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May 22, 2023
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Tenax Therapeutics, Inc. (TENX: NASDAQ)

TENX: Prioritizing Levosimendan

We use a DCF model and a 15% discount rate combined with a 40% probability of eventual sales of oral levosimendan in the United States to generate our valuation.

Current Price (4/4/2023)	$0.31
Valuation	**$5.00**

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. Tenax completed its Ph2 PH-HFpEF trial in 2020 and may start a Ph3 in 2023, pending an oral patent grant. 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 heart failure, 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	**13.80**
52-Week Low	**0.28**
One-Year Return (%)	**-97.6**
Beta	**2.2**
Average Daily Volume (sh)	**6,633,413**
Shares Outstanding (mil)	**21.7**
Market Capitalization ($mil)	**6.7**
Short Interest Ratio (days)	**0.2**
Institutional Ownership (%)	**1.9**
Insider Ownership (%)	**2.5**
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 2023 Estimate	**N/A**
P/E using 2024 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)
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2024					$0.0 E
2025					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$2.16 A	-$2.27 A	-$2.22 A	-$1.94 A	-$8.57 A
2023	-$0.15 A	-$0.13 E	-$0.12 E	-$0.12 E	-$0.51 E
2024					-$0.24 E
2025					-$0.17 E

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WHAT'S NEW

First Quarter Financial and Operational Review

Tenax Therapeutics, Inc. (NASDAQ: TENX) reported 1Q:23 results on May 15, 2023 via its filing of Form 10-Q with the SEC. Despite the slow pace of advancement, we are impressed with the clinical data for both of Tenax' PAH assets: levosimendan and imatinib. We see tremendous upside if dilution concerns can be addressed and a dramatic quality of life improvement for patients. Levosimendan is an especially remarkable opportunity in pulmonary hypertension in patients with heart failure and preserved ejection fraction (PH-HFpEF) which offers no other approved therapies.

Based on the confidence inspired by the recent patent issuance for intravenous (IV) levosimendan in PH-HFpEF, Tenax plans to pursue a Phase III study of oral levosimendan in PH-HFpEF patients. The US Patent Office set a precedent by recognizing PH-HFpEF as a condition separate from heart failure. This provides support for later approval of a patent for an oral version of levosimendan in a follow-on patent application that is being reviewed by the agency. With the recent $15.6 million raise, Tenax is in a position to start its Phase III levosimendan trial

Highlights for 2023 include:

- Reverse stock split executed - January 5, 2023
- $15.6 million public offering completed – February 2023
- IV levosimendan patent for PH-HFpEF issued – March - 2023
- Prioritization of TNX-103 (levosimendan for PH-HFpEF) in clinical trials – April 2023

Tenax produced no revenues in 1Q:23 and incurred operating expenses of $1.5 million resulting in net loss of ($1.4) million, or ($0.15) per share.

For the quarter ending March 31, 2023 versus the same prior year period:

- General and administrative expenses fell 17% to $1.3 million primarily due to lower legal and professional fees related to decreased intellectual property and investor relations costs. A reduction in the amount of office space also contributed to the decline. These amounts were partially offset by an increase in personnel costs, and a rise in other miscellaneous charges;
- Research and development expenses fell 77% to $261,000 from $1.2 million on lower clinical and preclinical development costs as the company paused development activity as it evaluated its strategic direction. Prior year spending comprised the HELP study and imatinib PK study. Personnel costs also fell due to timing while other costs rose primarily related to consulting increased over prior period levels;
- Net loss was ($1.4) million versus ($2.7) million, or ($0.15) and ($2.16) per share, respectively.

At the end of 1Q:23, cash and equivalents totaled $14.4 million, compared to $2.1 million at the end of 2022. During the first quarter, cash burn was ($1.7) million as the company caught up with accounts payable following its capital raise. Financing cash flows were $14.0 million on the contribution from stock issuance and warrant exercise which was partially offset by offering costs and payments on a short-term note.

