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Tenax Therapeutics, Inc. (TENX-NASDAQ)

FDA Meetings for Phase 3 Design

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

Current Price (11/23/20)	$0.99
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 research supporting the use of Levo in pulmonary hypertension and its inotropic and lusitropic effects and the results from the HELP trial, 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	**$0.25**
One-Year Return (%)	**-19.7**
Beta	**2.46**
Average Daily Volume (sh)	**170,058**
Shares Outstanding (mil)	**12.6**
Market Capitalization ($mil)	**$12.4**
Short Interest Ratio (days)	**0.62**
Institutional Ownership (%)	**32.3**
Insider Ownership (%)	**0.33**
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 A	$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	-$0.18 A	-$0.10 E	-$0.79 E
2021					-$0.63 E
2022					-$1.76 E

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WHAT'S NEW

Third Quarter 2020 Financial and Operational Review

Since Tenax Therapeutics, Incorporated's (NASDAQ: TENX) second quarter update in August, the company has broadly shared the results from the **H**emodynamic **E**valuation of **L**evosimendan in **P**atients with PH-HFpEF (HELP) trial with the scientific and investment community. The most important announcement since then was the announced switch to oral levosimendan that will be used in the registrational trial. A levosimendan capsule will simplify and reduce the cost of the upcoming Phase III trial compared to infusion and also make life easier for patients who use the drug. Increased efficacy may also result as a consequence of the change as drug levels will be more consistent with a daily dose as opposed to a weekly infusion. Looking forward, Tenax will be continuing its work to design the protocol for the upcoming Phase III and consult with the FDA to obtain further guidance. We see additional details regarding anticipated trial design and start date being available some time in the second quarter after all parties have a chance to interact and review data.

Other important events during the third quarter and to date include the raise of $8.0 million in capital and the addition of 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. Tenax representatives also attended investor and scientific conferences including the Tenax Investor Webinar, H.C. Wainwright Conference, Heart Failure Society of America (HFSA) and American Heart Association (AHA) meetings.

On November 16th, Tenax filed its 3Q:20 Form 10-Q with the SEC and posted a press release providing a business update. No revenues were reported in the period and operating expenses totaled $2.2 million. Net loss per share was ($0.18) which compares to ($0.33) per share in third quarter of 2019. Third quarter research and development costs of $1.1 million rose 15% from the $0.9 million spent in the comparable 2019 period reflecting greater expenditures for the Phase II HELP study partially offset by lower consulting and other costs. General and administrative expenses totaled $1.2 million, down 13%. Lower legal and professional fees related to a dispute regarding the oral form of levosimendan in 2019 that was resolved in Tenax' favor and not repeated in 2020. This was offset by slightly higher personnel costs and other costs. Net loss was ($2.2) million or ($0.18) per share.

Cash and securities balance was $8.7 million as of September 30, 2020 and cash burn totaled ($2.4) million for 3Q:20. Cash from financing was a net $6.5 million and represented flows from a registered direct and PIPE offering.

New Directors

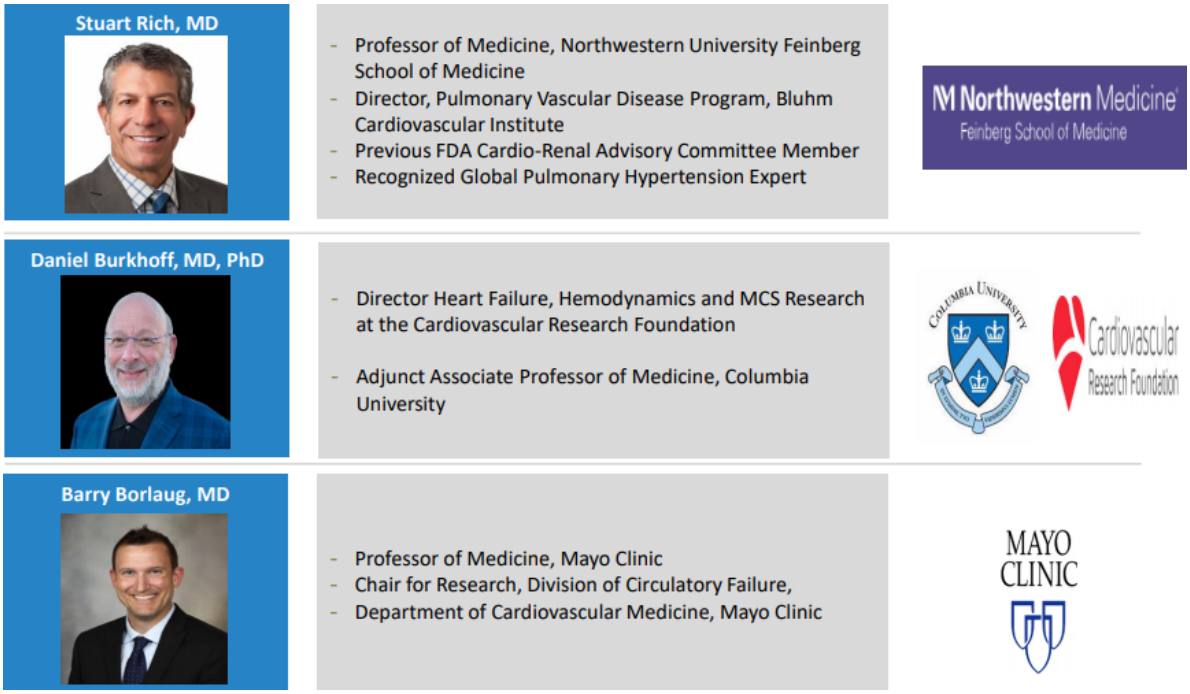
Tenax added two new directors to its board from Armistice Capital that were made in conjunction with a recent investment. They are Steven Boyd and Keith Maher, MD. Armistice participated in the July 2020 financing and joined the board of directors to help guide the company's advance as they launch a 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

