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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Infectious Disease Investments Likely to Pay Off…

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL in fibromyalgia, TNX-1800, TNX-1900 and TNX-1300, TNXP is valued at $2.25/share. This model is highly dependent upon continued clinical success of the company's assets and will be adjusted accordingly based upon future clinical results.

Current Price (12/13/21)	$0.38
Valuation	**$2.25**

OUTLOOK

Tonix Pharmaceuticals Holding Corp. (TNXP) has recently expanded its in-house research capabilities through the purchase of a 48,000 square foot research and development center (RDC) in Frederick, MD and construction is also underway on the company's advanced development center (ADC) in New Bedford, MA. These investments in infectious disease research are likely to pay dividends, particularly with the recent emergence of a new SARS-CoV-2 variant of interest.

The company also recently presented results from the positive Phase 3 RELIEF study of TNX-102 SL (cyclobenzaprine HCl sublingual tablet) in patients with fibromyalgia (FM) at the American College of Rheumatology Convergence 2021. In December 2020, the company announced the trial met its pre-specified primary endpoint of significantly reducing daily pain compared to placebo (*P*=0.01). We anticipate results from the second Phase 3 trial (RALLY) in the first quarter of 2022, although the company stopped enrolling patients following disappointing results at the interim efficacy analysis in July 2021. We expect another Phase 3 trial in FM to initiate in the first half of 2022.

SUMMARY DATA

52-Week High	**$2.00**
52-Week Low	**$0.38**
One-Year Return (%)	**-36.24**
Beta	**1.16**
Average Daily Volume (sh)	**23,187,082**
Shares Outstanding (mil)	**440**
Market Capitalization ($mil)	**$168**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**21**
Insider Ownership (%)	**1**
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 2018 Estimate	**-1.4**
P/E using 2019 Estimate	**-2.0**

Risk Level	**Above Avg.**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 A	0 A	0 A	0 E	0 E
2022					0 E
2023					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.37 A	-$0.23 A	-$0.09 A	-$0.10 A	-$0.55 A
2021	-$0.07 A	-$0.07 A	-$0.05 A	-$0.07 E	-$0.26 E
2022					-$0.16 E
2023					-$0.15 E

WHAT'S NEW

Business Update

In-House Research Capabilities Bolstered

Tonix Pharmaceuticals Holding Corp. (TNXP) has increased its in-house research capabilities with the purchase, construction, and planned construction of multiple research centers. These facilities will allow the company to have better control over the early development of its pipeline candidates, which could help to avoid unforeseen delays. In addition, the recent emergence of a new SARS-CoV-2 variant of interest shows that the coronavirus pandemic is likely to be an issue for some time to come.

- In October 2021, the company held a ribbon-cutting ceremony at the company's 48,000 square foot research and development center (RDC) in Frederick, MD. This facility is expected to provide the ability to research and discover vaccines and antiviral therapies to COVID-19 and other infectious diseases. The RDC is currently operating as a BSL-2 facility, but the company has plans to make the appropriate upgrades such that BSL-3 research can take place.

- In August 2021, the company began construction on the advanced development center (ADC) for the development and manufacturing of GMP live-virus vaccines for Phase 1 and 2 clinical trials. The facility is located in New Bedford, MA with plans to operate at BSL-2. Tonix expects the ADC to be operational in the first half of 2022.

- Following its purchase of 44 acres of land in Hamilton, MT, Tonix is planning to construct a commercial manufacturing center (CMC) for the development and manufacturing of commercial scale live-virus vaccines. The company plans for the CMC to operate at BSL-2 and construction is expected to commence in 2022.

In Vitro *Studies of TNX-3500 Show Efficacy Against Multiple Variants of SARS-CoV-2*

On November 22, 2021, Tonix announced the publication of a manuscript in *JCI Insight* titled "Sangivamycin is highly effective against SARS-CoV-2 in vitro and has favorable drug properties" (Bennett *et al*., 2021). The results of the studies showed that sangivamycin (TNX-3500) exhibited greater antiviral properties against SARS-CoV-2 than remdesivir (Veklury®), including suppression of viral replication.

