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Tenax Therapeutics, Inc. (TENX-NASDAQ)

3Q Start to Pulmonary Hypertension Trial

Based on our DCF model and a 15% discount rate, TENX is valued at approximately $41.00 per share. We apply a 15% probability of eventual sales of levosimendan in the United States.

Current Price (8/21/18)	$5.38
Valuation	**$41.00**

OUTLOOK

Tenax has licensed the *calcium sensitizer/K-ATP activator* Levosimendan and is currently pursuing approval for an indication in Group 2 Pulmonary Hypertension in the US and Canada. 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.

In January 2018 Tenax announced a new indication for Levo and expects to launch a Phase 2 trial for PH-HFpEF in 3Q:18. This indication has a target population of between 1.5 and 2.0 million patients in the US and there is no existing treatment therapy. TENX will meet with the FDA in 1H:18 to design a Ph2 trial anticipated to begin in 2H:18. Based on trials for similar indications, the duration for Ph2 and Ph3 is expected to yield registrational data by 2023, followed by a 2024 launch of Levo in PH-HFpEF.

Levo 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 supporting the use of Levo in pulmonary hypertension and its inotropic and lusitropic effects, there is sufficient evidence to launch a Ph2 trial in PH-HFpEF. Additionally, this is a materially sized market with no current therapy, which provides substantial pricing and penetration opportunity.

SUMMARY DATA

52-Week High	**$12.63**
52-Week Low	**$4.41**
One-Year Return (%)	**-23.4**
Beta	**1.16**
Average Daily Volume (sh)	**12,387**
Shares Outstanding (mil)	**1.47**
Market Capitalization ($mil)	**$7.9**
Short Interest Ratio (days)	**11.4**
Institutional Ownership (%)	**12**
Insider Ownership (%)	**17**
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)
2017	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2018	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2019					$0.0 E
2020					$0.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$2.33 A	-$2.12 A	-$0.87 A	-$0.98 A	-$6.27 A
2018	-$0.83 A	-$1.29 A	-$1.50 E	-$1.66 E	-$5.33 E
2019					-$9.40 E
2020					-$9.87 E

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WHAT'S NEW

Second Quarter 2018 Review

In January, Tenax Therapeutics, Inc. (NASDAQ: TENX) announced its plan to advance the development of levosimendan for Pulmonary Hypertension associated with Heart Failure and preserved Ejection Fraction (PH-HFpEF). This announcement was followed shortly after by the installation of a scientific advisory board chaired by Stuart Rich, M.D. A reverse stock split occurred in February, followed by the publication of data supporting the use of levosimendan in PH. Positive news was released on April 4 when the FDA announced that the Phase II clinical protocol that is in effect for levosimendan can be used for the PH-HFpEF indication. This clears the pathway for a 3Q:18 start to the Phase II trial. In the last month of the second quarter, Tenax named its new CEO, Anthony DiTonno, who will lead the company through the regulatory process. Over the last two months, the news front has been quiet as Tenax has prepared for site activation, approved sites through the IRBs, prepared the CRO and made arrangements with vendors. In the very near term databases will be completed and screening will start. Tenax has planned an investigator meeting for October.

As expected, Tenax reported no revenues in the second quarter of 2018. Research and development costs rose sequentially to $0.3 million as preparations for a Phase II trial targeting PH-HFpEF ramp up for a 3Q:18 launch of enrollment. This compares to $1.2 million in the same prior year quarter. The year over year change was due to lower clinical and preclinical expenditures as the LEVO-CTS trial wound down in 2017. General and administrative expenses totaled $1.6 million, a 12% decline. Lower personnel and legal & professional costs contributed to the contraction. These changes were offset by an increase in other costs such as travel, supplies and insurance. Net loss for the period was ($1.9) million or ($1.29) per share.

Cash balance was $6.7 million and cash burn in the quarter was ($1.2) million. The company continues with no debt.

Trial Design

In April the FDA allowed Tenax to submit their Investigational New Drug (IND) application under the existing clinical protocol for levosimendan. The agency also also addressed the company's questions and provided guidance on the upcoming Phase II. This announcement allowed for a timely IND submission and prepares for enrollment in 2H:18. Substantial safety work has been performed on Levosimendan, negating the need for another Phase I trial. The FDA recognized that there are no approved drug therapies to treat PH-HFpEF patients and acknowledged this may allow a limited Phase III clinical program. Tenax will provide additional detail on the implications of a limited Phase III study at the End-of-Phase II Meeting for PH-HFpEF.

