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Tenax Therapeutics, Inc. (TENX: NASDAQ)

TENX: Second Quarter Results

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 (8/25/2023)	$0.36
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 is expected to start a Ph3 in 2023. Additionally, Tenax merged with PH Precision Med bringing Ph3-ready imatinib for PAH in house which is on hold pending additional funding.

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	**7.40**
52-Week Low	**0.25**
One-Year Return (%)	**-93.0**
Beta	**2.1**
Average Daily Volume (sh)	**827,859**
Shares Outstanding (mil)	**23.8**
Market Capitalization ($mil)	**8.6**
Short Interest Ratio (days)	**0.1**
Institutional Ownership (%)	**3.2**
Insider Ownership (%)	**2.6**
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 A	$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	-$0.05 A	-$0.12 E	-$0.12 E	-$0.42 E
2024					-$0.24 E
2025					-$0.17 E

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WHAT'S NEW

Second Quarter Financial and Operational Review

Tenax Therapeutics, Inc. (NASDAQ: TENX) reported 2Q:23 results on August 14, 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 for pulmonary hypertension 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 oral and IV administration of 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. With the recent $15.6 million raise, Tenax is in a position to start its Phase III levosimendan trial. We expect an Investigational New Drug (IND) application to be made in the near term reflecting the change to the oral formulation of levosimendan, initial trial preparation in 4Q:23 and first patient enrollment in 2024.

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
- PH-HFpEF patent for oral levosimendan issued – July 2023

Tenax produced no revenues in 2Q:23 and incurred operating expenses of $1.2 million resulting in net loss of ($1.1) million, or ($0.05) per share.

For the quarter ending June 30, 2023 versus the same prior year period:

- General and administrative expenses fell 22% to $1.0 million primarily due to lower personnel costs related to reduced headcount, reduced legal and professional fees related and a decline in miscellaneous costs. A reduction in the amount of office space also contributed to the decline;
- Research and development expenses fell 87% to $198,000 from $1.5 million on lower clinical and preclinical development costs as the company paused development activity as it prepares to begin a pivotal clinical trial in PH-HFpEF. These amounts were partially offset by an increase in regulatory consulting costs;
- Net interest income was $131,000 due to greater cash balances and higher interest rates;
- Net loss was ($1.1) million versus ($2.9) million, or ($0.05) and ($2.27) per share, respectively.

At the end of 2Q:23, cash and equivalents totaled $13.4 million, compared to $2.1 million at the end of 2022. During the second quarter, cash burn was ($0.9) million. Financing cash flows were ($0.1) million related to the repayment of a short-term note. A capital raise was conducted in 1Q:23 which led to net financing cash flows of around $14 million during the first three months of the year.

Additional Support for Oral Levosimendan

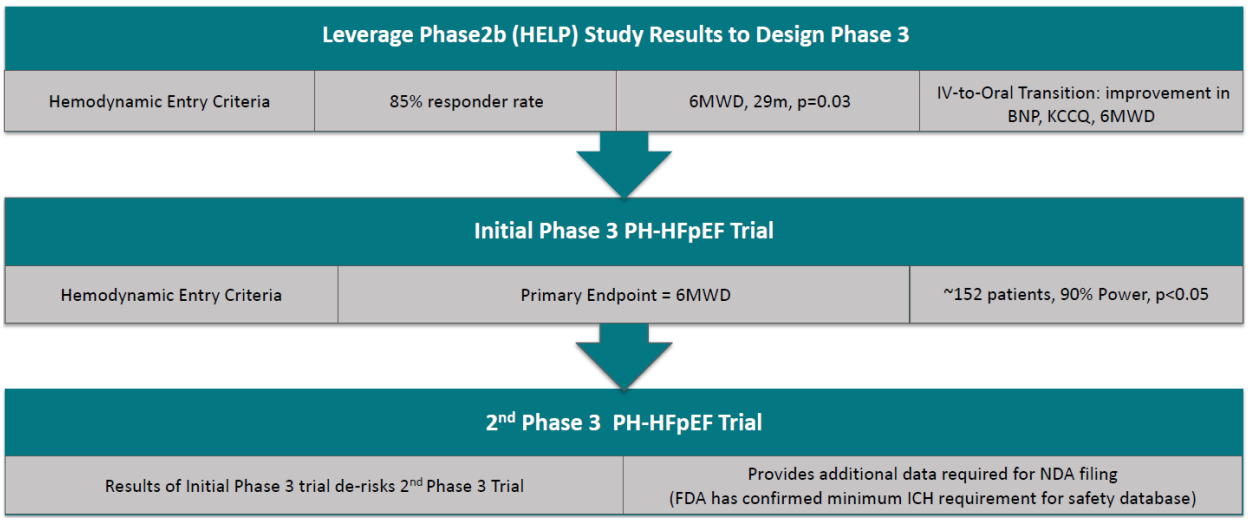
Tenax announced that the US Patent and Trademark Office (USPTO) had granted a Notice of Allowance for its patent covering the use of oral levosimendan in pulmonary hypertension in patients with heart failure and preserved ejection fraction (PH-HFpEF). The Notice of Allowance is a precursor to patent issuance and declares that the invention meets the requirements for patentability. A fee is required prior to grant of the patent, which is the next anticipated step for Tenax prior to the grant of the patent.

