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Tenax Therapeutics, Inc. (TENX-NASDAQ)

Upcoming FDA Meetings for Ph3 Design

Based on our DCF model and a 15% discount rate, TENX is valued at approximately $4.00 per share. We apply a 25% probability of eventual sales of Levosimendan in the United States.

Current Price (8/24/20)	$1.44
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	**$2.68**
52-Week Low	**$0.25**
One-Year Return (%)	**15.2**
Beta	**2.4**
Average Daily Volume (sh)	**1,329,720**
Shares Outstanding (mil)	**12.6**
Market Capitalization ($mil)	**$18.2**
Short Interest Ratio (days)	**0.14**
Institutional Ownership (%)	**30.0**
Insider Ownership (%)	**30.0**
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)
2019	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2020	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2021					$0.0 E
2022					$0.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.33 A	-$0.28 A	-$0.33 A	-$0.41 A	-$1.35 A
2020	-$0.38 A	-$0.23 A	-$0.13 E	-$0.10 E	-$0.73 E
2021					-$0.67 E
2022					-$1.78 E

WHAT'S NEW

Second Quarter 2020 Financial and Operational Review

Tenax Therapeutics, Inc. (NASDAQ: TENX) has completed its **H**emodynamic **E**valuation of **L**evosimendan in **P**atients with PH-HFpEF (HELP) trial and announced positive results on June 2nd. HELP study results were positive and meaningful for key measures critical to a successful Phase III trial. The six minute walk test generated statistically significant results that were 29 meters greater for the Levosimendan group compared to the placebo group and a reduction in pulmonary capillary wedge pressure (PCWP). We expect further analysis and the development of an academic paper on the results to be presented at an upcoming conference. Tenax will hold an end of Phase II meeting with the FDA in the fourth quarter to identify next steps and accept feedback to design a Phase III.

Following the end of the quarter, Tenax raised $8.0 million in registered direct and private investment in public equity (PIPE) offering priced at the market, $1.03/share. The company also added two new directors to the board, Steven Boyd and Keith Maher, MD. Both individuals are principals from Armistice Capital, which contributed to the aforementioned capital raise.

On August 14th, Tenax filed its 2Q:20 Form 10-Q with the SEC and posted a press release the following business day. No revenues were reported in the period and operating expenses totaled $2.1 million. Net loss per share was ($0.23). Second quarter research and development costs of $0.9 million rose 34% from the $0.6 million spent in the comparable period reflecting greater expenditures for the Phase II HELP study. The uptick in spend was attributable to higher contract research organization costs, additional clinical research associates to help manage the trial and increased patient enrollment costs. General and administrative expenses totaled $1.3 million, up 9%. Higher personnel costs related to stock options, vacation costs and salary increases, greater expenditure for insurance premiums Increased legal fees, investor relations costs and insurance costs were partially offset by lower legal fees. Net loss was ($2.1) million or ($0.23) per share.

Cash and securities balance was $4.6 million as of June 30, 2020 and cash burn totaled ($2.2) million for 2Q:20. Cash from financing was $1.9 million and represented flows from warrant exercise and a Paycheck Protection Program (PPP) loan of $245,000. The loan has a two year term and may be forgiven under certain circumstances. We anticipate a decrease in expenses for the balance of 2020 and in 2021 as the HELP trial undergoes finalization, data lock up and data analysis and papers are drafted for conference presentation. We anticipate that the majority of 2021 will be spent designing the Phase III trial, identifying sites and preparing for first enrollment. Additional funds of $8 million gross were raised following the end of the quarter through the issuance of 7.8 million shares and prefunded warrants.

