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Tenax Therapeutics, Inc. (TENX-NASDAQ)

HELP Fully Enrolled; Topline Next

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 (4/3/20)	$0.57
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	**$2.05**
52-Week Low	**$0.25**
One-Year Return (%)	**-68.7**
Beta	**1.9**
Average Daily Volume (sh)	**77,571**
Shares Outstanding (mil)	**7.6**
Market Capitalization ($mil)	**$4.3**
Short Interest Ratio (days)	**0.07**
Institutional Ownership (%)	**26.4**
Insider Ownership (%)	**0.5**
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 A	$0.0 A
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	-$0.41 A	-$1.35 A
2020					-$0.57 E
2021					-$0.69 E

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WHAT'S NEW

Full Year 2019 Financial and Operational Review

Tenax Therapeutics, Inc. (NASDAQ: TENX) completed enrollment of its **H**emodynamic **E**valuation of **L**evosimendan in **P**atients with PH-HFpEF (HELP) study as of March 12, 2020. This 37 patient open-label trial achieved an 84% initial response rate for screened patients, and is expected to finish collecting data in 2Q:20. Topline results are expected to be available in the second quarter of 2020.

On March 30, Tenax filed its 2019 Form 10-K with the SEC. No revenues were reported in the period and operating expenses totaled $8.6 million. Net loss per share was ($1.35). Full year research and development costs of $3.5 million rose 180% from the $1.2 million spent in the prior period as the HELP trial was underway screening and enrolling patients. General and administrative expenses totaled $5.1 million, down 10%. Lower bonuses, a reduction in stock based compensation and decreased travel led to the change. Net loss for the period was ($8.4) million or ($1.35) per share.

Cash and securities balance was $5.4 million as of December 31, 2019 and cash burn totaled ($7.6) million for 2019. The company continues with no debt. We anticipate a decrease in expenses in the second half as the HELP trial completes and Tenax moves into the data analysis stage.

The HELP Trial

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 2019, the first of what would eventually be 37[1] patients was enrolled in the trial and by March 12th, 2020, all patients had been enrolled. Top line data is expected to be reported during 2Q:20. Now that the HELP trial is close to completing analysis of its last enrollees, we anticipate data collection and analysis to take place over the next months. Many data points were collected during the study, which will provide fertile ground for researchers to develop academic papers on the results. We anticipate presentations in the academic community and at conferences in the latter half of the year. Tenax management will develop its own materials and Phase III trial design to present at the end of Phase II meeting with the FDA prior to year end.

A Phase III trial may begin in 2021, assuming the HELP trial results are favorable. Its design is highly dependent on the results and strength of signal generated by the current Phase II. A rough estimate of time, cost and size of the registrational trial range from 18 to 36 months, $30 to $50 million and 200 to 300 patients. While none of these estimates have been confirmed by the company, we believe they are reasonable ranges based on the likely outcome of a successful Phase II.

