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Tenax Therapeutics, Inc. (TENX-NASDAQ)

Second Quarter Results

Based on our DCF model and a 15% discount rate, Tenax is valued at approximately $4.50 per share. We apply a combined 40% probability of eventual sales of levosimendan in the United States and of imatinib globally.

Current Price (9/10/21)	$1.42
Valuation	**$4.50**

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. TENX completed its Ph2 PH-HFpEF trial in 2020 and should start a Ph3 in 2022. 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 pulmonary hypertension, its inotropic and lusitropic effects and the results from the HELP trial, there is sufficient support 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	**$3.68**
52-Week Low	**$0.80**
One-Year Return (%)	**-0.7**
Beta	**2.41**
Average Daily Volume (sh)	**114,403**
Shares Outstanding (mil)	**25.2**
Market Capitalization ($mil)	**$35.8**
Short Interest Ratio (days)	**2.83**
Institutional Ownership (%)	**13.9**
Insider Ownership (%)	**34.2**
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 2020 Estimate	**N/A**
P/E using 2021 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 $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2021	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2022					$0.0 E
2023					$0.0 E

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.38 A	-$0.23 A	-$0.18 A	-$0.12 A	-$0.95 A
2021	-$1.64 A	-$0.10 A	-$0.13 E	-$0.12 E	-$1.71 E
2022					-$0.56 E
2023					-$0.81 E

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WHAT'S NEW

Second Quarter 2021 Financial and Operational Review

Tenax Therapeutics, Inc. (NASDAQ: TENX) reported second quarter 2021 results via the issuance of a press release and the filing of Form 10-Q to the SEC on August 16, 2021.

Highlights for the second quarter and to-date:

- Publication of HELP trial results - April 2021
- Addition of company Russell Microcap Index - June 2021
- Announced CEO transition - July 2021
- $10 million PIPE ATM offering - July 2021
- KOL webinar on Levosimendan in PH-HFpEF - August 2021
- Publication highlighting novel levosimendan MOA in PH-HFpEF - August 2021

Tenax produced no revenues during 2Q:21 and incurred operating expenses of $1.96 million resulting in net loss of ($1.72) million, or ($0.10) per share.

For the quarter ending June 30, 2021 versus the quarter ending June 30, 2020:

- General and administrative expenses increased 46% to $1.27 million from $869,000 driven by reimbursement of approximately $358,000 in legal fees associated with arbitration proceedings in the prior year as well as increases in Board of Directors fees and capital market expenses, partially offset by a reduction in investor relations services behind the difference;
- Research and development expenses decreased 46% to $693,222 from $1,274,837 with the conclusion of Phase II HELP and associated CRO and patient enrollment costs, partially offset by imatinib formulation development contributing to the change;
- Other income increased to income of $247,820 from a loss of ($2,101) with forgiveness of Paycheck Protection Program (PPP) loan;
- Net loss was ($1.72) million versus ($2.14) million, or ($0.10) and ($0.23) per share, respectively.

At the end of the second quarter, cash, equivalents and marketable securities totaled $2.18 million, compared to $6.71 million at the end of 2020. Following forgiveness of the PPP Tenax holds no debt on its balance sheet. Cash burn for the six months ended June 30th totaled $5.07 million. Following the end of the quarter, Tenax raised gross proceeds of $10 million from a securities purchase agreement with an institutional investor. Management has guided that cash reserves, including the $10 million recently secured, are sufficient to sustain the firm through 2Q:22.

KOL Webinar on Levosimendan for PH-HFpEF

Tenax announced, on August 5th, a Key Opinion Leader (KOL) webinar that was held on August 16, 2021 at 10 AM ET. The event focused on the current treatment landscape and therapeutic potential of levosimendan in pulmonary hypertension with heart failure with preserved ejection fraction (PH-HFpEF). The webinar featured KOL Daniel Burkhoff, MD, Ph.D., member of Tenax' Scientific Advisory Board, who discussed the unmet medical need in treating patients with PH-HFpEF and how Tenax' levosimendan could become a new treatment option. Stuart Rich, M.D., Tenax' Chief Medical Officer then discussed clinical development plans for levosimendan.

