Zacks Small-Cap Research

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Tenax Therapeutics, Inc. (TENX-NASDAQ)

TENX: Patient Enrollment Accelerates in Phase 3 LEVO-CTS; Enrollment Complete for Phase 2 LeoPARDS Trial

Current Recommendation	**BUY**
Prior Recommendation	N/A
Date of Last Change	09/16/2015
Current Price (2/1/16)	$2.68
Target Price	**$10.00**

UPDATE

On February 1, 2016, Tenax Therapeutics, Inc. (NASDAQ:TENX) provided an update for its ongoing Phase 3 LEVO-CTS trial of levosimendan for low cardiac output syndrome (LCOS) in cardiac surgery. Trial enrollment has picked up considerably, and the Data Safety Monitoring Board (DSMB) has recommended that the company continue with the trial as planned without any modifications. Trial data are expected by the end of 2016, and if all goes well, we could see potential FDA approval occurring in 2017. Additionally, the LeoPARDS trial for levosimendan in septic shock is fully enrolled, and we expect to see data during the first half of calendar year 2016.

We continue to believe that levosimendan, is a relatively de-risked clinical development opportunity for the indication of low cardiac output syndrome (LCOS). We still view Tenax shares as undervalued, and as providing significant long-term upside potential. We are maintaining our "Buy" rating and a price target of $10.00 per share.

SUMMARY DATA

52-Week High	**$3.81**
52-Week Low	**$2.61**
One-Year Return (%)	**-22.65**
Beta	**0.64**
Average Daily Volume (sh)	**26,160**
Shares Outstanding (mil)	**28**
Market Capitalization ($mil)	**$74**
Short Interest Ratio (days)	**23.16**
Institutional Ownership (%)	**42**
Insider Ownership (%)	**16**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2014	$0.19 A	$0.06 A	$0.04 A	-$0.01 A	$0.29 A
2015	$0.00 A	$0.00 A	$0.00 A	$0.05 A	$0.05 A
2016	$0.00 A	$0.00 A	$0.00 E	$0.00 E	$0.00 E
2017					$25.3 E

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

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2014	-$2.06 A	-$1.23 A	-$0.43 A	-$0.52 A	-$2.71 A
2015	-$0.08 A	-$0.14 A	-$0.14 A	-$0.14 A	-$0.50 A
2016	-$0.11 A	-$0.13 A	-$0.15 E	-$0.15 E	-$0.55 E
2017					$0.09 E

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WHAT'S NEW

Business Update

Levosimendan in Cardiac Surgery: Ongoing Phase 3 LEVO-CTS in LCOS Trial

On February 1, 2016, Tenax Therapeutics, Inc. (NASDAQ:TENX) provided an update for its ongoing Phase 3 LEVO-CTS trial for its lead product candidate, levosimendan for low cardiac output syndrome (LCOS) in cardiac surgery. Levosimendan has been granted Fast Track status by the U.S. Food and Drug Administration (FDA), which approved Tenax's Phase 3 LEVO-CTS clinical trial protocol under a Special Protocol Assessment (SPA) in 2012.

As per the update, the independent Data and Safety Monitoring Board (DSMB) for LEVO-CTS has completed its review of the first 254 patients enrolled in the trial and has recommended that the company continue with the trial as planned without any modifications. The DSMB's review is based on any potential safety issues that may have surfaced thus far in the trial. We see this as great news for Tenax as things continue to progress in the right direction. We believe that the DSMB will review data and conduct the first interim analysis when 400 patients have been enrolled, followed by a second interim analysis when 600 patients have been enrolled. The interim analyses will be testing for efficacy and futility after approximately 50% and 70% of the planned primary endpoint events have been recorded in calendar year 2016. We believe that the 50% and 70% marks should fall somewhere in the second and third quarters of calendar year 2016, respectively. We do not expect to see any data at these points, but should see an acknowledgement from the company that it has reached these marks.

As a reminder, Tenax achieved the first milestone in its ongoing Phase 3 LEVO-CTS trial following the enrollment of its 200th patient on October 1, 2015. Currently, 388 patients have been enrolled out of an estimated 760 total patients, or approximately 51%. There has been a marked increase in enrollment rate from the previously reported 301 patients enrolled as of December 15, 2015. As a reference point, 63 patients were enrolled in the trial during the month of January 2016, which surpasses the previous monthly high of 44 patients.

