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Tenax Therapeutics, Inc. (TENX-NASDAQ)

1Q:21 Results

Based on our DCF model and a 15% discount rate, Tenax is valued at approximately $4.50 per share. We apply a combined 40% probability of eventual sales of levosimendan in the United States and of imatinib globally.

Current Price (5/24/21)	$1.89
Valuation	**$4.50**

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 completed its Ph2 PH-HFpEF trial in 2020 and should start a Ph3 in 2022. In January 2021, Tenax merged with PH Precision Med bringing Ph3-ready imatinib for PAH in house.

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, its inotropic and lusitropic effects and the results from the HELP trial, there is sufficient support to support a Ph3 trial in PH-HFpEF. Additionally, this is a materially sized market with no effective therapy available, which provides substantial pricing and penetration opportunity.

SUMMARY DATA

52-Week High	**$3.68**
52-Week Low	**$0.80**
One-Year Return (%)	**60.2**
Beta	**2.41**
Average Daily Volume (sh)	**1,310,788**
Shares Outstanding (mil)	**15.0**
Market Capitalization ($mil)	**$28.4**
Short Interest Ratio (days)	**0.12**
Institutional Ownership (%)	**25.4**
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)
2020	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2021	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2022					$0.0 E
2023					$0.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.38 A	-$0.23 A	-$0.18 A	-$0.12 A	-$0.95 A
2021	-$1.64 A	-$0.13 E	-$0.12 E	-$0.12 E	-$1.75 E
2022					-$0.56 E
2023					-$0.81 E

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WHAT'S NEW

First Quarter 2021 Financial and Operational Review

Tenax Therapeutics, Inc. (NASDAQ: TENX) reported first quarter 2021 results via the issuance of a press release and the filing of Form 10-Q the SEC on May 17, 2021.

Highlights for the first quarter and to-date:

- Acquisition of PH Precision Med - January 2021
- Board additions: Drs. June Almenoff, Michael Davidson, Delcan Doogan and Stuart Rich - March 2021
- Publication of HELP trial results - April 2021

Tenax did not generate revenues during 1Q:21 and incurred operating expenses of $23.7 million resulting in net loss of $23.7 million, or ($1.64) per share.

For the quarter ending March 31, 2021 versus the quarter ending March 31, 2020:

- General and administrative expenses rose 4% to $1.37 million from $1.32 million as increases in personnel costs and legal and professional fees were partially offset by decreases in other costs;
- Research and development expenses rose 1,572% to $22.4 million from $1.34 million, driven by $21.7 million in recognition of in-process research and development (IPR&D) acquired from the merger with PHPM. This increase was partially offset by a $782,000 decrease in clinical and preclinical development costs, namely CRO and patient enrollment costs related to the HELP trial. Excluding the expensed $21.7 million IPR&D from PHPM, R&D was $644,000, down 52%.
- Net loss was ($23.7) million versus ($2.66) million, or ($1.64) and ($0.38) per share, respectively. Excluding the impacts of the IPR&D, loss for the quarter was ($2.0) million or ($0.14) per share.

At the end of the first quarter, cash, equivalents and marketable securities totaled $4.0 million, compared to $6.7 million at the end of 2020. Tenax continues with no debt on its balance sheet, other than the Paycheck Protection Program loan for $245 thousand. Loan service is deferred until September 2021 and the balance may be forgiven. Cash burn for the quarter amounted to $3.2 million. Management has guided that cash reserves are sufficient to sustain the firm through 3Q:21.

HELP Trial Results

In June 2020, 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. HELP is the first study conducted in PH-HFpEF patients to show material positive improvements in hemodynamics and 6-minute walk distance. The distance for the six minute walk test,[1] 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. We discussed the details of this trial in a previous report.

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.

End-of-Phase II Meeting with FDA

In October 2020, Tenax met with the FDA for an end-of-phase II meeting to discuss Phase II HELP trial data. The FDA agreed that one or two Phase III trials, depending on size, with primary endpoint of change in 6-minute walk distance over 12 weeks or a single Phase III trial with clinical worsening over 24 weeks would be sufficient to demonstrate efficacy. The FDA also gave the nod to replacing IV levosimendan with oral in Phase III. The FDA

[1] 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.

expressed concern regarding the necessity of a safety database, which should be addressed as Phase III protocol is finalized and submitted.

Next Steps

Tenax plans to switch from infused to oral levosimendan in patients who participated in the open-label extension of the HELP study, who continue treatment and remain eligible to participate in the HELP study amendment. The next regulatory meeting will likely be held in 2H:21. The additional meeting with the FDA is necessary to report on results related to the shift to oral from infused levosimendan. In parallel with the crossover work with the oral dosage, Tenax is identifying sites for the upcoming Phase III with some already contracted. The institutional review boards (IRBs) are granting approvals at the sites and preparation for registrational studies is advancing as expected.