New Directors

Tenax added two new directors to its board from Armistice Capital that were made in conjunction with a recent investment. They are Steven Boyd and Keith Maher, MD. Armistice made an $8 million investment in the company's equity securities and joined the board of directors to help guide the company's advance as they launch a Phase III program and chart the future course of the firm. We anticipate that Armistice's increased involvement with Tenax can help the company raise capital in subsequent rounds and also identify partners for either advancing Levosimendan or identifying new candidates. In addition to his role on the board of Tenax, Steven is Chief Investment Officer of Armistice with a long history working in health care equities and long short investment funds. Dr. Maher is Managing Director at Armistice, focusing on healthcare and a history at top tier investment firms. We see these additions to the board a material positives and a vote of confidence by Armistice

HELP Trial Results

In early June Tenax announced topline results from its Phase II **H**emodynamic **E**valuation of **L**evosimendan in **P**atients with PH-HFpEF[1] (HELP). We include the text and exhibits from our report following the announcement below. Results were complemented by a conference call with company CEO Tony DiTonno, CFO Michael Jebsen and Scientific Advisory Board chair and expert in the field of PH and PH-HFpEF, Dr. Stuart Rich.

[1] Pulmonary Hypertension in Heart Failure with Preserved Ejection Fraction (PH-HFpEF)

Exhibit I – HELP Trial Logo[2]

HELP study results were positive and statistically significant for key measures critical to a successful Phase III trial. The distance for the six minute walk test,[3] which has been used as a primary endpoint in other pulmonary hypertension trials, was 29 meters greater for the Levosimendan group compared to the placebo group. This measure had a p-value of 0.0329, better than the 0.05 threshold required for statistical significance.

Other important measures, such as pulmonary capillary wedge pressure (PCWP) at rest, with legs up and during exercise were all directionally correct; however, the primary endpoint of PCWP during exercise was not statistically significant. These additional measures helped to provide additional detail on the drugs mechanism and effect and are not expected to be assessed in Phase III. Below is a summary of the data as presented by Tenax. Additional analysis was performed to determine the statistical significance of the difference between the arms on all three measures using a mixed effect model that used treatments as factors and position as a random effect. It generated a p-value of 0.0475.

Exhibit II – Summary of HELP Trial Data[4]

PCWP Change From Baseline at Week 6				
mmHg	Placebo	Levosimendan	Difference	p-value
At Rest	-1.7	-5.1	-3.4	0.0894
Leg Up	-0.3	-6.0	-5.7	0.0184
Exercise	-0.5	-1.9	-1.4	0.6472

The trial's primary goal was to determine safety for extended use of Levosimendan, to further determine the mechanism of action of the drug and to help inform the design for Phase III. Other secondary measures that were obtained in this effort include right atrial pressure (RAP) and mean pulmonary arterial pressure (mPAP)[5]. These measures examined the change in pressure compared to baseline at rest, with legs up and during exercise. Data were all directionally correct and with the exception of mPAP during exercise, were all statistically significant. A comparison of Levosimendan patients relative to baseline is provided in the subsequent exhibits.

[2] Source: Tenax Corporate Presentation for HELP trial topline, June 2, 2020.
[3] The 6 Minute Walk Test is a sub-maximal exercise test used to assess aerobic capacity and endurance. The distance covered over a time of 6 minutes is used as the outcome by which to compare changes in performance capacity.
[4] Author's own work.
[5] The is the average of systolic and diastolic pressures.

Exhibit III – RAP vs. Baseline[6]