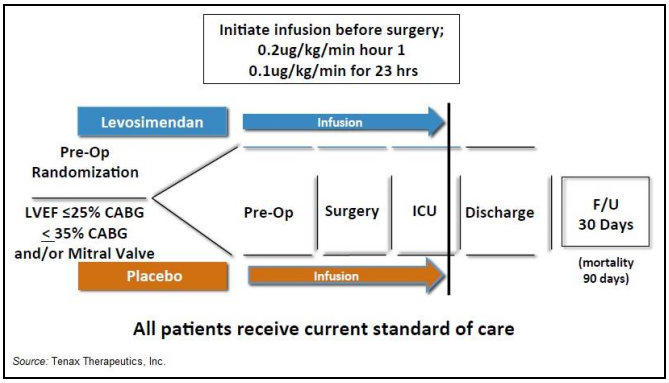
We believe that the rise in enrollment is largely due to the FDA approving the Phase 3 LEVO-CTS protocol amendment back in October 2015. Under the previous protocol, patients undergoing only a coronary artery bypass grafting (CABG) procedure were limited to those with a left ventricular ejection fraction (LVEF) of ≤ 25%. This amendment changes the inclusion criteria for the trial to cardiac surgery patients with a LVEF of ≤ 35% undergoing CABG, CABG and an aortic valve procedure, and CABG and/or a mitral valve procedure. Entry criteria were also clarified so that unjustified patient exclusions are avoided. We believe this amendment increases the potential patient population that is eligible for enrollment in the trial. We also think that the approval of the protocol amendment by the FDA has simplified and expedited the overall enrollment process since more patients will now be eligible for the study. All activated hospitals now have IRB approval of the amendment, and 169 patients have been enrolled under the amended protocol. We are not quite sure at this point if the FDA will view the amended patient group differently, but management is pretty sure that the FDA will be looking at the event rates and should not need to look at the amended patient group separately.

There are currently 67 cardiac surgical sites in the U.S. and Canada that are activated. We would like to point out that the number of sites Tenax is looking to activate is around 70, and that 5 sites have been closed due to slow enrollment. We believe that closing some sites that have not been enrolling patients will allow for more focus on other sites that could potentially be more productive. We believe that a few more sites may be closed, while adding a handful of sites before shifting all focus to patient enrollment. As a reminder, patient enrollment began back in September 2014. We believe that the goal is to enroll approximately 760 patients undergoing coronary artery bypass graft or mitral valve surgery who are at a risk of developing LCOS. We believe that management continues to remain focused on increasing enrollment efforts, and continues to take numerous steps in order accelerate the process. For instance, these efforts include identifying additional sites for the trial (for example, by expanding to Canada), and increasing communication with current clinical sites by hiring two field based associates who will be in direct contact with the sites. Submission of the protocol amendment to the FDA to adjust inclusion criteria was one of these steps, and in our opinion, has helped expedite trial enrollment thus far as we discussed above.

Review of Phase 3 LEVO-CTS…

In 2014, Tenax initiated "*Levosimendan in Patients With Left Ventricular Systolic Dysfunction Undergoing Cardiac Surgery On Cardiopulmonary Bypass*" (LEVO-CTS) Phase 3 trial to evaluate the efficacy of levosimendan in the

reduction of the incidence of morbidity and mortality in cardiac surgery patients at risk of LCOS when levosimendan is administered before and during cardiopulmonary bypass. The LEVO-CTS trial is a double-blind, randomized, placebo-controlled study that looks at the 30-day composite event rate of all-cause death, perioperative myocardial infarction, the need for dialysis, or the use of mechanical assist (intra-aortic balloon pump [IABP], left ventricular assist device [LVAD], extracorporeal membrane oxygenation [ECMO]) in patients with left ventricular systolic dysfunction (reduced ejection fraction) preoperatively undergoing cardiac surgery via cardiopulmonary bypass. Duke Clinical Research Institute (DCRI) is conducting the trial, and helped design the Phase 3 protocol.



