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Tenax Therapeutics, Inc. (TENX-NASDAQ)

Over Halfway There

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 (11/15/19)	$1.15
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	**$5.12**
52-Week Low	**$1.03**
One-Year Return (%)	**-70.8**
Beta	**1.4**
Average Daily Volume (sh)	**60,304**
Shares Outstanding (mil)	**6.7**
Market Capitalization ($mil)	**$7.8**
Short Interest Ratio (days)	**1.62**
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 2019 Estimate	**N/A**
P/E using 2020 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 A	$0.0 A	$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	-$0.28 A	-$0.33 A	-$0.40 E	-$1.36 E
2020					-$1.06 E
2021					-$1.31 E

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WHAT'S NEW

Third Quarter 2019 Financial and Operational Review

Tenax Therapeutics, Inc. (NASDAQ: TENX) has enrolled 17 of the targeted 36 patients int is **H**emodynamic **E**valuation of **L**evosimendan in **P**atients with PH-HFpEF (HELP) study as of November 11, 2019. After a thorough screening process, the first patient was enrolled in March 2019 and additional sites were added as the year progressed to achieve the current 15 active locations. We anticipate continued addition of subjects over the next few months for the trial.

On November 14, Tenax filed its Form 10-Q with the SEC. No revenues were reported in the period and operating expenses totaled $2.3 million. Net loss per share was ($0.33). Research and development costs of $0.9 million rose 150% from the $0.4 million spent in the prior third quarter period as the HELP trial was underway screening and enrolling patients. General and administrative expenses totaled $1.3 million, up 13%. The change was attributed to higher legal and professional costs partially offset by lower personnel costs. Net loss for the period was ($2.2) million or ($0.33) per share.

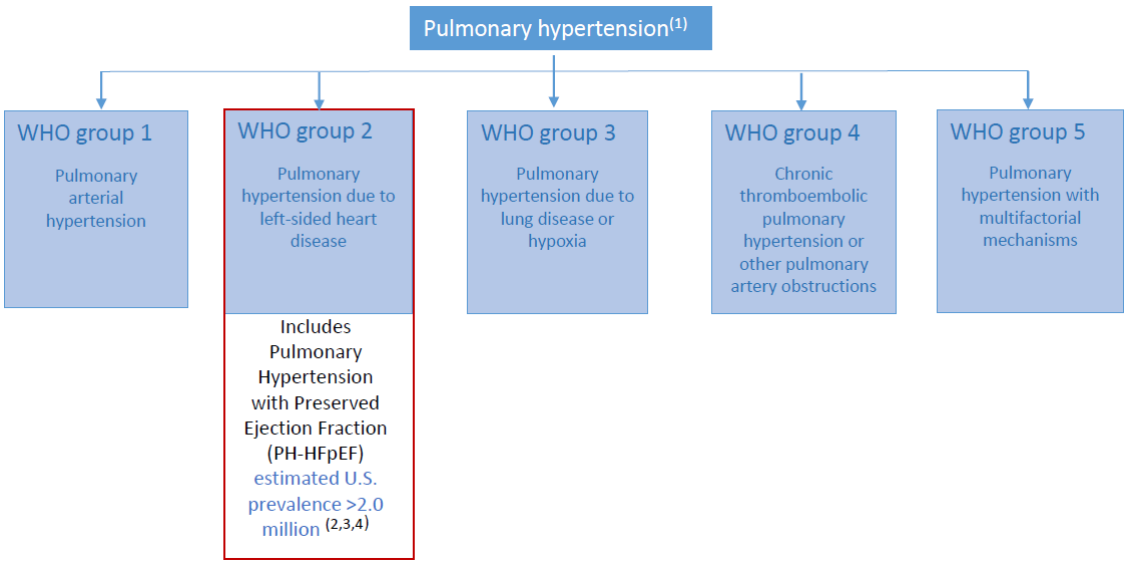
Cash and securities balance was $7.1 million and cash burn totaled ($1.8) million for 3Q:19. The company continues with no debt. We anticipate an increase in expenses in coming quarters as the Phase II trial advances enrollment.

Trial Design

In November 2018 Tenax announced the activation of the first clinical research site for the PH-HFpEF HELP trial at Stanford University School of Medicine. In March, the first of an expected 36 patients was enrolled in the trial and by August 23rd, eight patients had been added in 12 active sites. By October 2019, all 15 sites had been activated.

