

Tenax Therapeutics, Inc.

(TENX-NASDAQ)

Tenax 1Q:18 Results

Based on our DCF model and a 15% discount rate, TENX is valued at approximately \$41.00 per share. We apply a 15% probability of eventual sales of levosimendan in the United States.

Current Price (5/25/18)

\$6.11

Valuation

\$41.00

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. 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 expects to launch a Phase 2 trial for PH-HFpEF in 3Q:18. This indication has a target population of between 1.5 and 2.0 million patients in the US and there is no existing treatment therapy. TENX will meet with the FDA in 1H:18 to design a Ph2 trial anticipated to begin in 2H:18. Based on trials for similar indications, the duration for Ph2 and Ph3 is expected to yield registrational data by 2023, followed by a 2024 launch of Levo in PH-HFpEF.

Levo has a 16-year history of use in Europe with a substantial volume of literature supporting its safety and efficacy. Given the body of research supporting the use of Levo in pulmonary hypertension and its inotropic and lusitropic effects, there is sufficient evidence to launch a Ph2 trial in PH-HFpEF. Additionally, this is a materially sized market with no current therapy, which provides substantial pricing and penetration opportunity.

SUMMARY DATA

52-Week High	\$15.80
52-Week Low	\$4.41
One-Year Return (%)	-40.4
Beta	1.15
Average Daily Volume (sh)	359,706

Shares Outstanding (mil)	1.45
Market Capitalization (\$mil)	\$8.9
Short Interest Ratio (days)	3.45
Institutional Ownership (%)	10
Insider Ownership (%)	16

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 2017 Estimate	N/A
P/E using 2018 Estimate	N/A

Zacks Rank	N/A
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Risk Level

Type of Stock
Industry

Above Average
Small-Growth
Med-Biomed/Gene

ZACKS ESTIMATES

Revenue

(in millions of \$)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2017	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 A
2018	\$0.0 A	\$0.0 E	\$0.0 E	\$0.0 E	\$0.0 E
2019					\$0.0 E
2020					\$0.0 E

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2017	-\$2.33 A	-\$2.12 A	-\$0.87 A	-\$0.98 A	-\$6.27 A
2018	-\$0.83 A	-\$1.89 E	-\$2.24 E	-\$2.23 E	-\$7.23 E
2019					-\$9.56 E
2020					-\$9.87 E

WHAT'S NEW

First Quarter 2018 Review

In January, Tenax [announced](#) its plan to advance the development of levosimendan for Pulmonary Hypertension associated with Heart Failure and preserved Ejection Fraction (PH-HFpEF). This announcement was followed shortly after by the [installation](#) of a scientific advisory board chaired by Stuart Rich, M.D. A reverse stock split occurred in February, followed by the publication of data supporting the use of levosimendan in PH. Positive news was [released](#) on April 4 when the FDA announced that the Phase II clinical protocol that is in effect for levosimendan can be used for the PH-HFpEF indication. This clears the pathway for a 2H:18 start to the Phase II trial.

Tenax reported no revenues in the first quarter due to its status as a clinical stage company. Research and development costs were minimal and stood at \$59 thousand, compared to \$1.8 million in the prior year. The decline was due to the near absence of clinical development costs, and substantial declines in consulting and personnel spend. General and administrative expenses totaled \$1.2 million, a 20% decline. Lower personnel costs contributed the most to the contraction, while legal and professional expenses were second most important. These trends were offset by slight increases in facilities costs and D&A. Net loss for the period was (\$1.2) million or (\$0.83) per share.

Cash balance was \$7.9 million and cash burn in the quarter was (\$1.6) million. The company continues with no debt.

