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August 22, 2024
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Tenax Therapeutics, Inc. (TENX: NASDAQ)

TENX: $100 Million Capital Raise

We use a DCF model and a 15% discount rate combined with a 55% probability of eventual sales of oral levosimendan in the United States to generate our valuation.

Current Price (8/21/2024)	$4.22
Valuation	**$7.00**

OUTLOOK

Tenax has licensed the calcium sensitizer/K-ATP activator levosimendan and is pursuing approval for an indication in Group 2 Pulmonary Hypertension in the US and Canada. 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 to confirm trial design. This indication has a target population of nearly 2.0 million patients in the US with no existing treatment therapy. Tenax completed its Ph2 PH-HFpEF trial in 2020 and started the first of two Ph3 studies. In 2021, Tenax merged with PH Precision Med bringing Ph3-ready imatinib for PAH in house which is on hold.

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 pivotal trials in PH-HFpEF. Additionally, PH-HFpEF represents a materially sized market with no effective therapy available, which provides substantial pricing and penetration opportunity.

SUMMARY DATA

52-Week High	**61.20**
52-Week Low	**2.77**
One-Year Return (%)	**-87.2**
Beta	**2.2**
Average Daily Volume (sh)	**513,679**
Shares Outstanding (mil)	**35.3**
Market Capitalization ($mil)	**149.0**
Short Interest Ratio (days)	**0.7**
Institutional Ownership (%)	**38.7**
Insider Ownership (%)	**0.3**
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 2024 Estimate	**N/A**
P/E using 2025 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)
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2024	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2025					$0.0 E
2026					$0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2023	-$12.10 A	-$4.00 A	-$6.61 A	-$11.14 A	-$31.04 A
2024	-$3.12 A	-$1.83 A	-$1.47 E	-$1.66 E	-$7.35 E
2025					-$3.89 E
2026					-$2.52 E

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WHAT'S NEW

Tenax Therapeutics, Inc. (NASDAQ: TENX) reported second quarter 2024 results on August 13th, 2024 in a press release and through the filing of its Form 10-Q with the SEC. The big news for Tenax has been the impressive capital raise of $100 million in August 2024. Tenax' $100 million private placement closed one day before 2Q:24 results were announced. This capital raise enables the company to accelerate levosimendan's trial activity and maintains the company's momentum towards approval in pulmonary hypertension from heart failure with preserved ejection fraction (PH-HFpEF). Since the beginning of the year, the company has enrolled the first patient in the oral levosimendan (TNX-103) LEVEL trial, presented data at a cardiovascular conference for PH-HFpEF and hosted a KOL event. The company was also granted a new patent and expanded its license rights for levosimendan with Orion.

Below we summarize financial results.

No revenues were reported in the second quarter while operating expenses totaled $3.7 million resulting in a net loss of ($3.6) million or ($1.83) per share.

For the quarter ending June 30, 2024 versus the same prior year period:

- General and administrative expenses rose 29% to $1.3 million as costs were up across all major categories except for facilities costs which fell slightly. Higher performance-based compensation, legal and professional fees, and other costs contributed to the change;
- Research and development expenses rose by more than a factor 10 to $2.3 million from $200,000 as clinical and preclinical costs grew by $2.1 million. The increase reflects expenses related to Phase III LEVEL trial compared with wind down expenses attributable to the Phase II HELP open label extension study. Personnel costs were also up while other costs were down;
- Net interest expense was ($0.1) million, essentially flat with prior year levels;
- Net loss was ($3.6) million versus ($1.1) million. 2Q:24 loss per share was ($1.83).

As of June 30, 2024, cash and equivalents totaled $9.4 million, compared to $9.8 million at the end of 2023. Tenax consumed ($3.0) million in cash in 2Q:24 and ($8.2) million in the first six months. Financing cash flows were $7.8 million in 1H:24 reflecting the February capital raise. After the end of the reporting period, Tenax announced a $100 million private placement with several health care focused investors that dramatically changes the capitalization of the company and provides a runway until the end of 2027.

