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November 19, 2018
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Tenax Therapeutics, Inc. (TENX-NASDAQ)

We Have Liftoff: HELP Site Activated

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 (11/16/18)	$3.80
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 with the HELP trial. 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 met with the FDA in April to confirm trial design. This indication has a target population of between 1.5 and 2.0 million patients in the US with no existing treatment therapy. TENX activated its first site for PH-HFpEF in November 2018. Based on development 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 support to justify 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	**$3.75**
One-Year Return (%)	**-51.3**
Beta	**0.82**
Average Daily Volume (sh)	**8,295**
Shares Outstanding (mil)	**1.47**
Market Capitalization ($mil)	**$5.6**
Short Interest Ratio (days)	**9.5**
Institutional Ownership (%)	**12**
Insider Ownership (%)	**14**
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 2018 Estimate	**N/A**
P/E using 2019 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 A	$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	-$1.05 A	-$1.66 E	-$4.83 E
2019					-$9.40 E
2020					-$9.87 E

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WHAT'S NEW

Third Quarter 2018 Review

Durng the third quarter Tenax Therapeutics, Inc. (NASDAQ: TENX) continued to prepare its Phase II levosimendan trial for PH-HFpEF enrollment. Efforts in the areas of contracting, budgeting, scheduling, investigational review board approvals and site set up dominated the executive schedule during the fall quarter. On November 14, 2018, the company filed its Form 10-Q, providing a financial update for the July to September period.

No revenues were reported in the third quarter of 2018 for this clinical stage company. Research and development costs of $363,000 were up 43% on higher personnel and clinical & preclinical development spend. General and administrative expenses tipped the scale at $1.2 million, rising 13% compared to 3Q:17. The rise was also attributable to greater personnel costs related to the addition of the company's new CEO and slight increases in other expenses partially offset by a decline in depreciation and amortization expense. Net loss for the period was ($1.5) million or ($1.05) per share.

Cash balance was $5.2 million and cash burn in the quarter was ($1.6) million. The company continues with no debt. We anticipate expenses picking up in 4Q:18 as the Phase II trial launches and begins enrollment.

Trial Design

On November 19th, Tenax announced the activation of the first clinical research site for the PH-HFpEF trial at Stanford University School of Medicine. The trial was also given the acronym HELP: **H**emodynamic **E**valuation of **L**evosimendan in Patients with **P**H-HFpEF and is expected to enroll 36 patients over its life. Including the Stanford location, Tenax is expected to establish 12 to 15 sites throughout the US to enroll the anticipated population, some of which are expected to come on line in the next few weeks.

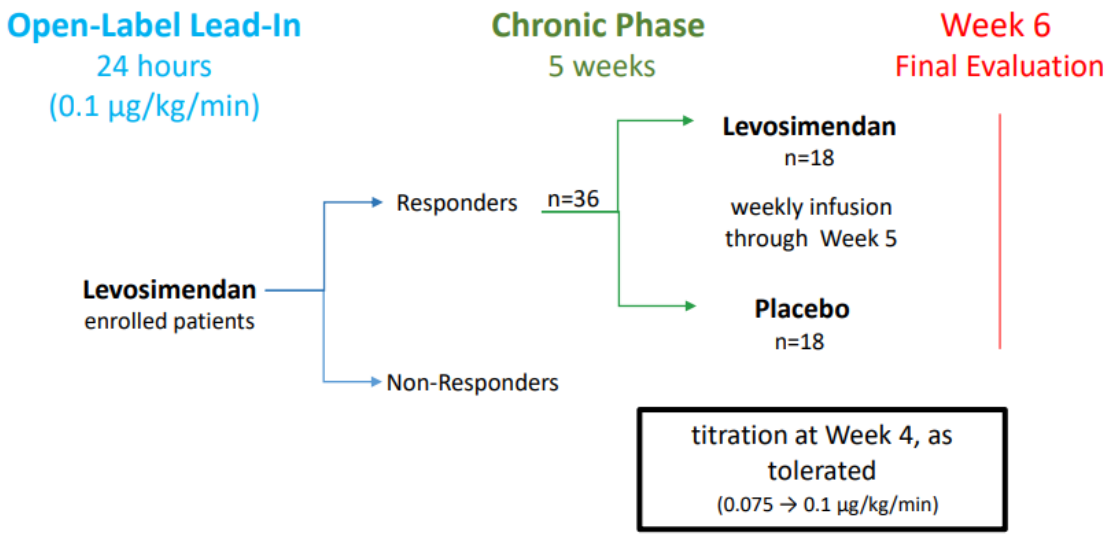
The process began in April when the FDA allowed Tenax to submit their Investigational New Drug (IND) application under the existing clinical protocol for levosimendan. The agency also addressed the company's questions and provided guidance on the Phase II trial. Substantial safety work has been performed on levosimendan, eliminating the need for Phase I work. The FDA recognized that there are no approved drug therapies to treat PH-HFpEF patients and acknowledged this may eventually allow for 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 which we anticipate taking place in late 2019/early 2020.