The trial has two arms, and in the experimental arm, patients will be administered 0.2 µg/kg/min of levosimendan for the first hour, followed by 0.1 µg/kg/min of levosimendan for an additional 23 hours (with infusion being initiated prior to surgery). In the placebo comparator arm, patients will be given 0.2 µg/kg/min of placebo for the first hour, followed by 0.1 µg/kg/min of placebo for an additional 23 hours (*above*). We would like to mention that endpoints of the trial were selected based on available clinical scientific evidence. Cardiac surgery patient criteria now includes: (1) Isolated CABG LVEF ≤ 35% ; (2) ≤ 35% CABG and/or mitral valve surgery; and (3) EF ≤ 35% CABG and aortic valve surgery (which is a recent amendment, and is expected to increases patient pool by 25%). The inclusion parameters above are intended to enhance the event rate and treatment effect. As per Tenax, a 32% event rate appears conservative, and a 35% treatment effect is conservative relative to 60-80% relative risk reduction in low EF clinical trials (DCRI Meta-analysis; Levin *et al.*, 2012; Baysal *et al.*, 2014).

Co-primary endpoints in the trial include: (1) "Dual": death or mechanical assist (IABP, LVAD) through day 5, $p<0.04$ sufficient, and (2) "Quad": death (through day 30), perioperative non-fatal MI (day 5), renal dialysis (day 30), or mechanical assist (day 5), $p<0.01$ sufficient, while secondary endpoints, which also intend to show the pharmacoeconomic benefit of the drug, include duration of ICU/CCU stay following surgery, and the incidence of LCOS. The safety endpoint is all-cause mortality through day 90, and since this an event-driven trial, there was a event rate check at 200 patients with interim analysis expected at 50% and 70% total events to ensure anticipated event rate. The trial may be stopped for profound efficacy in "dual" endpoint.

It appears that low left ventricular ejection fraction (LVEF) cardiac surgery patients represent a high-risk population that experiences a higher incidence of LCOS and more severe outcomes. Based on levosimendan's established clinical profile that has demonstrated potential benefits in LCOS, we see the potential in the drug to reduce mortality and morbidity in cardiac surgery patients at risk for LCOS, as well as lowering hospital related / pharmacoeconomic costs. In our opinion, the data that is available appears to be promising; however we do believe larger multi-site randomized controlled trials, like LEVO-CTS, with the proper dosage protocols in place will offer much needed data to confirm the benefit of levosimendan in cardiac surgery patients. We view levosimendan as potentially being able to address an unmet need with the dual value proposition mentioned above.

As per management, the FDA has provided guidance that a single successful trial will be sufficient to support approval of the drug for this particular indication. The LEVO-CTS data readout is expected near the end of calendar year 2016, and we are looking forward to reviewing the results once available. From start to finish, we believe that the trial will cost approximately $18 to $20 million. If all goes well, the company plans to request FDA Priority Review (6 months), and we think approval could occur at some point during the first half of calendar 2017. We are very much interested in watching the Tenax story unfold.

Levosimendan in Septic Shock: Phase 2b LeoPARDS trial

In addition to evaluating levosimendan in the Phase 3 LEVO-CTS trial for low cardiac output syndrome (LCOS) in cardiac surgery, Tenax is collaborating with the Imperial College London in the ongoing Phase 2 LeoPARDS trial of levosimendan in septic shock.

We view septic shock as an area of unmet clinical need, as the condition is often associated with high mortality, morbidity and critical care costs. In our opinion, LCOS and septic shock are potential large market opportunities because of the present day high mortality rates and insufficient standard of care practices in these patients. We think there is a demand for superior therapeutics in order to improve patient outcomes in both LCOS and septic shock, in addition to reducing the high costs associated with complications surrounding cardiac surgical patients.

The Phase 2 trial was initiated in the first quarter 2014, and on December 22, 2015, Tenax announced that the Imperial College London completed enrollment for the LeoPARDS trial. All 516 patients have now been enrolled. We view this as great news for the company as enrollment was completed slightly ahead of schedule. We believe that topline data will be presented by the Imperial College of London during the first half of calendar year 2016. At this point, we are not exactly sure when Tenax will receive the data from the trial, but we do expect that the Imperial College London will be presenting the data at medical conferences in the first half of 2016. We look forward to reviewing the data once available.

Background on LeoPARDS..

