Zacks Small-Cap Research

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Tenax Therapeutics, Inc. (TENX-NASDAQ)

LeoPARDS Trial Fails to Meet Endpoints; Septic Shock Indication Dropped. Year End 2016 Readout for LEVO-CTS Trial.

Based on our DCF model and a 15% discount rate, TENX is valued at approximately $9.00 per share. We apply a 75% probability of eventual sales of Levosimendan.

Current Price (10/5/16)	$2.11
Valuation	**$9.00**

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 with a single Phase 3 trial which is currently underway. The trial has enrolled 95% of the target patient volume and should provide topline data by year end 2016. We forecast launch of levosimendan in late 2017.

Tenax was also involved with a Phase 2 trial using levosimendan in the treatment of septic shock. This trial failed to meet primary or secondary endpoints and based on this result, TENX will not pursue a septic shock indication.

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 according to the expected timeline to address this unmet need. Our DCF model yields a $9 price target

SUMMARY DATA

52-Week High	**$3.47**
52-Week Low	**$1.94**
One-Year Return (%)	**-37.2**
Beta	**1.97**
Average Daily Volume (sh)	**33,900**
Shares Outstanding (mil)	**28.1**
Market Capitalization ($mil)	**$59.3**
Short Interest Ratio (days)	**21.9**
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 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	-$0.10 A	-$0.17 A	N/A	N/A	N/A
2016	-$0.19 A	-$0.17 A	-$0.17 E	-$0.15 E	-$0.67 E
2017					-$0.40 E
2018					$0.86 E

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WHAT'S NEW

Tenax Updates Trial Progress

On October 5, 2016, Tenax Therapeutics, Inc. (NASDAQ:TENX) submitted an update for its LEVO-CTS and LeoPARDS clinical trials. In our previous report, we estimated that Tenax would complete enrollment in the LEVO-CTS trial by the end of September 2016, however, enrollment rates slowed in August and September, pushing back the estimated date by a month. Currently Tenax is 95% complete with its target 880 patient panel size and has enrolled 833 individuals as of October 5. Based on current trends, the company anticipates full enrollment by the end of October, and following the 30 day follow up on the final patients, TENX plans to provide top-line analysis by year end.

Also since our last update, the LEVO-CTS Data and Safety Monitoring Board (DSMB) completed the final safety review from the three-quarters point of the way through the trial. The DSMB's futility analysis concluded that the trial should continue as planned.

Data for Tenax' second trial, LeoPARDS, was presented at the 29th Annual Congress of the European Society of Intensive Care Medicine (ESICM), held in Milan, Italy yesterday. In the presentation, Anthony Gordon, M.D., Chair in Anaesthesia and Critical Care, Imperial College London indicated that the trial did not achieve either its primary endpoint of reducing the incidence and severity of acute organ dysfunction in adult patients who have septic shock, or its secondary endpoints. Despite previously completed, third party meta-analysis that showed efficacy in septic shock, Tenax does not expect to pursue an NDA for levosimendan in this indication. While there is evidence of some use of the drug off-label for septic shock in Europe, we do not expect this will be a material volume of sales when and if it is approved for use in the United States. Therefore, our model will remove forecast revenues related to septic shock.

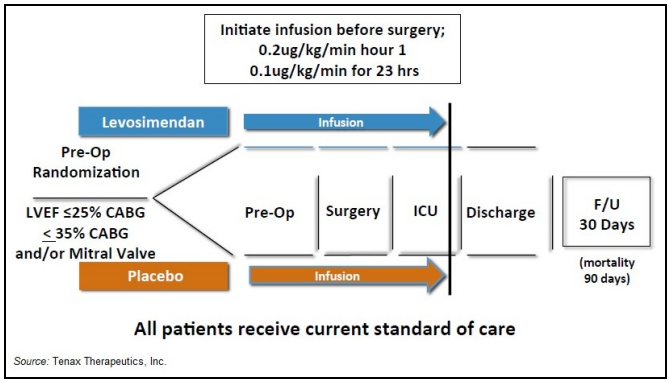
Levosimendan Background: Ongoing Phase 3 LEVO-CTS in LCOS Trial

As the trial settles into its last months, there are approximately 60 active cardiac surgical sites in the U.S. and Canada. Patient enrollment began back in September 2014 and has more or less maintained its target duration of approximately 24 months despite the late increase in targeted trial size. The trial anticipates enrollment of approximately 880 patients who will undergo coronary artery bypass graft or mitral valve surgery and are at a risk of developing LCOS. As of October 5, 2016, LEVO-CTS has enrolled 330 patients in the trial. Management continues to remain focused on enrollment efforts, and is currently in the final stages of the trial as the last 50 persons are added.