Trial Design

In April the FDA allowed Tenax to submit their Investigational New Drug (IND) application under the existing clinical protocol for levosimendan. The agency also addressed the company's questions and provided guidance on the upcoming Phase II. This announcement will allow for a timely IND submission and anticipated enrollment in 2H:18. Substantial safety work has been performed on Levosimendan, negating the need for another Phase I trial. The FDA recognized that there are no approved drug therapies to treat PH-HFpEF patients and acknowledged this may allow a limited Phase III clinical program. Tenax will provide additional detail on the implications of a limited Phase III study at the End-of-Phase II Meeting for PH-HFpEF.

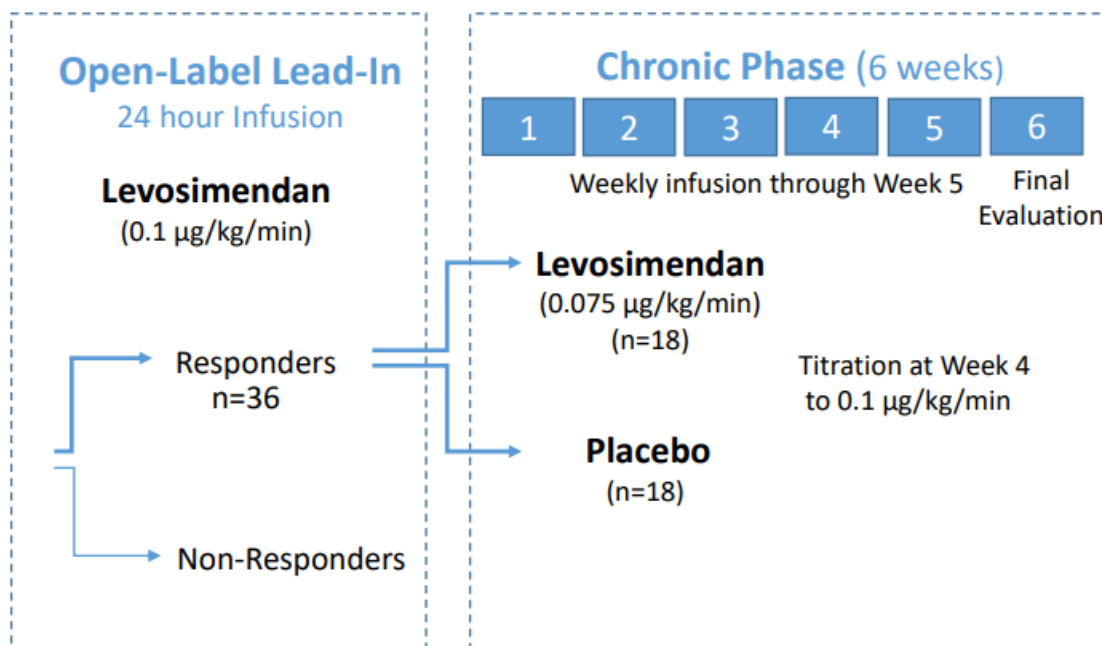
Based on details provided in the May corporate presentation which were updated slightly from expectations earlier in the year, we anticipate the study will be a double-blind clinical trial enrolling less than 40 PH-HFpEF patients in 20 sites, which should last 14 to 18 months. Based on preliminary work, enrollees will have a pulmonary arterial pressure (PAP) equal to or greater than 35, a pulmonary capillary wedge pressure (PCWP) equal to or greater than 20, a cardiac index (CI)¹ of less than or equal to 2.2, a left ventricular ejection fraction (LVEF) of over 40 and be NYHA Class IIb or III.

The primary endpoint of the study will be a change from baseline PCWP with bicycle exercise at Week 6. Expected secondary endpoints will relate to a change in resting PCWP under a variety of conditions, a change in resting & stressed CI, change in pulmonary vascular resistance (PVR) at rest & under stress, a global assessment at week six based on the Likert scale and length of exercise period, a physician's assessment of functional class and clinical events, including death and hospitalizations.

Based on management commentary and what has been accomplished in pre-clinical and clinical work to date, infusion for several hours one time per week appears to be the most likely dosing regimen; however, this will be confirmed in Phase II work.

