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Tenax Therapeutics, Inc. (TENX - NASDAQ)

TNX-103 & TNX-201 Near Ready for Phase III

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 (1/4/2022)	$1.01
Valuation	**$4.50**

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.

OUTLOOK

SUMMARY DATA

52-Week High	**3.68**
52-Week Low	**0.94**
One-Year Return (%)	**-44.8**
Beta	**2.06**
Average Daily Volume (sh)	**94,225**
Shares Outstanding (mil)	**25.2**
Market Capitalization ($mil)	**25.4**
Short Interest Ratio (days)	**2.44**
Institutional Ownership (%)	**30.6**
Insider Ownership (%)	**34.2**
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 2021 Estimate	**N/A**
P/E using 2022 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Instruments**

ZACKS ESTIMATES

Revenue

(In millions of US$)

	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 A	$0.0 A	$0.0 E	$0.0 E
2022					$0.0 E
2023					$0.0 E

Earnings per Share

	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	-$0.10 A	-$0.15 A	-$0.15 E	-$1.61 E
2022					-$0.56 E
2023					-$0.81 E

WHAT'S NEW

Clinical Program Update

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

Tenax has received a Notice of Allowance from the USPTO[1] for subcutaneous administration of levosimendan (TNX-102). The patent is expected to be issued in January 2022 and will cover subcutaneous administration of levosimendan for treatment of health conditions of any kind. If granted, the patent would expire at end of 2039, assuming no patent term extension. A Canadian patent of the same name, titled Pharmaceutical compositions for subcutaneous administration of levosimendan is pending approval.

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 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 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.

FDA Clears IND for Imatinib in PAH

See our April 9th report for background on imatinib. The asset was acquired as part of Tenax' purchase of PH Precision Med (PHPM), completed on January 15, 2021 in a deal valued at approximately $21.6 million. Dr. Stuart Rich, a globally recognized expert in the field of pulmonary arterial hypertension (PAH), founded PHPM to support the development of imatinib. Imatinib, a tyrosine kinase inhibitor, offers a different mechanism of action in contrast to other failed pulmonary vasodilators. While the compound has only been clinically evaluated once in PAH, imatinib is a relatively mature TKI that has been approved in a number of indications with the first in chronic myeloid leukemia. The drug was originally discovered in 1992 by Brian Druker, who sought a drug that, rather than be non-specifically cytotoxic, targeted the cancer itself.

In 2001[2] Novartis commercialized imatinib in leukemia as Gleevec, and in 2015 the drug generated $4.6 billion in sales before patent expiry in 2016. Novartis launched multiple trials for imatinib in PAH and by 2013, had advanced the candidate as far as Phase III, when unforeseen dropouts attributable to gastric intolerance sidetracked further advancement. Despite some favorable results, Novartis did not re-initiate studies in PAH, likely due to pending patent expiry, as imatinib was already a commercial success for Novartis in leukemia.

Imatinib is potentially the first disease modifying agent in PAH. Due to the GI issues observed in Novartis' unsuccessful Phase III and prior to Tenax' acquisition, a reformulation of oral imatinib was proposed to bypass the stomach and release the drug in the small intestine. A Phase I PK study is underway for the new formulation. Based on

[1] US Patent and Trademark Office
[2] https://www.hcp.novartis.com/products/gleevec/gleevechcp/

consultations with the FDA, Tenax management believes only one successful Phase III trial will be necessary to obtain market approval.

On October 6, 2021, Tenax announced that the FDA had cleared Tenax' IND application for a novel (oral) formulation of imatinib. The PK study compared the original formulation to the new oral formulation that is designed to address challenges that Novartis faced, bypassing the stomach and associated gastric discomfort. In the most recent January 2022 press release, Tenax announced that it anticipates starting the Phase III imatinib trial in 2H:22.