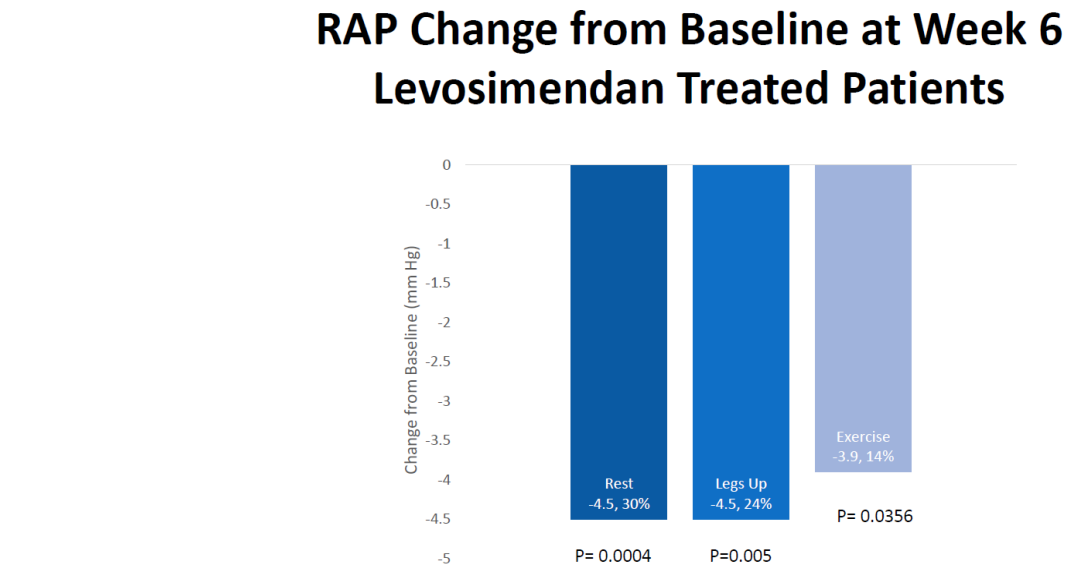

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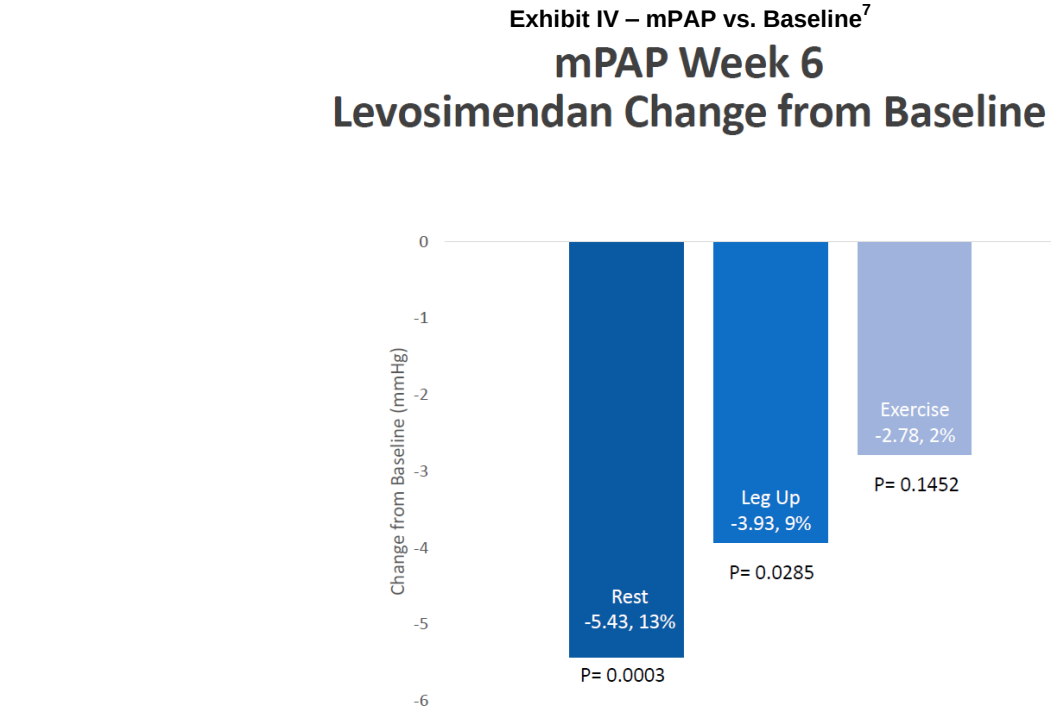
Exhibit IV – mPAP vs. Baseline[7]



