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Tenax Therapeutics, Inc. (TENX: NASDAQ)

New Funding Puts Wind in the Sails

Based on our DCF model and a 15% discount rate, Tenax is valued at approximately $6.00 per share. We apply a combined 40% probability of eventual sales of levosimendan in the United States and of imatinib globally and divide this value in half to reflect only one program moving forward.

Current Price (2/14/2023)	$0.91
Valuation	**$6.00**

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	**17.00**
52-Week Low	**0.90**
One-Year Return (%)	**-93**
Beta	**2.1**
Average Daily Volume (sh)	**1,005,800**
Shares Outstanding (mil)	**11.8**
Market Capitalization ($mil)	**10.7**
Short Interest Ratio (days)	**0.2**
Institutional Ownership (%)	**3.9**
Insider Ownership (%)	**4.6**
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 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 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					-$31.56 A
2022	-$2.16 A	-$2.27 A	-$2.22 A	-$3.03 E	-$9.69 E
2023					-$2.17 E
2024					-$1.62 E

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WHAT'S NEW

Update on Tenax

Tenax Therapeutics, Inc. (NASDAQ: TENX) 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 since our previous update with positive data presented at the HFSA Annual Meeting and the grant of a new patent. Over the last six months, Tenax has hired Roth Capital Partners to evaluate strategic alternatives and has executed a reverse stock split to bring it back into compliance with minimum share price requirements.

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 imatinib and levosimendan for PAH and pulmonary hypertension with left side heart failure and preserved ejection fraction (PH-HFpEF) respectively.

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 11,213,524 entitled Pharmaceutical compositions for subcutaneous administration of levosimendan. A notice of allowance is issued when an examiner determines that a patent application satisfies the requirements for patentability. The patent is expected to provide protection until 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.

The notice of allowance recognizing that PH-HFpEF is a distinct indication and is important for what we expect will be the next patent to be reviews for an oral formulation. When obtaining the patent, substantial effort was required to prove the point that PH-HFpEF was separate from heart disease. After in depth discussions supported by a broad selection of research, including the trial design and results from Tenax' very own HELP trial, the patent office relented and granted the notice of allowance for subcutaneous administration of levosimendan in PH-HFpEF. We expect the patent to be issued after final administrative requirements are completed.

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 come into compliance with the NASDAQ's minimum bid price requirement.

Data Presentation at HFSA
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 as reported in a press release. The title of the lecture was entitled "The Transition from Chronic Intravenous to Oral Levosimendan Is Safe and Effective in Patients with Pulmonary Hypertension with Heart Failure and Preserved Ejection Fraction" by Thenappan Thenappan, MD, *et al*. Results demonstrated an improvement in six-minute walk test, and a reduction in critical biomarkers BNP, NT-proBNP among other metrics.

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. Oral levosimendan was associated with further numerical improvements in six-minute walk distance, BNP/NT-ProBNP and all key Kansas City Cardiomyopathy Questionnaire domains, suggesting 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.

Valuation

With updated timelines and a shifting profile on which assets will be advanced first, we update our valuation to reflect only one program advancing and assign equal probabilities to both. Tenax has only raised sufficient funding to advance one program and must assess numerous considerations prior to selecting its path. Our valuation is dynamic and will reflect a greater probability of both programs advancing if sufficient funding is obtained.

The imatinib program, designated TNX-201, has demonstrated significant promise in pulmonary arterial hypertension in the IMPRES trial. The results provided the impetus for the use of a modified release/modified dose imatinib that could be a disease modifying therapy, a class of treatment that is not available. Competitors in the space are also working on a disease modifying therapy and are at critical points where the efficacy of their candidate will soon be determined. One competitor in particular, Aerovate (NASDAQ: AVTE) is developing a dry powder inhaled version of imatinib designated AV-101 which is the subject of a Phase IIb trial. If development of this product stumbles due to its method of administration, investors may turn their attention to Tenax and willingly provide the funding necessary to advance TNX-201 towards approval.

Gating factors for levosimendan rely on obtaining patent protection for an oral form of the drug in pulmonary hypertension in heart failure with preserved ejection fraction (PH-HFpEF). Recently, the US Patent Office granted a notice of allowance 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. A grant of patent with this definition would provide 20 years of protection for levosimendan in PH-HFpEF rather than the five years of patent exclusivity now available, substantially increasing the value of the franchise.

