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Tenax Therapeutics, Inc. (TENX-NASDAQ)

Screening & Enrollment Continue

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

Current Price (5/29/19)	$1.29
Valuation	**$4.00**

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 ~20 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	**$7.20**
52-Week Low	**$1.03**
One-Year Return (%)	**-79.2**
Beta	**1.7**
Average Daily Volume (sh)	**1,057,306**
Shares Outstanding (mil)	**6.2**
Market Capitalization ($mil)	**$8.0**
Short Interest Ratio (days)	**2.59**
Institutional Ownership (%)	**14.3**
Insider Ownership (%)	**4.7**
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)
2018	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2019	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2020					$0.0 E
2021					$0.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-$0.83 A	-$1.29 A	-$1.05 A	-$1.51 A	-$4.35 A
2019	-$0.33 A	-$0.45 E	-$0.44 E	-$0.40 E	-$1.64 E
2020					-$1.06 E
2021					-$1.31 E

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WHAT'S NEW

First Quarter 2019 Financial and Operational Review

Following the December 2018 activation of trial sites, Tenax Therapeutics, Inc. (NASDAQ: TENX) enrolled its first patient in 1Q:19. We anticipate a steady addition of patients in the 36-patient, six medical center site study as 2019 progresses. As a reminder, the **H**emodynamic **E**valuation of **L**evosimendan in **P**atients with PH-HFpEF or HELP trial is a multi-center, double-blind, placebo-controlled study in North America. Enrollment is anticipated to continue throughout the year.

On May 15, Tenax filed its Form 10-Q with the SEC. No revenues were reported in the period and operating expenses were $1.7 million. Net loss per share was ($0.33). Research and development costs of $0.5 million increased dramatically from the $59,000 spent in the prior period as the HELP trial was launched and first patient enrolled. General and administrative expenses totaled $1.2 million, up 1%. Higher personnel costs were offset by lower legal and professional costs. Net loss for the period was ($1.6) million or ($0.33) per share.

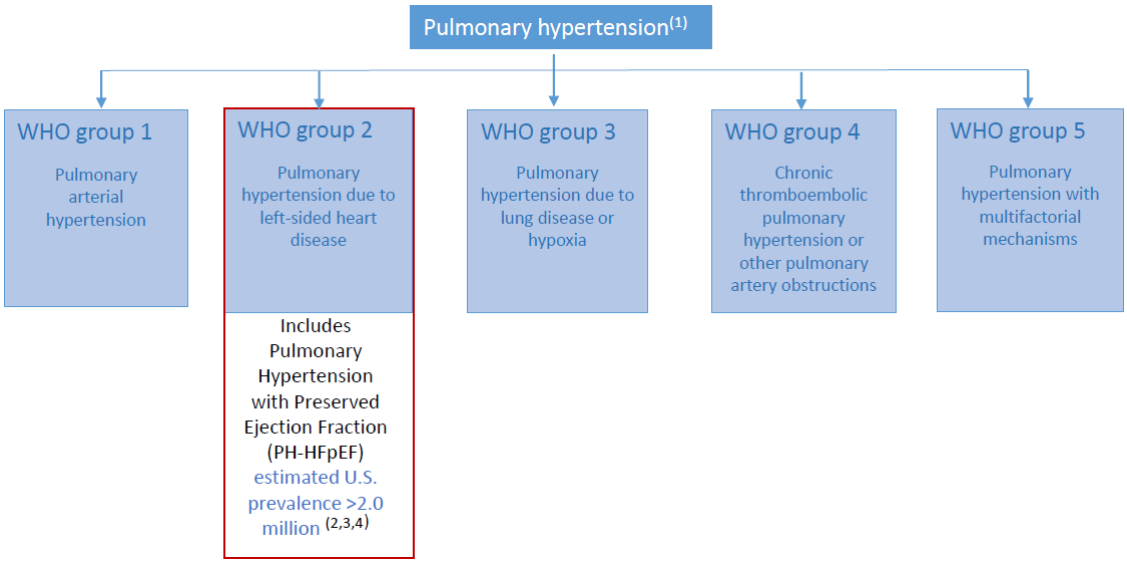
Cash balance was $10.8 million and cash burn totaled ($2.1) million for 1Q:19. The company continues with no debt. We anticipate an acceleration in expenses in coming quarters as the Phase II trial advances enrollment.

Trial Design

Last November Tenax announced the activation of the first clinical research site for the PH-HFpEF trial at Stanford University School of Medicine. In March, the first of an expected 36 patients was enrolled in the trial.

The process of developing the trial began last 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 another Phase I. 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.