In August 2014, Tenax announced a collaboration with the Imperial College London to provide an additional $0.5 million funding for the ongoing Phase 2 LeoPARDS trial ("Levosimendan for the Prevention of Acute oRgan Dysfunction in Sepsis") in the UK evaluating levosimendan in sepsis. The trial is being funded by the UK Medical Research Council (MRC) and National Institute for Health Research (NIHR), and is led by the Imperial College London with Tenax having assisted in the acceleration of the enrollment process. The trial is designed to evaluate if levosimendan reduces the incidence and severity of acute organ dysfunction in adult patients with septic shock, the effect of the drug on organ function, in addition to evaluation of the drug's safety profile in sepsis.

LeoPARDS is a randomized, double-blind, placebo-controlled multi-center trial based on previous smaller studies that have evaluated levosimendan as it pertains to sepsis. Adult patients with suspected or confirmed infection and 2 or more SIRS (systemic inflammatory response syndrome) criteria [fever or hypothermia: temp >38°C/100.4°F or <36°C/96.8°F; tachycardia: heart rate >90bpm; tachypnea or need for mechanical ventilation: respiratory rate >20 or PaCO2 <32mmHg; leukocyte count (>12,000cells/mm3, <4000cells/mm3, or >10% immature band forms)] who are dependent on vasopressors to maintain their blood pressure are eligible for LeoPARDS enrollment. Once eligibility criteria are met there is a 24 hour window for recruitment to the trial, and enrolled patients are randomized to receive either levosimendan (0.05 to 0.20µg/kg/min) or placebo for 24 hours in addition to the standard of care.

The primary outcome measure will be the mean SOFA (sequential organ failure assessment) score on ICU after randomization between treatment groups. Secondary outcomes that are also being evaluated include oxygen delivery (ScvO2) & cardiac output; incidence & duration of renal failure (AKIN criteria); serum bilirubin; time to extubation; 28-day, hospital and three & six-month survival; ICU and hospital length of stay, and ICU-free days; duration of renal replacement therapy; and days free from catecholamine therapy.

As mentioned above, LeoPARDS data are expected in early calendar year 2016. The data collected from the LeoPards trial will help guide Tenax regarding the future plans for U.S. development. We believe that positive LeoPARDs data could support an NDA filing. If all goes well and the data are positive, Tenax plans to request a pre-NDA meeting with the FDA regarding that path forward. We believe that Tenax could file an NDA in late 2017, and management believes that it may not be required to conduct a Phase 3 trial in the U.S. if the data are positive. At this point, we are taking a wait and see approach in regards to levosimendan in septic shock.

As an aside, in November 2014, Tenax had a meeting with the FDA regarding the development of levosimendan in septic shock, and received guidance on how LeoPARDS data might be analyzed to support regulatory filing. As per management, the Imperial College London recently submitted the statistical analysis plan (SAP), with an addendum from Tenax, to the FDA. The SAP included additional secondary endpoints around clinically-meaningful measurements. We believed that this submission was going to occur by the end of the third quarter 2015, and so it is nice to see its submission earlier than expected. We look forward to receiving more updates on the clinical and regulatory path forward in the near future.

The Path Forward for Tenax

We look forward to the upcoming expected milestones and events for Tenax in 2016, which are summarized below:

- Two interim analyses during LEVO-CTS trial testing for efficacy or futility after 50% and 70% of the planned primary endpoint events have been recorded in calendar year 2016
- Data reported from LeoPARDS trial in first half of calendar year 2016
- Updated regulatory strategy for levosimendan in septic shock following LeoPARDS data in first half of calendar year 2016
- Data reported from Phase 3 LEVO-CTS trial in calendar year 2016

Conclusion

We continue to believe that Tenax remains laser focused on its levosimendan program. The Phase 2 LeoPARDS in septic shock completed enrollment in December 2015, and we are happy to see continued progress in enrollment trends for Phase 3 LEVO-CTS with the DSMB recommending moving ahead with the study. We view the recent pullback in the biotechnology sector as a nice opportunity for investors to initiate or add to a position in Tenax.

The company is poised to have two-late stage readouts in calendar year 2016. In our opinion, the Tenax development portfolio includes a product candidate that has the potential to address various critical care conditions with high unmet medical need. There are currently no pharmacologic agents that are approved for the management, prevention and/or treatment of post-cardiac surgery LCOS. Tenax hopes to offer a solution with levosimendan, and believes that if administered pre- and peri-operatively, the incidence of LCOS and the associated morbidity and mortality could be decreased. Tenax is currently developing the drug in the U.S. and Canada for the reduction of morbidity and mortality in cardiac surgery patients at risk for developing low cardiac output syndrome (LCOS).

