Zacks Small-Cap Research

May 23, 2016
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Tenax Therapeutics, Inc. (TENX-NASDAQ)

Announces study extension, but maintains original timeline for completion, readout and filing of IND for Phase 3 LEVO-CTS trial.

Based on our DCF model and a 15% discount rate, TENX is valued at approximately $10.00 per share. We apply a 75% probability of eventual sales of Levosimendan.

Current Price (5/20/16)	$2.69
Valuation	**$10.00**

OUTLOOK

Tenax has licensed the *calcium sensitizer/K-ATP activator* levosimendan in the US and Canada to develop and commercialize for the treatment of LCOS. The drug has been approved in over 60 countries with 35 published trials supporting its safety and efficacy and has over 1 million patient exposures.

Addressing LCOS during and following cardiac surgery is an unmet need in the US and Canada and the FDA has granted Fast Track Authority in conjunction a single Phase 3 trial which is currently underway. The trial has enrolled over 75% of the target patient volume and should be completed by Fall 2016. We forecast launch of levosimendan in late 2017.

Tenax is also involved with a Phase 2 trial using levosimendan in the treatment of septic shock. In this study sponsored by the Imperial College of London, we anticipate results to be published this fall.

Levosimendan has a 15-year history of use in Europe with a substantial volume of literature supporting its safety and efficacy. Given the body of research, we believe that the compound has a relatively low risk profile and is likely to be approved as per the expected timeline to address this unmet need. Our DCF model supports a $10 price target

SUMMARY DATA

52-Week High	**$3.98**
52-Week Low	**$1.94**
One-Year Return (%)	**-22.5**
Beta	**1.58**
Average Daily Volume (sh)	**26,455**
Shares Outstanding (mil)	**28.1**
Market Capitalization ($mil)	**$75.6**
Short Interest Ratio (days)	**33.5**
Institutional Ownership (%)	**40**
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 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
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)
2015	$0.00 A	$0.00 A	$0.00 A	$0.00 A	$0.00 A
2016	$0.00 A	$0.00 E	$0.00 E	$0.00 E	$0.00 E
2017					$9.18 E
2018					$61.9 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	N/A	N/A	N/A	N/A	N/A
2016	-$0.19 A	-$0.16 E	-$0.13 E	-$0.12 E	-$0.60 E
2017					-$0.40 E
2018					$0.86 E

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WHAT'S NEW

Tenax Reports First Quarter 2016 Results

On May 19, 2015, Tenax Therapeutics, Inc. (NASDAQ:TENX) reported financial results for the three month period ending March 31, 2016. The company reported no revenues and a net loss of ($5.2) million or ($0.19) per share. This compares to our estimates also of zero revenues and a net loss of ($3.7) million or ($0.13) per share. Total operational expenses for the quarter were $5.7 million, increasing from the $3.2 million spent in the first quarter of the prior year. Both research & development and general & administrative expenses were higher, with costs related to the clinical trial driving the majority of the increase. Higher consulting fees were also a material contributor to the rise.

Research and development expenses increased from $1.6 million to $3.9 million in 1Q:16. Clinical and preclinical development costs rose by $2.1 million arising from increased contract research organization (CRO) costs related to the Levosimendan trial. Additionally, an increase in consulting fees related to training, communication and implementing best practices at clinical trial sites also contributed to the period over period change.

General and administrative expenses were $1.8 million for 1Q:16, compared to $1.6 million in 1Q:15. A rise in personnel costs related to stock option expenses and legal and professional fees were partially offset by declines in franchise taxes and depreciation and amortization.

Cash, cash equivalents and marketable securities were $34.8 million on March 31, 2016 and the balance sheet continues with no debt. Cash burn was $3.3 million in the quarter up from $2.5 million in the prior year.

TENX updated its expense guidance for calendar year 2016, increasing the amount due to higher clinical study costs. Overall research and development spend will be between $10.5 and $11.0 million, declining as the year progresses and as the trial winds down. As the company progresses into the late part of 2017 and early 2018, these amounts are anticipated to shift away from trial costs and reflect managing and monitoring fees, site close out costs, database clean up and data analysis. Total cash burn is forecasted to settle between $16.5 and $17.5 million for 2016 as the company moves toward filing the NDA with the FDA and ramping up a sales force.

