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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Animal Data for SARS-CoV-2 Vaccine Candidate Shows Robust Immune Response…

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL in fibromyalgia and TNX-1800, TNXP is valued at $2.50/share. This model is highly dependent upon continued clinical success of the company's assets and will be adjusted accordingly based upon future clinical results.

Current Price (11/30/20)	$0.57
Valuation	**$2.50**

OUTLOOK

On November 16, 2020, Tonix Pharmaceuticals Holding Corp. (TNXP) announced preliminary results for TNX-1800 following vaccination of non-human primates, which showed all eight animals manifested 'takes', a skin reaction that is a validated biomarker for T cell immunity, along with neutralizing antibody development. TNX-1800 is the company's lead COVID-19 vaccine candidate. Data from animal challenge studies are anticipated in the first quarter of 2021. In addition, two observational studies examining immunological responses from patients who have recovered from COVID-19 will read out in 2021. We also anticipate results from the Phase 3 RELIEF trial of TNX-102 SL (cyclobenzaprine HCl sublingual tablet) for fibromyalgia before the end of the fourth quarter of 2020. In addition, we anticipate results from the Phase 3 RECOVERY trial in the fourth quarter of 2020.

SUMMARY DATA

52-Week High	**$1.73**
52-Week Low	**$0.40**
One-Year Return (%)	**-49.38**
Beta	**1.44**
Average Daily Volume (sh)	**4,394,017**
Shares Outstanding (mil)	**157**
Market Capitalization ($mil)	**$90**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**2**
Insider Ownership (%)	**0**
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 2018 Estimate	**-0.7**
P/E using 2019 Estimate	**-1.6**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 A	0 A	0 A	0 E	0 E
2021					0 E
2022					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$12.90 A	-$9.50 A	-$5.69 A	-$2.86 A	-$19.33 A
2020	-$0.37 A	-$0.23 A	-$0.09 A	-$0.09 E	-$0.53 E
2021					-$0.28 E
2022					-$0.26 E

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WHAT'S NEW

Business Update

TNX-1800 Generates Positive Immune Response in Non-Human Primates

On November 16, 2020, Tonix Pharmaceuticals Holding Corp. (TNXP) announced a positive immune response in all eight animals vaccinated with TNX-1800, the company's lead COVID-19 vaccine candidate. Each of the vaccinated animals developed a 'take', which is a small lesion at the site of the immunization of a live virus (replicating) vaccine that occurs approximately one week following dosing. It is the result of an induced local inflammatory response caused by inoculation with a live virus, and it is the immune response to clear the virus that results in the small lesion. This reaction is a simple biomarker of functional T cell immunity, and is important as it is costly to measure the T cell response to a vaccine by *in vitro* studies, and also involve multiple tubes of blood.

In addition to the 'take', each of the immunized animals developed anti-SARS-CoV-2 neutralizing antibodies (≥1:40 titer), with the level of neutralizing antibodies similar between the high dose and low dose cohort. Importantly, the vaccine was well tolerated by all animals.

The next phase of this study will involve challenge of immunized animals with SARS-CoV-2, with results expected in the first quarter of 2021.

Multiple COVID-19 Vaccines in Development

Tonix is developing multiple vaccines against SARS-CoV-2. Contrary to almost all other coronavirus vaccines in development, Tonix's vaccine candidates are all designed to elicit a predominantly T cell response against the spike protein or other antigens of the SARS-CoV-2 virus. This is possible due to the use of a live, replicating viral vector.

- TNX-1800 is the company's lead development vaccine candidate that uses the company's horsepox vector and is designed to elicit a T cell response to the SARS-CoV-2 spike protein. The virus carries a copy of the SARS-CoV-2 spike protein gene in its genome, which is then expressed following immunization.

- TNX-2300 is a COVID-19 vaccine candidate based on the bovine parainfluenza virus that Tonix acquired through a partnership agreement with Kansas State University. This live attenuated viral vector is designed to elicit a predominantly T cell response by co-stimulation with the CD40 ligand.

- TNX-1810, TNX-1820, and TNX-1830 are being developed through a partnership with the University of Alberta. Each of those candidates uses the company's horsepox vector and are designed to elicit an almost exclusive T cell response to proteins from SARS-CoV-2 other than the spike protein.

Tonix is one of only a few companies developing a SARS-CoV-2 vaccine utilizing a live, attenuated replicating viral vector that is designed to generate a predominant T cell response and the only company utilizing the horsepox vector or the bovine parainfluenza virus. Orthopoxviruses are known to induce strong innate and adaptive immune responses along with long-lasting T cell immunity (Chaudhri *et al*., 2015), which we believe will be an important feature of a successful SARS-CoV-2 vaccine. In addition, orthopoxviruses do not integrate into the host genome and are not persistent.