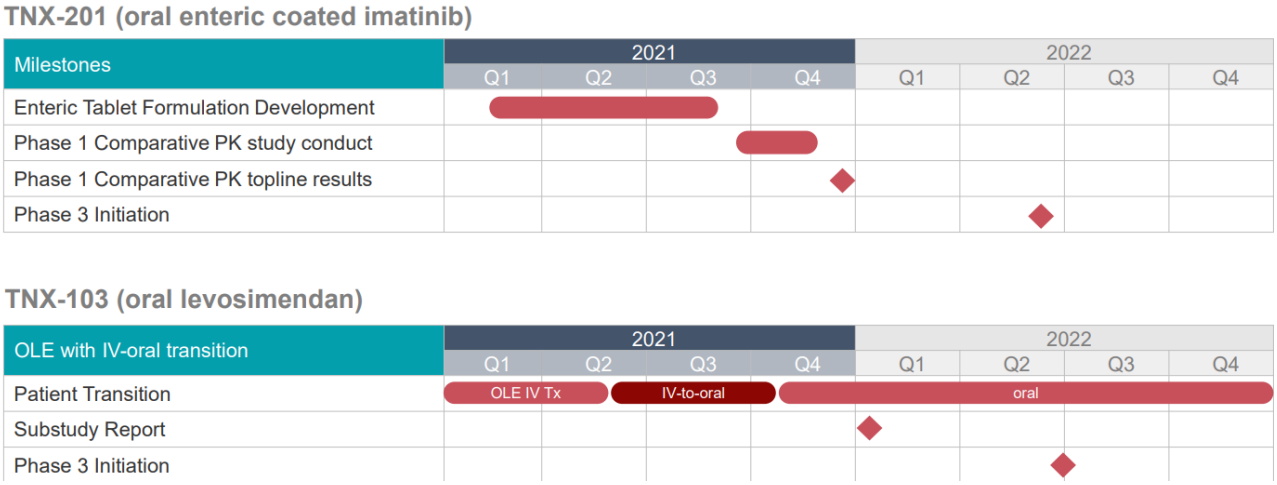
Interview with Tenax CEO and CMO

On October 7, 2021, Zacks' analyst John Vandermosten interviewed Tenax' Chief Executive Officer, Chris Giordano and Chief Medical Officer, Dr. Stuart Rich. The replay from the interview is available here. The interview discussed background on the pulmonary hypertension market, Tenax' two candidates, levosimendan and imatinib, and longer term prospects for the programs.

Exhibit I - Tenax Interview[3]

[3] TENX Interview - YouTube

Exhibit II – Tenax Development Timelines[4]



Milestones

- HELP Topline data - June 2020
- End of Phase II Meeting with FDA - October 2020
- Acquisition of PHPM - January 2021
- FDA clearance of IND for imatinib (TNX-201) in PAH - October 2021
- Initiation of Phase I PK trial for imatinib in PAH - October 2021
- PK and formulation results for imatinib in PAH - 4Q:21
- Site selection and enrollment for imatinib PAH trial - 1H:22
- Launch Phase III imatinib in PAH - 2H:22
- Launch Phase III levosimendan in PH-HFpEF - 2022
- Imatinib PH trial topline report - 2024
- Completion of Phase III in PH-HFpEF - 2024

Summary

Tenax updated investors on progress with its clinical assets 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 for TNX-102 with patent expected to be issued in January 2022 and anticipated expiry in 2039. Tenax also announced the completion of patient transition from the Phase II HELP study to the open-label extension where multiple measures of efficacy confirmed that oral levosimendan is comparable or even possibly more effective than the weekly IV regimen. Tenax also updated investors regarding TNX-201 announcing that the PK assessment in healthy volunteers has been completed, which has informed modifications to the TNX-102 formulation in anticipation of the 2H:22 start to Phase III trial in PAH. Additionally, Tenax has selected a CRO partner and formed a Scientific Advisory Board to support the candidate.

With imatinib's recent IND clearance, and two Phase III trials expected in the coming quarters, Tenax is a bright spot in our coverage universe with substantial upside and limited competition in the PAH areas its candidates are targeting. We maintain our valuation to $4.50 per share.