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

On February 1, 2016, Tenax 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.

In mid-May 2016 Tenax reported that the independent Data and Safety Monitoring Board (DSMB) for LEVO-CTS completed its first interim analysis for the trial. The group evaluated the safety and efficacy of the first 451 patients and 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. Based on the estimated completion of enrollment for the trial and the likelihood that the second interim analysis would not be ready until after enrollment has completed, the second interim analysis will not be performed.

As of May 2016, the company noted that some data was missing for patients and some patients did not receive the drug and as a result, in an effort to ensure the statistical robustness of the results, Tenax plans to enroll past the initial 760 patient target. This will result in the study being extended a month longer than it would have been otherwise; however, we note that the study was progressing ahead of target and the company maintains its guidance of providing a top line data readout before the end of the year. At the current rate of patient enrollment, the additional month equates to approximately 60[1] additional patients with the eventual number determined by the volume of patients with missing data.

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. As of May 19, 2016, 620 patients have been enrolled. At the current rate, the trial is anticipated to enroll the last patient in late August or early September.

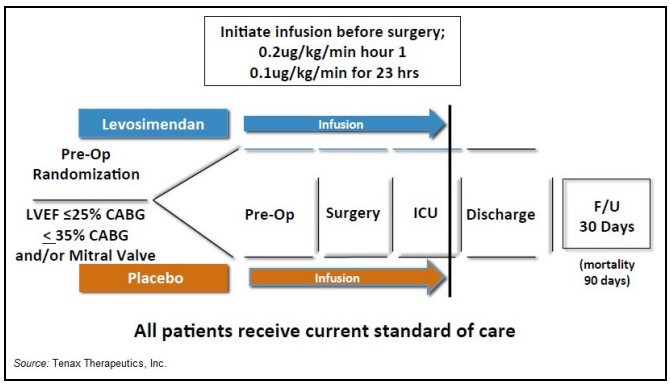
[1] As of April 7 there were 533 enrolled and on May 18, 620 enrolled. 87 patients over 41 days yields the current estimated rate of ~2.1 patients enrolled per day.

In the beginning of the year, Tenax made an investment in consulting services to optimize the efficiency at the trial sites. This effort added a field based associate that assumed the duties of a medical science liaison to ensure the research sites are using best practices. The interaction of the associate had the additional beneficial effect of increasing recruitment at the site due to the increased visibility of the program.

As of May 2016, there are 64 cardiac surgical sites in the U.S. and Canada that are activated, even with the prior month. Management noted that about 17% of total patients to date were enrolled in the top three sites. Several low or no volume sites were closed in January and February which has allowed additional focus on existing locations. Patient enrollment began back in September 2014 and is currently expected to have a duration of approximately 24 months despite the announced one month extension. The trial is targeting enrollment of approximately 820 patients based on our interpretation of management commentary who will undergo coronary artery bypass graft or mitral valve surgery and are at a risk of developing LCOS. Management continues to remain focused on increasing enrollment efforts, and continues to take steps in order to accelerate the process such as 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.

Review of Phase 3 LEVO-CTS…

In 2014, Tenax initiated the "*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.



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 at 450 patients to check for futility or profound efficacy and to ensure safety.

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.

The importance of the pharmacoeconomic analysis of the trial is of critical importance as it will support the pricing efforts of the compound. In recent presentations, Tenax has highlighted the results of a study they conducted with Premier Health, which is a large GPO serving 3,600 hospitals and other providers. The study used Premier's database to determine the additional costs of a LCOS patient in terms of additional time spent in the hospital, in the ICU and additional complications compared to other patients. Based on the analysis, the LCOS patient had an additional $15,000 of costs. The LCOS patient set also experienced $19,000 in additional readmission costs within 30 days of surgery. Based on the company's internal analysis, the use of levosimendan could reduce costs from $2,000 to $5,000 per patient.