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.

Exhibit I – Phase 3 Protocol



Co-primary endpoints in the trial include: (1) The all-cause death at 30 days or use of mechanical assist device (IABP, LVAD or ECMO) following the start of surgery for poor cardiac function despite inotropic support and adequate fluid replacement) through Day 5, and (2) Composite of all-cause death (at 30 days), or perioperative nonfatal MI [CK-MB >10xULN or >100 ng/mL, CK-MB >5xULN or 50 ng/mL with new Q wave (>0.04 seconds wide in two contiguous leads) or new left bundle branch block)] (through Day 5), or need for renal dialysis (through Day 30), or use of mechanical assist device (IABP, LVAD or ECMO) following the start of surgery for poor cardiac function despite inotropic support and adequate fluid replacement) (through Day 5). 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.

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.

If all goes as expected, 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

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. On October 5, 2016, Tenax filed a release promulgating that the trial did not achieve its primary or secondary endpoints. The trial was 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. Tenax had intended to use the data from the trial to run its own analysis and prove a primary endpoint of ventilator-free survival. However, the data showed that patients on levosimendan were on the ventilator longer. Given the outcome of the LeoPARDS trial, Tenax does not anticipate pursuing an indication in septic shock. As a result, we

will remove revenues associated with septic shock and adjust our model accordingly. Our mode hadl anticipated first revenues from septic shock to begin in 2020.

The Path Forward for Tenax

Below we summarize upcoming milestones and events for Tenax in 2016.

- Completion of enrollment for the LEVO-CTS trial, end of October 2016.
- Report of topline data for LEVO-CTS near end of year 2016

Conclusion

Tenax anticipates providing a readout on its LEVO-CTS trial near year-end 2016. While the unexpected results from the LeoPARDS trial remove some of the optionality in the stock, we do not think that these results imply any negative outcome from the LEVO-CTS trial the two have different patient populations, treatment regimens and endpoints. We also point to the large body of literature that has supported approval of the compound in the EU and the treatment of numerous patients for reduction of morbidity and mortality in cardiac surgery patients at risk for developing low cardiac output syndrome (LCOS). In our opinion, the Tenax development portfolio includes a product candidate that has the potential to address a critical care condition 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 for commercialization in the U.S. and Canada.

We view levosimendan as a relatively de-risked clinical development opportunity for the indication of LCOS due to the usage of 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 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 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. Based on our estimates, 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. 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 material upside at current levels but reduce our target price to $9.00 per share based on our DCF model to reflect the removal of levosimendan sales into the septic shock market. If levosimendan proves to be successful in the LEVO-CTS trial, there is upside to our valuation.

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement[1]

Tenax Therapeutics, Inc.	Q1 A	Q2 A	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	$3.4	$3.3	$2.6	$13.3	$5.0	$1.0
General & administration	$1.8	$1.2	$1.6	$1.6	$6.2	$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)	($4.7)	($4.9)	($4.2)	($19.5)	($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	($0.4)	$0.0	$0.0
Pre-Tax Income	($5.4)	($4.6)	($4.9)	($4.2)	($19.1)	($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)**	**($4.9)**	**($4.2)**	**($19.1)**	**($11.7)**	**$26.5**
Net Margin						*-127%*	*43%*
Reported EPS	**($0.19)**	**($0.17)**	**($0.17)**	**($0.15)**	**($0.67)**	**($0.40)**	**$0.86**
YOY Growth					*87%*	*12%*	*-313%*
Basic Shares Outstanding	28.12	28.12	28.80	28.90	28.48	29.00	31.00

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

[1] 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.

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HISTORICAL STOCK PRICE



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