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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)

TENX: First 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 (5/17/2024)	$3.55
Valuation	**$35.00**

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 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 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	**3.48**
One-Year Return (%)	**-85.4**
Beta	**2.2**
Average Daily Volume (sh)	**89,587**
Shares Outstanding (mil)	**2.0**
Market Capitalization ($mil)	**7.1**
Short Interest Ratio (days)	**0.5**
Institutional Ownership (%)	**7.4**
Insider Ownership (%)	**0.4**
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 E	$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	-$1.72 E	-$1.59 E	-$1.71 E	-$7.73 E
2025					-$1.94 E
2026					-$1.36 E

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WHAT'S NEW

What's New?

Tenax Therapeutics, Inc. (NASDAQ: TENX) reported first quarter 2024 results on May 14th, 2024 in a press release and the filing of its Form 10-Q with the SEC. Since the beginning of the year, the company has enrolled the first patient in the oral levosimendan (TNX-103) LEVEL trial and presented data at a cardiovascular conference for PH-HFpEF. The company was also granted a new patent and expanded its license rights for levosimendan with Orion.

Stakeholders had a chance to interact with key opinion leaders (KOLs) in heart failure at an event which highlighted the LEVEL trial and the scientific rationale for treatment with levosimendan in patients with heart failure and preserved ejection fraction (PH-HFpEF). Below we summarize these recent highlights and 1Q:24 financial results.

Recent Highlights:

- 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

No revenues were reported in the first quarter and operating expenses were $3.9 million resulting in a net loss of ($3.8) million or ($3.12) per share.

For the quarter ending March 31, 2024 versus the same prior year period:

- General and administrative expenses fell 3% to $1.2 million primarily due to declines in facility and personnel costs partially offset by an increase in other cost including non-income taxes;
- Research and development expenses rose by more than a factor of 9x to $2.7 million from $266,000 as clinical and preclinical costs grew by $2.3 million. The increase reflects expenses related to the Phase II HELP open label extension and costs related to the Phase III LEVEL trial. Other costs were down slightly;
- Net interest expense was ($8,000) compared to ($7,000);
- Net loss was ($3.8) million versus ($1.4) million. 1Q:24 loss per share was ($3.12).

As of March 31, 2024, cash and equivalents totaled $12.5 million, compared to $9.8 million at the end of 2023. Tenax consumed ($5.2) million in cash in 1Q:24 with a decrease in accounts payable and accrued liabilities explaining the difference between net loss and cash burn. Financing cash flows were $7.9 million in 1Q:24 reflecting the February capital raise. Management estimates that Tenax has sufficient cash to continue to fund operations through 2024.

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

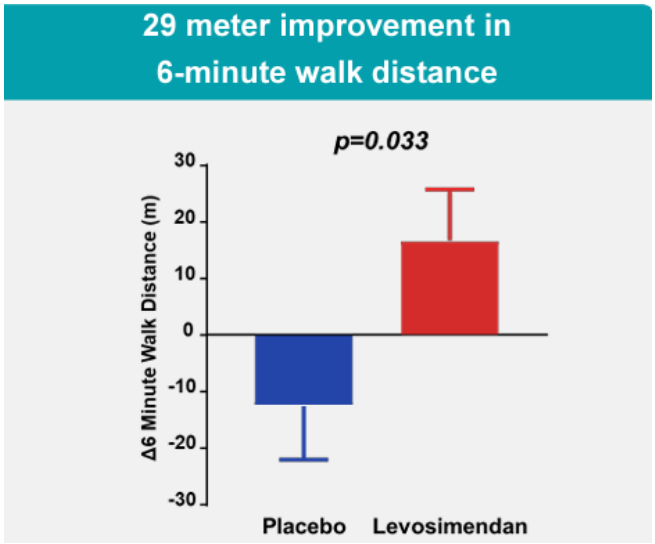
Enrollment of First Patient in Phase III LEVEL Trial

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 has now started. We expect that two Phase III trials will be conducted, each enrolling approximately 150 subjects.

LEVEL's primary endpoint is the six-minute walk distance (6MWD). 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.

