Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

April 5, 2023

John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

Tenax Therapeutics, Inc. (TENX: NASDAQ)

Patents Guide the Way

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)	$0.38
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	**16.20**
52-Week Low	**0.37**
One-Year Return (%)	**-97.6**
Beta	**2.2**
Average Daily Volume (sh)	**4,175,800**
Shares Outstanding (mil)	**22.4**
Market Capitalization ($mil)	**8.5**
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 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 A	$0.0 A	$0.0 A	$0.0 A
2023					$0.0 E
2024					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021					-$31.56 A
2022	-$2.16 A	-$2.27 A	-$2.22 A	-$1.94 A	-$8.57 A
2023					-$1.19 E
2024					-$0.49 E

WHAT'S NEW

2022 Financial and Operational Review

Tenax Therapeutics, Inc. (NASDAQ: TENX) reported 2022 results on March 31, 2023 via its filing of Form 10-K 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.

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
- Pharmacokinetic (PK) study completion for TNX-201 – May 2022
- KOL event examining imatinib for treatment of PAH – May 2022
- Issuance of IV levosimendan patent in PH-HFpEF – March 2022

Tenax produced no revenues in 2022 and incurred operating expenses of $11.1 million resulting in net loss of ($11.1) million, or ($8.57) per share.

For the year ending December 31, 2022 versus the same prior year period:

- General and administrative expenses fell 25% to $5.7 million primarily due to the absence of severance costs in 2022, and lower facilities fees partially offset by increases in professional and legal fees and higher costs for insurance, and administrative expense;
- Research and development expenses fell almost 80% to $5.4 million from $25.1 million with the majority of the change due to the recognition of $21.7 million of in process R&D (IPR&D) expensing related to the acquisition of PH PrecisionMed in 1Q:21. Ignoring the IPR&D charge, R&D increased 28% on higher clinical and preclinical development costs related to the ongoing open label extension study for levosimendan. Other expenses fell on a year over year period, including decreased costs related to the imatinib program and lower personnel costs;
- Net loss was ($11.1) million versus ($32.5) million, or ($8.57) and ($31.56) per share, respectively.

At the end of 2022, cash and equivalents totaled $2.1 million, compared to $5.6 million twelve months earlier. During 2022, Tenax announced an $8 million raise from the sale of 10.6 million units of pre-funded and other warrants and received proceeds of $0.6 million from the issuance of a note payable related to corporate insurance policies. These amounts offset cash burn of ($14.3) million reducing cash by $3.5 million over the year. Following the end of the reporting period, Tenax conducted a registered offering which raised gross proceeds of $15.6 million. The amount will support the start of a Phase III clinical trial in oral levosimendan for PH-HFpEF expected to begin later this year.

Update on Tenax

Tenax has 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 a gross $15.6 million to advance the pipeline. Other favorable news was also released over the last several months including positive data presented at the HFSA Annual Meeting and the grant of new patents.

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 With 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 granted 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
Following the beginning 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.

Valuation

Tenax has only raised sufficient funding to advance one program and based on the success with the levosimendan patents, the company has elected to pursue the PH-HFpEF program. The imatinib program, designated TNX-201, will be placed on hold awaiting additional funding.

Recently, the US Patent and Trademark Office (USPTO) issued a patent for the use of levosimendan via subcutaneous administration for PH-HFpEF among other classes of PAH. This is an important determination as it recognizes PH-HFpEF as separate from heart disease and supports another patent under consideration seeking protection for an oral form of levosimendan for use in PH-HFpEF. Just a few weeks ago, another patent was granted for IV administration of levosimendan in PH-HFpEF. These patents provide strong support for another patent that is being considered by the USPTO for oral formulation of levosimendan in PH-HFpEF, which is the method of administration that will be evaluated in the upcoming Phase III study.

Levosimendan
Due to the delays in obtaining capital, we expect the levosimendan oral program (TNX-103)[1] will complete pivotal trials, submit an NDA to the FDA, be granted approval and ultimately begin sales by 2029. Tenax' license from Orion grants them rights to US territories. We estimate a prevalence of about 1.6 million PH-HFpEF patients and initial penetration into this population of 1%, rising to 15% by year six. Treatment cost in 2029 is forecast to be $15,500 per year rising at a 3% inflation rate. We model a partner commercializing levosimendan and a net[2] economic value of 15% to be earned by Tenax in upfront, milestone and royalty payments.