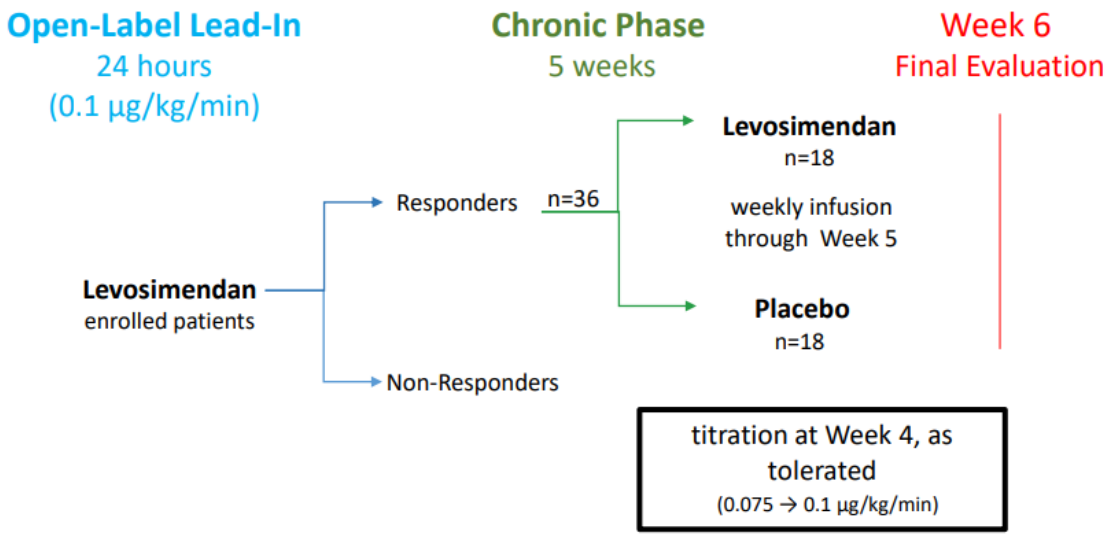
Based on details provided in the corporate presentation and on clinicaltrials.gov (NCT03541603), we anticipate the study will be a double-blind clinical trial enrolling less that 40 PH-HFpEF patients in 20 sites, which should last 14 to 18 months. Based on preliminary work, enrollees will have a pulmonary arterial pressure (PAP) equal to or greater than 35, a pulmonary capillary wedge pressure (PCWP) equal to or greater than 20, a cardiac index (CI)[1] of less than or equal to 2.2, a left ventricular ejection fraction (LVEF) of over 40 and be NYHA Class IIb or III.

The primary endpoint of the study will be a change from baseline PCWP with bicycle exercise at Week 6. Expected secondary endpoints will relate to a change in resting PCWP under a variety of conditions, a change in resting & stressed CI, change in pulmonary vascular resistance (PVR) at rest & under stress, a global assessment at week six based on the Likert scale and length of exercise period, a physician's assessment of functional class and clinical events, including death and hospitalizations.

Based on management commentary and what has been accomplished in pre-clinical and clinical work to date, infusion for several hours one time per week appears to be the most likely dosing regimen; however, this will be confirmed in Phase II work.

[1] Cardiac Index (CI) is a hemodynamic parameter that relates the cardiac output from left ventricle in one minute to body surface area, thus relating heart performance to the size of the individual. The unit of measurement is liters per minute per square meter (L/min/m2). Source: Wikipedia / https://en.wikipedia.org/wiki/Cardiac_index

Exhibit I – Phase II Study Design[2]



Milestones

- Meet with FDA for Phase II Trial Design – 1Q:18
- Complete Phase II Design – 2Q:18
- Begin Trial Enrollment – 3Q:18
- Conduct Comprehensive Strategic Alternative Review – 2018
- Raise Capital – 2H:18

Summary

The second quarter saw the favorable results of the pre-IND meeting with the FDA which allowed for the PH-HFpEF to move forward and permitted the use of the existing Phase II protocol for the launch of the trial. Following this early April event, trial design was finalized and submitted to the NIH. Tenax brought in a new CEO in June who will lead the company throught the development and regulatory process.

Based on the research and analysis included in our initiation, PH-HFpEF patients should benefit from Levosimendan's mechanism of action and clinical trials can be pursued with a reasonable cost and time commitment. The indication is also in an area with no other approved treatments. Market size is material and with no other approved therapy available, pricing should be strong and penetration high. We maintain our target price of $41.00.

[2] Source: Tenax July 2018 Investor Presentation

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2017 A	Q1 A	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Cost of goods sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Product Gross Margin	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Research and development	$3.5	$0.1	$1.5	$2.0	$2.0	$5.6	$8.8	$9.6
General & administration	$5.7	$1.2	$1.2	$1.2	$1.2	$4.8	$5.2	$5.6
Income from operations	($9.2)	($1.2)	($2.7)	($3.2)	($3.2)	($10.3)	($14.0)	($15.2)
Operating Margin	-	-	-	-	-	-	-	-
Interest Income (expense)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	($0.4)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($8.8)	($1.2)	($2.7)	($3.2)	($3.2)	($10.3)	($14.0)	($15.2)
Accrual for Income Taxes	$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	**($8.8)**	**($1.2)**	**($2.7)**	**($3.2)**	**($3.2)**	**($10.3)**	**($14.0)**	**($15.2)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($6.27)**	**($0.83)**	**($1.89)**	**($2.24)**	**($2.23)**	**($7.23)**	**($9.56)**	**($9.87)**
YOY Growth	*1650%*	*-64%*	*-10%*	*156%*	*128%*	*15%*	*32%*	*3%*
Basic Shares Outstanding	1.41	1.42	1.43	1.43	1.44	1.43	1.47	1.54

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

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