Capital Raise

On August 8th, 2024, Tenax closed a private placement financing generating gross proceeds of approximately $100 million. The purchase agreement for a private placement of 33.3 million shares of common stock or prefunded warrant with one-half warrant attached to each share or prefunded warrant (a unit) with an exercise price of $4.50. Each share and prefunded warrant were sold for $3.00 and $2.99 respectively. Details of the transaction are provided in a Form 8-K filed August 6th.

31.8 of the 33.3 million units are prefunded warrants. The $4.50 strike warrants are immediately exercisable and expire upon the earlier of 30 trading days after release of LEVEL topline data or when the prefunded warrant holder exercises the prefunded warrant, which comprise 31.9 of the 33.3 million units issued. If neither of these two events occurs, the warrants will expire in August 2029. This restriction aligns the prefunded warrant holders' interest with Tenax and encourages longer term ownership. If the data is strong, this also encourages $4.50 warrant holders to exercise their warrants following the topline announcement which could raise an additional $75 million.

Proceeds from the raise will support the ongoing Phase III LEVEL trial and accelerate its pace along with providing additional capital for other general corporate purposes. Monies are expected to fund the company's operations through the end of 2027. Leerink Partners acted as the lead placement agent for the private placement and is joined by Guggenheim Securities and William Blair as joint placement agents. Roth Capital Partners acted as financial advisor. As compensation in connection with the private placement, Tenax paid the placement agents a cash fee of 6% of the aggregate gross proceeds raised, certain capital market advisory fees and reimbursement of certain expenses and legal fees.

Several investors took part in the private placement including BVF Partners LP, Venrock Healthcare Capital Partners, Vivo Capital, Janus Henderson Investors, Vestal Point Capital, ADAR1 Capital Management, Stonepine Capital Management and Sphera Biotech.

Expansion of Levosimendan Rights

On February 20th, Tenax reported that it had negotiated a favorable amendment to its global license agreement with Orion Corporation. The amendment broadens the geographic scope of the original license granting Tenax the exclusive right to develop and commercialize levosimendan products worldwide. Previously the license had only applied to the US and Canada. Compared with the previous agreement, the amendment reduces the royalty rates on sales but has increased some milestone payments as outlined in the company's Form 8-K filing. Royalties are now in the high single digit to low-teen percentages. Furthermore, the agreement reduced the maximum capsule cost that will be negotiated in the future for oral levosimendan product. In return, Tenax relinquishes its right to negotiate for indications in the neurological space. Overall, the addition of Japan to future potential markets stands out as an attractive new opportunity. The broader suite of rights makes Tenax more appealing as an acquisition candidate and partner.

KOL Event

Tenax hosted a key opinion leader (KOL) event on April 18, 2024, moderated by Tenax' Chief Medical Officer, Stuart Rich, MD. He led a panel featuring several experts in the field of heart failure and treating patients with pulmonary hypertension. The event reviewed emerging science, clinical experience with Tenax' levosimendan (TNX-103) and the evolving heart failure landscape. Tenax further provided an update on the LEVEL study followed by audience questions. Panelists who are all members of Tenax' scientific advisory board (SAB) include:

- Sanjiv Shah, MD, Northwestern University and chair of Tenax' SAB
  - Understanding the setting of PH-HFpEF
- Daniel Burkhoff, MD, PhD, CRF/Columbia University
  - Mechanism of Action of Levosimendan
- Barry Borlaug, MD, Mayo Clinic
  - Review of Phase II HELP study data
- Javed Butler, MD, MPH, MBA, Baylor Scott & White and recent addition to Tenax' SAB
  - Current treatment landscape in PH-HFpEF

