokinetic Reference Study…

Along with the phase 2b study noted above, Tonix plans to conduct a multi-dose pharmacokinetic study with TNX-102-SL in comparison to generic cyclobenzaprine in a multiple-day dosing (once daily) study. In the study, peak and trough blood levels of cyclobenzaprine will be measured in subjects that receive either TNX-102-SL or generic cyclobenzaprine immediate release for 4-5 consecutive days. The goal of the study is to show a bridge between 2.8 mg TNX-102-SL and generic 5 mg cyclobenzaprine that will allow for use of the generic tablet as a reference product in the planned 505(b)(2) NDA submission. We estimate the cost here at around $0.5 million.

…Next Day Drowsiness / Cognitive Effects Study…

In order to differential TNX-102-SL from the readily available generic cyclobenzaprine, Tonix plans to conduct a small study designed to evaluate next morning drowsiness and other cognitive measures following the bedtime dosing of either TNX-102-SL or generic cyclobenzaprine immediate release. We believe it is imperative for Tonix to clearly show a benefit to dosing 2.8 mg TNX-102-SL versus generic 5 mg cyclobenzaprine on measures such as next morning drowsiness and on other cognitive functions for else market penetration for the product will be negligible.

The commercial failure of Silenor (3 mg or 6 mg doxepin) is a direct result of the lack of differentiation between Silenor and generic 5 mg or 10 mg doxepin. To date, sales of Intermezzo (1.75 mg or 3.5 mg zolpidem tartrate SL) have been a significant disappointment to Transcept Pharmaceuticals and commercial partner, Purdue Pharma L.P. We believe this creates a significant perception hurdle for Tonix with investors, because Transcept did studies to show differentiation between Intermezzo 3.5 mg and generic 10 mg zolpidem (Ambien®), and uptake is still far below what both Transcept and Purdue had hoped. We estimate the cost here at around $0.5 million.

…Safety Extension Study…

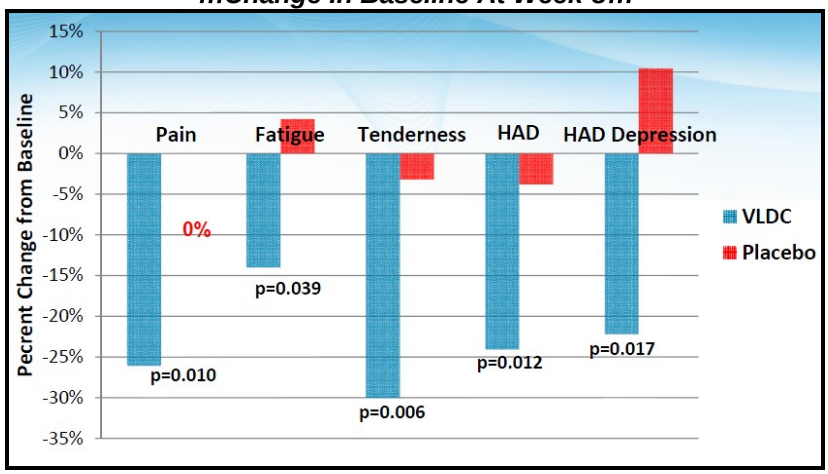
Following the completion of the double-blind randomized portion of these studies, patients may be eligible to enroll in open-label extension studies of TNX-102-SL. The FDA agreed that the safety database needed to support a 505(b)(2) NDA submission for TNX-102-SL would contain a total exposure of at least 300 fibromyalgia patients, with at least 100 patients receiving TNX-102-SL for six months and at least 50 patients for one year.

Quick Review Of Phase 2a Data

In December 2011, data from a phase 2a study with an oral formulation of cyclobenzaprine was published by the Sleep Disorders Clinics of the Centre for Sleep and Chronobiology, University of Toronto, Ontario, Canada (supported by Tonix Pharmaceuticals Inc.) in the Journal of Rheumatology (38(12):2653-63). The paper is called, "Effects of bedtime very low dose cyclobenzaprine on symptoms and sleep physiology in patients with fibromyalgia syndrome: a double-blind randomized placebo-controlled study."