Exhibit I – PH WHO Groups[1]



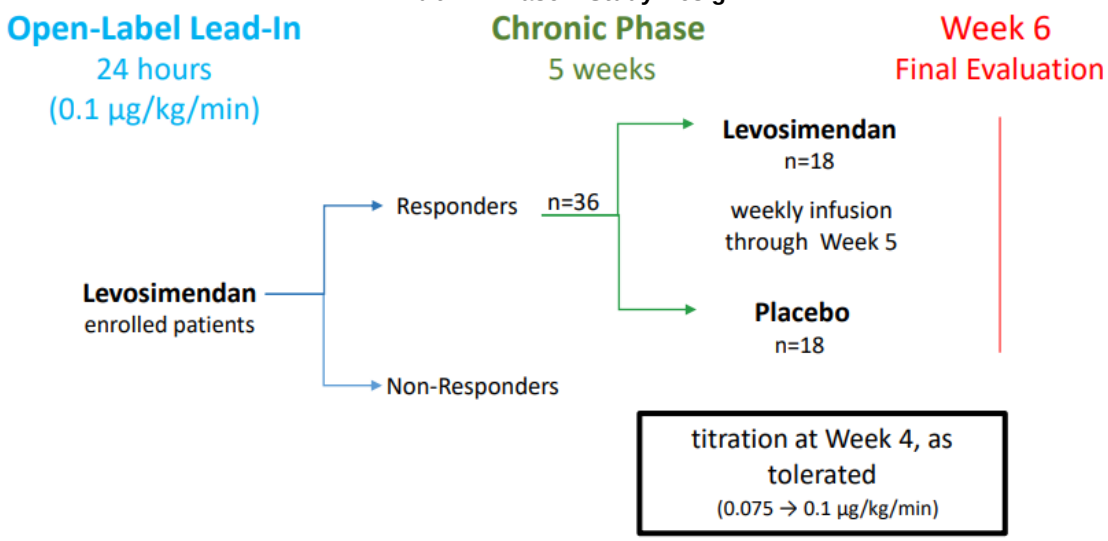
After meeting with the FDA for the pre-IND meeting, Tenax refined its trial design to reflect the input provided by the agency. The study is anticipated to enroll 36 PH-HFpEF patients in twelve to thirteen sites with a trial duration of 14 to 18 months. Based on preliminary work, enrollees will have a pulmonary arterial pressure (PAP) equal to or

[1] Exhibit from TENX Corporate Presentation, January 2019

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.

Exhibit II – Phase II Study Design[2]



Milestones

- Activate First Sites – November 2018
- Raise Capital – December 2018
- Enroll First Patient – March 2019
- End of Phase II Meeting with FDA – 2020
- Raise capital – Mid 2020
- Launch Phase III - 2020

Summary

2019 has begun with HELP sites activated and the first paitent enrolled. While the trial took longer than expected to launch, we are hopeful that it will enroll quickly and produce results by early 2020. 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 to $4.00.

[2] Source: Tenax January 2019 Investor Presentation.
https://s3.amazonaws.com/cdn.irdirect.net/PIR/942/3392/TENX%20Investor%20Presentation%20Jan%202019.pdf

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2018 A	Q1 A	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 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%*
Research and development	$1.2	$0.5	$1.4	$1.4	$1.5	$4.8	$9.6	$10.6
General & administration	$5.7	$1.2	$1.4	$1.4	$1.3	$5.3	$5.6	$5.8
Income from operations	($6.9)	($1.7)	($2.8)	($2.8)	($2.8)	($10.1)	($15.2)	($16.4)
Operating Margin	-					-	-	-
Interest Income (expense)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	($0.1)	($0.0)	$0.0	$0.0	$0.0	($0.0)	$0.0	$0.0
Pre-Tax Income	($6.8)	($1.6)	($2.8)	($2.8)	($2.8)	($10.0)	($15.2)	($16.4)
Accrual for Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$16.4
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*100%*
Net Income	**($6.8)**	**($1.6)**	**($2.8)**	**($2.8)**	**($2.8)**	**($10.0)**	**($15.2)**	**($32.7)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($4.35)**	**($0.33)**	**($0.45)**	**($0.44)**	**($0.40)**	**($1.64)**	**($1.06)**	**($1.31)**
YOY Growth	*-31%*					*-62%*	*-35%*	*23%*
Basic Shares Outstanding	1.56	4.89	6.20	6.40	7.00	6.12	14.30	25.00

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

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HISTORICAL STOCK PRICE

Tenax Therapeutics, Inc. – Share Price Chart



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