Merck & Co., Inc. (MRK) is one of the other companies utilizing live viral vectors for developing a SARS-CoV-2 vaccine. The company previously announced the acquisition of Themis, a privately-held company that utilizes a modified measles vaccine virus (live replicating) as a vector. Merck has initiated a Phase 1 clinical trial for that vaccine (NCT04497298). In addition, Merck is developing a second COVID-19 vaccine using an engineered vesicular stomatitis virus (VSV), which is also a live, replicating vector. We view Merck's approach to developing a COVID-19 vaccine using live, replicating vectors as an important validation of that technology.

Observational COVID-19 Studies

In addition to the aforementioned vaccine candidates, Tonix also has two ongoing observational studies with COVID-19 patients.

- COV-LOGIC is a multi-cohort sample collection study in which T cell and antibody responses will be collected from healthy volunteers that have recovered from SARS-CoV-2 infection. The T cell and antibody analyses are similar to that which will be conducted for the company's vaccine clinical trials. The study is being conducted in collaboration with Southern Research, which is also working with Tonix on the animal testing of TNX-1800. We anticipate results from the study in the first half of 2021.

- PRECISION is examining the immune responses from healthy volunteers who have recovered from COVID-19 or who were infected with SARS-CoV-2 but did not exhibit symptoms. This study is taking place in collaboration with Columbia University and will focus on an in-depth analysis of T cell and antibody responses following SARS-CoV-2 infection. We anticipate results in 2021.

Pfizer Reports Positive Data for COVID-19 Vaccine

On November 18, 2020, Pfizer, Inc. (PFE) and BioNTech SE (BNTX) announced their mRNA-based SARS-CoV-2 vaccine candidate (BNT162b2) was 95% effective against COVID-19 based on 162 COVID-19 cases confirmed in the placebo group compared to 8 in the vaccine group. In addition, the efficacy was consistent across various age, gender, race, and ethnicity demographics, with the efficacy in those age 65 and older being 94%. The vaccine was well tolerated with the only Grade 3 adverse event occurring in >2% of participants being fatigue at 3.8% and headache at 2.0%.

While this news is certainly encouraging, there are a number of questions that remain following the first interim efficacy analysis, including:

- How long will immunity last for? Antibody immunity, for which all the lead COVID-19 vaccine candidates are focused, is known to wane after several months, thus while the vaccine may offer protection from SARS-CoV-2 infection shortly after immunization, how long that immunity lasts for is unclear.
- What percentage of patients will fail to get the second dose of vaccine? With two immunizations necessary, it will be interesting to see what percentage of patients who receive the first dose of vaccine would remember to get a second dose, and how this might affect efficacy.
- Does the vaccine prevent forward transmission? The only way to bring the current pandemic under control is through the elimination of forward transmission from an infected individual to non-infected persons. The ongoing Phase 3 clinical trials for the lead COVID-19 vaccine candidates are only designed to determine if they can prevent the occurrence of COVID-19 and will not offer insight into whether the vaccines prevent the spread of the virus. Eliminating forward transmission can only be achieved through sterilizing immunity. Given that the vaccines emphasize an antibody response, we are unsure whether sterilizing immunity will be induced.

As mentioned previously, Tonix's COVID-19 vaccine candidates emphasize a T cell immune response, which we believe is more likely to result in sterilizing immunity and the elimination of forward transmission. Thus, while the first set of COVID-19 vaccines is farther along in development, until we learn more about the longevity of protection and ability to reduce forward transmission, we believe an opportunity exists for TNX-1800 as a long-term solution as an effective COVID-19 vaccine.

Lastly, since the initial COVID-19 vaccines all emphasize an antibody mediated response there is the potential for antibody dependent enhancement (ADE) and/or vaccine-associated enhanced respiratory disease (VAERD). ADE is an enhancement of infection through the Fc region of antibodies and has previously been seen with dengue virus (Dowd *et al*., 2011). VAERD is a distinct phenomenon from ADE that was first seen in children in the 1960's when they were vaccinated with whole-inactivated virus vaccines for measles and respiratory syncytial virus (RSV) that is mediated through immune complex formation (Polack *et al*., 2002; Polack *et al*., 2003). There are a number of mitigation strategies to decrease the chance of ADE or VAERD occurring, including the generation of high-quality neutralizing antibodies along with promoting a balanced T_H1/T_H2 T cell response or a T_H1-biased response. Thus far, there have been no indications of either ADE or VAERD occurring, however we only have safety data for a very short time, thus it will be important to verify that no safety issues occur with a longer term follow up.

Results for Phase 3 RELIEF Trial in 4Q20

In September 2020, Tonix announced the outcome of the pre-planned interim analysis for the Phase 3 RELIEF trial of TNX-102 SL for the management of fibromyalgia. The independent data monitoring committee (IDMC) made the non-binding recommendation that the trial continue to completion with the addition of 210 participants to the original sample size of 470 participants, which is the maximum number of participants that could be added under the interim

statistical analysis plan. The company decided to complete the trial with the 503 currently enrolled participants and we anticipate topline results in the fourth quarter of 2020.