Exhibit I – Phase II HELP Trial Improvement in 6-Minute Walk Distance

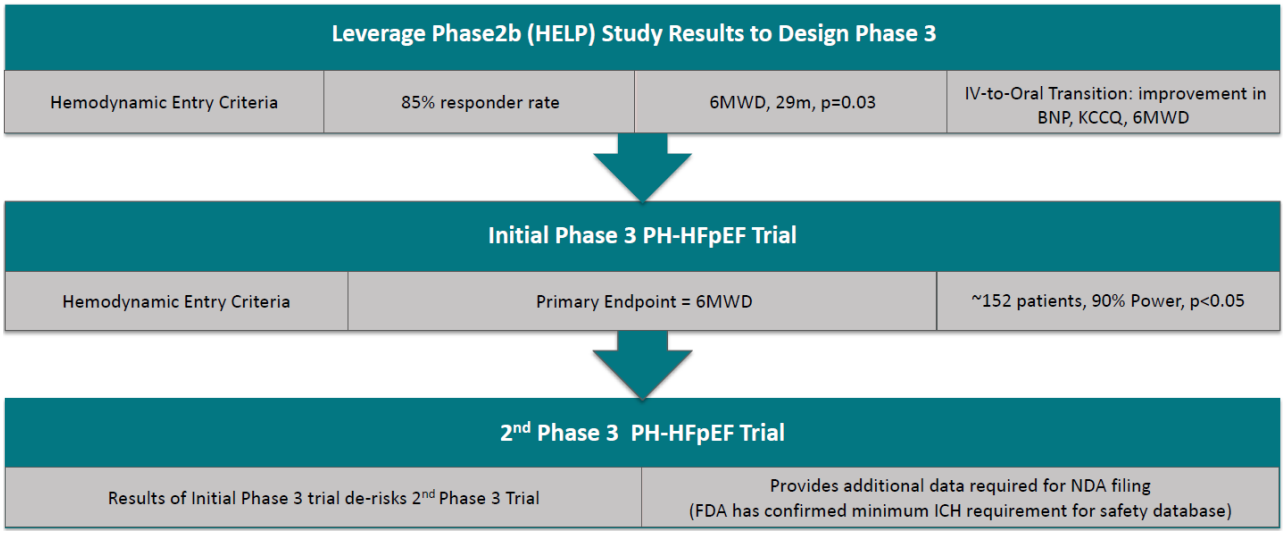


Tenax Therapeutics' February 2024 Corporate Presentation

[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.

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



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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

$9 Million Public Offering

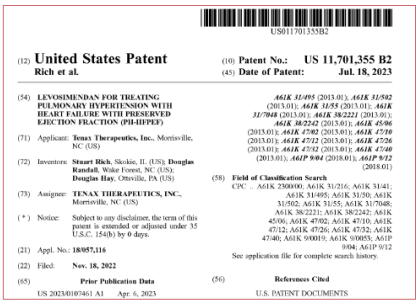
On February 8th, 2024 Tenax announced that it had priced $9 million in a public offering to access additional funds to support its Phase III LEVEL trial. The deal includes the issuance of 1.6 million shares and 3.2 million warrants at a purchase price of $5.65 per share. Warrants have a duration of five years with an exercise price of $5.65. Roth Capital Partners is serving as the placement agent. Net proceeds of $8.0 million will be used to advance the initiation of sites and the enrollment and treatment of patients in the LEVEL study, as well as for working capital, capital expenditures, and other general corporate purposes.

Patents

Notice of Allowance for Additional PH-HFpEF Patent
Tenax issued a press release on February 6th, 2024 that it had been granted a notice of allowance from the US Patent and Trademark Office (USPTO) for the use of levosimendan in PH-HFpEF. On April 30, the company announced that the patent had been granted. It is entitled Levosimendan for treating pulmonary hypertension with heart failure with preserved ejection fraction (PH-HFpEF) and has an anticipated expiration in December 2040. The patent will grant the use of oral, subcutaneous and intravenous administration of levosimendan at all therapeutic doses and in combination with various cardiovascular drugs in PH-HFpEF patients.

Exhibit III – Levosimendan Issued Patents

TNX-103 (Oral Use in PH-HFpEF)



(12) **United States Patent**
Rich et al.

(10) **Patent No.: US 11,701,355 B2**
(45) **Date of Patent: Jul. 18, 2023**

(54) **LEVOSIMENDAN FOR TREATING PULMONARY HYPERTENSION WITH HEART FAILURE WITH PRESERVED EJECTION FRACTION (PH-HFPEF)**

(71) Applicant: **Tenax Therapeutics, Inc.**, Morrisville, NC (US)

(72) Inventors: **Stuart Rich**, Skokie, IL (US); **Douglas Randall**, Wake Forest, NC (US); **Douglas Hay**, Ottsville, PA (US)

(73) Assignee: **TENAX THERAPEUTICS, INC.**, Morrisville, NC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **18/057,116**

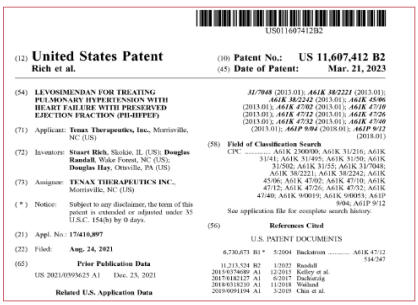
(22) Filed: **Nov. 18, 2022**

(65) **Prior Publication Data**

US 2023/0107461 A1 Apr. 6, 2023

Expires **December 2040**

TNX-101 (IV Use in PH-HFpEF)



(12) **United States Patent**
Rich et al.