A patent for oral levosimendan in PH-HFpEF is significant as it extends protection for this use until the end of 2040. Patent extension and potentially other mechanisms could extend this even further. A patent grant would lengthen what would otherwise be available, which is five years of exclusivity as a New Chemical Entity (NCE). NCE exclu-

sivity is available to drugs that contain an active moiety that has not been previously approved by the FDA in any other drug.

Based on the confidence inspired by the recent USPTO successes with levosimendan in PH-HFpEF, Tenax plans to pursue a Phase III study of oral levosimendan in these 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 following clearance from the FDA regarding the use of oral levosimendan in PH-HFpEF patients.

Exhibit I – Levosimendan Planned Phase III Development Path[1]



Imatinib Program

With its near-term development focus on PH-HFpEF, Tenax will soon begin its oral levosimendan trial. The company's second program with imatinib for pulmonary arterial hypertension (PAH) will take a back seat due to financial considerations. While not active, there are events in motion that may orient investor interest towards Tenax' imatinib program. This could complement any good news that emerges from the levosimendan trial next year. Tenax is not the only company pursuing a disease modifying therapy for PAH, as others including Aerovate Therapeutics (AVTE), Gossamer Bio (GOSS) and Acceleron/Merck (MRK) are all traveling along this route. We provide a review of the other programs and also identify some of the hurdles that Aerovate faces with using an inhaled form of imatinib. If Aerovate is not able to achieve favorable results with its inhaled imatinib, the focus may turn to Tenax which offers a modified formulation that sidesteps the gastrointestinal (GI) side effects that plagued the oral form of imatinib used in the IMPRES study.

Inhaled Imatinib

Imatinib is the subject of a trial by Aerovate Therapeutics (AVTE) that is investigating a dry powder formulation of imatinib for PAH. The sponsor is running a Phase III clinical trial designated IMPAHCT and a long term extension of this trial called IMPAHCT-FUL. The primary endpoint for the Phase III will be the placebo-corrected change in the six-minute walk distance after 24 weeks of treatment. There will be ~460 participants in the randomized trial. As of mid-May, Aerovate expects to report topline data in 2Q:24.

Imatinib is a tyrosine kinase inhibitor (TKI) and was shown to improve a PAH subject's six-minute walk test in the IMPRES study. Another TKI, seralutinib, was effective in animal models using an inhaled route of administration but had limited effect in humans. Due to its mechanism, the inhaled route of administration may have limitations in humans that are not fully represented in the animal model.

While the inhalation route is attractive on many fronts, including avoiding GI related side effects and direct delivery to the organ of interest, clinical efficacy using this route may not be feasible. Precise dosing and delivery to the al-

[1] Tenax Therapeutics June 2023 Corporate Presentation

veolar-capillary region is difficult. Furthermore, drug delivered via the peripheral airways has a shorter effect than drug delivered via other routes as it is absorbed quickly.[2]

Seralutinib
Gossamer Bio (GOSS) conducted a Phase 2 study of seralutinib in patients with pulmonary arterial hypertension (PAH). Seralutinib is a tyrosine kinase inhibitor (TKI) that targets PDGFRα/β, CSF1R, and c-KIT. It is specifically designed to be delivered via dry powder inhaler for the treatment of PAH. The company reported topline data in December 2022. While the primary endpoint of pulmonary vascular resistance (PVR) improved by 14.3% (p value = 0.031), the magnitude was lower than expected. The secondary endpoint was improvement in six-minute walk distance. Active arm results were better than placebo for this endpoint; however, they were not significant. Gossamer is expected to move forward with a Phase III, but lacks investor confidence as indicated by a market cap below cash holdings.