[4] Source: Tenax Therapeutics October 2021 Corporate Presentation

PROJECTED FINANCIALS

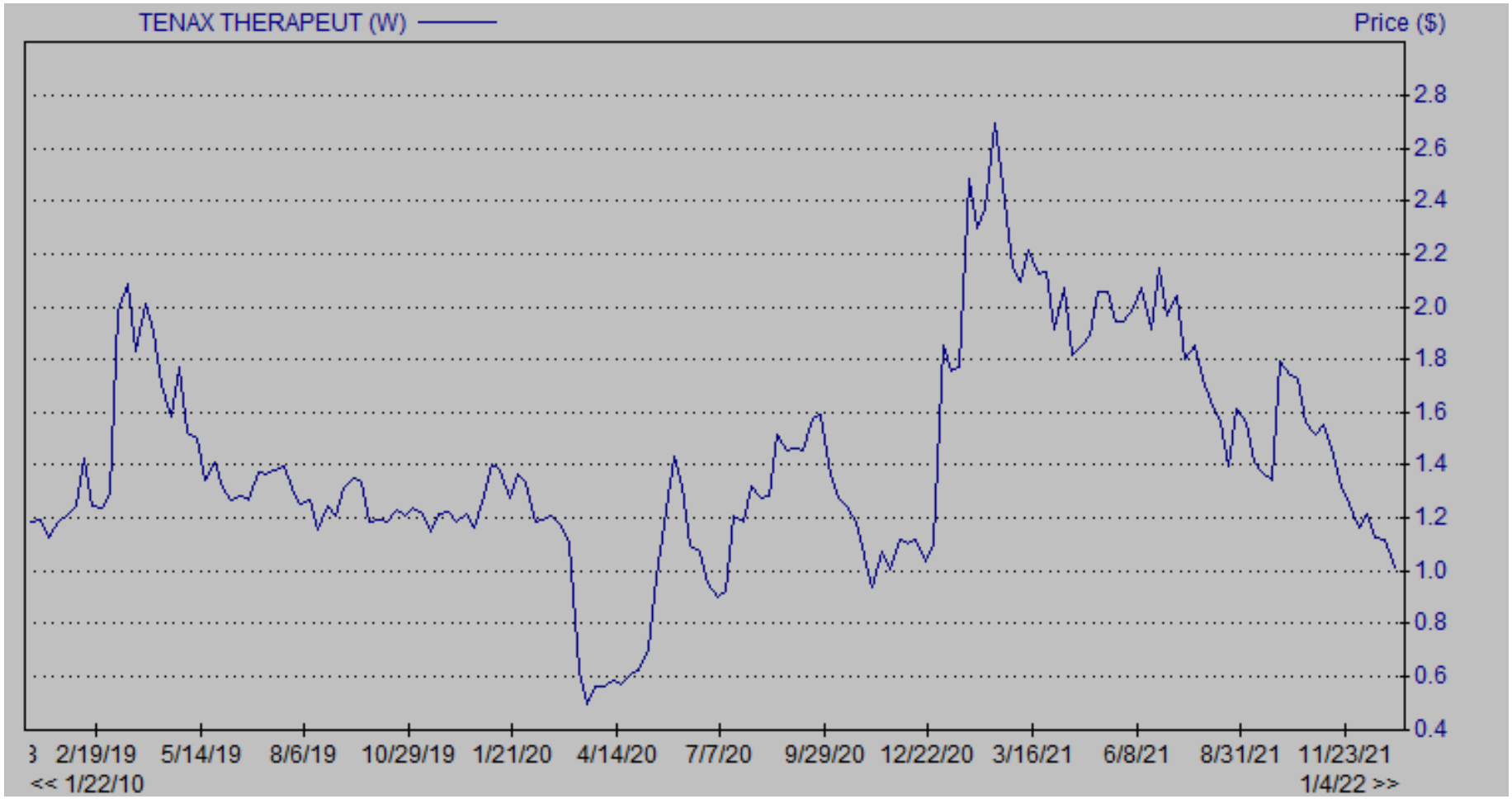
Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2020 A	Q1 A	Q2 A	Q3 A	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%*	*0%*
Research and development	$4.6	$22.4	$0.7	$1.2	$1.2	$25.4	$11.0	$19.5
General & administrative	$5.3	$1.4	$1.3	$2.6	$2.5	$7.8	$5.7	$5.9
Income from operations	($9.9)	($23.7)	($2.0)	($3.8)	($3.7)	($33.2)	($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)	($0.2)	($0.0)	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($9.9)	($23.7)	($1.7)	($3.8)	($3.7)	($33.2)	($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)**	**($1.7)**	**($3.8)**	**($3.7)**	**($33.2)**	**($16.7)**	**($25.4)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.95)**	**($1.64)**	**($0.10)**	**($0.15)**	**($0.15)**	**($1.61)**	**($0.56)**	**($0.81)**
YOY Growth	*-30%*					*70%*	*-66%*	*45%*
Basic Shares Outstanding	10.37	14.52	17.22	25.20	25.40	20.58	30.00	31.50

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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