In addition, TNX-3500 was found to have favorable pharmacokinetic properties, including high solubility (up to 500 μM), limited cytochrome P450 inhibition, low plasma protein binding, and the compound was not metabolized by either human or mouse liver microsomes. Taken together, these data show that TNX-3500 could become a much-needed antiviral treatment option as the world continues to battle the COVID-19 pandemic.

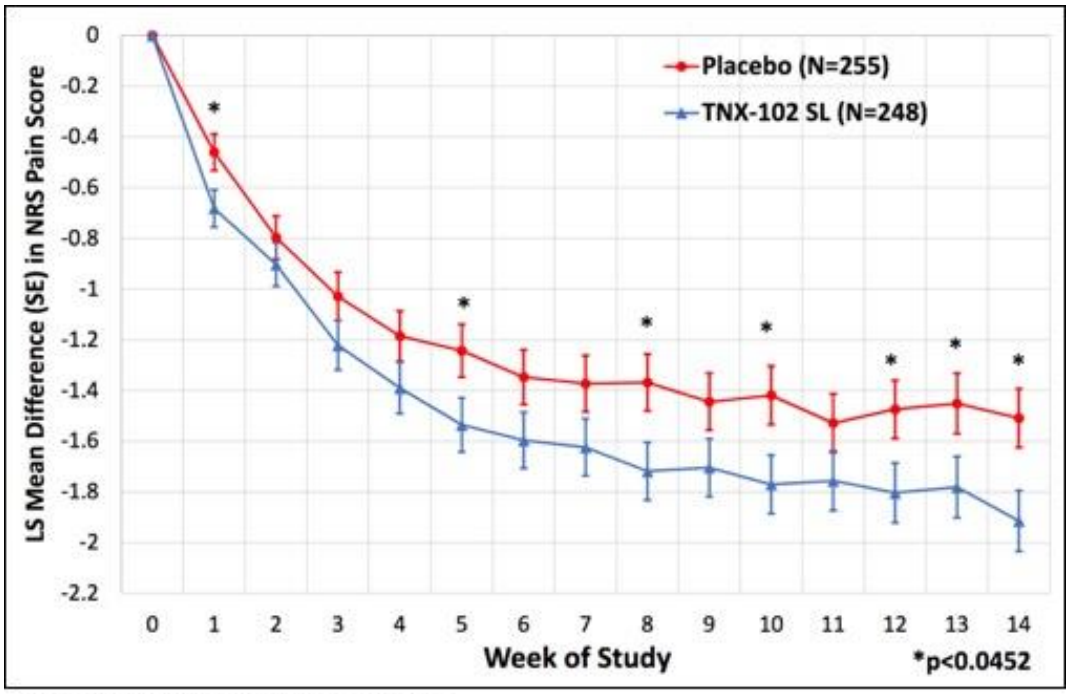
Positive Phase 3 Data from RELIEF Study Presented

On November 8, 2021, Tonix announced that positive results from the company's Phase 3 RELIEF study of TNX-102 SL 5.6 mg in patients with fibromyalgia (FM) were presented at the American College of Rheumatology Convergence 2021 (NCT04172831). A copy of the presentation can be accessed here. The positive results of the RELIEF study were previously announced by the company in December 2020.

This was a randomized, double blind, placebo controlled trial that enrolled 503 participants at 39 centers in the U.S. In September 2020, the company announced that at the interim analysis the independent data monitoring committee (IDMC) made the non-binding recommendation that the trial continue to completion with the addition of 210 participants to the original sample size of 470 participants, which is the maximum number of participants that could be added under the interim statistical analysis plan. The company decided at the time to complete the trial with the 503 enrolled participants.