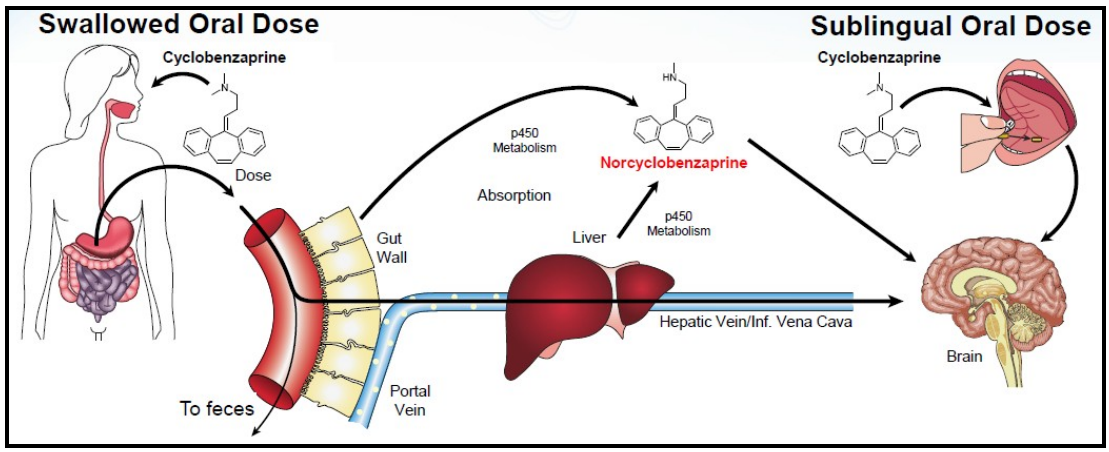
The trial was a randomized, double-blind, placebo-controlled, dose-escalating, parallel-design study in patients with FM and disrupted sleep. A total of 36 patients (1:1 very low dose (VLD) cyclobenzaprine vs. placebo) were treated for 8 weeks. Doses were taken between dinner and bedtime. The dosage was 1 mg for the first 7 days, after which, if clinically indicated and according to tolerability, the daily dose could be increased up to 4 mg (mean dose was 3.1 mg at week 8). We present the key findings form the data below:

…Change In Baseline At Week-8…



…The Benefits of SL…

The SL formulation dissolves quickly under the tongue and provides rapid absorption of cyclobenzaprine across the mucous membrane into the bloodstream. As noted above, this avoids the pH variability and food effect seen with generic oral cyclobenzaprine. It also avoids first-pass metabolism in the liver. This is very important because cyclobenzaprine, when taken orally, is absorbed into the small intestines and transported directly to the liver where it is metabolized into norcyclobenzaprine. According to the literature, norcyclobenzaprine is a long-lived, psychoactive metabolite believed to interfere with cyclobenzaprine's efficacy over time, potentially contributing to the reported decrease of benefit of oral cyclobenzaprine in fibromyalgia when taken chronically. We note the company has generated pharmacokinetic data showing 2.8 mg of the SL formulation is equivalent to 3.1 mg of the oral formulation (mean dose from phase 2a study).

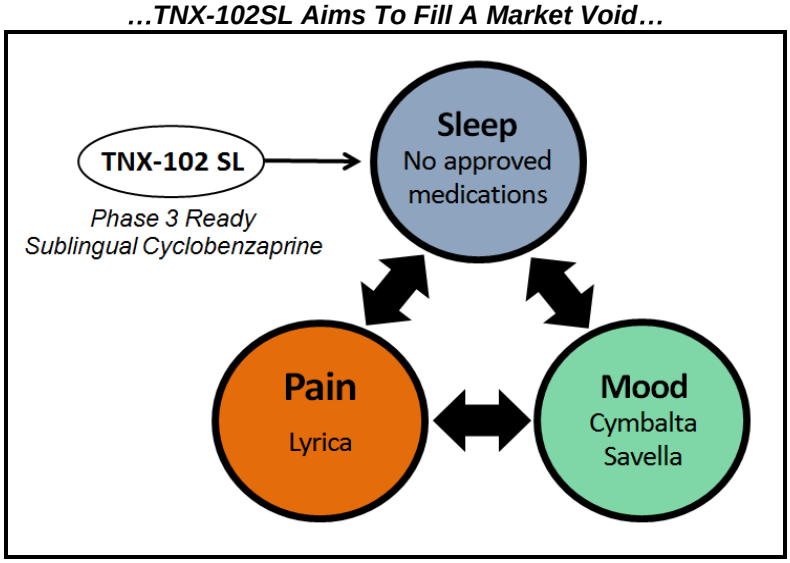


Source: Tonix Inc Investor Presentation (Sept. 2012)