Dr. Burkhoff began with an overview of HFpEF, exercise hemodynamics, stressed blood volume and its role in exercise hemodynamics comparing between normal and HFpEF patients, and the effects of levosimendan in this context. Preserved ejection fraction includes patients with 50% ejection fraction and greater, which can include a variety of underlying pathophysiology. Symptoms for these patients include congestion, enlarged left atria, and exercise intolerance. Pulmonary hypertension is common in those with HFpEF, and for those with PH-HFpEF, prognosis is worse. Patients are diagnosed using an assessment of hemodynamic exercise test, namely supine bicycle while catheterized to measure a panel of pressure metrics. Measurement of patients during sustained exercise allows segmentation of the severity of PH-HFpEF. Those with PH-HFpEF show a distinct, dynamic increase in pulmonary wedge pressure under exercise. Central venous pressure is also increased, allowing insight into the underlying

physiology. Some mechanistic theories have suggested the ventricle as a driver in the condition, including decrease in chamber size, abnormal stiffness, and other aspects directly related to the ventricles. More recently, potential tests shifted to peripheral factors such as the inability of arteries to vasodilate, decreased oxygen extraction from the muscle and venoconstriction. Venoconstriction represents a novel mechanism relating to levosimendan's efficacy that had not been significantly studied due to technological limitations.

In particular, volume distribution and volume metabolism in the body may both be modulated with sympathetic activation. The acute effects of exercise, which is one form of sympathetic activation, results in rapid mobilization of venous reservoir, causing venoconstriction leading to increase in effective circulating blood volume, or stressed blood volume. The sympathetic nervous system and its interaction with venous system create conditions where relatively small changes in venous property can result in potent regulation of stressed blood volume. In PH-HFpEF, patients' resting stressed blood volume is increased compared to normal, and they have a greater increase in stressed blood volume compared to normals during exercise. Among the many factors that change during exercise, heart rate, contractility and systemic vascular resistance are primarily responsible for increase in cardiac output and blood pressure observed during exercise. Keeping all factors constant, changing only venous compliance, changes in stressed blood volume account for almost all changes in central venous pressure (CVP) and wedge pressure, suggesting stressed blood volume as a therapeutic target. Tenax' HELP trial, after six weeks, saw almost no change in placebo group in CVP or wedge pressure at rest or with legs up versus the treated group that had 5 mm reduction in CVP and wedge pressure at rest and with legs up. Analysis of stressed blood volume found no significant change in the placebo group whereas a 500 mL reduction in stressed blood volume was observed in the treated group. This was in line with expectations as results from a previous study[1] (Fudim *et al.)* at Duke University which showed that splanchnic nerve block, which is responsible for venoconstriction, reduced resting and exercise-induced pulmonary arterial and wedge pressure.

Dr. Stuart Rich recapitulated many of the points that Dr. Burkhoff made. Rich emphasized that HFpEF, which is group 2 of pulmonary hypertension, is considered the largest unmet medical need in cardiovascular medicine at this time, and that PH-HFpEF is a distinct pathology. Every approved pulmonary vasodilator has been tried in PH-HFpEF and failed. Levosimendan is not only a calcium channel activator, as it was developed as an inotrope to treat systolic heart failure, but it is also a potent potassium channel activator of ATP type. And this was shown when levosimendan-treated patients displayed improvements in pressure metrics that translated to statistically significant exercise tolerance improvement, an important feature in securing market approval. Tenax is now in the process of transitioning intravenously-administered patients to an oral formulation that were in the open label extension. This process is expected to be complete by 4Q:21. We expect to see a 2022 start to a Phase III trial for levosimendan.

Novel Levosimendan MOA in PH-HFpEF

On August 12th, Tenax issued a press release announcing the publication of a new study identifying a novel mechanism of action behind the improved cardiovascular hemodynamics and exercise tolerance observed in Phase II HELP study. The publication, entitled "Changes in Stressed Blood Volume with Levosimendan in Pulmonary Hypertension from Heart Failure with Preserved Ejection Fraction: Insights Regarding Mechanism of Action," was published in the *Journal of Cardiac Failure.* Through an in-depth analysis of data from the HELP Study, the authors elucidated the underlying mechanism and found that the reductions in pulmonary wedge pressure (PCWP) and central venous pressure (CVP) did not depend on any effect of the drug on the force or speed of contraction of cardiac muscle. Instead, the study concluded that the reduction in PCWP and CVP was attributable to levosimendan's effect on K+ATP channel activation, lowering stressed blood volume (SBV), or the volume of blood that is being pushed by the heart. The work validated that dilating the splanchnic[2] circulation will lower SBV and by extension CVP and PCWP in PH-HFpEF as observed in the HELP trial.