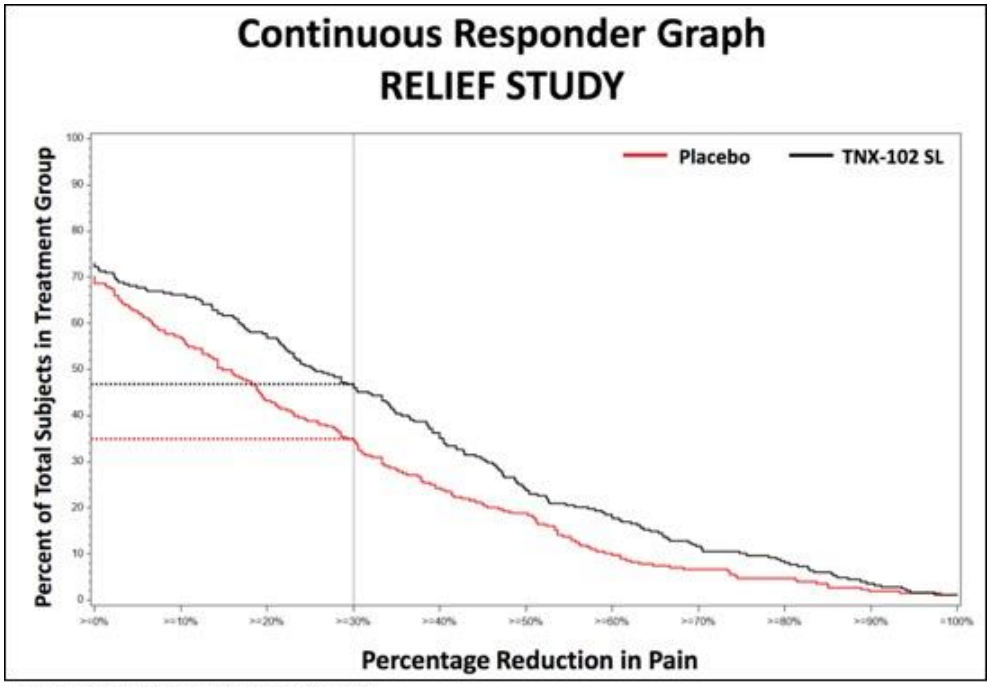
The following graph shows the results for the primary efficacy endpoint of the trial, the mean change from baseline in weekly averages of the daily diary pain numerical rating scale (NRS) scores. At week 14, participants on TNX-

102 SL had a LS mean change from baseline of -1.9 units compared to -1.5 units for participants on placebo (*P*=0.01). The graph shows that a statistically significant separation between TNX-102 SL-treated and placebo-treated participants was evident at Week 1, Week 5, Week 8, and Week 10 and continues consistently from Week 12 to Week 14 (all *P*<0.0452).



Source: Tonix Pharmaceuticals Holding Corp.

The following image shows a continuous responder graph with a selected percent pain reduction rate (x-axis) for responder status versus percent of responders in each treatment group. For a ≥30% pain reduction analysis, the line is drawn to intersect with 30% reduction in pain on the x-axis, and on the y-axis it shows that TNX-102 SL treatment is at 46.8% and placebo is at 34.9%. This is a statistically significant difference with a logistic regression odds ratio (95% CI) of 1.67 (1.16, 2.40; *P*=0.006).



Source: Tonix Pharmaceuticals Holding Corp.

The following table shows the results for the Fibromyalgia Impact Questionnaire – Revised. This questionnaire covers a wide range of FM symptoms, with results showing that TNX-102 SL separated from placebo (*P*<0.0452) for all problems except for anxiety and balance. This is important as TNX-102 SL reduced a number of symptoms that are common to most FM patients, including widespread pain, fatigue, sleep disturbance, memory problems, and sensory sensitivity.

Week 14 FIQR Please rate your...(last 7 days)	TNX-102 SL LS MCFB (SE)	Placebo LS MCFB (SE)	Difference in LS Means (SE)	p-value
Level of Pain	-2.3 (0.15)	-1.9 (0.15)	-0.5 (0.20)	0.014*
Level of Energy	-2.1 (0.16)	-1.3 (0.16)	-0.7 (0.22)	<0.001***
Level of Stiffness	-2.4 (0.17)	-1.8 (0.17)	-0.6 (0.23)	0.009**
Quality of Sleep	-3.1 (0.20)	-2.1 (0.20)	-0.9 (0.26)	<0.001***
Level of Depression	-1.1 (0.14)	-0.4 (0.13)	-0.7 (0.18)	<0.001***
Level of Memory Problems	-1.6 (0.16)	-1.0 (0.16)	-0.6 (0.21)	0.004**
Level of Anxiety	-1.2 (0.16)	-0.9 (0.16)	-0.4 (0.22)	0.084
Level of Tenderness to Touch	-2.4 (0.19)	-1.8 (0.19)	-0.6 (0.25)	0.017*
Level of Balance Problems	-1.4 (0.15)	-1.1 (0.15)	-0.3 (0.19)	0.149
Level of (Sensory) Sensitivity^	-2.4 (0.18)	-1.8 (0.18)	-0.5 (0.23)	0.021*
FM over the last 7 days...				
Prevented Accomplishing Goals	-2.6 (0.18)	-1.9 (0.18)	-0.7 (0.24)	0.003**
Completely Overwhelmed Me	-2.1 (0.18)	-1.5 (0.18)	-0.7 (0.24)	0.005**