¹ Cardiac Index (CI) is a hemodynamic parameter that relates the cardiac output from left ventricle in one minute to body surface area, thus relating heart performance to the size of the individual. The unit of measurement is liters per minute per square meter (L/min/m²). Source: Wikipedia / https://en.wikipedia.org/wiki/Cardiac_index

Exhibit I – Phase II Study Design²



Reverse Stock Split

Tenax received a notice from the NASDAQ in 2017 notifying the company that they could be at risk of delisting due to the shares trading below \$1.00. The notice indicated that they were not in compliance with Nasdaq Listing Rule 5550(a)(2), due to the minimum bid price falling below \$1.00 for 30 consecutive days. On February 15, 2018, Tenax proposed an amendment to allow for a reverse stock split to take place prior to year-end 2018. The primary reasons for recommending the reverse split is to maintain NASDAQ compliance and listing on the exchange and to encourage investor interest in the company's shares. After receiving a favorable shareholder vote, a reverse stock split became effective on February 23, 2018 at a ratio of 1:20. On March 12, 2018, the NASDAQ indicated that Tenax had regained compliance with NASDAQ minimum bid price requirements.

Milestones

- Meet with FDA for Phase II Trial Design – 1Q:18
- Complete Phase II Design – 2Q:18
- Begin Trial Enrollment – 2H:18
- Conduct Comprehensive Strategic Alternative Review – 2018
- Raise Capital – 2H:18

Summary

The first quarter began with an announcement that a new indication would be pursued for levosimendan. Following the announcement, Tenax has populated its scientific advisory board, and highlighted the opportunity for levosimendan in PH-HFpEF to the scientific and investment community. After a favorable meeting with the FDA, the company will launch a Phase II trial for HF-PHpEF in the next couple months. Based on the research and analysis included in our initiation, PH-HFpEF patients should benefit from Levosimendan's mechanism of action and clinical trials can be pursued with a reasonable cost and time commitment. The indication is also in an area with no other approved treatments. Market size is material and with no other approved therapy available, pricing should be strong and penetration high. We maintain our target price of \$41.00.