[1] TNX-103 is the oral, TNX-102 is the subcutaneous and TNX-101 is the intravenous method of administration for levosimendan.
[2] Net of licensing and other amounts owed to Orion.

We generate an NPV for levosimendan of over $700 million, not adjusted for probability of ultimate success. To this we add cash and apply a 40% probability of success to the levosimendan program. Shares outstanding, including the number from the recent capital raise and prefunded warrants, total 22.4 million to which we add the warrant and option dilution of 19.0 million and another 30 million shares to reflect a future capital raise. The result of our estimates and assumptions produces a target price of $5.00.

Update on HELP Open Label Extension

Tenax presented data from a PH-HFpEF study at the Heart Failure Society of America (HFSA) Scientific Sessions 2022, held from October 1-3, 2022. On October 10th, Tenax provided an update on the patients who had enrolled in the open label extension (OLE) of the HELP (Hemodynamic Evaluation of Levosimendan in PH-HFpEF) trial. A presentation was given that summarized the data from the patients who switched from the intravenous (IV) form of levosimendan to the oral form. "The Transition from Chronic Intravenous to Oral Levosimendan Is Safe and Effective in Patients with Pulmonary Hypertension with Heart Failure and Preserved Ejection Fraction" was authored by Thenappan Thenappan, MD, *et al*.

The substudy included 18 patients who transitioned from IV to oral levosimendan who showed improvement across a number of metrics summarized below. The study concluded that the levosimendan oral formulation was well tolerated without safety concerns over a 6-8-week period in patients with PH-HFpEF who received IV levosimendan for an average of 18 months. There were no serious adverse events (SAEs) related to oral levosimendan therapy. The six-minute walk test increased compared to baseline by over 13 meters, while measures of heart failure declined (improved) over the measurement period. Improvement in the measures led to an increase in the Kansas City Cardiomyopathy Questionnaire scores (KCCQ-TS, KCCQ-CS and KCCQ-OS) (n=16) improved by 4.7, 2.5 points and 3.7 points, respectively. The results suggest that oral levosimendan at 3-4 mg/day may provide a superior formulation for chronic use in PH-HFpEF patients when compared to the intravenous administration of levosimendan.

Exhibit I – Metrics for OLE Study[3]

Metric	Change	St Dev	Units
Resting Heart Rate	+4.9	7.5	beats/min
Systolic BP	+4.1	12.6	mm Hg
6-min Walk Distance	+13.1	39.5	meters
BNP	-133.6	136.6	pg/dl
NT-proBNP	-239.4	548.1	pg/dl
Total	**0**	**744.3**	**0**

Summary

Tenax recently 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 update our valuation to reflect the levosimendan program moving forward and shares outstanding. Based on our updated assumptions we adjust our target price to $5.00 per share.

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.

[3] Compiled by Zacks analyst from company press release.