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 $20 to $21 million, up slightly from previous levels due to the extension of the study and site shut-down costs. If all goes well, the company plans to request FDA Priority Review (6 to 8 months), and we think approval could occur at some point after mid-year 2017.

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 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 for 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 of 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. As of April 2016, management updated their expectations for timing regarding the release of results and data from the study. The Imperial College of London has medical meetings that they are targeting for initial public presentation and they would like to publish in conjunction with this event. Based on the company's conversation, we now expect the initial data to be available in the September or October 2016 timeframe.

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 for 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 whether or not levosimendan reduces the incidence and severity of acute organ dysfunction in adult patients with septic shock, the effect of the drug on organ function, and evaluate 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.

Due to scheduling objectives, LeoPARDS data are now expected sometime in the fall of 2016. The data collected from the LeoPARDS trial will help guide Tenax regarding the future plans for U.S. development. We believe that positive data from this trial 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. We have included a modest level of sales in our forecasts for septic shock.

In November 2014, Tenax held 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.

The Path Forward for Tenax

Below we have provided the upcoming milestones and events for Tenax in 2016.

- Completion of enrollment for the LEVO-CTS trial, end of summer 2016.
- Report of topline data for LEVO-CTS trial in 4Q:16
- LeoPARDS data release in 2H:16
- Follow-up data analysis of LeoPARDS data by Tenax

Conclusion

Tenax is poised to have two-late stage readouts in 2H:16. 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 Levosimendan (Simdax) in over 1 million patients outside of North America. There is extensive scientific evidence that supports the use of the drug 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 for 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 surgery patients.

We believe that the Tenax management team has the critical care, clinical, and commercial experience necessary to obtain North American approval of levosimendan. With a focus on accelerating patient enrollment for LEVO-CTS, we believe that the company will achieve the projected second half of 2016 trial completion date, with data readout expected in the latter part of 2016.

As of March 31, 2015, Tenax held $34.8 million in cash, including the fair value of its short and long term marketable securities, compared to $38.2 million on December 31, 2015. We believe that Tenax has sufficient cash to fund activities through calendar year 2017, which will allow for the completion of the 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 anticipate approval of levosimendan in the U.S. during calendar year 2017, with product launch late in the year. We believe there is a high probability of approval given the success of the drug outside of the U.S, but ultimately, FDA approval will hinge 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 at current levels and generate a price target of $10.00 per share based on our DCF model. 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, the company continues to evaluate other products and critical care opportunities to add to the pipeline, which could also provide investors with additional value.