The process of developing the trial began in April 2018 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 had 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 1H:20.

Exhibit I – PH WHO Groups[1]

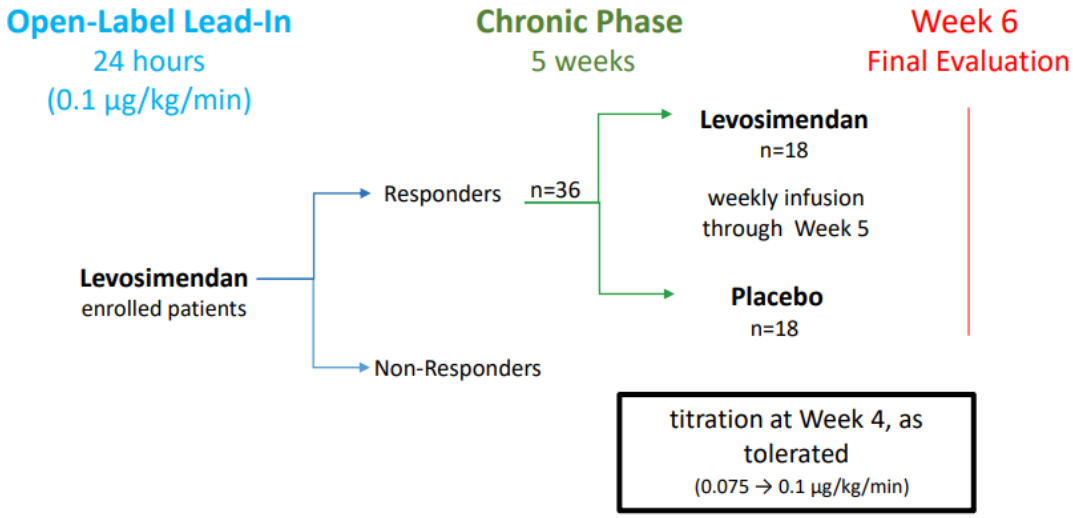


[1] Source: TENX September 2019 Investor Presentation.

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 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]



Tenax provided a trial update on October 31st which we discussed in a short note. Fifteen patients had been enrolled and average PCWP for successfully screened patients (responders)[3] was 8 mmHg, well above the defined threshold for inclusion of 4.0 mmHg. Tenax updated this number to seventeen patients as of November 11.

Milestones

- Activate First Sites – November 2018
- Enroll First Patient – March 2019
- Full Enrollment – 1Q:20
- End of Phase II Meeting with FDA – 2020
- Raise capital – Mid 2020
- Launch Phase III - 2020

Summary

Now that all fifteen targeted sites are active, we anticipate a faster pace of patient enrollment and conclusion of the HELP trial by 1Q:20. Data should be available shortly after. As of November 11, over half of the targeted 36 patients have been enrolled and all sites are able to start responders for the five week chronic phase. 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 September 2019 Investor Presentation.
https://s3.amazonaws.com/cdn.irdirect.net/PIR/942/3392/TENX%20Investor%20Presentation%20Jan%202019.pdf
[3] Following the initial administration of Levosimendan to determine whether or not the patient is a responder, responders are given five additional 24-hour infusions of Levosimendan over the subsequent five weeks.

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2018 A	Q1 A	Q2 A	Q3 A	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%*	*0%*	*0%*	*0%*
Research and development	$1.2	$0.5	$0.6	$0.9	$1.5	$3.5	$9.6	$10.6
General & administration	$5.7	$1.2	$1.2	$1.3	$1.3	$5.0	$5.6	$5.8
Income from operations	($6.9)	($1.7)	($1.8)	($2.3)	($2.8)	($8.5)	($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)	($0.1)	($0.0)	$0.0	($0.1)	$0.0	$0.0
Pre-Tax Income	($6.8)	($1.6)	($1.8)	($2.2)	($2.8)	($8.4)	($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)**	**($1.8)**	**($2.2)**	**($2.8)**	**($8.4)**	**($15.2)**	**($32.7)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($4.35)**	**($0.33)**	**($0.28)**	**($0.33)**	**($0.41)**	**($1.36)**	**($1.06)**	**($1.31)**
YOY Growth	*-31%*	*-60%*	*-79%*	*-68%*	*-72%*	*-69%*	*-22%*	*23%*
Basic Shares Outstanding	1.56	4.89	6.39	6.74	6.75	6.19	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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