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Tenax Therapeutics, Inc. (TENX: NASDAQ)

Walking Further with Levo

Based on our DCF model and a 15% discount rate, Tenax is valued at approximately $4.00 per share. We apply a combined 40% probability of eventual sales of levosimendan in the United States and of imatinib globally.

Current Price (5/18/2022)	$0.68
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 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 evidence 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	**2.30**
52-Week Low	**0.50**
One-Year Return (%)	**-65.2**
Beta	**2.0**
Average Daily Volume (sh)	**37,214**
Shares Outstanding (mil)	**35.8**
Market Capitalization ($mil)	**24.3**
Short Interest Ratio (days)	**0.49**
Institutional Ownership (%)	**38.5**
Insider Ownership (%)	**36.2**
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 2022 Estimate	**N/A**
P/E using 2023 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 US$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2022	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2023					$0.0 E
2024					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$1.64 A	-$0.10 A	-$0.15 A	-$0.13 A	-$1.58 A
2022	-$0.11 A	-$0.09 E	-$0.12 E	-$0.11 E	-$0.44 E
2023					-$0.53 E
2024					-$0.46 E

WHAT'S NEW

1Q:22 Financial and Operational Review

Tenax Therapeutics, Inc. (NASDAQ: TENX) reported first quarter 2022 results on May 16, 2022 via its filing of Form 10-Q with the SEC. The company provided no updates since the full year report released at the end of March; however, on March 18, the company announced a much needed cash infusion from an $8 million PIPE offering. On June 2nd, Tenax will hold a KOL event in conjunction with LifeSci advisors to discuss the treatment landscape and unmet need in pulmonary arterial hypertension. Even with abnormally low probabilities of success applied to the potential for the company's two development products in PAH, levosimendan and imatinib, the upside for these products and ability to address a material unmet need is tremendous if dilution concerns can be addressed.

Highlights for 2022 include:

- TNX-102 patent allowed by USPTO - January 2022
- Transition to oral levosimendan open label extension completed - January 2022
- Formation of Scientific Advisory Board (SAB) - January 2022
- US patent granted for subcutaneous TNX-102 (levosimendan) - January 2022
- Robyn Hunter appointed to Board - January 2022
- $8 million PIPE offered at the market – May 2022

Tenax produced no revenues in 1Q:21 and incurred operating expenses of $2.7 million resulting in net loss of ($2.7) million, or ($0.11) per share.

For the quarter ended March 31, 2022 versus the same ended March 31, 2021:

- General and administrative rose 12% to $1.5 million compared to $1.4 million primarily due to increases in legal fees due to the outsourcing of this function, and higher costs for insurance, and administrative expense, partially offset by lower personnel costs due to lower headcount;
- Research and development expenses fell 95% to $1.2 million from $22.4 million as $21.8 million in in-process R&D expense was recognized in the prior year period related to PHPM which was not repeated. Other components of R&D were up on a year over year basis including clinical and preclinical development costs due to ongoing clinical trials and formulation work for imatinib. Personnel costs also rose on a year over year basis related to the hiring of a new Chief Medical Officer;
- Net loss was ($2.7) million versus ($23.7) million, or ($0.11) and ($1.64) per share, respectively.

At the end of the quarter, cash and equivalents totaled $2.9 million, compared to $5.6 million at the end of 2021. During the quarter, Tenax issued an 8-month, $365,000 note to Premium Funding Associates, which it is already in the process of repaying. On May 18, 2022, Tenax announced an $8 million raise from the sale of 10.6 million units of pre-funded and other warrants.

$8 Million PIPE Offered

On May 18th Tenax announced an $8 million private investment in public equity (PIPE) that is expected to raise $8 million from the sale of 10,596,027 units at $0.755 per unit. Each unit consists of a pre funded warrant exercisable at $0.0001 and one warrant with an exercise price of $0.63. Both warrants are immediately exercisable. The pre-funded warrant is perpetual and the $0.63 strike price warrants offer a duration of 5.5 years. Proceeds will support research and development activities for levosimendan and imatinib as well as general corporate purposes.