Enrollment of First Patient in Phase III LEVEL Trial

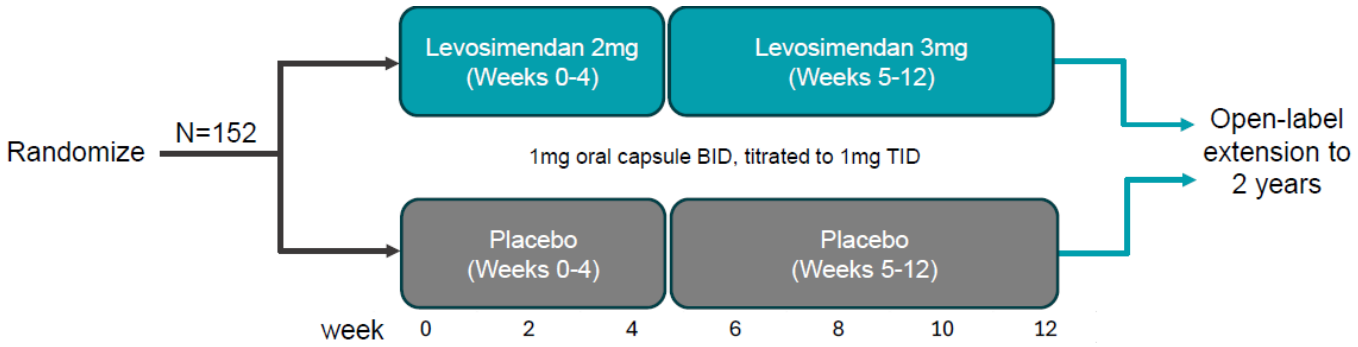
A February 7th press release signaled the enrollment of the first patent in Tenax' Phase 3 LEVEL Study (**LEV**osimendan to Improve **E**xercise Limitation in PH-HFpEF Patients). The study is listed under NCT05983250 in the National Library of Medicine's Clinical Trials database. Over 40 sites have agreed to participate in the Group 2 pulmonary arterial hypertension (PAH) trial which is expected to generate topline results by 2H:25.

Tenax filed its investigational new drug (IND) application for the Phase III study in pulmonary hypertension in heart failure with preserved ejection fraction (PH-HFpEF) during 3Q:24 and announced the program's clearance in a November 13th press release. Activity to initiate the trial began with site qualification and selection work taking place in Fall of 2023. Trial launch and site activity accelerated in the fourth quarter and enrollment started in 1Q:24. We expect that two Phase III trials will be conducted, with the first enrolling 152 subjects in the US and Canada and the second up to 300 subjects globally.

LEVEL's primary endpoint is the six-minute walk distance (6MWD) with over 90% power to detect a 25-meter change. Secondary endpoints will include the Kansas City Cardiomyopathy Questionnaire (KCCQ)[1] and BNP/NT-proBNP (B-type natriuretic peptide and N-terminal pro-B-type natriuretic peptide). The latter elements are biomarkers used to help diagnose and monitor heart failure. Clinical worsening events and change in NYHA (New York Heart Association) functional class are other outcome measures that will be monitored.

[1] The KCCQ is a disease-specific health status measure for patients with heart failure. It consists of 23 items grouped into symptom frequency, symptom burden, self-efficacy, social limitation, quality of life and physical limitation. Categories are scored, with higher values indicating better health status related to heart failure.

