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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Developing Potential Vaccine Against COVID-19 Based on Horsepox Virus…

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL in fibromyalgia, TNXP is valued at $2.00/share. This model is highly dependent upon continued clinical success of TNX-102 SL in fibromyalgia and will be adjusted accordingly based upon future clinical results.

Current Price (04/03/20)	$0.68
Valuation	**$2.00**

OUTLOOK

Tonix Pharmaceuticals Holding Corp. (TNXP) recently announced a research collaboration with Southern Research to develop a vaccine (TNX-1800) against the novel coronavirus, SARS-CoV-2, based on Tonix's horsepox vaccine platform. The vaccine will be designed to express the SARS-CoV-2 spike protein to elicit immune responses. Potential advantages of using horsepox instead of vaccinia include the strong immunogenicity elicited by horsepox virus and since it replicates in human cells it results in direct antigen presentation through Class I MHC. This should drive both a strong humoral and cell-based (adaptive) immune response along with an innate immune response, both of which are known to be important in clearing SARS-CoV in mice. We anticipate initial data on the SARS-CoV-2 vaccine in the second quarter of 2020.

In addition, we continue to anticipate interim data from the ongoing Phase 3 fibromyalgia trial of TNX-102 SL in the third quarter of 2020.

SUMMARY DATA

52-Week High	**$28.10**
52-Week Low	**$0.40**
One-Year Return (%)	**-97.58**
Beta	**1.31**
Average Daily Volume (sh)	**9,636,434**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$34**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
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	**-0.4**
P/E using 2019 Estimate	**-0.6**

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 E	0 E	0 E	0 E	0 E
2021					0 E
2022					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$12.86 A	-$9.47 A	-$5.69 A	-$2.86 A	-$19.33 A
2020	-$0.21 E	-$0.21 E	-$0.22 E	-$0.16 E	-$0.79 E
2021					-$0.57 E
2022					-$0.53 E

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WHAT'S NEW

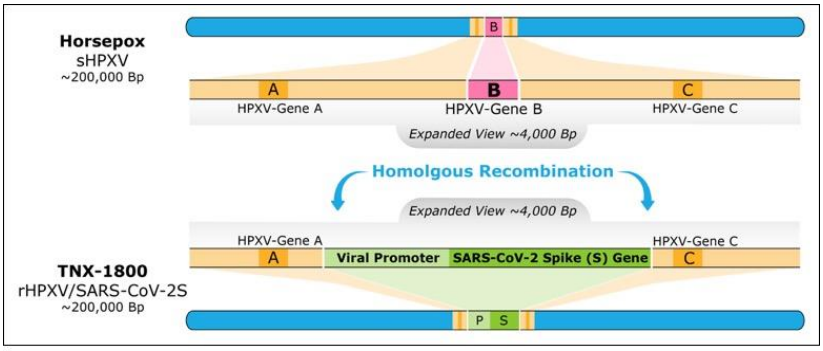
Business Update

Interim Analysis of Phase 3 RELIEF Trial in 3Q20

In December 2019, Tonix Pharmaceutical Holding Corp. (TNXP) announced the first participant enrolled into the Phase 3 RELIEF trial, a pivotal study for TNX-102 SL 5.6 mg for the management of fibromyalgia (NCT04172831). The study is a randomized, double blind, placebo controlled trial and is expected to enroll approximately 470 participants at approximately 40 sites in the U.S. All participants assigned to TNX-102 SL will initiate on 2.8 mg daily for the first two weeks. Following that, the dosage will be 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. We expect an interim analysis to be performed once the first 50% of patients enrolled are evaluable for efficacy, which we estimate will be in the third quarter of 2020. Topline results, assuming the target population remains 470 participants, are expected in the first half of 2021. For a discussion of prior data for TNX-102 SL in fibromyalgia, see our previous report.

Tonix to Develop SARS-CoV-2 Vaccine

On February 26, 2020, Tonix announced a research collaboration with Southern Research to develop a vaccine against the novel coronavirus, SARS-CoV-2. This includes a $1.3 million collaboration to conduct animal research in mouse and non-human primate models of SARS-CoV-2. The vaccine (TNX-1800) will be based on Tonix's horsepox vaccine technology and will be designed to express the SARS-CoV-2 spike protein, assess the immunogenicity to the spike protein, and whether the immune response is sufficient to protect against the novel coronavirus disease, COVID-19.



Source: Tonix Pharmaceutical Holding Corp.

There are a large number of companies developing vaccines to SARS-CoV-2, however Tonix is the only company utilizing horsepox as a vector. In addition, we have identified other companies utilizing a non-replicating vaccinia vector, however we are unaware of other companies using a replicating viral vector such as horsepox. We believe a horsepox vector may be superior to a non-replicating vaccinia vector and elicit a more robust immune response, both innate and adaptive, due to deletions in the vaccinia genome compared to horsepox that are involved in host immune interactions (discussed further in the next section).