HELP Trial Design

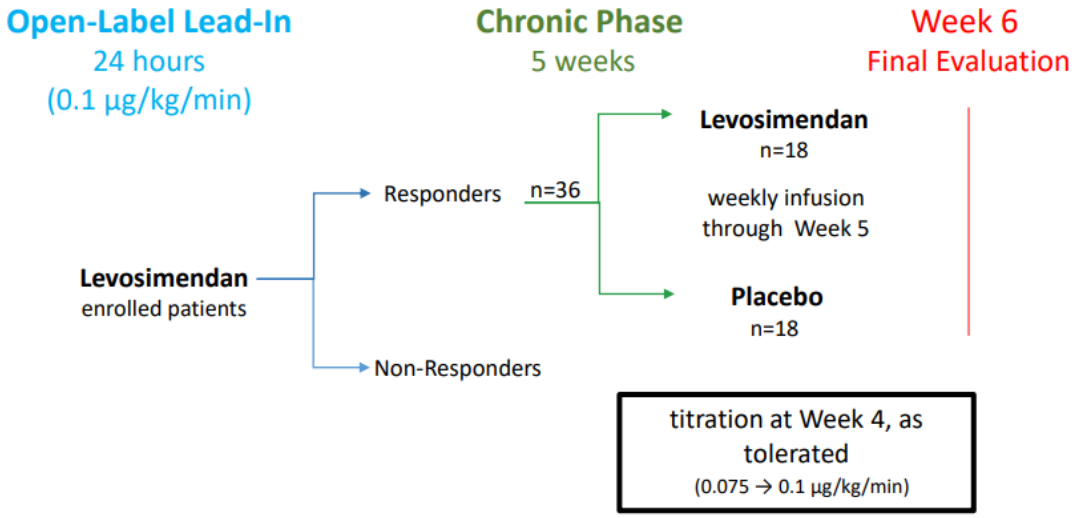
Required thresholds for inclusion in the trial call for patients with pulmonary arterial pressure (PAP) equal to or greater than 35, a pulmonary capillary wedge pressure (PCWP) equal to or greater than 20, a cardiac index (CI) of less than or equal to 2.2, a left ventricular ejection fraction (LVEF) of over 40 and be NYHA Class IIb or III. The primary endpoints of the study are:

- Change from baseline PCWP with bicycle exercise (25 watts) at Week 6
- Detect a greater than or equal to 4.8 mmHg change in PCWP from baseline

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.

[1] The trial originally targeted 36 patients and exceeded this number by 1.

Exhibit I – Phase I Study Design[2]



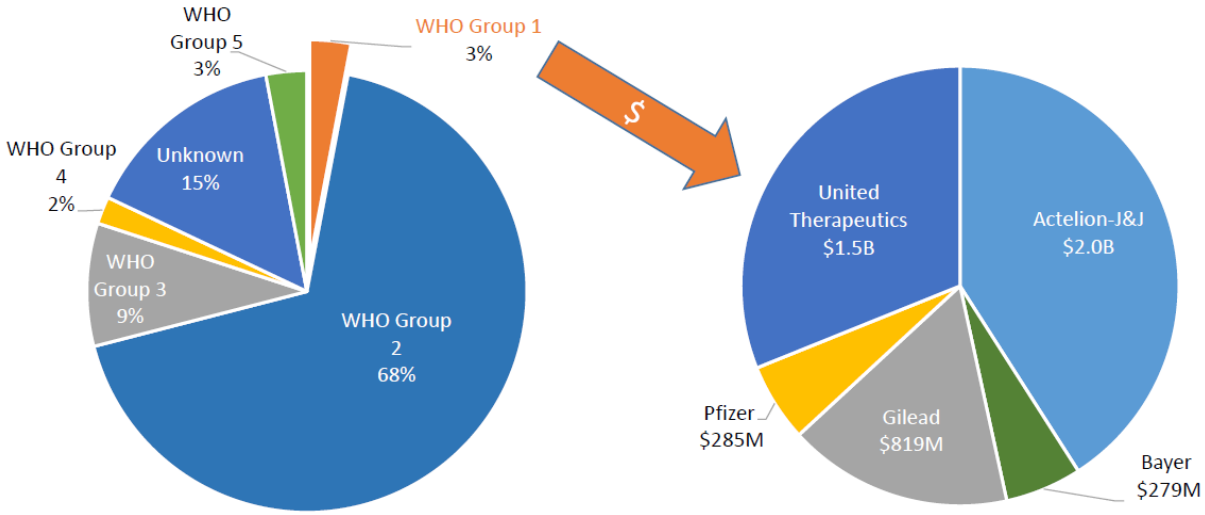
Since our last report in November, Tenax provided a trial update on January 13th which we discussed in a short note. At that time, twenty-four patients had been enrolled and average PCWP for successfully screened patients (responders)[3] was 7.6 mmHg, well above the defined threshold for inclusion of 4.0 mmHg.