DiTonno Retires, Giordano Takes the Helm as CEO

Announced on July 7th, Tenax announced that CEO Anthony DiTonno retired, effective July 13, 2021. DiTonno served as CEO, since 2018, and Director for Tenax. The Board has appointed Christopher Giordano to serve as Tenax' CEO, effective July 14, 2021. To facilitate the transition, Giordano will serve as an employee of Tenax starting July 6 until he begins his role as CEO.

[1] Fudim M, Boortz-Marx RL, Ganesh A, DeVore AD, Patel CB, Rogers JG, Coburn A, Johnson I, Paul A, Coyne BJ, Rao SV, Gutierrez JA, Kiefer TL, Kong DF, Green CL, Jones WS, Felker GM, Hernandez AF, Patel MR. Splanchnic Nerve Block for Chronic Heart Failure. JACC Heart Fail. 2020 Sep;8(9):742-752. doi: 10.1016/j.jchf.2020.04.010. Epub 2020 Jun 10. PMID: 32535123.

[2] Circulation that flows to the abdominal gastrointestinal organs including stomach, liver, spleen, pancreas, etc.

$10 Million PIPE ATM Offer

Tenax disclosed that it had entered into a definitive agreement with a single healthcare-focused institutional investor for issuance and sale of 4,773,269 units at $2.095 per unit, with each unit consisting of one unregistered, pre-funded warrant to purchase one share of common stock and one unregistered warrant to purchase one share of common stock for a total of 9,546,538 shares underlying the warrants. The unregistered pre-funded warrants are immediately exercisable, have an exercise price of $1.97 per share and will expire 5.5 years from date of issuance.

HELP Trial Results

In June 2020, Tenax announced topline results from its Phase II **H**emodynamic **E**valuation of **L**evosimendan in **P**atients with PH-HFpEF (HELP). Results were positive and statistically significant for key measures critical to a successful Phase III trial. HELP is the first study conducted in PH-HFpEF patients to show material positive improvements in hemodynamics and 6-minute walk distance. The distance for the six minute walk test,[3] which has been used as a primary endpoint in other pulmonary hypertension trials, was 29 meters greater for the levosimendan group compared to the placebo group. This measure had a p-value of 0.0329, better than the 0.05 threshold required for statistical significance. We discussed the details of this trial in a previous report.

The Phase II trial provided substantial support for advancing levosimendan to the next stage that includes publication of results in a major cardiovascular journal, request for an end-of-Phase-II meeting with the FDA and preparation for a Phase III trial.

End-of-Phase II Meeting with FDA

In October 2020, Tenax met with the FDA for an end-of-phase II meeting to discuss Phase II HELP trial data. The FDA agreed that one or two Phase III trials, depending on size, with primary endpoint of change in 6-minute walk distance over 12 weeks or a single Phase III trial with clinical worsening over 24 weeks would be sufficient to demonstrate efficacy. The FDA has indicated that a composite primary endpoint, which will include the six minute walk test, will be required. The agency also highlighted the necessity of a safety database, which should be addressed as Phase III protocol is finalized and submitted.

Next Steps

Tenax is currently switching from infused to oral levosimendan in patients who participated in the open-label extension of the HELP study, who continue treatment and remain eligible to participate in the HELP study amendment. The next regulatory contact will likely be prior to year end. The additional meeting with the FDA is necessary to report on results related to the shift to oral from infused levosimendan. In parallel with the crossover work with the oral dosage, Tenax is identifying sites for the upcoming Phase III. Institutional review boards (IRBs) are granting approvals at the sites and preparation for registrational studies is advancing as expected. Management has guided toward a 2022 start to the Phase III trial.

While it is too early to determine Phase III trial design, based on commentary we anticipate a composite primary endpoint that will include the six minute walk test. Our best estimate is that continued preparatory work will take place in 2021 and first patients will be enrolled in 2022. A rough estimate of time, cost and size of the registrational trial range from 18 to 36 months, $30 to $50 million and 200 to 300 patients. While these estimates have not been confirmed by the company, we believe they are reasonable based on precedent.

Additions to the Board

Tenax added four new members to its board of directors, which was announced on March 2nd, 2021. The new directors included June Almenoff, MD, Ph.D., Michael Davidson, MD, Delcan Doogan, MD, and Stuart Rich, MD, who was recently appointed the company's Chief Medical Officer.