Safety was a strong point in the trial. Levosimendan has a long history of use in Europe and is well understood in treatment of acute decompensated heart failure. However, the drug has not been used as chronic therapy. Going into the trial, the FDA was concerned about treatment emergent adverse events related to hemodynamic issues and development of atrial and ventricular arrhythmias. These were not observed and the majority of adverse events were mild. Headache was the most common side effect, with three incidents observed in the Levo group compared to one event in the placebo group. Severe adverse events were related to infections and infestations or device related infections which were attributed to failure to employ current best practices for a peripherally inserted central catheter (PICC) line. Dr. Rich's is well versed in effective use of PICC lines and he believes this issue can be successfully addressed in Phase III.

[6] Source: Tenax Corporate Presentation for HELP trial topline, June 2, 2020.
[7] Source: Tenax Corporate Presentation for HELP trial topline, June 2, 2020.
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Exhibit V – Treatment Emergent Adverse Events[8]

	Placebo n=18	Levosimendan n=18
Any Treatment Emergent AEs (TEAEs)	8 (44%)	13 (72%)
TEAEs by Severity Mild Moderate Severe	 5 (28%) 2 (11%) 1 (6%)	 9 (50%) 2 (11%) 2 (11%)
Any Drug-Related TEAEs	5 (28%)	9 (50%)
TEAEs of Special Interest †	0	0
Serious TEAEs	1 (6%)	3 (17%)

† hypotension, atrial fibrillation, other significant arrhythmia, resuscitated death stroke

The Phase II trial provided substantial support for advancing Levosimendan to the next stage that includes publication of results in a major cardiovascular journal, request for an end-of-Phase-II meeting with the FDA and preparation for a Phase III trial. We expect further announcements related to these milestones in the coming months as the team continues to work through the data. While it is too early to determine Phase III trial design, based on commentary and precedent we think it is likely that the six minute walk test will be the primary endpoint for a Phase III. Our best estimate is that this trial may begin in 2021. 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 based on precedent.

HELP Trial Background

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[9] patients was enrolled in the trial. In early June 2020, topline results were presented to the investment community.

HELP Trial Design

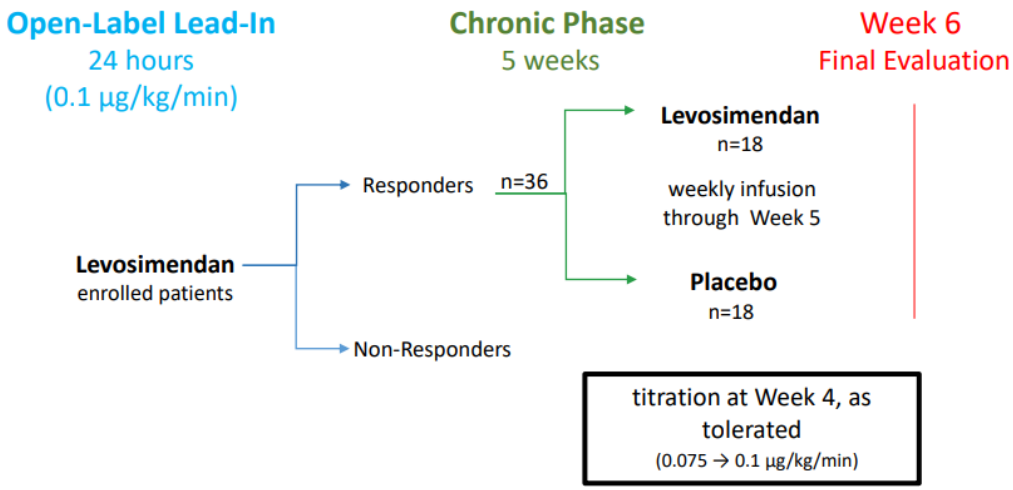
Required thresholds for inclusion in the trial were pulmonary arterial pressure (PAP) equal to or greater than 35, a pulmonary capillary wedge pressure (PCWP) equal to or greater than 20, a cardiac index (CI) of less than or equal to 2.2, a left ventricular ejection fraction (LVEF) of over 40 and NYHA 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 include: change in resting PCWP under a variety of conditions, change in resting & stressed CI, change in pulmonary vascular resistance (PVR) at rest & under stress, global assessment at week six based on the Likert scale and length of exercise period and a physician's assessment of functional class and clinical events, including death and hospitalizations.