Certain warrants issued by the company over the last several years were modified to reduce the exercise price to $0.63 and extend their term by two years.

American College of Cardiology Scientific Sessions

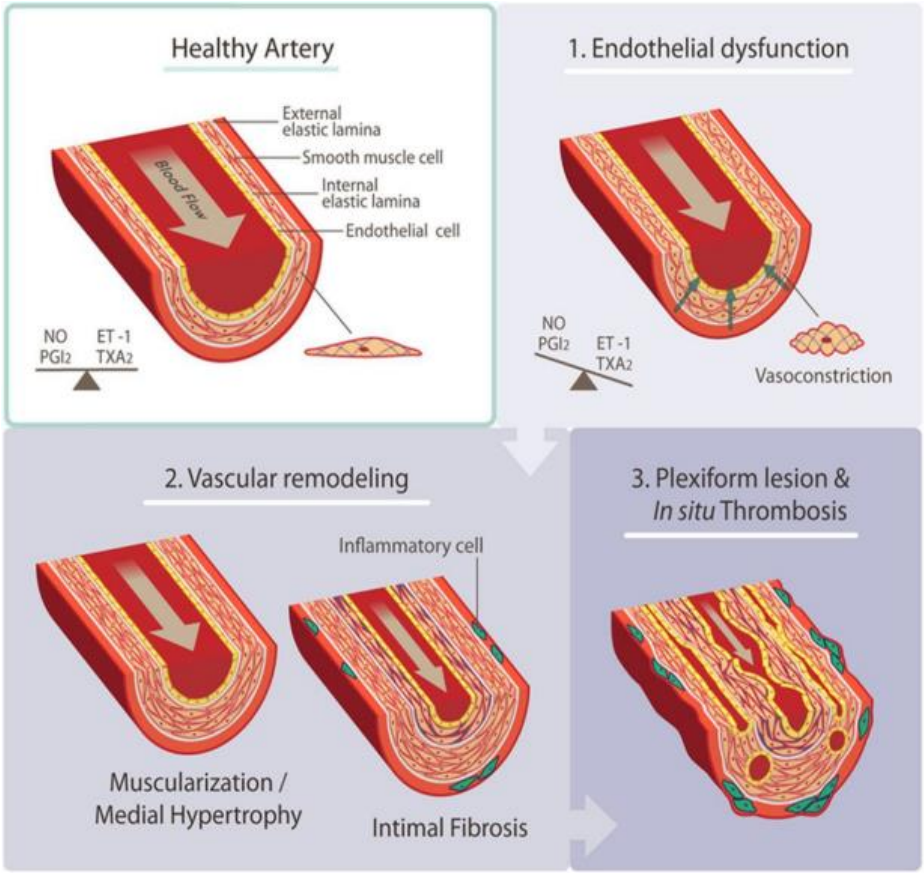
Tenax announced that drug candidates levosimendan and imatinib would be featured at the American College of Cardiology (ACC) Scientific Sessions on April 3rd and 4th. Tenax' scientific advisory board member Barry Borlaug, MD shared data from the Phase II HELP trial[1] in a presentation entitled "Helping PH-HFpEF Patients Walk Further with Levosimendan." His presentation will be part of the session "A Whole New World in Pulmonary Hypertension: Randomized Clinical Trial Updates For 2022" held April 3rd. Professor Stuart Rich, Tenax' Chief Medical Officer, presented on April 4th at the "Back to the Future: Old Drugs with a New Purpose in PAH" session. Dr. Rich's address is called "Next-generation Tyrosine Kinase Inhibitors for PAH" where he will review the mechanisms underlying the TKI class.

Clinical Asset Update

On January 4, 2022, Tenax provided an update on TNX-102 (subcutaneous levosimendan), TNX-103 (oral levosimendan) and TNX-201 (enteric-coated imatinib in PAH).

Tenax received a Notice of Allowance from the USPTO[2] for patent number 11,213,524, Pharmaceutical Compositions for Subcutaneous Administration of Levosimendan (TNX-102) in early January. The patent covers subcutaneous administration of levosimendan for treatment of health conditions of any kind. On January 12th, Tenax announced that the patent had been granted, confirmed that it will offer protection through the end of 2039 and will be eligible for patent term extension. A Canadian patent of the same name, titled: Pharmaceutical compositions for subcutaneous administration of levosimendan is pending approval.