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 continued preparatory 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 million and 200 to 300 patients. While these estimates have not been confirmed by the company, we believe they are reasonable based on precedent.

Additions to the Board

Tenax added four new members to its board of directors, which was announced on March 2nd, 2021. The new directors included June Almenoff, MD, Ph.D., Michael Davidson, MD, Delcan Doogan, MD, and Stuart Rich, MD, who was recently appointed the company's Chief Medical Officer.

Dr. Almenoff brings over 20 years of senior leadership experience in the biopharma space. She served as President and Chief Medical Officer of Furiex Pharmaceuticals, which was acquired by Actavis (now AbbVie), and held various ascending positions at GlaxoSmithKline for 12 years. Dr. Almenoff is currently Chief Scientific Officer of RedHill Biopharma (NASDAQ: RDHL) and also serves on the investment advisory board of Harrington Discovery Institute and on the boards of Brainstorm Cell Therapeutics (NASDAQ: BCLI) and Kurome Therapeutics. Dr. Almenoff received her bachelor's from Smith College and graduated with AOA honors from the MD-Ph.D. program at Mount Sinai School of Medicine, completing post-graduate medical training at Stanford University Medical Center.

Dr. Michael Davidson was founder and former Chief Scientific Officer of Corvidia Therapeutics, which was acquired by Novo Nordisk. He is Clinical Professor and Director of the Lipid Clinic at the University of Chicago Pritzker School of Medicine. Dr. Davidson co-founder and Chief Medical Officer of Omthera Pharmaceuticals, acquired by AstraZeneca Pharmaceutical. He also founded the Chicago Center for Clinical Research that was acquired by Pharmaceutical Product Development. Dr. Davidson received his bachelor's and master's from Northwestern University and MD from Ohio State University School of Medicine.

Dr. Declan Doogan adds over 30 years of pharma and biotech industry experience. He served as Senior Vice President and Head of Worldwide Development at Pfizer and held positions at Pfizer in the US, UK and Japan. Dr. Doogan also held positions as CMO and acting CEO of Amarin (NASDAQ: AMRN) and is Chairman and co-founder of Biohaven (NYSE: BHVN). He serves on a number of Board appointments and received his MD from Glasgow University.

On April 7, three long-serving directors elected to step down. Ronald R. Blanck, D.O., Gregory Pepin and Chris A. Rallis will depart their posts on the Board of Directors of Tenax Therapeutics, effective as of the Annual Meeting of Stockholders scheduled for June 10, 2021.

Exhibit I – Change in Board of Directors Composition[2]

2020 Board	Interim Board	Refreshed Board
Dr. Ronald Blank (Chairman)	Dr. Ronald Blank (Chairman)	Gerald Proehl (Chairman)
Anthony DiTonno	Anthony DiTonno	Anthony DiTonno
Steven Boyd	Dr. June Almenoff	Dr. June Almenoff
Dr. Keith Maher	Steven Boyd	Steven Boyd
James Mitchum	Dr. Michael Davidson	Dr. Michael Davidson
Gregory Pepin	Dr. Declan Doogan	Dr. Declan Doogan
Gerald Proehl	Dr. Keith Maher	Dr. Keith Maher
Chris A. Rallis	James Mitchum	James Mitchum
	Gregory Pepin	Dr. Stuart Rich
	Gerald Proehl	
	Chris A. Rallis	
	Dr. Stuart Rich	

PH Precision Med Acquisition

On January 19, 2021, Tenax announced the acquisition, through merger with wholly owned subsidiary Life Newco II, of privately held, clinical stage PH Precision Med (PHPM). The transaction was completed on January 15, 2021, in an equity deal valued at approximately $21.6 million, which we discuss here. PHPM's shareholders were issued the equivalent of 12.124 million equity shares as consideration for the deal, comprised of 1,892,905 shares of Tenax common stock, representing ~15% of Tenax' shares outstanding, and 10,232 shares of Class B Preferred Stock, which convert to 10,232,000 shares of common stock, pending stockholder approval. Tenax is required to hold a stockholder meeting no later than July 31, 2021 to obtain stockholder approval. If not approved, meetings will be held every 90 days to seek approval until either approved or the convertible preferred stock is no longer outstanding. Based on the closing price of Tenax on January 18, 2021 of $1.78, the acquisition is valued at approximately $21.6 million.