Sotatercept
Acceleron/Merck (MRK) are developing sotatercept, which is a is a first-in-class therapeutic fusion protein that targets an imbalance in activin–growth differentiation factor and BMP pathway signaling. Sotatercept is the subject of clinical trials investigating PAH. In a Phase III study designated STELLAR, Merck reported a clinically meaningful improvement in the six minute walk distance after 24 weeks in October 2022. An improvement in NT-proBNP level was also achieved in the study. Further analysis was provided in a New England Journal of Medicine article Phase 3 Trial of Sotatercept for Treatment of Pulmonary Arterial Hypertension.

Selection of Zacks' explanatory research for the levosimendan and imatinib programs:

- ***June 3, 2020 – Results from Phase II levosimendan study***
  - TENX: Target Up on Solid HELP Results
- ***April 9, 2021 – Background on imatinib***
  - TENX: HELP Results & New Asset to Boot
- ***June 2023 – Corporate Presentation***
  - Tenax Therapeutics Corporate Presentation

Upcoming Milestones

- Filing of IND for levosimendan for oral PH-HFpEF – 3Q:23
- First enrollment of Phase III PH-HFpEF subject in levosimendan trial – 1H:24

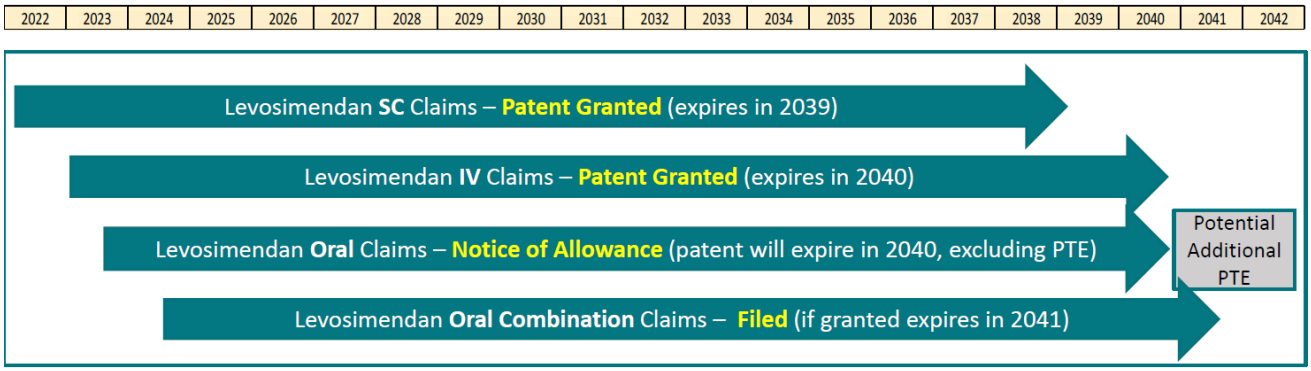
Patents

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 composition of matter patent expired many years ago; however, the drug was not approved in the US in any form. With the additional protection that is expected to be provided by this patent, the value of levosimendan in PH-HFpEF has improved.

Tenax was granted a Notice of Allowance for oral levosimendan in PH-HFpEF as memorialized in a May 31 press release. Following the notice, several administrative requirements were completed, including the payment of the issue fee. The patent was eventually issued as reported in mid-July.

[2] Agnihotri, V., *et al*. An Update on Advancements and Challenges in Inhalational Drug Delivery for Pulmonary Arterial Hypertension. Molecules, May 2022.

Exhibit II – Levosimendan Patent Timeline[3]



Summary

The patent for oral levosimendan in PH-HFpEF will provide intellectual property protection for Tenax until at least the end of 2040. With sufficient capital in the bank, we expect Tenax to begin its Phase III trial soon following IND clearance for the oral formulation with potential interim data reported next year. While imatinib for PAH is on hold, it may move into the spotlight next year if peer Aerovate fails to show beneficial effect for inhaled imatinib in PAH patients. This could stimulate investor interest in Tenax' imatinib program and attract capital to run a Phase III in a second indication.

We see therapeutic potential for Tenax' two candidates that may provide a material improvement in multiple PAH groups. With existing cash on hand, Tenax has sufficient capital to advance its levosimendan program in PH-HFpEF. 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] Tenax Therapeutics June 2023 Corporate Presentation