Exhibit I – Narrowing of Pulmonary Artery in PAH[3]



Tenax also announced the completion of the IV to oral levosimendan transition (TNX-103) for patients currently enrolled in the open label extension rollover study (TNX-LVO-05) who advanced from the Phase II HELP trial. The goal of the extension was to determine the safety and tolerability of oral levosimendan and establish an oral dose

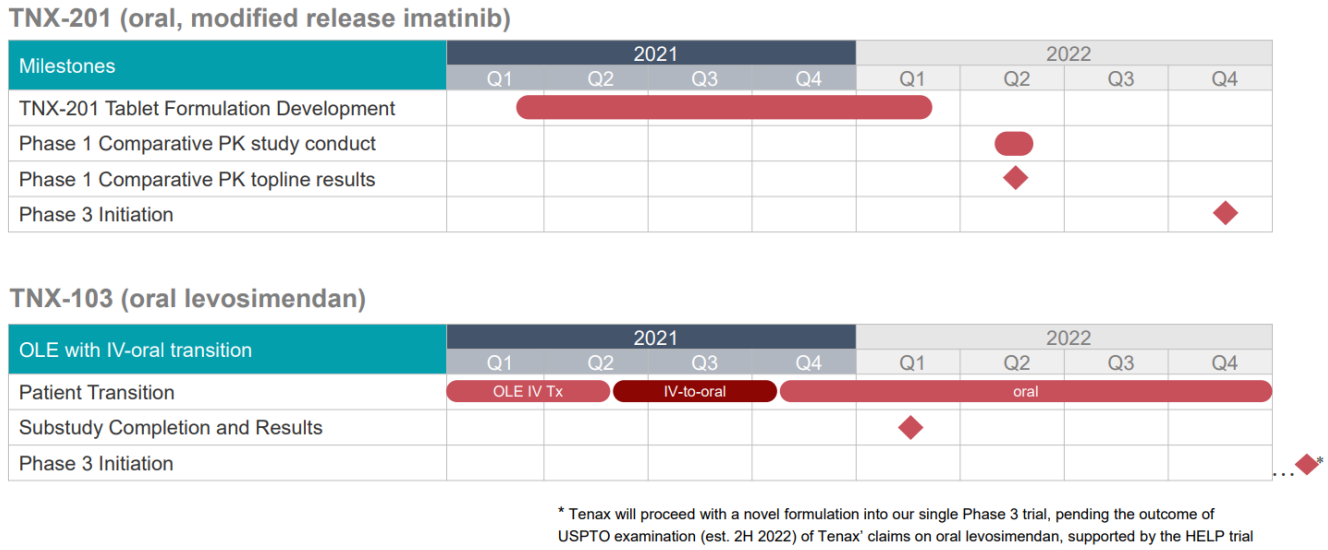
[1] Discussion of HELP trial in our report here.
[2] US Patent and Trademark Office
[3] Source: March 2022 Tenax Corporate Presentation

that would maintain its efficacy. All patients in the extension successfully shifted from IV to oral without any unexpected safety issues or serious drug related adverse events. Data from the extension confirms that oral levosimendan, when dosed at 3-4 mg per day, was safe, well-tolerated, and maintained the efficacy of IV levosimendan therapy in PH-HFpEF patients. Multiple measures of efficacy confirmed that oral levosimendan is comparable or possibly more effective than the weekly IV regimen in this group of patients.

Tenax updated investors on its TNX-201 (enteric-coated imatinib in PAH) program. The pharmacokinetic (PK) assessment in healthy volunteers has been completed. The PK study assessed imatinib versus its enteric-coated formulation to help ensure optimal efficacy and tolerance in its upcoming Phase III trial, anticipated to start in 2H:22. Tenax also announced that it had selected a large, global contract research organization (CRO) partner, which has successfully completed over 20 PAH projects including multiple Phase III trials. Key Opinion Leader (KOL) and site engagement is expected to commence early this year.