PROJECTED FINANCIALS

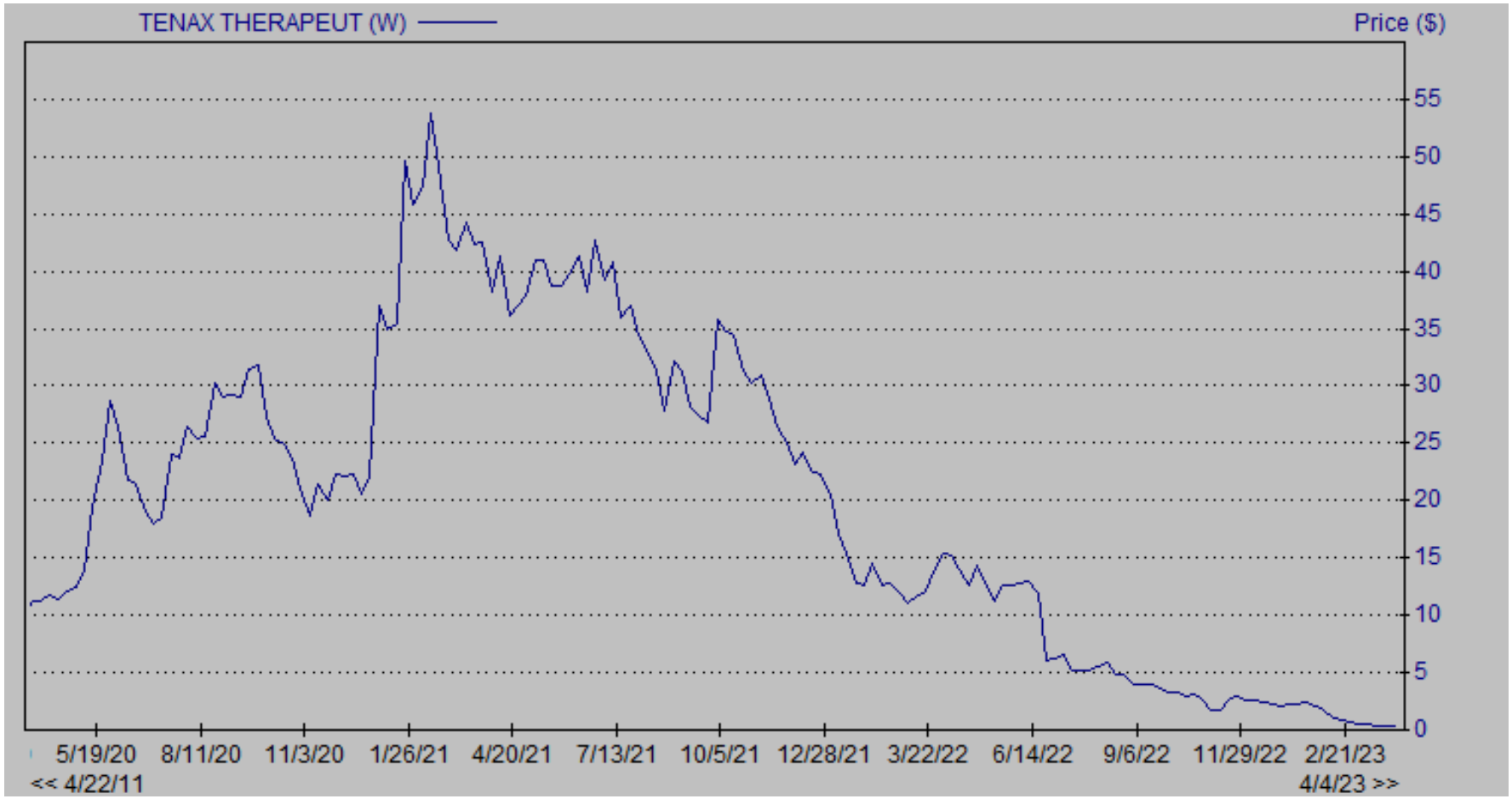
Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2021 A	Q1 A	Q2 A	Q3 A	Q4 A	2022 A	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	$1.5	$1.5	$1.1	$5.4	$19.5	$20.0
General & administrative	$7.6	$1.5	$1.3	$1.4	$1.4	$5.7	$6.5	$7.5
Income from operations	($32.7)	($2.7)	($2.9)	($2.9)	($2.6)	($11.1)	($26.0)	($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)	($2.9)	($2.9)	($2.6)	($11.1)	($26.0)	($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)**	**($2.9)**	**($2.9)**	**($2.6)**	**($11.1)**	**($26.0)**	**($27.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($31.56)**	**($2.16)**	**($2.27)**	**($2.22)**	**($1.94)**	**($8.57)**	**($1.19)**	**($0.49)**
YOY Growth	*3221%*					*-73%*	*-86%*	*-59%*
Basic Shares Outstanding	1.03	1.26	1.26	1.32	1.32	1.29	21.80	56.00

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

HISTORICAL STOCK PRICE

Tenax Therapeutics, Inc. – Stock Price Chart[4]



[4] Source: Zacks Research System

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, John Vandermosten, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.