^to loud noises, bright lights, odors, and cold *p<0.0452; **p<0.01; ***p<0.001
Abbreviations: FIQR = Fibromyalgia Impact Questionnaire – Revised; FM = fibromyalgia; LS = least squares; MCFB = mean change from baseline; p = probability; SE = standard error

Source: Tonix Pharmaceuticals Holding Corp.

The following table shows all treatment emergent adverse events (TEAEs) that were experience by ≥3% of participants in the TNX-102 SL group. The most common adverse event in the active group was oral hypoaesthesia, which is a sensory administration site reaction that is typically transient, never rated as severe, and only lead to 1 discontinuation in the study.

All TEAEs at a rate of ≥ 3% in the TNX-102 SL group

	TNX-102 SL	Placebo	Total
Oral Cavity Adverse Events			
Hypoaesthesia oral	43 (17.3%)	1 (0.4%)	44 (8.7%)
Paraesthesia oral	14 (5.6%)	1 (0.4%)	15 (3.0%)
Dysgeusia	13 (5.2%)	1 (0.4%)	14 (2.8%)
Glossodynia	9 (3.6%)	2 (0.8%)	11 (2.2%)
Dry mouth	8 (3.2%)	7 (2.7%)	15 (3.0%)
Systemic Adverse Events			
Sedation	9 (3.6%)	1 (0.4%)	10 (2.0%)
Fatigue	9 (3.6%)	4 (1.6%)	13 (2.6%)

Source: Tonix Pharmaceuticals Holding Corp.

In July 2021, Tonix announced that the RALLY trial, the second Phase 3 clinical trial of TNX-102 SL 5.6 mg for the treatment of fibromyalgia, stopped enrolling patients following a pre-planned interim analysis by the Independent Data Monitoring Committee (IDMC). Based on interim analysis results of the first 50% of patients (n=337), the IDMC

recommended stopping the trial for futility as TNX-102 SL 5.6 mg was unlikely to demonstrate a statistically significant improvement in the primary endpoint. The company remains blinded to the data and all enrolled patients in the study have completed the trial. Topline results are expected in the first quarter of 2022 and will include a pharmacogenomic comparison between the RELIEF and RALLY trials. The design of the next Phase 3 trial for TNX-102 SL, which we anticipate initiating in the first half of 2022, may be modified based upon the results of the pharmacogenomic analysis.

Multiple Clinical Trials Expected to Initiate Over the Next Year

Tonix has built a diverse pipeline that includes development candidates for COVID, biodefense, immunology, and multiple central nervous system (CNS) diseases. Two of those candidates are expected to enter the clinic before the end of 2022:

- **TNX-2100**: This is a diagnostic skin test as a means to test for a delayed-type hypersensitivity (DTH) reaction to SARS-CoV-2, the virus that causes COVID-19. It is modeled after the tuberculosis (TB) skin test (Tubersol®, Aplisol®, or the generic Mantoux test) that can determine if an individual has been exposed to the bacteria that causes tuberculosis, *Mycobacterium tuberculosis*. TNX-2100 is comprised of three different mixtures (TNX-2110, -2120, -2130) of synthetic peptides that correspond to different proteins of SARS-CoV-2. TNX-2110 represents multiple proteins from SARS-CoV-2, TNX-2120 represents only the spike protein of SARS-CoV-2, and TNX-2130 is representative of several proteins but not the spike protein. All three tests will be administered during the same procedure by application to three separate areas on the forearm in a similar manner to the TB skin test. They are designed for multiple potential applications: 1) As a biomarker for cellular immunity and protective immunity to SARS-CoV-2; 2) a method for stratifying participants in a COVID-19 vaccine trial by immune status; 3) an endpoint in COVID-19 vaccine trials; and 4) a biomarker of durability of vaccine protection. We anticipate a first-in-human clinical study to initiate in the fourth quarter of 2021.