Dr. Almenoff brings over 20 years of senior leadership experience in the biopharma space. She served as President and Chief Medical Officer of Furiex Pharmaceuticals, which was acquired by Actavis (now AbbVie), and held various ascending positions at GlaxoSmithKline for 12 years. Dr. Almenoff is currently Chief Scientific Officer of RedHill Biopharma (NASDAQ: RDHL) and also serves on the investment advisory board of Harrington Discovery Institute and on the boards of Brainstorm Cell Therapeutics (NASDAQ: BCLI) and Kurome Therapeutics. Dr. Al-

[3] The 6 Minute Walk Test is a sub-maximal exercise test used to assess aerobic capacity and endurance. The distance covered over a time of 6 minutes is used as the outcome by which to compare changes in performance capacity.

menoff received her bachelor's from Smith College and graduated with AOA honors from the MD-Ph.D. program at Mount Sinai School of Medicine, completing post-graduate medical training at Stanford University Medical Center.

Dr. Michael Davidson was founder and former Chief Scientific Officer of Corvidia Therapeutics, which was acquired by Novo Nordisk. He is Clinical Professor and Director of the Lipid Clinic at the University of Chicago Pritzker School of Medicine. Dr. Davidson co-founder and Chief Medical Officer of Omthera Pharmaceuticals, acquired by AstraZeneca Pharmaceutical. He also founded the Chicago Center for Clinical Research that was acquired by Pharmaceutical Product Development. Dr. Davidson received his bachelor's and master's from Northwestern University and MD from Ohio State University School of Medicine.

Dr. Declan Doogan adds over 30 years of pharma and biotech industry experience. He served as Senior Vice President and Head of Worldwide Development at Pfizer and held positions at Pfizer in the US, UK and Japan. Dr. Doogan also held positions as CMO and acting CEO of Amarin (NASDAQ: AMRN) and is Chairman and co-founder of Biohaven (NYSE: BHVN). He serves on a number of Board appointments and received his MD from Glasgow University.

On April 7, three long-serving directors elected to step down. Ronald R. Blanck, D.O., Gregory Pepin and Chris A. Rallis will depart their posts on the Board of Directors of Tenax Therapeutics, effective as of the Annual Meeting of Stockholders scheduled for June 10, 2021.

Exhibit I – Change in Board of Directors Composition[4]

2020 Board	Interim Board	Refreshed Board
Dr. Ronald Blank (Chairman)	Dr. Ronald Blank (Chairman)	Gerald Proehl (Chairman)
Anthony DiTonno	Anthony DiTonno	Anthony DiTonno
Steven Boyd	Dr. June Almenoff	Dr. June Almenoff
Dr. Keith Maher	Steven Boyd	Steven Boyd
James Mitchum	Dr. Michael Davidson	Dr. Michael Davidson
Gregory Pepin	Dr. Declan Doogan	Dr. Declan Doogan
Gerald Proehl	Dr. Keith Maher	Dr. Keith Maher
Chris A. Rallis	James Mitchum	James Mitchum
	Gregory Pepin	Dr. Stuart Rich
	Gerald Proehl	
	Chris A. Rallis	
	Dr. Stuart Rich	