² Source: Tenax May 2018 Investor Presentation

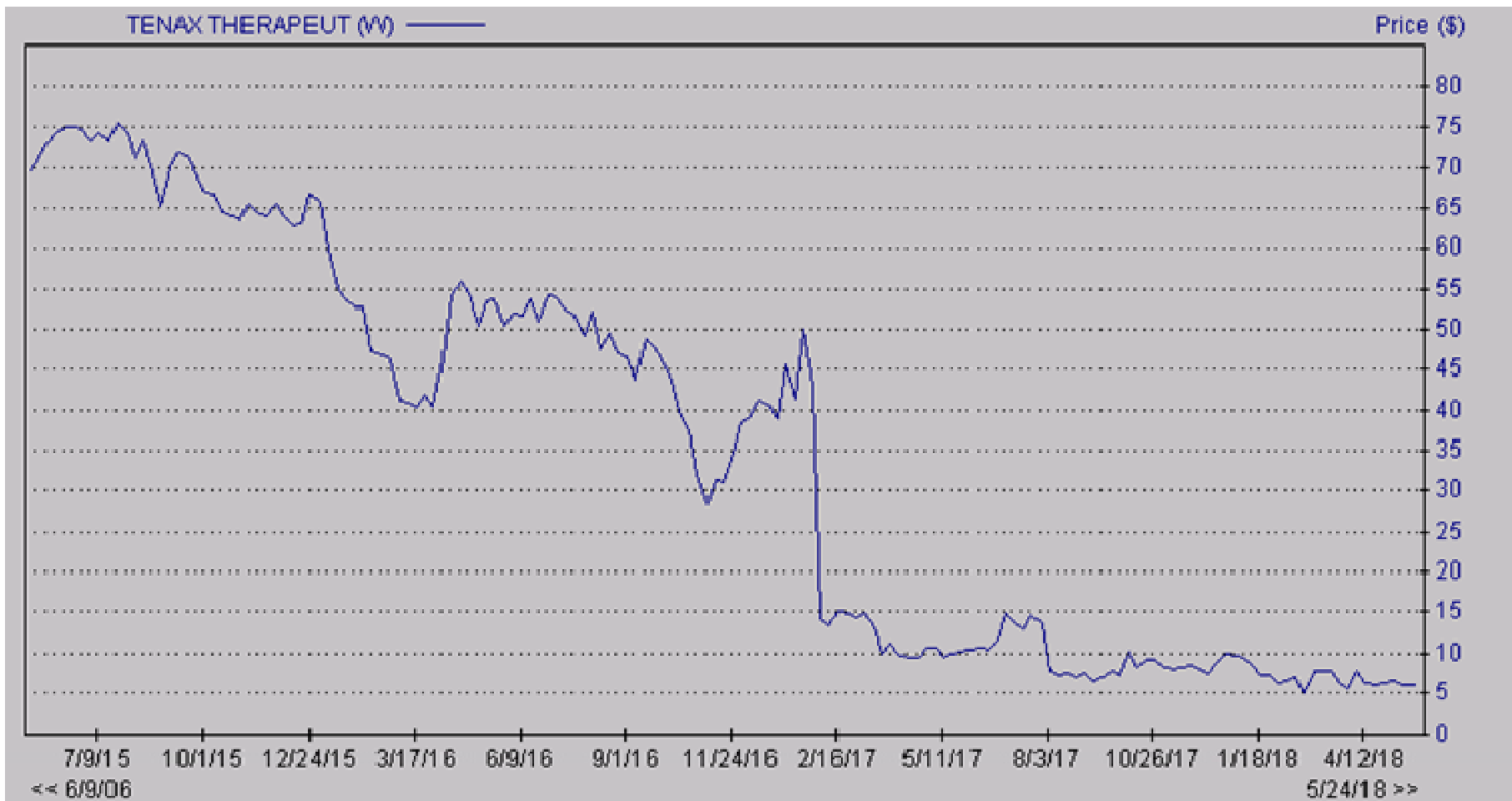
PROJECTED FINANCIALS

Tenax Therapeutics, Inc. - Income Statement

Tenax Therapeutics, Inc.	2017 A	Q1 A	Q2 E	Q3 E	Q4 E	2018 E	2019 E	2020 E
Total Revenues	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>YOY Growth</i>	0%	0%	0%	0%	0%	0%	0%	0%
Cost of goods sold	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Product Gross Margin</i>	0%	0%	0%	0%	0%	0%	0%	0%
Research and development	\$3.5	\$0.1	\$1.5	\$2.0	\$2.0	\$5.6	\$8.8	\$9.6
General & administration	\$5.7	\$1.2	\$1.2	\$1.2	\$1.2	\$4.8	\$5.2	\$5.6
Income from operations	(\$9.2)	(\$1.2)	(\$2.7)	(\$3.2)	(\$3.2)	(\$10.3)	(\$14.0)	(\$15.2)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Interest Income (expense)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Other expense	(\$0.4)	(\$0.0)	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
Pre-Tax Income	(\$8.8)	(\$1.2)	(\$2.7)	(\$3.2)	(\$3.2)	(\$10.3)	(\$14.0)	(\$15.2)
Accrual for Income Taxes	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$8.8)	(\$1.2)	(\$2.7)	(\$3.2)	(\$3.2)	(\$10.3)	(\$14.0)	(\$15.2)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$6.27)	(\$0.83)	(\$1.89)	(\$2.24)	(\$2.23)	(\$7.23)	(\$9.56)	(\$9.87)
<i>YOY Growth</i>	1650%	-64%	-10%	156%	128%	15%	32%	3%
Basic Shares Outstanding	1.41	1.42	1.43	1.43	1.44	1.43	1.47	1.54

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

HISTORICAL STOCK PRICE



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