- **TNX-1300**: The company will be initiating a Phase 2 clinical trial of TNX-1300 for the treatment of cocaine overdose in the fourth quarter of 2021. TNX-1300 is a recombinant enzyme derived from the *cocE* gene of a *Rhodococcus* species that utilizes cocaine as a sole source of carbon and nitrogen (Bresler *et al*., 2000). Results from a previous Phase 2 clinical trial showed that the recombinant CocE enzyme (then called RBP-8000, now TNX-1300) rapidly degraded plasma cocaine levels in volunteer cocaine users and was safe and well tolerated.

In addition to the above clinical trials expected to initiate soon, we also anticipate multiple clinical trials initiating in 2022, including for:

TNX-102 SL: Phase 3 trial in FM: Initiation – 1H22
TNX-102 SL: Phase 3 trial in PTSD (in Kenya): Initiation – 1Q22
TNX-102 SL: Phase 2 trial in Long COVID: Initiation – 1H22
TNX-601 CR: Phase 2 trial in Major Depressive Disorder: Initiation – 1H22
TNX-1800: Phase 1 trial for COVID-19 vaccine: Initiation – 2H22
TNX-1500: Phase 1 trial for organ transplant rejection: Initiation – 2H22
TNX-1900: Phase 2 trial for chronic migraine: Initiation – 2H22

Financial Update

On November 8, 2021, Tonix announced financial results for the third quarter of 2021. As expected, the company did not report any revenues for the third quarter of 2021. Net loss available to common shareholders for the third quarter of 2021 was $18.5 million, or $0.05 per share, compared to a net loss available to common shareholders of $12.0 million, or $0.09 per share, for the third quarter of 2020. The weighted average common shares outstanding for the third quarter of 2021 were approximately 366.4 million compared to approximately 127.2 million in the third quarter of 2020.

R&D expenses for the third quarter of 2021 were $13.1 million, compared to $8.8 million for the third quarter of 2020. The increase was primarily due to increased manufacturing expenses, non-clinical expenses, employee-related expenses, and regulatory/legal expenses. G&A expenses for the third quarter of 2021 were $5.5 million, compared to $3.2 million for the third quarter of 2020. The increase was primarily due to increased employee-related expenses.

As of September 30, 2021, Tonix had approximately $183.0 million in cash and cash equivalents. As of November 5, 2021, Tonix had approximately 439.6 million common shares outstanding and, when factoring in stock options and reasonably priced warrants, a fully diluted share count of approximately 465.5 million.