[8] Source: Tenax Corporate Presentation for HELP trial topline, June 2, 2020.
[9] The trial originally targeted 36 patients.

Exhibit VI – Phase II Study Design[10]



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

We anticipate that 2021 will be spent preparing for a Phase III trial. During the end of Phase II meeting coming up in 4Q and armed with additional analysis from the HELP trial, we anticipate that Tenax will explore the feasibility of seeking breakthrough status or fast track authorization given the unmet need for Group II pulmonary hypertension. We have previously given 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 based on information available to date. Following consultation with the FDA, we expect to revise them.

Milestones

- Enroll First Patient – March 2019
- Full Enrollment – 1Q:20
- Last Patient, Last Visit – April 2020
- Topline data – 2Q:20
- Regain compliance with NASDAQ minimum bid requirement – June 2020
- $8 million capital raise – July 2020
- New board directors appointed – July 2020
- Presentation of data at conference – Fall/Winter 2020
- End of Phase II Meeting with FDA – 4Q:20
- Launch Phase III – 2022

Summary

The HELP trial has ended and Tenax is now seeking regulatory guidance on next steps. The strong results from this Phase II study attracted further investment from Armistice Capital, a group that may catalyze additional funding to move forward into a pivotal study. Based on management's guidance we expect an end of Phase II meeting with the FDA in the fourth quarter, after which details on the construction of a Phase III trial will be provided. Tenax has generated strong data for the PH-HFpEF indication with statistically significant results for the six minute walk test and other parameters that we think will be required in a Phase III. 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. The market is sizeable and with no other approved therapy available, pricing should be strong and penetration high. We maintain our valuation at $4.00 per share.

[10] Source: Tenax September 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.	2019 A	Q1 A	Q2 A	Q3 E	Q4 E	2020 E	2021 E	2022 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	$1.3	$0.9	$0.3	$0.2	$2.7	$3.0	$11.0
General & administration	$5.1	$1.3	$1.3	$1.3	$1.3	$5.2	$5.4	$5.6
Income from operations	($8.6)	($2.7)	($2.1)	($1.6)	($1.5)	($7.9)	($8.4)	($16.6)
Operating Margin	-					-	-	-
Interest Income (expense)	$0.0	$0.0	($0.0)	$0.0	$0.0	($0.0)	$0.0	$0.0
Other expense	($0.2)	($0.0)	($0.0)	$0.0	$0.0	($0.0)	$0.0	$0.0
Pre-Tax Income	($8.4)	($2.7)	($2.1)	($1.6)	($1.5)	($7.9)	($8.4)	($16.6)
Accrual for Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$8.4	$33.1
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*100%*	*200%*
Net Income	**($8.4)**	**($2.7)**	**($2.1)**	**($1.6)**	**($1.5)**	**($7.9)**	**($16.8)**	**($49.7)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.35)**	**($0.38)**	**($0.23)**	**($0.13)**	**($0.10)**	**($0.73)**	**($0.67)**	**($1.78)**
YOY Growth	*-69%*	*15%*	*-17%*	*-62%*	*-75%*	*-46%*	*-8%*	*165%*
Basic Shares Outstanding	6.20	6.97	9.34	12.60	14.60	10.88	25.00	28.00

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

HISTORICAL STOCK PRICE

Tenax Therapeutics, Inc. – Share Price Chart

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