The RELIEF trial is a randomized, double blind, placebo controlled trial that enrolled 503 participants in the U.S. (NCT04172831). All participants assigned to TNX-102 SL initiated on 2.8 mg daily for the first two weeks. Following that, the dosage increased to 5.6 mg daily for 12 weeks. The primary outcome measure is the daily diary pain severity score change from baseline to Week 14 analyzed by mixed model repeated measures with multiple imputation. For a discussion of prior data for TNX-102 SL at 2.8 mg per day in fibromyalgia, see our previous report.

Update on TNX-1900

In June 2020, Tonix announced the acquisition of TNX-1900, a proprietary, patented enhanced formulation of intranasally administered oxytocin that has demonstrated activity in various non-clinical studies in migraine prophylaxis and neuropsychiatric models. Earlier this year, the company presented the preclinical results of TNX-1900 at the American Academy of Neurology first ever Sports Concussion Conference that investigated the efficacy of intranasal oxytocin in relieving pain and associated depressive behavior following traumatic brain injury (TBI). The presentation can be accessed here.

TBI disrupts the usual functioning of the brain and is typically brought on by a bump, blow, blast, or jolt to the head (CDC). Some of the consequences of TBI are post traumatic headache (PTH), changes in memory, attention, and concentration, changes in mood (irritability, anxiety, depression, etc.), and sleep disturbances. TBI may also develop alongside posttraumatic stress disorder (PTSD). Approximately 1.7 million TBIs occur every year in the U.S.

The preclinical data presented by Tonix showed that intranasal oxytocin, but not IV oxytocin, attenuates pain responses in a rat model of TBI, and showed no evidence of addictive potential in a conditioned place preference model. The effects could be blocked by an oxytocin antagonist, showing that the results were driven specifically via oxytocin receptors. Lastly, intranasal oxytocin attenuated post-TBI mood effects such as anxious and depressive behaviors in the elevated plus maze and forced swim models, respectively.

We anticipate Tonix filing an IND in the first quarter of 2021 such that a Phase 2 clinical trial of TNX-1900 can be initiated in the second quarter of 2021. The first indication for TNX-1900 will be the prophylactic treatment of chronic migraine.

Financial Update

On November 9, 2020, Tonix announced financial results for the third quarter of 2020. As expected, the company did not report any revenues for the third quarter of 2020. Net loss available to common stockholders for the third quarter of 2020 was $12.0 million, or $0.09 per share, compared to a net loss of $7.8 million, or $5.69 per share, for the third quarter of 2019. R&D expenses for the third quarter of 2020 were $8.8 million, compared to $5.1 million for the third quarter of 2019. The increase was primarily due to the timing of development milestones related to the Phase 3 RELIEF and RALLY studies in 2020 along with increased development activities for TNX-1800 and TNX-801. G&A expenses for the third quarter of 2020 were $3.2 million, compared to $2.8 million for the third quarter of 2019. The increase was primarily due to an increase in financial reporting expenses and non-cash compensation expenses.

The company exited the third quarter of 2020 with approximately $55.7 million in cash and cash equivalents. As of November 6, 2020, the company had approximately 156.6 million shares outstanding and, when factoring in reasonably priced warrants and stock options, a fully diluted share count of approximately 166.9 million.

Conclusion

We are looking forward to the animal efficacy data for TNX-1800, with the data from the challenge studies expected in the first quarter of 2021. In addition, we await the topline results of the RELIEF trial and will be particularly interested to see if there is a difference in how patients responded in the trial based on whether they were enrolled prior to or after the pandemic got underway. Based on the company raising additional capital during the third quarter of 2020 we have slightly lowered our valuation to $2.50.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2019 A	Q1 A	Q2 A	Q3 A	Q4 E	2020 E	2021 E	2022 E
TNX-102 SL (FM)	$0	$0	$0	$0	$0	$0	$0	$0
Research & Collaborations	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
CoGS	$0.0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$18.2	$4.7	$10.6	$8.8	$11.0	$35.1	$38.0	$40.0
SG&A	$10.6	$2.6	$3.6	$3.2	$3.0	$12.4	$12.0	$13.0
Operating Income	($28.8)	($7.3)	($14.2)	($12.0)	($14.0)	($47.5)	($50.0)	($53.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.2	$0.0	$0.0	$0.0	$0.1	$0.1	$0.4	$0.4
Pre-Tax Income	($28.6)	($7.3)	($14.2)	($12.0)	($13.9)	($47.3)	($49.6)	($52.6)
Preferred Stock Deemed Dividend	$2.5	$1.26	$0.0	$0.0	$0.0	$1.3	$0.0	$0.0
Warrant Deemed Dividend	$0.0	$0.45	$0.0	$0.0	$0.0	$0.5	$0.0	$0.0
Taxes & Other	$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	($31.1)	($9.0)	($14.2)	($12.0)	($13.9)	($49.1)	($49.6)	($52.6)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($19.33)**	**($0.37)**	**($0.23)**	**($0.09)**	**($0.09)**	**($0.53)**	**($0.28)**	**($0.26)**
YOY Growth	*-92.8%*	-	-	-	-	*-97.3%*	*-46.6%*	*-7.2%*
Weighted Shares Outstanding	1.6	24.0	62.4	127.2	156.0	92.4	175.0	200.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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