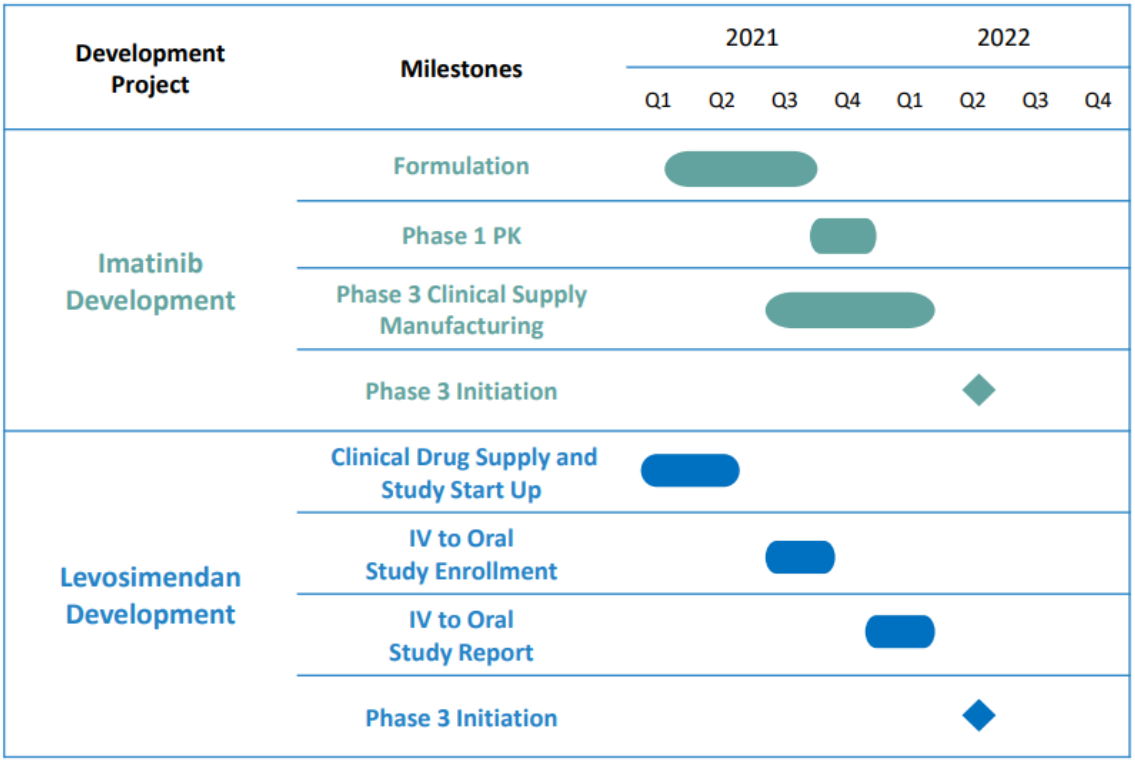
To add detail to Tenax' recent acquisition of PH Precision Med and its candidate imatinib, Tenax hosted a web conference on January 21, 2021, a few days after the acquisition was announced. We discuss the specifics of the deal, provide background on imatinib and its use in PAH and review existing therapies for the indication in a previous report. Efforts are now underway to identify a formulation of the drug using an enteric coating to address GI-related side effects that were identified in previous trials. A Phase I study testing the new formulation is expected to be conducted in 2H:21.

Milestones

- HELP Topline data – June 2020
- End of Phase II Meeting with FDA – October 2020
- Acquisition of PHPM – January 2021
- Finalize PH-HFpEF Phase III Trial Design – 2021
- PK and formulation work for imatinib in PAH – 2H:21
- Phase I trial for imatinib in PAH – 2H:21
- Launch Phase III PH-HFpEF Trial – 1H:22
- Site selection and enrollment for imatinib PH trial - 2022
- Launch Phase III in PH-HFpEF – 2022
- Imatinib PH trial topline report – 2024
- Completion of Phase III in PH-HFpEF - 2024

[2] Compiled by Zacks Analysts

Exhibit II – Projected Development Timelines[3]



Summary

The HELP trial has ended and Tenax is now seeking regulatory guidance on next steps required to begin the Phase III portion of development. 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. 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 PAH update report, 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 addition of PHPM and its Phase III ready asset drove our price increase along with the successful outcome of the HELP trial. We now look forward to prepatory work required before Phase III studies can begin in select PAH indications. We maintain our valuation to $4.50 per share.