Update on Tenax

Tenax had been navigating rough waters over the last few months as the need for capital to advance their Phase III clinical trials in pulmonary arterial hypertension (PAH) intensified. This issue was largely resolved with the February 2023 capital raise which provides approximately $14 million to advance the pipeline. Other favorable news was also released over the last several months including and the grant of new patents and renewed focus on the levosimendan PH-HFpEF program.

Capital Raise
On February 3, 2023, Tenax announced that it had priced the sale of 8.67 million shares or pre-funded warrant with associated warrants at $1.80 per unit. Two warrants with an exercise price of $2.25 per share were issued for each underlying equity share or pre-funded warrant. Proceeds will support the clinical development of levosimendan for pulmonary hypertension with left side heart failure and preserved ejection fraction (PH-HFpEF).

Tenax had engaged Roth Capital Partners as a financial advisor in September 2022. The goal was exploration of a diverse range of strategic options including a sale, merger or other strategic transaction which ultimately culminated in the announced equity raise.

Patent Application Granted Notice of Allowance
On February 1st, Tenax announced it had received a notice of allowance from the US Patent and Trademark Office (USPTO) for patent number 11,607,412 entitled Levosimendan for Treating Pulmonary Hypertension with Heart Failure and Preserved Ejection Fraction (PH-HFpEF). A notice of allowance is issued when an examiner determines that a patent application satisfies the requirements for patentability. On March 22nd, Tenax reported that the patent was issued. The patent is expected to provide protection until December 2040 and addresses the subcutaneous use of levosimendan. Intravenous levosimendan has been available generically for many years in Europe as the patent expired in 2015; however, the drug was not approved in the US in any form. With the additional protection that is expected to be provided in this patent, the value of levosimendan in PH-HFpEF is increased. Tenax asserts that the USPTO's decision to grant a patent for the use of IV levosimendan for the specific indication of PH-HFpEF confirms the proprietary nature of the work Tenax is doing and provides precedent for action in the pending U.S. patent application that covers the oral formulation (TNX-103) in the same patients.

Reverse Stock Split
After the start of the new year, Tenax executed a 1:20 reverse stock split that became effective on the close of business as of January 4, 2023. The number of shares was reduced from 45,836,215 to 2,291,811. Fractional shares were rounded up. The reverse split enabled Tenax to comply with the NASDAQ's minimum bid price requirement.

Summary

In February, Tenax raised sufficient cash to begin its Phase III study in PH-HFpEF. Based on the progress in obtaining patent protection for levosimendan in PH-HFpEF, Tenax will advance a Phase III program in this indication. We see therapeutic potential for Tenax' two candidates that may provide a material improvement in multiple PAH groups. While both assets have substantial promise, the company must attract sufficient capital or partner support to advance them. Based on the financial opportunity and the low entry price, the opportunity for investors with sufficient funds to see the programs to conclusion appears to be substantial.

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2022 A	Q1 A	Q2 E	Q3 E	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$2.0**
YOY Growth	*0%*					*0%*		
Research and development	$5.4	$0.3	$1.3	$1.4	$1.6	$4.6	$8.2	$8.3
General & administrative	$5.7	$1.3	$1.2	$1.2	$1.2	$4.9	$5.1	$5.3
Income from operations	($11.1)	($1.5)	($2.5)	($2.6)	($2.8)	($9.4)	($13.3)	($11.6)
Operating Margin	-					-	-	-
Interest Income (expense)	$0.0	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	$0.0	($0.1)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($11.1)	($1.4)	($2.5)	($2.6)	($2.8)	($9.4)	($13.3)	($11.6)
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	**($11.1)**	**($1.4)**	**($2.5)**	**($2.6)**	**($2.8)**	**($9.4)**	**($13.3)**	**($11.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($8.57)**	**($0.15)**	**($0.13)**	**($0.12)**	**($0.12)**	**($0.51)**	**($0.24)**	**($0.17)**
YOY Growth	*-73%*					*-94%*	*-53%*	*-30%*
Basic Shares Outstanding	1.29	9.30	19.00	22.00	24.00	18.58	56.00	70.00