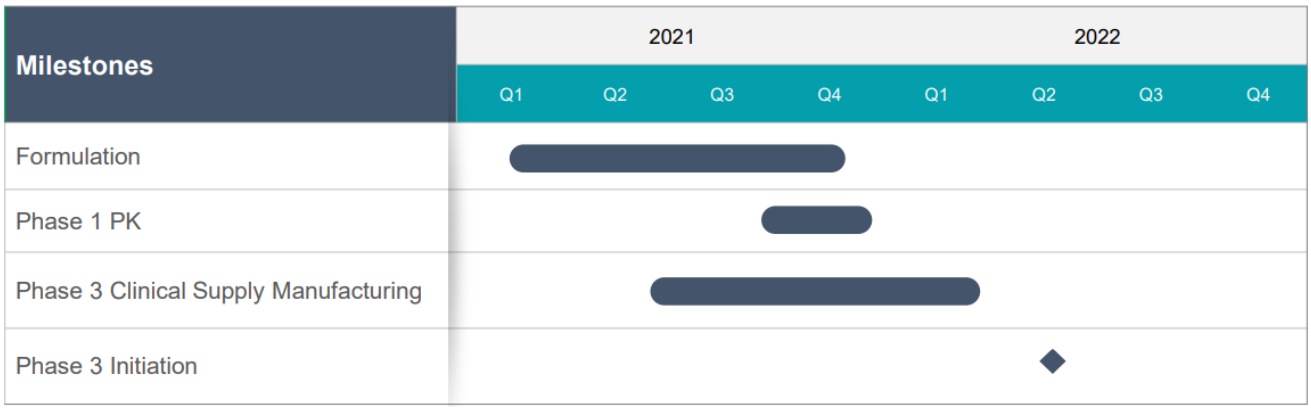
PH Precision Med Acquisition

On January 19, 2021, Tenax announced the acquisition, through merger with wholly owned subsidiary Life Newco II, of privately held, clinical stage PH Precision Med (PHPM). The transaction was completed on January 15, 2021, in an equity deal valued at approximately $21.6 million, which we discuss here. PHPM's shareholders were issued the equivalent of 12.124 million equity shares as consideration for the deal, comprised of 1,892,905 shares of Tenax common stock, representing ~15% of Tenax' shares outstanding, and 10,232 shares of Class B Preferred Stock, which convert to 10,232,000 shares of common stock, pending stockholder approval. Tenax is required to hold a stockholder meeting no later than July 31, 2021 to obtain stockholder approval. If not approved, meetings will be held every 90 days to seek approval until either approved or the convertible preferred stock is no longer outstanding. Based on the closing price of Tenax on January 18, 2021 of $1.78, the acquisition is valued at approximately $21.6 million.

To add detail to Tenax' recent acquisition of PH Precision Med and its candidate imatinib, Tenax hosted a web conference on January 21, 2021, a few days after the acquisition was announced. We discuss the specifics of the deal, provide background on imatinib and its use in PAH and review existing therapies for the indication in a previous report. Efforts are now underway to identify a formulation of the drug using an enteric coating to address GI-related side effects that were identified in previous trials. A pharmacokinetic (PK) study testing the new formulation is expected to be conducted and provide results in 2H:21.

[4] Compiled by Zacks Analysts

Exhibit II – Imatinib Development Timeline[5]



Milestones

- HELP Topline data – June 2020
- End of Phase II Meeting with FDA – October 2020
- Acquisition of PHPM – January 2021
- Finalize PH-HFpEF Phase III Trial Design – 2021
- PK and formulation work for imatinib in PAH – 2H:21
- Phase I trial for imatinib in PAH – 2H:21
- Launch Phase III PH-HFpEF Trial – 1H:22
- Site selection and enrollment for imatinib PH trial - 2022
- Launch Phase III in PH-HFpEF – 2022
- Imatinib PH trial topline report – 2024
- Completion of Phase III in PH-HFpEF - 2024

Summary

The HELP trial has ended and Tenax is now seeking regulatory guidance on next steps required to begin the Phase III portion of development. HELP's encouraging results have attracted further investment from Armistice Capital, a group that may catalyze additional funding to move forward into a pivotal study. Tenax has generated strong data for the PH-HFpEF indication with statistically significant results for the six minute walk test and other parameters that we think will be required in a Phase III. Based on the research and analysis included in our PAH update report, we believe PH-HFpEF patients will benefit from levosimendan's mechanism of action and clinical trials can be pursued with a reasonable cost and time commitment. The addition of PHPM and its Phase III ready asset drove our recent price increase along with the successful outcome of the HELP trial. Several near term objectives are expected to be completed for the imatinib program including FDA guidance and trial site identification which should support a 2022 start to the Phase III trial. We maintain our valuation to $4.50 per share.

[5] Source: Tenax Therapeutics August 2021 Corporate Presentation

PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2020 A	Q1 A	Q2 A	Q3 E	Q4 E	2021 E	2022 E	2023 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%*	*0%*
Research and development	$4.6	$22.4	$0.7	$1.2	$1.2	$25.5	$11.0	$19.5
General & administrative	$5.3	$1.4	$1.3	$1.5	$1.3	$5.4	$5.7	$5.9
Income from operations	($9.9)	($23.7)	($2.0)	($2.7)	($2.5)	($30.9)	($16.7)	($25.4)
Operating Margin	-					-	-	-
Interest Income (expense)	($0.0)	($0.0)	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0
Other expense	($0.0)	($0.0)	($0.2)	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($9.9)	($23.7)	($1.7)	($2.7)	($2.5)	($30.9)	($16.7)	($25.4)
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	**($9.9)**	**($23.7)**	**($1.7)**	**($2.7)**	**($2.5)**	**($30.9)**	**($16.7)**	**($25.4)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.95)**	**($1.64)**	**($0.10)**	**($0.13)**	**($0.12)**	**($1.71)**	**($0.56)**	**($0.81)**
YOY Growth	*-30%*					*79%*	*-67%*	*45%*
Basic Shares Outstanding	10.37	14.52	17.22	20.20	20.56	18.12	30.00	31.50