(10) **Patent No.: US 11,607,412 B2**
(45) **Date of Patent: Mar. 21, 2023**

(54) **LEVOSIMENDAN FOR TREATING PULMONARY HYPERTENSION WITH HEART FAILURE WITH PRESERVED EJECTION FRACTION (PH-HFPEF)**

(71) Applicant: **Tenax Therapeutics, Inc.**, Morrisville, NC (US)

(72) Inventors: **Stuart Rich**, Skokie, IL (US); **Douglas Randall**, Wake Forest, NC (US); **Douglas Hay**, Ottsville, PA (US)

(73) Assignee: **TENAX THERAPEUTICS INC.**, Morrisville, NC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **17/410,897**

(22) Filed: **Aug. 24, 2021**

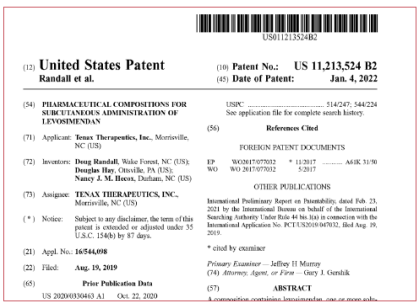
(65) **Prior Publication Data**

US 2021/0395625 A1 Dec. 23, 2021

Related U.S. Application Data

Expires **December 2040**

TNX-102 (SC Use in PH-HFpEF)



(12) **United States Patent**
Randall et al.

(10) **Patent No.: US 11,213,524 B2**
(45) **Date of Patent: Jan. 4, 2022**

(54) **PHARMACEUTICAL COMPOSITIONS FOR SUBCUTANEOUS ADMINISTRATION OF LEVOSIMENDAN**

(71) Applicant: **Tenax Therapeutics, Inc.**, Morrisville, NC (US)

(72) Inventors: **Doug Randall**, Wake Forest, NC (US); **Douglas Hay**, Ottsville, PA (US); **Nancy J. M. Buess**, Durham, NC (US)

(73) Assignee: **TENAX THERAPEUTICS, INC.**, Morrisville, NC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 87 days.

(21) Appl. No.: **16/544,038**

(22) Filed: **Aug. 19, 2019**

(65) **Prior Publication Data**

US 2020/0330463 A1 Oct. 22, 2020

Expires **December 2039**

Tenax Therapeutics' February 2024 Corporate Presentation

Milestones

- Reverse stock split – January 2024
- CEO presentation at Roth Conference – March 2024
- KOL event discussing LEVEL – April 18, 2024, 10 am ET
- Complete enrollment in LEVEL trial – 1H:25
- LEVEL topline results – 2H:25

Exhibit IV – LEVEL Study Milestones

The LEVEL Study Phase 3 PH-HFpEF oral levosimendan	2023		2024		2025	
	H1	H2	H1	H2	H1	H2
Phase 3 Initiation		◆				
First Patient Enrolled			◆			
Last Patient Enrolled					◆	
Topline						◆

Tenax Therapeutics' February 2024 Corporate Presentation

Summary

Tenax is advancing on many fronts including trial enrollment, interaction with investor and scientific communities, raising capital, negotiating stronger license agreements and improving its intellectual property position. With sufficient capital in the bank and the first patient enrolled, we expect Tenax to accelerate its Phase III efforts at an increasing number of sites as 2024 progresses. While imatinib for PAH is on hold, it may move into the spotlight depending on the performance of other programs and capital availability.

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 maintain our valuation of $35.00 per share.

