Zacks Small-Cap Research

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Tenax Therapeutics, Inc. (TENX-NASDAQ)

2016 Results; Subgroup Analysis Shows CABG Survival Benefit

Based on our DCF model and a 15% discount rate, TENX is valued at approximately $4.00 per share. We apply a 50% probability of eventual sales of levosimendan in the United States.

Current Price (3/21/17)	$0.57
Valuation	**$4.00**

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.

On January 31, 2017 Tenax announced the Phase 3 LEVO-CTS trial failed to achieve primary endpoints, but did show statistical significance in two of the trial's secondary endpoints. Due to the primary endpoint miss, we forecast a year delay and eventual launch of levosimendan in early 2019. TENX will meet with the FDA in the near term and believes that based on current data, an NDA for levosimendan will be accepted for use in ADHF and/or CABG.

Levosimendan has a 16-year history of use in Europe with a substantial volume of literature supporting its safety and efficacy. Given the body of research reinforcing indications in LCOS, and meta-analysis supporting reductions in mortality and hospitalizations, we believe there is a possibility of FDA approval to address these unmet needs.

SUMMARY DATA

52-Week High	**$0.41**
52-Week Low	**$2.94**
One-Year Return (%)	**-71.7**
Beta	**1.52**
Average Daily Volume (sh)	**1,630,000**
Shares Outstanding (mil)	**28.1**
Market Capitalization ($mil)	**$16.0**
Short Interest Ratio (days)	**0.67**
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 A	$0.00 A	$0.00 E	$0.00 E
2017					$0.00 E
2018					$0.00 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.10 A	-$0.17 A	-$0.10 A	N/A	N/A
2016	-$0.19 A	-$0.17 A	-$0.15 A	-$1.05 A	-$1.56 A
2017					-$0.28 E
2018					-$0.33 E

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WHAT'S NEW

Tenax Reports Full Year 2016 Operating and Financial Results

On March 16, 2017, Tenax Therapeutics, Inc. (NASDAQ:TENX) filed its 2016 form 10-K and provided its operating and financial results for the year ending December 31, 2016. The release was followed by an earnings call on March 21. Net loss of ($1.56) per share or ($43.9) million for the full year was less than our estimate of ($0.65) due to a $33.3 million write down of levosimendan, which failed to meet primary endpoints in its Phase III clinical trial. Zero revenues were expected as Tenax is a development stage biotechnology company.

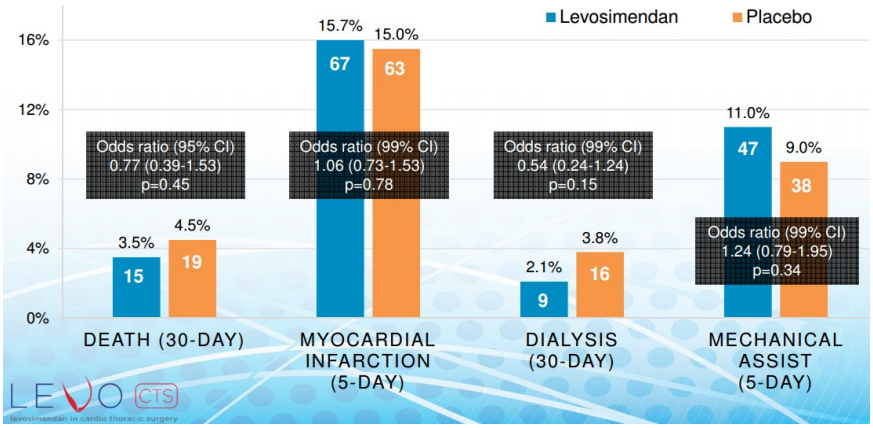
Research and development expenses of $13.1 million were slightly higher than our estimates of $13.0 million. A 50% increase in clinical and preclinical development spend to $11.7 million drove the overall increase which was mainly related to clinical costs for the Phase III LEVO-CTS clinical trial. Increases in consulting and personnel expenses were slightly offset by lower depreciation in the R&D category resulting in an overall 48% rise in R&D expenses.