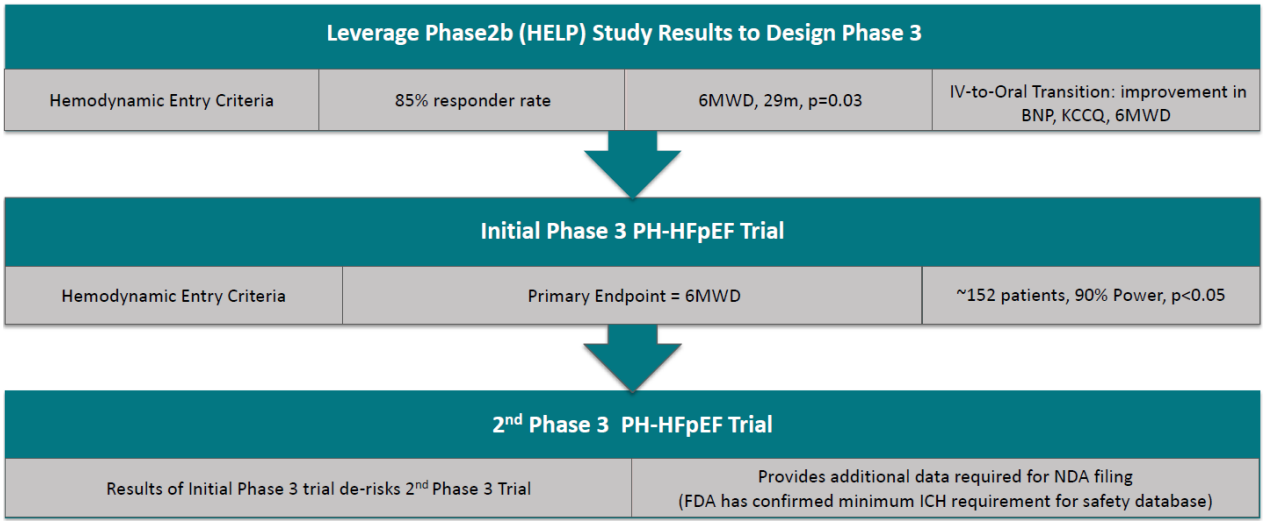
Exhibit I – LEVEL Study Design



Tenax Therapeutics' August 2024 Corporate Presentation

No long-term, cardiovascular outcomes trial will be required given the long-term data related to levosimendan use in patients. This allowance will reduce the cost and shorten the time to develop a new drug application (NDA) for TNX-103. Twenty-four sites have been initiated and others are in the process of being added at leading cardiovascular centers in the US and Canada. This includes sites that participated in the Phase II HELP study.

Exhibit II – Levosimendan Planned Phase III Development Path



Tenax Therapeutics' February 2024 Corporate Presentation

Key LEVEL details:

- Launched in 4Q:23
- 6-minute walk distance is primary endpoint
- 6-month drug exposure required for 300 patients
- 12-month drug exposure required for 100 patients
- No cardiovascular outcomes trial required
- Oral administration