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2023 A	Q1 A	Q2 E	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	$2.1	$2.1	$2.0	$8.9	$8.3	$8.5
General & administrative	$5.0	$1.2	$1.2	$1.1	$1.6	$5.1	$5.3	$5.1
Income from operations	($8.2)	($3.9)	($3.3)	($3.2)	($3.6)	($14.0)	($13.6)	($13.6)
Operating Margin	-					-	-	-
Interest Income (expense)	($0.0)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	($0.5)	($0.1)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($7.7)	($3.8)	($3.3)	($3.2)	($3.6)	($14.0)	($13.6)	($13.6)
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	**($7.7)**	**($3.8)**	**($3.3)**	**($3.2)**	**($3.6)**	**($14.0)**	**($13.6)**	**($13.6)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($31.04)**	**($3.12)**	**($1.72)**	**($1.59)**	**($1.71)**	**($7.73)**	**($1.94)**	**($1.36)**
YOY Growth	*-95%*					*-75%*	*-75%*	*-30%*
Basic Shares Outstanding	0.25	1.22	1.92	2.01	2.10	1.81	7.00	10.00

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

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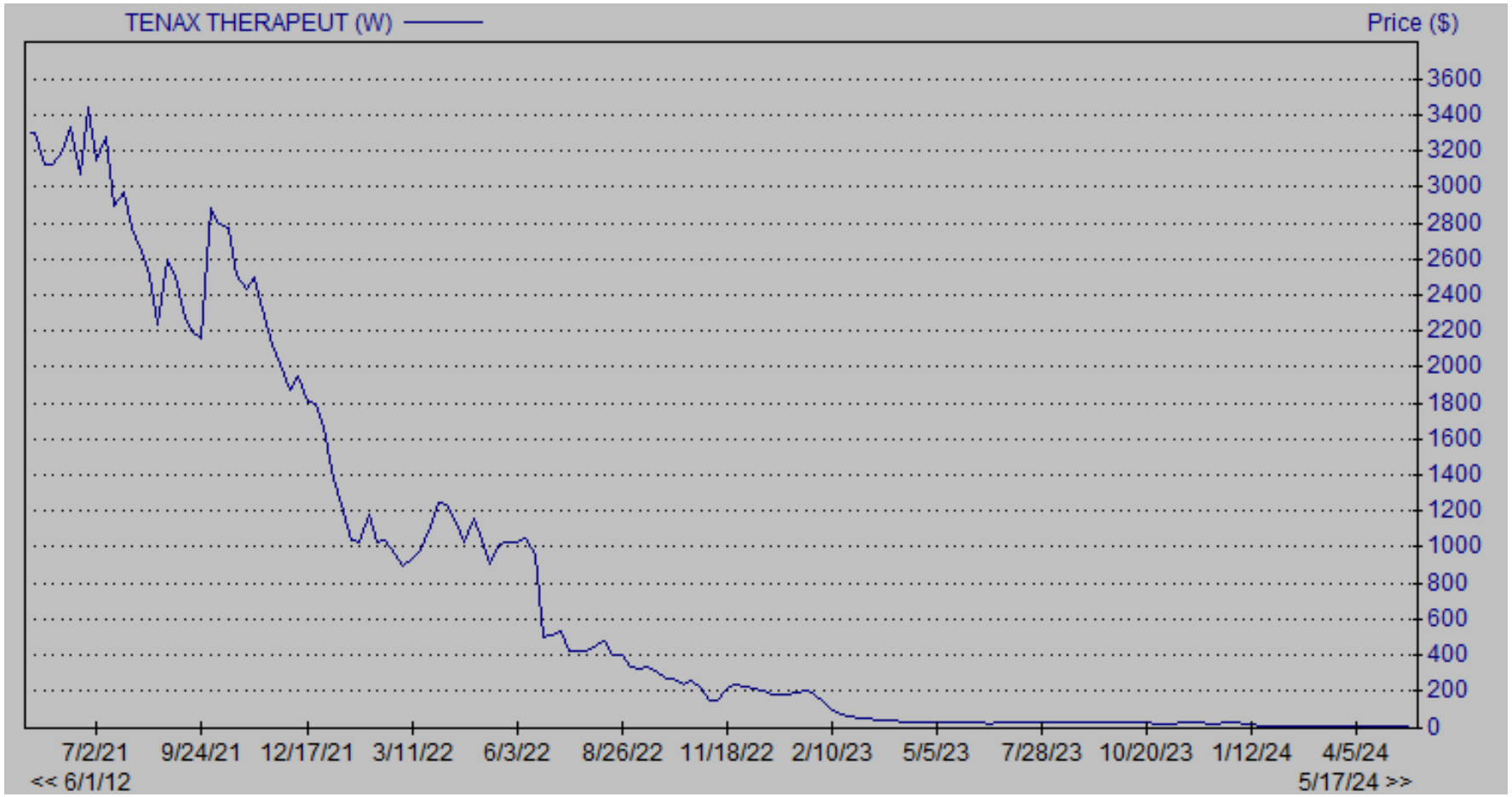
HISTORICAL STOCK PRICE

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



[2] Source: Zacks Research System

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