[3] Source: Tenax Therapeutics February 2021 Corporate Presentation

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2020 A	Q1 A	Q2 E	Q3 E	Q4 E	2021 E	2022 E	2023 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth	*0%*					*0%*	*0%*	*200%*
Research and development	$4.6	$22.4	$0.7	$1.2	$1.2	$25.5	$11.0	$19.5
General & administrative	$5.3	$1.4	$1.3	$1.3	$1.3	$5.3	$5.7	$5.9
Income from operations	($9.9)	($23.7)	($2.0)	($2.5)	($2.5)	($30.7)	($16.7)	($25.4)
Operating Margin	-					-	-	-
Interest Income (expense)	($0.0)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	($0.0)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($9.9)	($23.7)	($2.0)	($2.5)	($2.5)	($30.7)	($16.7)	($25.4)
Accrual for Income Taxes	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($9.9)**	**($23.7)**	**($2.0)**	**($2.5)**	**($2.5)**	**($30.7)**	**($16.7)**	**($25.4)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.95)**	**($1.64)**	**($0.13)**	**($0.12)**	**($0.12)**	**($1.75)**	**($0.56)**	**($0.81)**
YOY Growth	*-30%*					*84%*	*-68%*	*45%*
Basic Shares Outstanding	10.37	14.52	15.00	20.20	20.56	17.57	30.00	31.50

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

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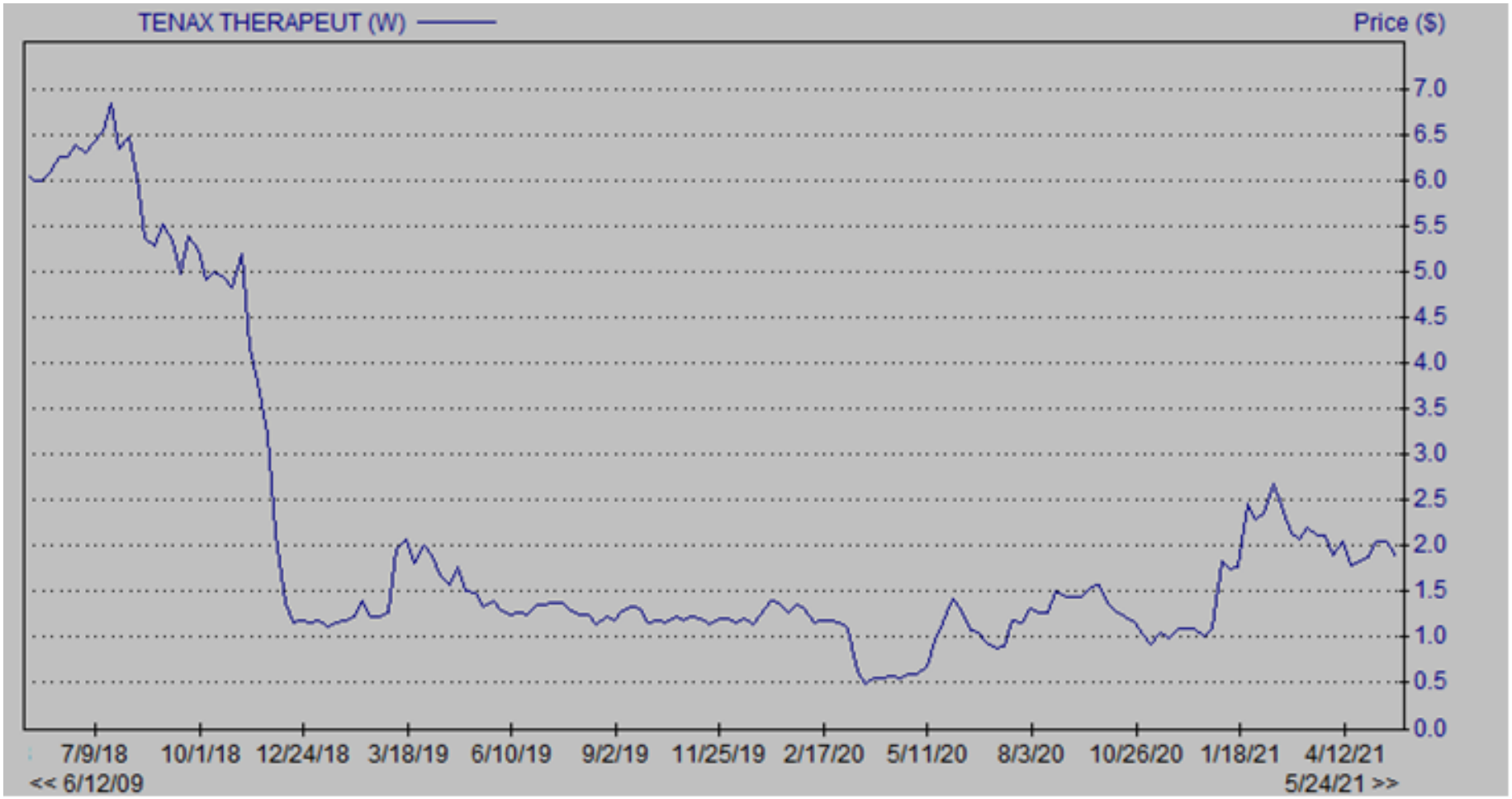
HISTORICAL STOCK PRICE

Tenax Therapeutics, Inc. – Share Price Chart



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