Sales and Commercial Potential

Averaging the data obtained from the NIH, AFSA, and NFA, we estimate there are approximately 8 million Americans living with FM. Over 90% of these patients have sleep problems. Approximately 70% of FM patients report difficult in conducting normal daily tasks, such as light housework due to chronic fatigue. According to Decision Resources, U.S. sales of prescription drugs specifically for the treatment of FM totaled $1.4 billion in 2011. This figure includes sales of Cymbalta, Lyrica, and Savella of $595 million, $504 million, and $110 million, respectively. Despite the availability of FDA approved products, we believe the current treatment options for FM continue to leave many patients dissatisfied. Existing approved FM medications such as Lyrica and Cymbalta, which focus on reducing FM-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 FM.

…TNX-102SL Aims To Fill A Market Void…



If Tonix can gain approval for TNX-102-SL in FM 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 50 million tablets of cyclobenzaprine were sold specifically for FM in 2010. We believe at least a third of FM 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 VLD cyclobenzaprine. Tonix has successfully designed a superior 2.4 mg sublingual formulation of cyclobenzaprine to the readily available oral 10 mg generic. Does that mean there will be no, or even limited, generic substitution or competition once TNX-102-SL hits the market? No.

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 $6-7 per pill ($2,500 per year by 2020), with decent tier-2 and tier-3 coverage, we see TNX-102-SL as a $250 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 FM available.

VALUATION & RECOMMENDATION

Tonix is developing a sublingual very low dose cyclobenzaprine product, TNX-102-SL, that offers improved pharmacokinetics and convenient sublingual dose formulation for the treatment of fibromyalgia (FM). FM is a complex medical disorder characterized by widespread musculoskeletal pain, fatigue, lack of sleep, and mood and memory issues. The National Pain Foundation estimates that 90% of all FM patients have sleep problems. Tonix is developing a sublingual formulation of cyclobenzaprine designed specifically for bedtime dosing in order to help patients improve quality (restorative) sleep and reduce the next-day pain and "fibro-fog" that is persistent with FM.

We believe this is a meaningful opportunity for Tonix, mainly because currently approved FM medications, such as Pfizer's Lyrica (pregabalin) and Lilly's Cymbalta (duloxetine), do little to improve sleep quality. Plus, cyclobenzaprine is a well-known and commonly used medication already for FM. Market research conducted by Frost & Sullivan found that cyclobenzaprine was the third most commonly prescribed medication for FM behind Lyrica and Cymbalta in 2011. Decision Resources estimates that approximately 50 million cyclobenzaprine tablets were taken by FM patients, off-label, in 2011. That's 5% of the cyclobenzaprine market.

Our primary concern is the potential for off-label use of split tablets and/or slightly higher doses of generic cyclobenzaprine, which is currently available in tablets containing as little as