Tenax Virtual R&D Webinar

Following the announcement of third quarter results, Tenax held a virtual R&D webinar to introduce new investors to and update existing investors on levosimendan and related clinical trials for PH-HFpEF[1]. The hour-long presentation was moderated by CEO, Tony DiTonno and featured pulmonary hypertension experts Drs. Stuart Rich, Daniel Burkhoff and Barry Borlaug. Dr. Rich outlined the unmet medical need in the indication while Dr. Burkhoff shared his interpretation of the HELP trial study results and Dr. Borlaug reviewed safety and efficacy data on levosimendan in PH-HFpEF. The presentation reminded investors that almost 50% of pulmonary hypertension patients are Group 2, or PH-HFpEF patients that have no treatment alternatives.

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

Exhibit I – R&D Webinar Experts[2]



The event addressed the anticipated change to an oral dose of levosimendan as opposed to the once per week infused regimen that was used in the HELP trial. This change, that is now possible through the expanded license agreement with Orion, will use a 1 mg oral dose of the drug to be used in the Phase III trial. This will eliminate many of the complexities and costs related to using an infused formulation, from the need for peripherally inserted central catheter (PICC) lines to the need for a nurse to perform the home infusion and the consistency of plasma drug levels. Work needs to be performed to identify the optimal dose and translate the data that is available in the PH-HFpEF trials and other preclinical and clinical data generated on oral levosimendan.

While the details for the Phase III trial design are not yet available, management and the scientific advisory board are consulting frequently prior to an anticipated meeting with the FDA which should happen in the next few months. We think that details on the trial structure will be available by 2Q:21, after which all of the components of the trial, such as identifying the CRO, securing trial sites and other items will be addressed.

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 (HELP). 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.

[2] Source: Tenax Virtual R&D Webinar Slide Presentation. November 18, 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.

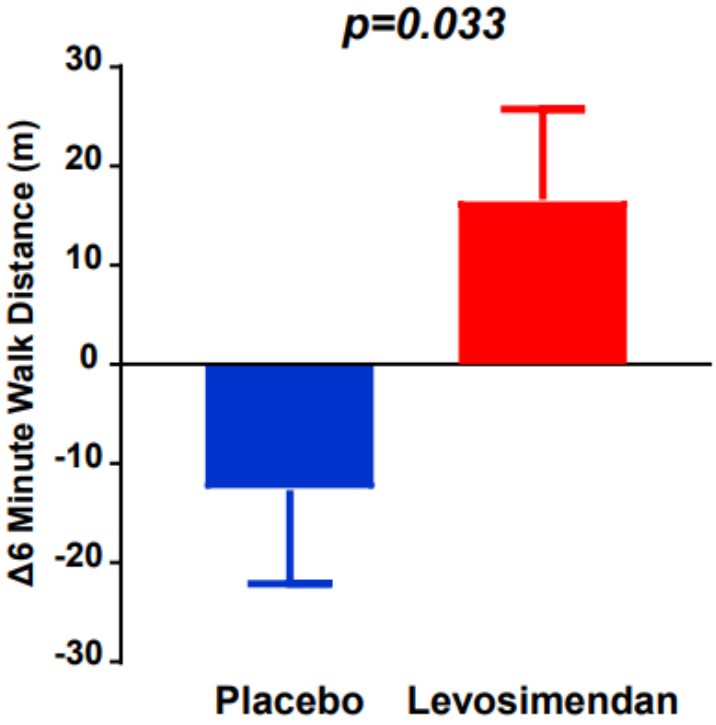
Other important measures, such as pulmonary capillary wedge pressure (PCWP) at rest, with legs up and during exercise were all directionally correct; however, the primary endpoint of PCWP during exercise was not statistically significant. These additional measures helped to provide additional detail 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