As events unfold in the imatinib and levosimendan spaces, we anticipate Tenax will select the most attractive option and begin its Phase III trial.

Imatinib
We modify the timing of our forecasts for imatinib and anticipate pivotal trials and FDA submission timelines will allow for a 2027 launch of TNX-201 in the United States. Sales outside of the United States are expected the following year. PAH is considered an orphan indication and will be granted seven years of exclusivity in the United States and ten years of exclusivity in the EU if approved. Our estimates for sales are based on a historical revenue arc generated by other products in the indication including remodulin, opsumit, uptravi and adempas. First year sales are estimated at $101 million, rising to over $700 million by year seven, then falling as US exclusivity expires. We expect Tenax will work with partners and receive upfronts, milestones and royalties in return for granting license rights. We forecast that Tenax will receive 30% of the economic value generated by TNX-201 and assume these are all received via royalties.

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 approve sales in 2029. Assuming an oral patent is approved, this will provide 15 years of patent protection for levosimendan assuming the oral form of levosimendan receives a patent in 2024. Tenax' license from Orion grants them rights to US territories. We estimate a prevalence of about 1.6 million for PH-HFpEF 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. As with TNX-201, 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.

We generate an NPV and terminal value for the two assets of $1.1 billion, not adjusted for probability of ultimate success. To this we add cash, including the amount assuming that the recent $2.25 exercise price warrants are exercised. We apply a 40% probability of success to both the imatinib and levosimendan programs, then divide it in half to recognize that only one program will move forward. Shares outstanding, including the number from the recent capital raise and prefunded warrants, total 11.0 million to which we add the warrant and option dilution of 19.0 million and another 5.0 million shares to reflect a future capital raise to produce 35.0 million shares used to calculate our valuation. The result of our estimates and assumptions produces a target price of $6.00.

[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.

The Assets

We have discussed Tenax' assets in depth in previous reports and have provided a summary of supportive clinical data for advancing them to clinical trials. Both imatinib and levosimendan offer to address an unmet need in Group 1 and Group 2 pulmonary hypertension. Imatinib has demonstrated the ability to be disease modifying in Group 1 PAH patients and Tenax' formulation of the drug may address the delivery hurdles that are necessary to be surmounted before the drug can be effective. 2021 sales for products serving this indication are $6.5 billion and expected to grow at mid to high single digits over the next several years.[3] Levosimendan has shown the ability to reduce wedge pressure, increase patient physical performance and improve how patients feel for Group 2 PAH patients. If approved in the United States for Group 2 PAH, levosimendan could potentially treat 2 million patients that suffer from the condition. Assuming a modest 5% penetration at $1,000 per month could generate over $1 billion in sales. Given that there are no other treatments for Group 2 PAH, penetration and price could reasonably go higher.

Update on HELP Open Label Extension

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 entitled "The Transition from Chronic Intravenous to Oral Levosimendan Is Safe and Effective in Patients with Pulmonary Hypertension with Heart Failure and Preserved Ejection Fraction."

The substudy included 18 patients who transitioned from IV to oral levosimendan who showed improvement across a number of metrics summarized below. 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.

Exhibit I – Metrics for OLE Study[4]

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 a Phase III study in pulmonary hypertension. The environment for advancing candidates in this space is in flux with other competitors at pivotal points in development and patents on the verge of being approved. Tenax plans to assess its options over the next months and select the best option when it arises. We update our valuation of the levosimendan and imatinib programs, refining the timing of the development process and extending the life of levosimendan, assuming the grant of an oral patent for PH-HFpEF. Based on our updated assumptions we adjust our target price.

We see therapeutic potential for Tenax' two candidates that may provide a material improvement in multiple PAH groups. While the 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] Source: Evaluate Pharma, Ltd. Pulmonary hypertension indication overview. Accessed November 2022.
[4] 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 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	$1.5	$1.5	$2.6	$6.8	$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)	($4.0)	($12.5)	($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)	($4.0)	($12.5)	($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)**	**($4.0)**	**($12.5)**	**($26.0)**	**($27.5)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($31.56)**	**($2.16)**	**($2.27)**	**($2.22)**	**($3.03)**	**($9.69)**	**($0.52)**	**($0.46)**
YOY Growth	*3221%*					*-69%*	*-95%*	*-12%*
Basic Shares Outstanding	1.03	1.26	1.26	1.32	1.32	1.29	50.00	60.00

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

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HISTORICAL STOCK PRICE

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



[5] Source: Zacks Research System

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