Conclusion

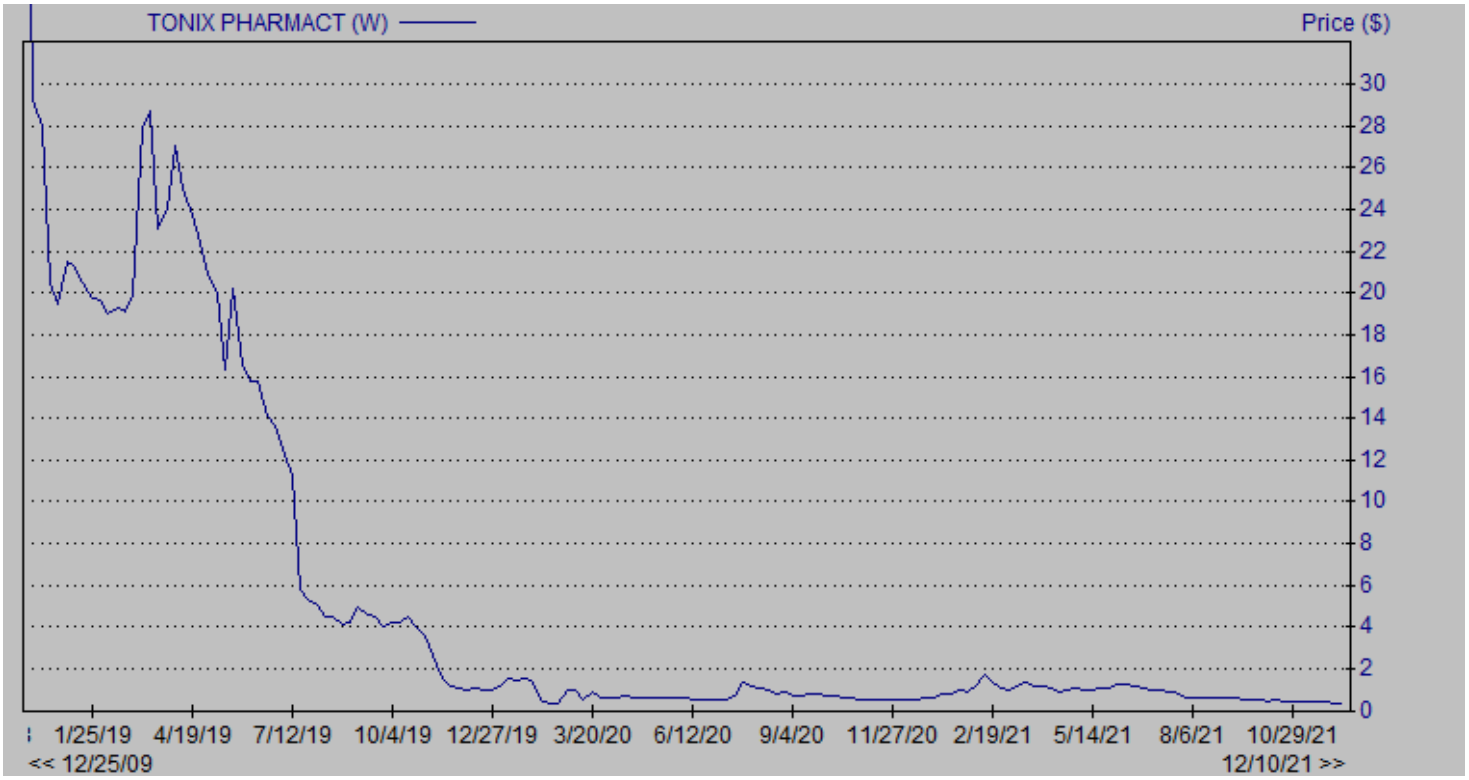
With $183 million in cash and cash equivalents, Tonix is well financed to advance its multiple pipeline products along with its new research facilities. Bringing research capabilities under the company's control is a smart move, as the response to the COVID-19 pandemic showed that there is only so much capacity for contract research organizations to handle, thus it should help Tonix move its early stage assets more quickly through development and into clinical trials. The positive results of the RELIEF trial are indicative that TNX-102 SL is having a positive effect in fibromyalgia patients and places Tonix potentially one positive Phase 3 study away from filing an NDA. We anticipate another Phase 3 trial in fibromyalgia to initiate in the first half of 2022. Given the increased share count over the past quarter, our valuation has decreased to $2.25.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2020 A	Q1 A	Q2 A	Q3 A	Q4 E	2021 E	2022 E	2023 E
TNX-102 SL (FM)	$0	$0	$0	$0	$0	$0	$0	$0
Research & Collaborations	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
CoGS	$0.0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$36.2	$15.3	$18.1	$13.1	$24.0	$70.5	$80.0	$90.0
SG&A	$14.4	$5.4	$5.4	$5.5	$6.0	$22.3	$13.5	$14.0
Operating Income	($50.5)	($20.7)	($23.6)	($18.5)	($30.0)	($92.8)	($93.5)	($104.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.0	$0.1	$0.0	$0.0	$0.0	$0.1	$0.2	$0.2
Pre-Tax Income	($50.5)	($20.7)	($23.6)	($18.5)	($30.0)	($92.7)	($93.3)	($103.8)
Preferred Stock Deemed Dividend	$1.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Warrant Deemed Dividend	$0.5	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($52.2)	($20.7)	($23.6)	($18.5)	($30.0)	($92.7)	($93.3)	($103.8)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.55)**	**($0.07)**	**($0.07)**	**($0.05)**	**($0.07)**	**($0.26)**	**($0.16)**	**($0.15)**
YOY Growth	*-97.1%*	-	-	-	-	*-52.1%*	*115.4%*	*-43.9%*
Weighted Shares Outstanding	94.6	290.1	331.3	366.4	415.0	350.7	600.0	700.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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