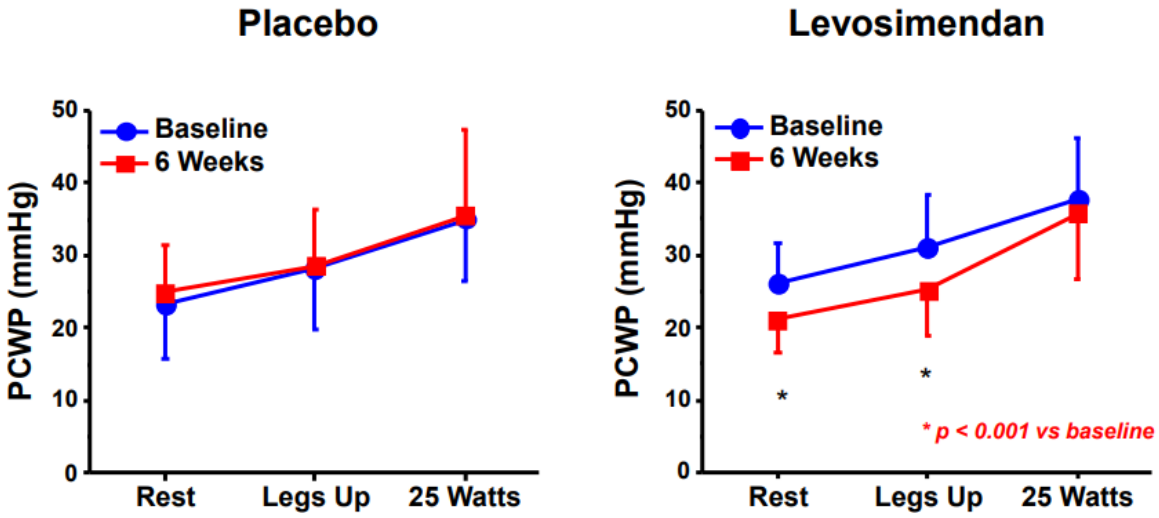
The trial's primary goal was to determine safety for extended use of Levosimendan, to further determine the mechanism of action of the drug and to help inform the design for Phase III. Other secondary measures that were obtained in this effort include right atrial pressure (RAP) and mean pulmonary arterial 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.

Exhibit III – Levo Effects on Six Minute Walk Test[6]



[4] Author's own work and data provided by Tenax.
[5] The is the average of systolic and diastolic pressures.
[6] Source: Tenax Virtual R&D Webinar Slide Presentation. November 18, 2020.

Exhibit IV – Comparison of HELP Endpoints[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.

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	5 (28%)	9 (50%)
Moderate	2 (11%)	2 (11%)
Severe	1 (6%)	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 prepatory work will take place in 2021 and first patients will be enrolled in 2022. A rough estimate of time, cost and size of the registrational trial range from 18 to 36 months, $30 to $50

[7] Source: Tenax Virtual R&D Webinar Slide Presentation. November 18, 2020.
[8] Source: Tenax Corporate Presentation for HELP trial topline, June 2, 2020.

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.

Looking Forward

During the upcoming end of Phase II meeting, 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.

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 / 1Q:20
- Finalize Phase III Trial Design – 2Q:21
- Prepare for Launch of Trial – 2H:21
- Launch Phase III – 2022

Summary

The HELP trial has ended and Tenax is now seeking regulatory guidance on next steps required to begin the Phase III. HELP's encouraging results have 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 next few months, 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 new development since our previous update is the shift to oral levosimendan that is expected for the Phase III trial which may address several shortcomings of infused administration and dramatically simplify both the trial and ultimate patient use of the drug. We maintain our valuation of $4.00 per share.

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2019 A	Q1 A	Q2 A	Q3 A	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	$1.1	$0.2	$3.5	$2.8	$11.0
General & administrative	$5.1	$1.3	$1.3	$1.2	$1.3	$5.1	$5.0	$5.4
Income from operations	($8.6)	($2.7)	($2.1)	($2.2)	($1.5)	($8.5)	($7.8)	($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	($0.2)	($0.0)	($0.0)	($0.0)	$0.0	($0.0)	$0.0	$0.0
Pre-Tax Income	($8.4)	($2.7)	($2.1)	($2.2)	($1.5)	($8.5)	($7.8)	($16.4)
Accrual for Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$7.8	$32.9
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*100%*	*200%*
Net Income	**($8.4)**	**($2.7)**	**($2.1)**	**($2.2)**	**($1.5)**	**($8.5)**	**($15.7)**	**($49.3)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.35)**	**($0.38)**	**($0.23)**	**($0.18)**	**($0.10)**	**($0.79)**	**($0.63)**	**($1.76)**
YOY Growth	*-69%*	*15%*	*-17%*	*-46%*	*-75%*	*-42%*	*-20%*	*181%*
Basic Shares Outstanding	6.20	6.97	9.34	12.43	14.60	10.84	25.00	28.00

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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