To conclude the announcement, Tenax reported the formation of a Scientific Advisory Board for imatinib, chaired by Dr. Anna Hemnes of Vanderbilt University and including Dr. Robert Frantz of the Mayo Clinic, Dr. Bradley Maron of Harvard University, and Dr. John Ryan of the University of Utah. The members are globally renowned scientists with deep experience in PAH clinical trials as well as translational science in pulmonary vascular disease.

Exhibit II – Tenax Development Timelines[4]



* Tenax will proceed with a novel formulation into our single Phase 3 trial, pending the outcome of USPTO examination (est. 2H 2022) of Tenax' claims on oral levosimendan, supported by the HELP trial

Robyn Hunter Appointed to Board

On January 31, 2021, Tenax announced that Robyn Hunter had been appointed to its Board of Directors and will chair the Board's audit and compliance committee, effective January 28th. Ms. Hunter currently serves as the Chief Financial Officer of Fortress Biotech, Inc., having served from 2011 to 2017 as its Vice President and Corporate Controller. Prior to joining Fortress Biotech, she served as Senior Vice President and Chief Financial Officer of Schochet Associates, Inc. from 2006 to 2011. From 2004 to 2006, Ms. Hunter served as the Corporate Controller for Indevus Pharmaceuticals, Inc., and earlier in her career, Ms. Hunter held several positions from Accounting Manager to Vice President and Treasurer of The Stackpole Corporation. Hunter holds a B.A. in Economics from Union College.

[4] Source: Tenax Therapeutics March 2022 Corporate Presentation

Milestones

- Site selection and enrollment for imatinib PAH trial - 1H:22
- KOL event – June 2nd, 2022
- Phase I comparative PK study for enteric imatinib topline readout – Summer 2022
- Launch Phase III imatinib in PAH - 2H:22
- Launch Phase III levosimendan in PH-HFpEF - 2023
- Imatinib PH trial topline report - 2024
- Completion of Phase III in PH-HFpEF – 2024

Summary

Tenax reported first quarter results on May 16th. Following the report, a much needed $8 million PIPE was announced, which was priced at $0.755 per unit and included a prefunded and a $0.63 strike warrant. Tenax produced no revenues in the quarter and incurred a net loss of ($2.7) million, or ($0.11) per share.

Highlights for 2022 include patent allowance by the USPTO, completion of transition to oral levosimendan, formation of a SAB, a board appointment and capital raise. We are eager to addend the upcoming KOL event on June 2nd which will feature four PAH experts to discuss imatinib and treatment of PAH.

We continue to see tremendous opportunity with Tenax with two candidates that may provide a material improvement in multiple groups of PAH. Tenax is a bright spot in our coverage universe with substantial upside and limited competition in the PAH areas its candidates are targeting. We adjust our target price to reflect the anticipated issuance of shares related to the $8 million PIPE and offer a valuation of $4.00 per share.