General and administrative expenses of $6.2 million in 2016 fell by 6.4% over the same period in the prior year. A slight rise in personnel costs were offset by declines in legal and professional fees, other costs, facilities, and depreciation and amortization. The largest year over year dollar decline in legal and professional fees was related to lower spend on investor relations services, legal fees and fees paid to the Board of Directors.

LEVO-CTS Abstract Presentation

On March 19, 2017, John Alexander, MD of the Duke Clinical Research Institute presented the primary results of the LEVO-CTS trial[1] and a copy of the article was also made available. In the trial, randomization placed 442 patients in the levosimendan arm and 440 in the placebo arm. For the quad outcome of death, dialysis, myocardial infarction or mechanical assist device use, both the test arm and the control arm showed 24.5% incidence rate. For the dual outcome of death or mechanical assist device use, the levosimendan arm had a higher rate of 13.1% compared to the control arm of 11.4%, indicating that the levosimendan arm was slightly worse than placebo. Below, we show the summary of the individual components of the trial, showing death and dialysis better in the levosimendan arm and MI and mechanical assist better with placebo.

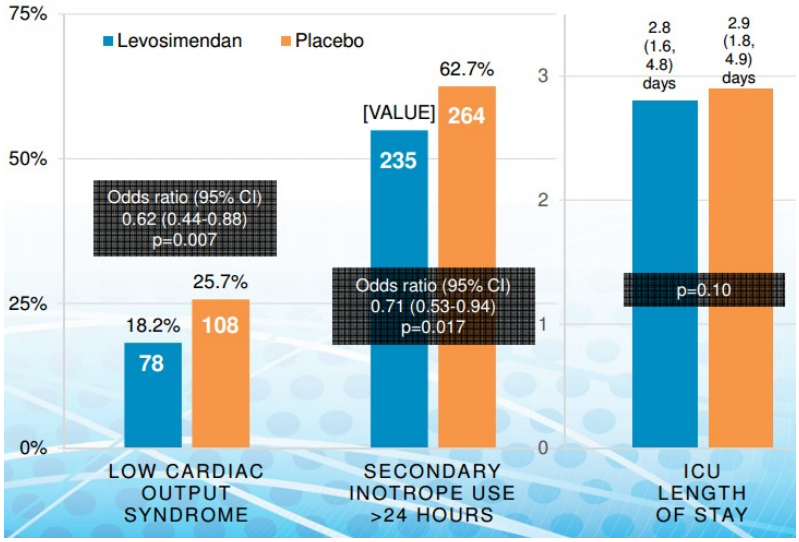
Exhibit I – Individual Outcome Components



Secondary outcomes favored levosimendan with LCOS observed in 18.2% of the levosimendan arm vs. 25.7% of the placebo arm. There was also lower secondary inotrope use, and lower ICU stay (2.8 days for levosimendan versus 2.9 days for placebo), both reflecting the opportunity for cost savings with use of the drug. The secondary outcomes are shown in the following exhibit.

[1] See link for download of slide presentation: http://www.acc.org/education-and-meetings/image-and-slide-gallery/media-detail?id=dfb21bd8ccc94d3fa462cc2b064b416d

