Zacks Small-Cap Research

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Tenax Therapeutics, Inc. (TENX-NASDAQ)

Waiting for FDA Response on NDA Submission

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 (5/16/17)	$0.46
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	**$2.78**
52-Week Low	**$0.41**
One-Year Return (%)	**-82.9**
Beta	**1.56**
Average Daily Volume (sh)	**669,236**
Shares Outstanding (mil)	**28.2**
Market Capitalization ($mil)	**$13.0**
Short Interest Ratio (days)	**3.03**
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 2017 Estimate	**N/A**
P/E using 2018 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)
2016	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2017	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2018					$0.0 E
2019					$58.3 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.19 A	-$0.17 A	-$0.15 A	-$1.05 A	-$1.56 A
2017	-$0.12 A	-$0.09 E	-$0.04 E	-$0.04 E	-$0.29 E
2018					-$0.33 E
2019					$0.78 E

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WHAT'S NEW

Tenax Reports 1Q:17 Results and Provides FDA Meeting Update

On May 10, 2017, Tenax Therapeutics, Inc. (NASDAQ:TENX) filed its first quarter form 10-Q providing its operating and financial results for the three months ending March 31, 2017. Net loss of ($0.12) per share matched our estimates as did the operational loss of ($3.5) million. No revenues were generated.

Research and development expenses of $2.1 million were also in line with our estimates and represent a 48% decline over R&D incurred in the prior year. Of the various components of R&D expenditures, Clinical and preclinical development was the largest at $1.8 million, declining by $1.7 million of the year due to decreased expenditures for CRO costs to manage the Levo-CTS Phase III clinical trial. Consulting expenses were down $146 thousand to $111 thousand on lower consulting expenses related to training and communication at clinical sites. Personnel and other costs were also down sharply from the first quarter of 2016.

General and administrative expenses of $1.4 million fell 18% over the prior year's level as legal and professional, facility and other costs declined and were partially offset by a $75,000 increase in personnel costs. Lower auditing, legal and consulting related to the change in fiscal year did not appear in the most recent quarter nor did the pre-launch commercialization preparation expenses for LCOS, both of which were present in 1Q:16.

Cash and equivalents of $17.8 million was held on the balance sheet as of March 31, 2017 and cash burn in the quarter was approximately ($4.0) million. We anticipate cash burn to ease substantially in coming quarters as trial wind down costs are completed. Costs could exceed our estimates depending on the outcome of the strategic review.

FDA Meeting

Tenax has completed additional analysis of subgroup data and continues to feel confident that they can make an argument for approval to submit an NDA. On May 10th, Tenax held their pre-NDA meeting with the FDA which expressed interest in continuing the process leading up to filing an NDA. The main focus of the subgroup analysis is the coronary artery bypass surgery (CABG) group, which comprised 66% of the 882 patients in the trial. 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. Following the meeting, the FDA asked several questions which Tenax will respond to in the next two weeks, after which we expect confirmation from the agency in July as to whether or not they will accept the NDA. Given that there have been other successful trials conducted to confirm the subset analysis that was performed on CABG patients in LEVO-CTS, Tenax believes another trial will not be necessary.

Tenax provided new data and analysis in the meeting which focused on the two thirds of patients who underwent CABG. This group experienced a 73% relative risk reduction in all-cause mortality at day 90 where placebo patients experienced 7.9% mortality and levosimendan patients 2.1%. The p-value for the risk reduction was a very significant 0.0016. Levosimendan patients who received valve surgery experienced a non-statistically significant increase in 90-day mortality.

Evidence also showed that CABG patients benefitted from an improvement in post-operative hemodynamics. There was a 46% relative risk reduction in low cardiac output syndrome (LCOS) in comparison with the placebo group. This finding is important as LCOS was a secondary endpoint in the LEVO-CTS trial and LCOS patients have a higher incidence of mortality following cardiac surgery. The p-value for this observation was 0.0014.

The company also provided other published trial and study data on levosimendan supportive of its safety and efficacy in the FDA meeting. There is strong evidence that levosimendan can provide benefits for limited cardiac surgery in CABG patients. Based on data generated by the Society of Thoracic Surgeons national database, there are as many as 150,000 to 200,000 CABG surgery patients per year in the United States. Review of the Premier hospital database, as provided by Tenax, shows that 38% of CABG surgery patients have two or more pre-operative risk factors for LCOS, which may benefit from the use of levosimendan.

Tenax plans to pursue approval for indications in acute decompensated heart failure (ADHF) and/or CABG. Based on a substantial set of data, levosimendan appears to be safe and 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 the drug until there is more clarity regarding the path potential approval will take.