PROJECTED FINANCIALS

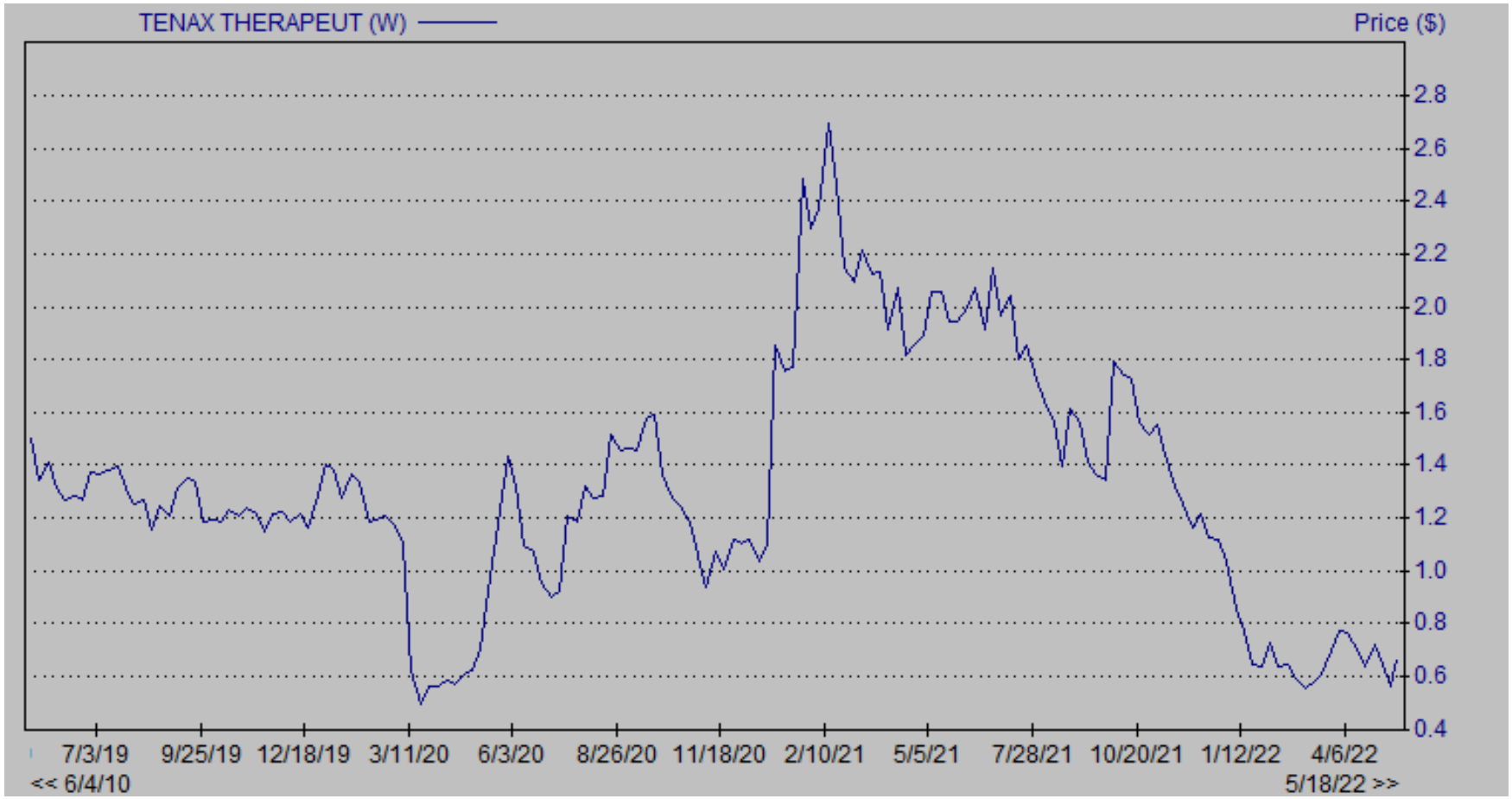
Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2021 A	Q1 A	Q2 E	Q3 E	Q4 E	2022 E	2023 E	2024 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%*	
Research and development	$25.1	$1.2	$1.2	$2.4	$3.0	$7.8	$19.5	$20.0
General & administrative	$7.6	$1.5	$1.3	$2.0	$2.2	$7.0	$7.0	$7.5
Income from operations	($32.7)	($2.7)	($2.5)	($4.4)	($5.2)	($14.8)	($26.5)	($27.5)
Operating Margin	-					-	-	-
Interest Income (expense)	($0.0)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	($0.3)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($32.5)	($2.7)	($2.5)	($4.4)	($5.2)	($14.8)	($26.5)	($27.5)
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	**($32.5)**	**($2.7)**	**($2.5)**	**($4.4)**	**($5.2)**	**($14.8)**	**($26.5)**	**($27.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($1.58)**	**($0.11)**	**($0.09)**	**($0.12)**	**($0.11)**	**($0.44)**	**($0.53)**	**($0.46)**
YOY Growth	*66%*					*-72%*	*19%*	*-14%*
Basic Shares Outstanding	20.58	25.21	26.40	35.82	46.00	33.36	50.00	60.00

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

HISTORICAL STOCK PRICE

Tenax Therapeutics, Inc. – Stock Price Chart[5]



[5] Source: Zacks Research System

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