The HELP study uses a 24-hour, once per week infusion regimen of between 0.075 to 0.100 µm/kg/min via home-based intravenous infusion using an ambulatory infusion pump. The home-based approach allows for a less frequent infusion regimen as compared to what would be possible in a hospital setting.

Update on PH-HFpEF Unmet Need

Tenax provided a review of the unmet need in its latest corporate presentation dated February 2020. The review reminded investors of the over two million PH-HFpEF patients in the United States who lack a treatment and suffer from high mortality and a poor quality of life. There are five groups of pulmonary hypertension and only Group 1 has approved treatments. This group comprises 3% of the total population of PH, in contrast to Group 2, which makes up 68%. Group 2 is the population that Tenax is pursuing with its Levosimendan trials.

Exhibit II – PH Prevalence and Market Size[4]



[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.
[4] Source: Tenax Corporate Presentation, February 2020. Pulmonary Hypertension Association Strange G, *et al*. Heart. 2012;98(24):1805 11

Several other studies have been launched in PH-HFpEF, using a variety of products including Bosentan, Macitentan and Riociguat. However, none of these trials demonstrated an effective treatment for the condition and further pursuit for these candidates in this indication was abandoned.

Exhibit III – Trials Conducted for PH-HFpEF[5]

Trial	BADDHY	MELODY	DILATE	HELP
Sponsor	Actelion/J&J	Actelion/J&J	Bayer	Tenax
Product	Bosentan	Macitentan	Riocigaut	Levosimendan
Approved Indication	PAH	PAH	PAH/CETPH	ADHF-Outside US
Patients (#)	20	63	39	36
Design	Randomized, Placebo- Controlled	Randomized, Placebo- Controlled	Randomized, Placebo- Controlled	Randomized, Placebo- Controlled
Study Duration	12 weeks	12 weeks	Single Dose	6 weeks
MOA	Pulmonary Vasodilator	Pulmonary Vasodilator	Pulmonary Vasodilator	Lusitrope Inotrope Vasodilator
Result	Ineffective, Stopped early	Ineffective, Fluid retention	Ineffective	Ongoing-TBD

Milestones

- Activate First Sites – November 2018
- Enroll First Patient – March 2019
- Full Enrollment – 1Q:20
- Topline data announced – 2Q:20
- End of Phase II Meeting with FDA – 2H:20
- Launch Phase III – 2021

Summary

Now that the HELP trial has been fully enrolled, the six week duration of treatment suggests that all enrollees will complete their course of treatment before the end of April, and topline data will be announced shortly after. 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 valuation at $4.00 per share.

[5] Source: Tenax Corporate Presentation, February 2020.

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2018 A	Q1 A	Q2 A	Q3 A	Q4 A	2019 A	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	$1.4	$3.5	$3.4	$10.6
General & administration	$5.7	$1.2	$1.2	$1.3	$1.4	$5.1	$4.9	$5.1
Income from operations	($6.9)	($1.7)	($1.8)	($2.3)	($2.8)	($8.6)	($8.3)	($15.7)
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)	($0.2)	$0.0	$0.0
Pre-Tax Income	($6.8)	($1.6)	($1.8)	($2.2)	($2.8)	($8.4)	($8.3)	($15.7)
Accrual for Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$15.7
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*100%*
Net Income	**($6.8)**	**($1.6)**	**($1.8)**	**($2.2)**	**($2.8)**	**($8.4)**	**($8.3)**	**($31.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($4.35)**	**($0.33)**	**($0.28)**	**($0.33)**	**($0.41)**	**($1.35)**	**($0.58)**	**($1.25)**
YOY Growth	*-31%*	*-60%*	*-79%*	*-68%*	*-73%*	*-69%*	*-57%*	*116%*
Basic Shares Outstanding	1.56	4.89	6.39	6.74	6.74	6.20	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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