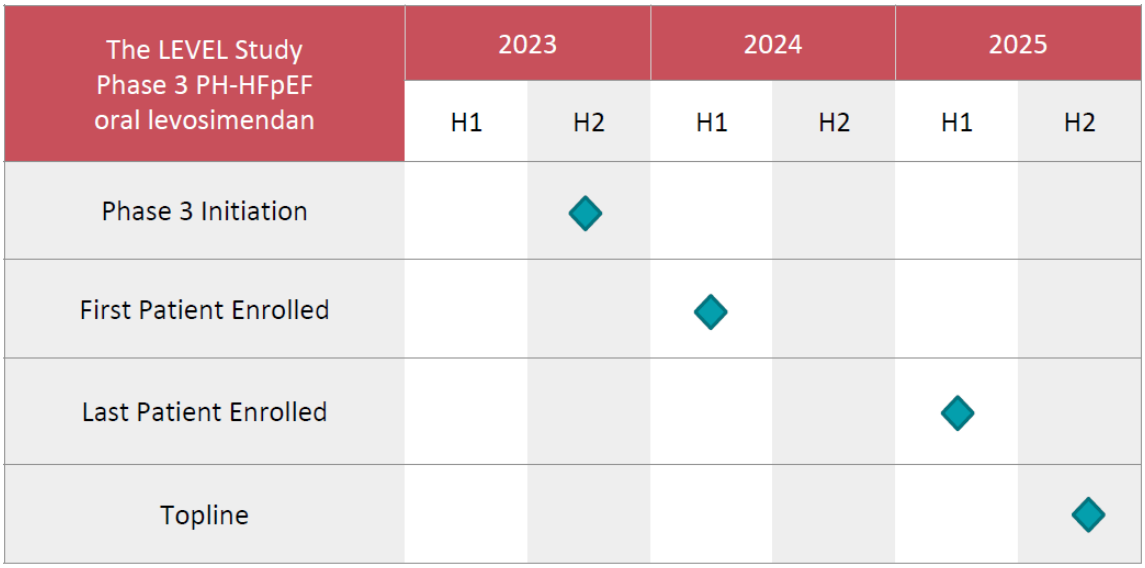
Valuation

We update Tenax' valuation on the issuance of new shares and warrants to fund the advancement of the LEVEL and forthcoming LEVEL 2 trial. Now that Tenax has started LEVEL and is on the cusp of a second Phase III, we increase our probability of success to 55% from 40%. We also account for the new shares and warrants outstanding to reflect the August 2024 $100 million capital raise. Estimates for research and development spending increase, representing the costs of what we are calling the LEVEL 2 trial. Participation in the capital raise and the associated due diligence by the investors listed above provide increased confidence in the program's viability and the likelihood that it will be funded to completion. Our timeline assumes that data from the LEVEL 2 trial will be available by year end 2027, supporting a new drug application (NDA) in 2028 followed by approval and sales in 2029. The result of our modifications generates a valuation of $7.00 per share.

Milestones

- First patient enrolled in LEVEL study – February 2024
- Expansion of levosimendan rights – February 2024
- Oral presentation at Technology and Heart Failure Therapeutics (THT) conference – March 2024
- LEVEL trial KOL event – April 2024
- USPTO patent grant for levosimendan in PH-HFpEF patent – April 2024
- Close of $100 million capital raise – August 2024
- Launch LEVEL 2 trial – 2H:24/1H:25
- Complete enrollment in LEVEL trial – 1H:25
- LEVEL topline results – 2H:25

Exhibit III – LEVEL Study Milestones



Tenax Therapeutics' August 2024 Corporate Presentation

Summary

Tenax' raise of $100 million is a big vote of confidence from investors that are respected for their due diligence. The funds will support the completion of the LEVEL trial and the open label extension as well as fund the first year of the LEVEL 2 trial based on our cost estimates. The structure of the capital raise incentivizes unit holders to exercise their $4.50 strike warrants shortly after LEVEL topline is announced, which could provide up to another $75 million in funds. With sufficient capital in the bank and patient enrollment accelerating, we expect Tenax to immediately begin preparations for the LEVEL 2 trial potentially enrolling the first patient by 1H:25 in this global trial.

Levosimendan may provide a material improvement in quality of life and disease symptoms for patients suffering from Group 2 pulmonary arterial hypertension. Based on the size of an unpenetrated market with no other options, the supportive data generated in the HELP trial and the low entry price for Tenax stock, the opportunity for investors with sufficient funds to see the programs to conclusion appears to be substantial. We update our valuation to reflect new estimates as well as the shares, prefunded warrants and warrants associated with the $100 million capital raise generating a valuation of $7.00 per share.

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2023 A	Q1 A	Q2 A	Q3 E	Q4 E	2024 E	2025 E	2026 E
Total Revenues ($MM)	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
YOY Growth								
Research and development	$3.2	$2.7	$2.3	$2.9	$4.0	$11.9	$20.0	$17.8
General & administrative	$5.0	$1.2	$1.3	$1.5	$1.8	$5.9	$7.2	$7.4
Income from operations	($8.2)	($3.9)	($3.7)	($4.4)	($5.8)	($17.8)	($27.2)	($25.2)
Operating Margin	-					-	-	-
Interest Income (expense)	($0.0)	($0.0)	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	($0.5)	($0.1)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($7.7)	($3.8)	($3.6)	($4.4)	($5.8)	($17.8)	($27.2)	($25.2)
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	**($7.7)**	**($3.8)**	**($3.6)**	**($4.4)**	**($5.8)**	**($17.8)**	**($27.2)**	**($25.2)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($31.04)**	**($3.12)**	**($1.83)**	**($1.47)**	**($1.66)**	**($7.35)**	**($3.89)**	**($2.52)**
YOY Growth	*-95%*					*-76%*	*-47%*	*-35%*
Basic Shares Outstanding	0.25	1.22	1.96	3.00	3.50	2.42	7.00	10.00