PROJECTED FINANCIALS

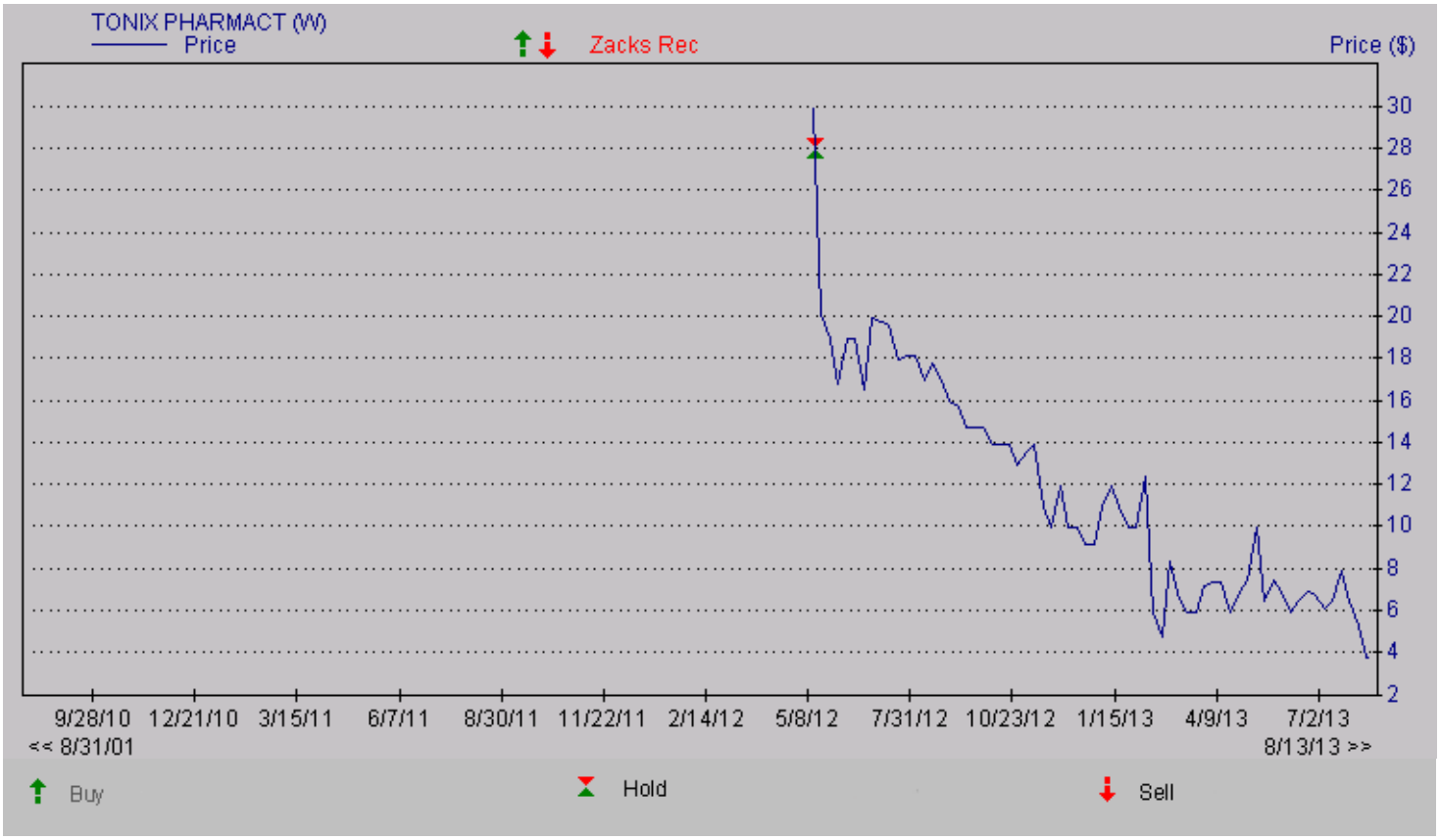
Tonix Pharma
Income Statement

Tonix Pharmaceuticals	2011 A	2012 A	Q1 A	Q2 A	Q3 E	Q4 E	2013 E	2014 E	2015 E
TNX-102SL (FM)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
TNX-102SL (PTSD)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Pipeline	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Research & Collaborations	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$10**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$10**
YOY Growth	*100.0%*	-	-	-	-	-	-	-	-
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-	-
R&D	$1.2	$2.6	$0.7	$0.9	$1.1	$1.4	$4.2	$5.0	$5.0
% R&D	-	-	-	-	-	-	-	-	-
SG&A	$2.2	$4.1	$1.3	$1.1	$1.2	$1.3	$4.9	$4.6	$4.8
% SG&A	-	-	-	-	-	-	-	-	-
Operating Income	($3.4)	($6.7)	($2.0)	($2.1)	($2.3)	($2.7)	($9.1)	($9.6)	$0.2
Operating Margin	*#DIV/0!*	-	-	-	-	-	-	-	-
Interest & Other Income	($0.1)	($2.8)	$0.0	$0.0	($0.1)	($0.1)	($1.5)	($1.2)	($1.0)
Pre-Tax Income	($3.5)	($9.4)	($2.0)	($2.1)	($2.4)	($2.8)	($10.6)	($10.8)	($0.8)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($3.5)	($9.4)	($2.0)	($2.1)	($2.4)	($2.8)	($10.6)	($10.8)	($0.8)
Net Margin	*#DIV/0!*	-	-	-	-	-	-	-	-
Reported EPS	**($3.24)**	**($5.58)**	**($0.93)**	**($0.95)**	**($0.49)**	**($0.56)**	**($2.08)**	**($2.08)**	**($0.15)**
YOY Growth	*#REF!*	*72.3%*	-	-	-	-	*-62.8%*	*0.1%*	*-92.7%*
Basic Shares Outstanding	1.07	1.69	2.16	2.20	4.88	5.00	5.10	5.20	5.30

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

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HISTORICAL ZACKS RECOMMENDATIONS



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