We view levosimendan as a relatively de-risked clinical development opportunity for the indication of LCOS due to the usage of the drug [Simdax® (levosimendan i.v.)] in over 1 million patients outside of North America. There is extensive scientific evidence that supports the use of levosimendan in cardiovascular surgery, with over 35 published clinical trials, meta-analyses, and articles. We also believe that the interest surrounding the drug continues to increase. We also view septic shock as an area of unmet clinical need, as the condition is often associated with high mortality, morbidity and critical care costs. In our opinion, LCOS and septic shock are potential large market opportunities because of the present day high mortality rates and insufficient standard of care practices in these patients. We think there is a demand for superior therapeutics in order to improve patient outcomes in both LCOS and septic shock, in addition to reducing the high costs associated with complications surrounding cardiac surgical patients.

We believe that the Tenax management team has the critical care, clinical, and commercial experience necessary to obtain North American approval of levosimendan. We are hoping that by continuing to focus efforts on accelerating patient enrollment for LEVO-CTS that the company stays on track with the currently projected second half of 2016 trial completion date, with data readout expected in the latter part of 2016. We view the FDA's approval of the protocol amendment to be good news for the company, and this appears to be helping to expedite the enrollment process.

As of October 31, 2015, Tenax had $40.8 million in cash, including the fair value of its short and long term marketable securities, compared to $43.9 million at July 31, 2015. We believe that Tenax has enough cash to fund activities through calendar year 2017, which should be sufficient to fund completion of Phase 3 LEVO-CTS trial and a potential New Drug Application (NDA) for levosimendan for the low cardiac output (LCOS) indication. We do believe that the company will need additional capital to support Tenax's future commercialization activities including the anticipated commercial launch of levosimendan for LCOS.

We continue to assume approval of levosimendan in the U.S. during calendar year 2017, with product launch later in the year. We believe there is a high probability of approval given the success of the drug outside of the U.S, but will be dependent on positive Phase 3 data. In our opinion, Tenax shares remain significantly undervalued given the potential market opportunity for levosimendan. We think the stock continues to have meaningful upside left

given the big pullback. We are maintaining our “Buy” rating and a price target of $10.00 per share. If levosimendan proves to be successful in the cardiac surgical market, and if the company makes further progress with additional indications, including septic shock, we believe that there is the possibility for significant upside to this valuation. Additionally, we also believe that the company continues to evaluate other products and critical care opportunities to add to the pipeline, which could also provide investors with additional upside in the future.