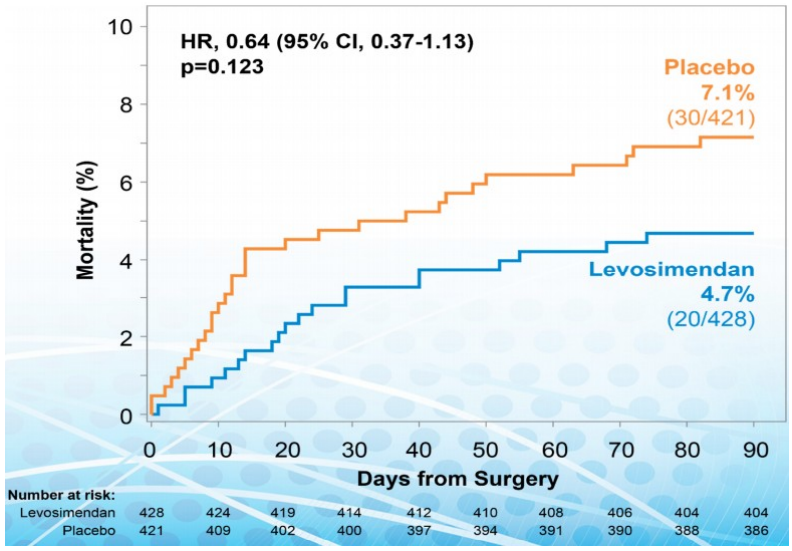
Exhibit II – Secondary Outcomes



Following the initial topline read, Tenax was able to perform subgroup analysis and collect data regarding 90-day mortality. Subgroup analysis showed that there was a significantly better survival rate for those patients who were undergoing CABG in comparison with those undergoing some type of valve procedure. Approximately two thirds of the patients in both arms were CABG candidates and the remainder were valve surgery patients, with most in conjunction with CABG.

90-day mortality was another important endpoint that was not available for Tenax's first meeting with the FDA following the topline read in January. Levosimendan showed a 2.6% absolute and a 35% relative reduction in this metric, with much of the benefit observed in the first third of the 90-day period. While the results were not statistically significant, with a p-value of 0.12, they did show movement in the right direction.

Exhibit III – 90-Day Mortality



Tenax management feels confident that the data that they have from the LEVO-CTS trial in combination with the data available from the numerous other trials that have taken place will be sufficient to obtain acceptance of an NDA by the FDA. The company plans to pursue approval for indications in acute decompensated heart failure (ADHF) and/or coronary artery bypass surgery (CABG). Based on a substantial set of data, levosimendan appears to be fairly safe and may have a mortality benefit, which is superior to the characteristics of other inotropes. While there is evidence of subgroup efficacy and safety in the LEVO-CTS analysis and substantial literature supporting levosimendan, we continue to apply a 50/50 chance of approval for levosimendan until there is more clarity regarding the path potential approval will take.

Trial Results

Tenax provided topline results from its Phase 3 LEVO-CTS trial in cardiac surgery in a release on January 31, 2017. Based on the results of the study, levosimendan, when given prior to cardiac surgery in patients with reduced left ventricular ejection fraction, did not provide benefit in any of the co-primary outcome areas of death, dialysis, myocardial infarction and use of mechanical assist device, or death or mechanical assist device use. However, two secondary endpoints were statistically significant.

The trial's primary endpoints measured at 30 days were:

1. All-cause death or use of mechanical assist device following the start of surgery for poor cardiac function despite inotropic support and adequate fluid replacement through Day 5 (dual endpoint) **– Not statistically significant**
2. Composite of all-cause death, or perioperative nonfatal myocardial infarction, or need for renal dialysis, or use of mechanical assist device following the start of surgery for poor cardiac function despite inotropic support and adequate fluid replacement through Day 5 (quad endpoint) **– Not statistically significant**

Secondary endpoints included:

1. Duration of intensive care or coronary care unit - **Not statistically significant**
2. Incidence of LCOS **- Statistically significant and favorable**
3. Postoperative use of secondary inotrope - **Statistically significant and favorable**

Next Steps

Tenax's main objective now is to meet with the FDA to find a path forward for filing an NDA. Now that management is armed with positive data from the 90-day mortality analysis and favorable outcomes based on type of surgery (CABG vs. valve), they are confident that in conjunction with previous studies for levosimendan, an NDA will be possible. We anticipate a filing sometime in the second half of 2017.

Tenax also anticipates starting the application filing process for levosimendan in Canada. We believe that the regulatory agency, Health Canada, is less US-centric compared to the FDA in considering studies supportive of drug efficacy, making the argument somewhat easier to the North. While the market is only about 10% of the size of the US market, Canada does represent a material market for the company.