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

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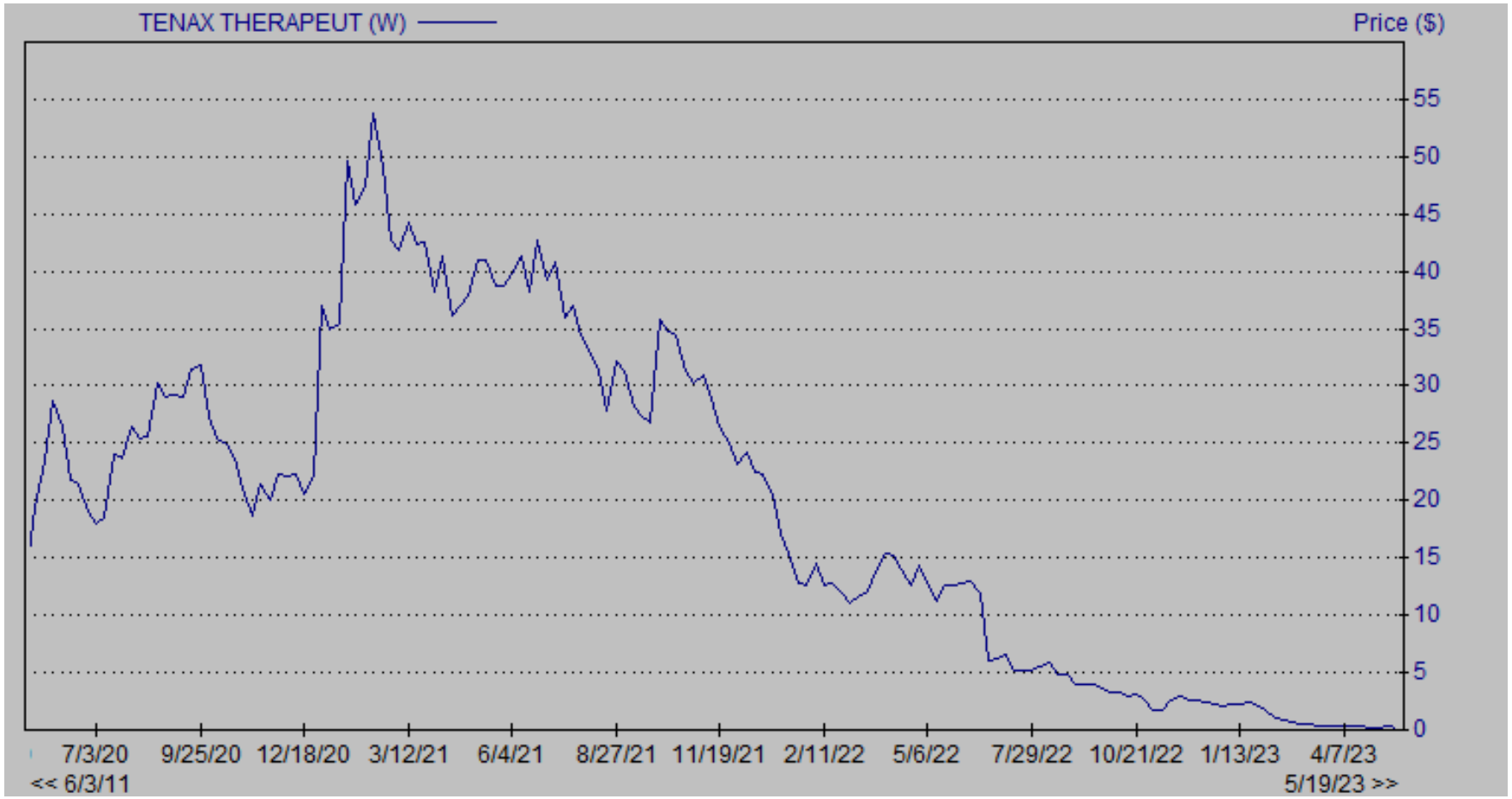
HISTORICAL STOCK PRICE

Tenax Therapeutics, Inc. – Stock Price Chart[1]



[1] Source: Zacks Research System

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