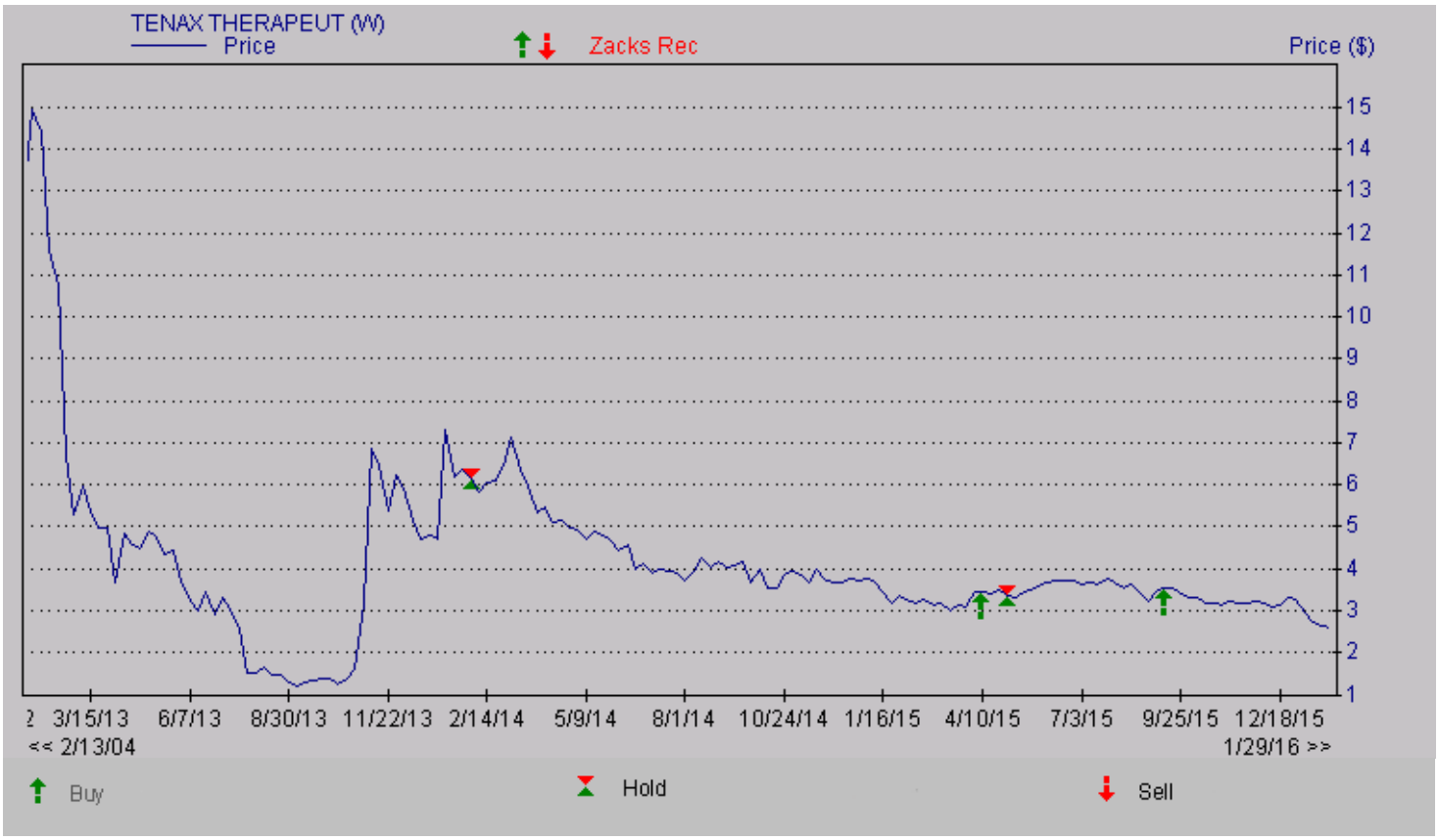
PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	FY-15 A	Jul. 2015 Q1 A	Oct. 2015 Q2 A	Jan. 2016 Q3 E	Apr. 2016 Q4 E	Apr. 2016 FY-16 E	2017 E	2018 E
Product Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$25.3	$54.6
YOY Growth	*-100%*							*116%*
Government Grant Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	*-81%*				*0%*	*-100%*		
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$25.3**	**$54.6**
YOY Growth	*-83%*							*116%*
Cost of goods sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$5.1	$10.9
Product Gross Margin							*80%*	*80%*
Research and development	$6.7	$1.7	$2.5	$2.5	$2.5	$9.3	$9.7	$10.2
General & administration	$7.2	$1.4	$1.2	$1.8	$1.9	$6.2	$8.0	$8.4
Restructuring & Other Opex	$1.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Finance costs	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Margin							*10%*	*46%*
Interest Income (expense)	($0.0)	($0.0)	($0.0)	$0.0	$0.0	($0.0)	$0.0	$0.0
Other expense	($0.8)	($0.1)	($0.2)	$0.0	$0.0	($0.3)	$0.0	$0.0
Pre-Tax Income	($14.1)	($3.0)	($3.5)	($4.3)	($4.4)	($15.5)	$2.5	$25.1
Income Taxes Paid	$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	**($14.1)**	**($3.0)**	**($3.5)**	**($4.3)**	**($4.4)**	**($15.5)**	**$2.5**	**$25.1**
Net Margin							*10%*	*46%*
Reported EPS	**($0.50)**	**($0.11)**	**($0.13)**	**($0.15)**	**($0.15)**	**($0.55)**	**$0.09**	**$0.81**
YOY Growth	*-81%*	*33%*	*-13%*	*12%*	*8%*	*9%*	*-116%*	*849%*
Basic Shares Outstanding	28.08	28.12	28.12	28.12	28.75	28.28	29.00	31.00

Source: Company Filing // Zacks Investment Research, Inc. Estimates

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- 25.8%, Hold/Neutral- 51.7%, Sell/Underperform – 17.3%. Data is as of midnight on the business day immediately prior to this publication.