After meeting with the FDA for the pre-IND meeting, Tenax refined its trial design to reflect the input provided by the agency. Based on details provided in the corporate presentation and the press release, the structure required fewer enrollees and a greater number of sites. The trial will enroll PH-HFpEF patients in an open trial and responders will be randomized into the placebo-control trial (see exhibit). The study is anticipated to enroll 36 PH-HFpEF patients in 12 to 15 sites with a trial duration of 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) 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.

Exhibit I – Phase II Study Design[1]



Tenax S-1 Filing

On November 6th Tenax Therapeutics (NASDAQ: TENX) filed an S-1 proposing to raise $10 million in equity capital to support operations into 2020. While the funds are not needed to launch the Phase II trial for Levosimendan, they should be sufficient to support the completion of the Phase II trial and the end of Phase II meeting with the FDA. Total direct trial cost is anticipated to be from $4.5 to $5.0 million.

Milestones

- Meet with FDA for Phase II Trial Design – 1Q:18
- Complete Phase II Design – 2Q:18
- Begin Trial Enrollment – 4Q:18
- Raise Capital – 4Q:18
- End of Phase II Meeting with FDA – 4Q:19 / 1Q:20

Summary

Activities in the third quarter were dominated by preparations for the launch of the PH-HFpEF trial. There was a delay relative to our initial expectations as the company worked through administrative issues with partner institutions, such as contracting and budgeting and IRB approvals. The first site has now been launched and we anticipate that Tenax will begin to enroll participants; however, initial enrollment rates may be slow due to the holiday calendar over the next six weeks.

Based on the research and analysis included in our initiation, we believe PH-HFpEF patients will 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.

[1] Source: Tenax July 2018 Investor Presentation

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2017 A	Q1 A	Q2 A	Q3 A	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%*
Research and development	$3.5	$0.1	$0.3	$0.4	$1.3	$2.0	$8.8	$9.6
General & administration	$5.7	$1.2	$1.6	$1.2	$1.2	$5.1	$5.2	$5.6
Income from operations	($9.2)	($1.2)	($1.9)	($1.6)	($2.5)	($7.1)	($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	($0.1)	$0.0	$0.0
Pre-Tax Income	($8.8)	($1.2)	($1.9)	($1.5)	($2.5)	($7.0)	($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)**	**($1.9)**	**($1.5)**	**($2.5)**	**($7.0)**	**($14.0)**	**($15.2)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($6.27)**	**($0.83)**	**($1.29)**	**($1.05)**	**($1.66)**	**($4.83)**	**($9.40)**	**($9.87)**
YOY Growth	*1650%*	*-64%*	*-39%*	*20%*	*69%*	*-23%*	*94%*	*5%*
Basic Shares Outstanding	1.41	1.42	1.45	1.46	1.48	1.45	1.49	1.54

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

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