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

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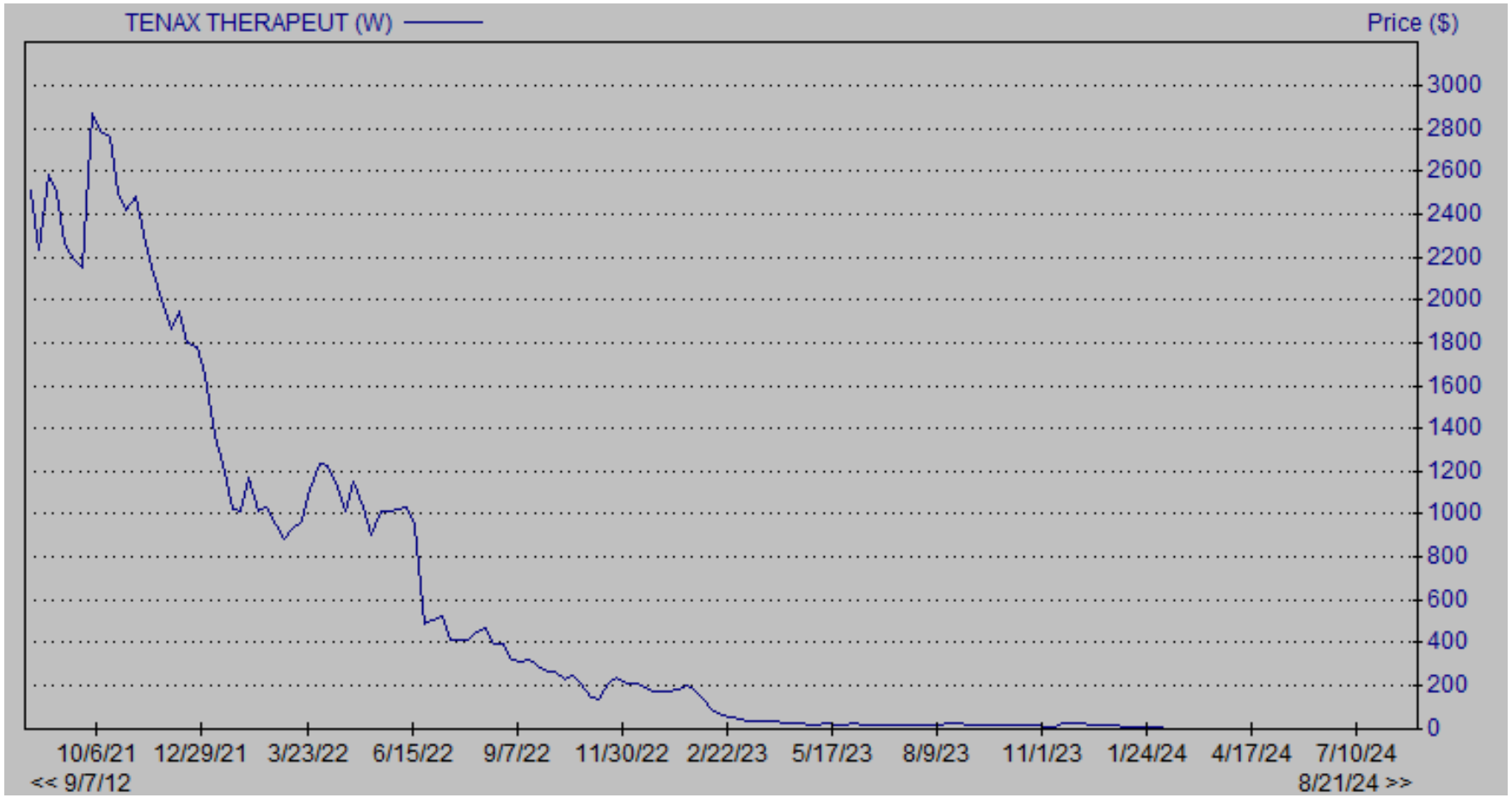
HISTORICAL STOCK PRICE

Tenax Therapeutics, Inc. – Stock Price Chart[2]



[2] Source: Zacks Research System

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