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

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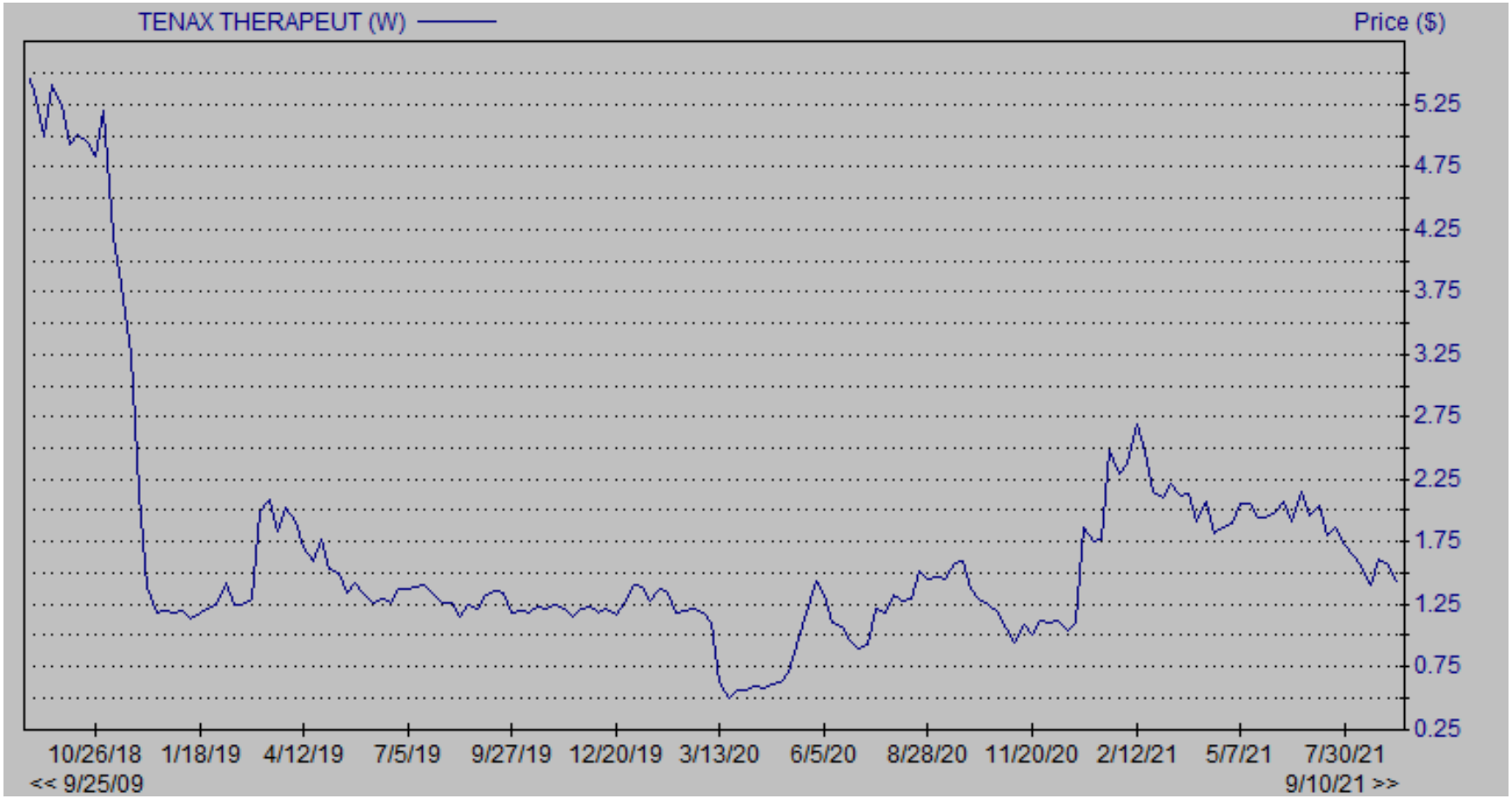
HISTORICAL STOCK PRICE

Tenax Therapeutics, Inc. – Share Price Chart



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