Tenax is also scheduled for a pre-submission meeting with Health Canada in the second half of July after which the agency will indicate next steps for the submission. Health Canada accepts a broader scope of data and studies as compared to the FDA when making its determination and also follows approvals given in northern European countries. Given the wide approval of the drug in Europe, we attach a higher probability of acceptance with Health Canada than we do in the United States.

Next Steps

Following the pre-NDA meeting, Tenax will now respond to questions and wait. Armed with positive data from the 90-day mortality analysis and favorable outcomes based on type of surgery (CABG vs. valve), management will address outstanding questions and anticipates receiving an answer regarding an NDA filing in July.

Tenax is also planning the application filing process for levosimendan in Canada. We believe that 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 given the body of literature available and wide acceptance of levosimendan in Europe. While the Canadian market is only about 10% of the size of the US, Canada does represent a material geography 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.

Strategic Review Process

Ladenburg Thalmann & Co. Inc. was engaged by Tenax in April and is in the process of identifying an appropriate strategic direction for the company. This includes a merger, business combination, purchase, license or other acquisition of assets. Based on progress so far, the company anticipates that ideas will begin to be presented in the next month or two at which time due diligence will be performed on the options provided and an announcement will be made. The CEO search is tied to the strategic review process and will be defined by the ultimate direction the company will take and the transaction that Tenax pursues.

NASDAQ Delisting

On March 5th, 2017, Tenax received a letter from the Nasdaq's Listing Qualifications Department indicating that the company was not in compliance with Nasdaq Listing Rule 5550(a)(2). This requires that the minimum bid price of TENX common stock not close below $1.00 per share for 30 consecutive business days in order to maintain an exchange listing. Tenax has 180 days, until September 11, 2017, for its stock to trade above $1.00 per share for a minimum of 10 business days. Extensions are available if the company can show evidence that it can regain compliance. Additionally, there are a number of catalysts in July with respect to the NDA submission process in the US and Canada as well as recommendations from the strategic review that, if positive, could provide the necessary support for the share price.

Conclusion

Despite missing the primary endpoints related to the LEVO-CTS trial, Tenax has outlined a plan to move forward with new drug applications in the US and Canada. 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 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 $18 million of cash on the balance sheet as of March 31, 2017, we believe that Tenax has sufficient cash to fund activities through late 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 will be 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 model. Total expenses for 2017, excluding any new R&D for additional strategic options or a new levosimendan trial, are approximately $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. Note that our forecasts do not include and costs or benefits from the strategic review.

We update our forecast for approval of levosimendan in the U.S. and forecast first sales in 2019. We will adjust our timing and estimates as more information becomes available regarding FDA's response and progress with Health Canada. Currently, Tenax is trading at a market value of approximately $13 million, below the $18 million of cash on the balance sheet. To adjust for the unknowns regarding the approval process and upcoming milestones, we maintain our 50% probability of success estimate. Our target price remains $4.00.

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2016 A	Q1 A	Q2 E	Q3 E	Q4 E	2017 E	2018 E	2019 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$58.3**
YOY Growth								*#DIV/0!*
Cost of goods sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$11.7
Product Gross Margin						*0%*	*0%*	*80%*
Research and development	$13.1	$2.1	$1.3	$0.0	$0.0	$3.4	$1.0	$1.0
General & administration	$6.2	$1.4	$1.2	$1.2	$1.2	$5.0	$8.5	$23.0
Restructuring & Other Opex	$33.3	$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
Income from operations	($52.7)	($3.5)	($2.5)	($1.2)	($1.2)	($8.4)	($9.5)	$22.6
Operating Margin								*39%*
Interest Income (expense)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	($0.8)	($0.2)	$0.0	$0.0	$0.0	($0.2)	$0.0	$0.0
Pre-Tax Income	($51.9)	($3.3)	($2.5)	($1.2)	($1.2)	($8.2)	($9.5)	$22.6
Accrual for Income Taxes	($8.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*15%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($43.9)**	**($3.3)**	**($2.5)**	**($1.2)**	**($1.2)**	**($8.2)**	**($9.5)**	**$22.6**
Net Margin						*#DIV/0!*	*#DIV/0!*	*39%*
Reported EPS	**($1.56)**	**($0.12)**	**($0.09)**	**($0.04)**	**($0.04)**	**($0.29)**	**($0.33)**	**$0.78**
YOY Growth	*336%*		*-82%*	*-60%*	*-66%*	*-19%*	*14%*	*-334%*
Basic Shares Outstanding	28.12	28.14	28.15	28.15	28.15	28.15	28.65	29.15

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

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