Tenax will also seek additional strategic options to leverage the infrastructure that they have in place and will engage an investment bank to help with the process. We read this to mean that the company may seek a new compound to take through the clinical development and drug approval process in North America, however, at this point this is only speculation. An additional compound would provide the opportunity for Tenax to raise additional capital in support of this effort and we believe that there are many opportunities in this area that the company can pursue.

Conclusion

Due to the unanticipated failure in the LEVO-CTS primary endpoints, there is a great deal of uncertainty as to what next steps for Tenax will be. Our original thesis regarding levosimendan found the drug to be a relatively low risk pursuit given the long-term and broad usage history and support the drug has globally for use in cardiac surgery. Given the favorable data available from other studies and due to the potential levosimendan has to address a critical care condition with high unmet medical need, there remains a case for FDA approval despite the LEVO-CTS trial results. There are currently no pharmacologic agents that are approved for the management, prevention and/or treatment of post-cardiac surgery LCOS, and furthermore given the statistically significant results on this secondary endpoint and the positive results for the CABG subgroup, we do believe there is a possibility the FDA grants approval.

With approximately $22 million of cash on the balance sheet as of year-end 2016, we believe that Tenax has sufficient cash to fund activities through mid-year 2018, which should allow Tenax to address the additional information requests from the FDA, up to but not including an additional Phase 3 trial. Given that there is currently no R&D being conducted (following LEVO-CTS wind-down) and Tenax is in a wait and see mode, operational expenses will be at a minimum, which we reflect in our updated model. Total expenses for 2017, excluding any new R&D for additional strategic options or a new levosimendan trial, are $8 million. Further funding will also be

required if approval is granted to support milestone payments and Tenax's future commercialization activities including hiring a salesforce and launching levosimendan for LCOS.

We update our forecast for approval of levosimendan in the U.S. to occur in 4Q:18, with the year delay relative to our prior estimates necessary to gather additional information for the FDA. At this point our estimates are purely conjecture as we lack any guidance from the regulatory agency regarding their needs. We will adjust our estimates as more information becomes available regarding the upcoming meeting with the FDA, an event we foresee occurring in the next month or two.

To adjust for the unknowns regarding the approval process and upcoming milestones, we maintain our probability of success estimate of 50% and forecast ultimate sales of levosimendan in 2019. Our target price remains $4.00.

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement[2]

Tenax Therapeutics, Inc.	Q1 A	Q2 A	Q3 A	Q4 A	Jan 1- Dec 31 CY - 16 A	2017 E	2018 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth							
Cost of goods sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin						*0%*	*0%*
Research and development	$3.9	$3.4	$3.2	$2.5	$13.1	$2.5	$1.0
General & administration	$1.8	$1.2	$1.3	$2.0	$6.2	$5.5	$8.5
Restructuring & Other Opex	$0.0	$0.0	$0.0	$33.3	$33.3	$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)	($4.7)	($4.5)	($37.8)	($52.7)	($8.0)	($9.5)
Operating Margin						*# DIV/0!*	*# DIV/0!*
Interest Income (expense)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	($0.3)	($0.0)	($0.2)	($0.2)	($0.8)	$0.0	$0.0
Pre-Tax Income	($5.4)	($4.6)	($4.3)	($37.6)	($51.9)	($8.0)	($9.5)
Income Taxes Paid	$0.0	$0.0	$0.0	($8.0)	($8.0)	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($5.4)**	**($4.6)**	**($4.3)**	**($29.6)**	**($43.9)**	**($8.0)**	**($9.5)**
Net Margin						*# DIV/0!*	*# DIV/0!*
Reported EPS	**($0.19)**	**($0.17)**	**($0.15)**	**($1.05)**	**($1.56)**	**($0.28)**	**($0.33)**
YOY Growth					*336%*	*-21%*	*17%*
Basic Shares Outstanding	28.12	28.12	28.12	28.12	28.12	28.15	28.65

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 provide comparable financial results for 2015.

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HISTORICAL STOCK PRICE



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