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2022 A	Q1 A	Q2 A	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	$0.2	$1.4	$1.6	$3.5	$8.2	$8.3
General & administrative	$5.7	$1.3	$1.0	$1.2	$1.2	$4.7	$5.1	$5.3
Income from operations	($11.1)	($1.5)	($1.2)	($2.6)	($2.8)	($8.2)	($13.3)	($11.6)
Operating Margin	-					-	-	-
Interest Income (expense)	$0.0	($0.0)	$0.1	$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)	($1.1)	($2.6)	($2.8)	($8.2)	($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)**	**($1.1)**	**($2.6)**	**($2.8)**	**($8.2)**	**($13.3)**	**($11.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($8.57)**	**($0.15)**	**($0.05)**	**($0.12)**	**($0.12)**	**($0.42)**	**($0.24)**	**($0.17)**
YOY Growth	*-73%*					*-95%*	*-44%*	*-30%*
Basic Shares Outstanding	1.29	9.30	22.12	22.32	24.00	19.43	56.00	70.00

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

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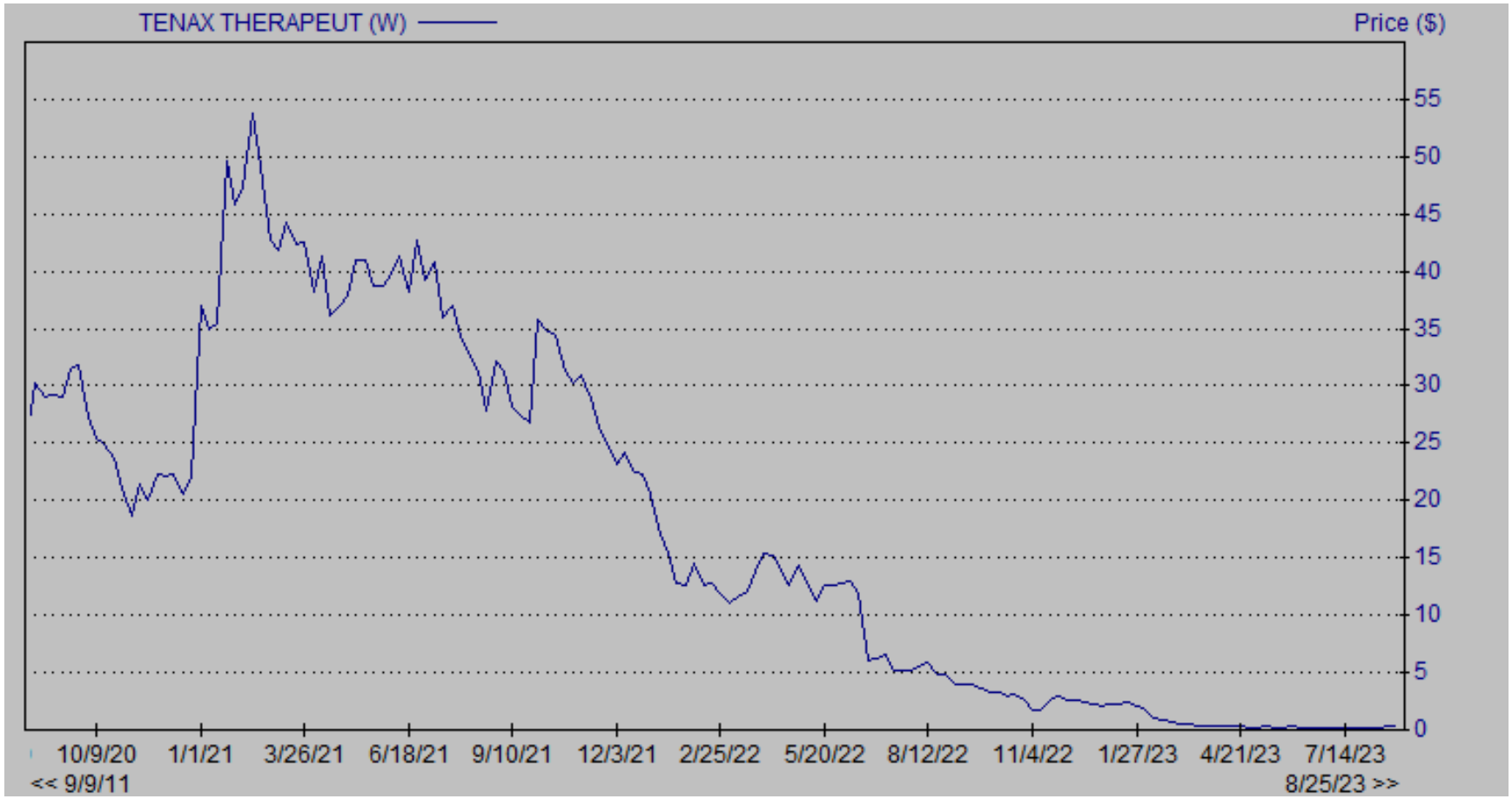
HISTORICAL STOCK PRICE

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



[4] Source: Zacks Research System

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