PROJECTED FINANCIALS

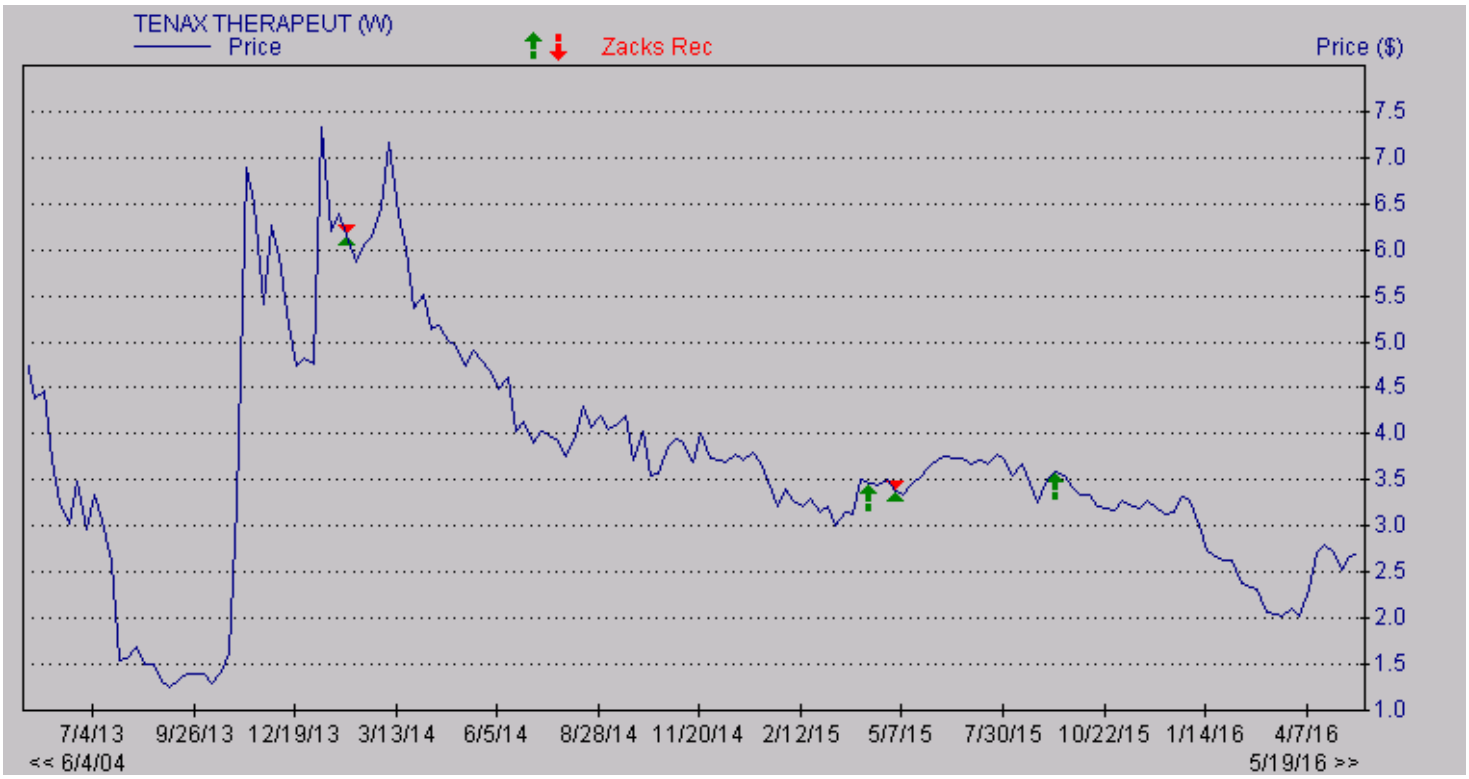
Tenax Therapeutics, Inc. - Income Statement[2]

Tenax Therapeutics, Inc.	Q1 A	Q2 E	Q3 E	Q4 E	Jan 1- Dec 31 CY - 16 E	2017 E	2018 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$9.2**	**$61.9**
YOY Growth							*574%*
Cost of goods sold	$0.0	$0.0	$0.0	$0.0	$0.0	$1.8	$12.4
Product Gross Margin						*80%*	*80%*
Research and development	$3.9	$3.0	$2.1	$1.9	$10.9	$5.0	$1.0
General & administration	$1.8	$1.6	$1.6	$1.6	$6.6	$14.0	$22.0
Restructuring & Other Opex	$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
Income from operations	($5.7)	($4.6)	($3.7)	($3.5)	($17.5)	($11.7)	$26.5
Operating Margin						*-127%*	*43%*
Interest Income (expense)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	($0.3)	$0.0	$0.0	$0.0	($0.3)	$0.0	$0.0
Pre-Tax Income	($5.4)	($4.6)	($3.7)	($3.5)	($17.2)	($11.7)	$26.5
Income Taxes Paid	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($5.4)**	**($4.6)**	**($3.7)**	**($3.5)**	**($17.2)**	**($11.7)**	**$26.5**
Net Margin						*-127%*	*43%*
Reported EPS	**($0.19)**	**($0.16)**	**($0.13)**	**($0.12)**	**($0.60)**	**($0.40)**	**$0.86**
YOY Growth					*68%*	*12%*	*-313%*
Basic Shares Outstanding	28.12	28.60	28.80	28.90	28.60	29.00	31.00

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

[2] In 2016, Tenax changed its reporting calendar from an April 30 fiscal year end to a December 31 fiscal year end. As such, the company does not have comparable financial results for 2015.

HISTORICAL STOCK PRICE



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