The necessity for robust cellular and humoral immunity to coronaviruses is shown by research into SARS-CoV, which is related to SARS-CoV-2 and emerged in Asia in the early 2000's (Ksiazek *et al.*, 2003). In mice, a robust B cell or T cell response is required for protection from infection (Yang *et al.*, 2004; Zhao *et al.*, 2010). A T cell response to the SARS spike protein is sufficient to confer resistance to re-infection for at least one year in humans (Yang *et al.*, 2006). In addition to an adaptive immune response, there is data to indicate that an innate immune response is also necessary (Glass *et al.*, 2004; Hogan *et al.*, 2004).

In summary, we believe there is ample evidence to support the development of a vaccine expressing the S protein of SARS-CoV-2 in a horsepox vector. The vaccine should elicit a strong immunological response, and we eagerly await data on whether it is sufficient to provide protection against infection with SARS-CoV-2.

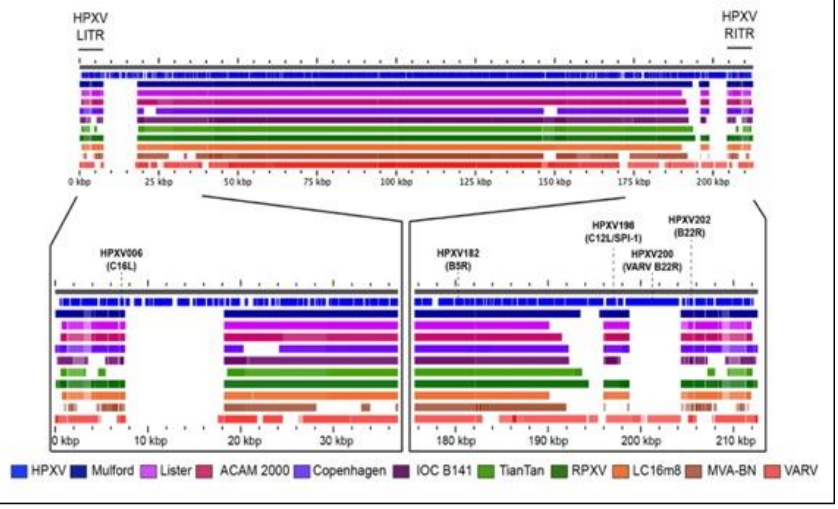
TNX-801 Preclinical Data Presented at ASM Biothreats Conference

In January 2020, Tonix announced the presentation of preclinical results for TNX-801, which is a live virus vaccine based on synthesized horsepox virus (HPXV) and is being developed to potentially prevent smallpox and monkeypox. The data was presented on a poster titled "Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox" (Noyce *et al*., 2020) at the 2020 American Society for Microbiology (ASM) Biothreats Conference.

The current smallpox vaccine, ACAM2000®, is a clonal, live vaccinia virus (VACV). It is only administered to certain military personnel (e.g., troops stationed on the Korean peninsula) due to safety concerns outweighing its potential benefit (Engler *et al*., 2015), however it is stored as part of the Strategic National Stockpile (SNS).

Sequence analysis of polyclonal or legacy smallpox vaccines point to a common ancestor with HPXV (Shrick *et al*., 2017) and that current vaccines based on VACV diverged at some point through genetic deletions. The following figure shows genetic similarities and differences between HPXV and various VACV strains, with deletions in the left and right inverted terminal repeats in VACV when compared to HPXV readily apparent. The genes that are deleted in VACV compared to HPXV are mostly involved in host immune interactions, but could also serve as antigens for developing protective immunity.

Legend: Alignment of orthopoxvirus genomes and location of horsepox (HPXV) genes within telomeres. Orthopoxvirus genomes were aligned using the program GView (https://server.gview.ca). The actual nucleotide sequence of each gene within the genome was compared to the coding sequence (CDS) of each gene within the horsepox (HPXV) reference genome (NCBI Accession DQ792504) and the following orthopoxvirus genomes (VACV Mulford 1902 - MF477237; VACV Lister - AY678276; VACV ACAM2000 - AY313847; VACV Copenhagen - M35027; VACV IOC-B141 - KT184690; VACV TianTan -KC207810; Rabbitpox virus (RPXV) Utrecht -AY484669; MVA-BN - DQ983238; VACV LC16m8 - AY678275; Variola virus (VARV) (Bangladesh 1975 - L22579). The white gaps in the HPXV reference sequence represent non-coding sequences within the genome. The percent identity (PID) cutoff was set to 85%, meaning that only matches with PID values over 85% are displayed. Abbreviations: BLAST = Basic Local Alignment Search Tool; LITR = left inverted terminal repeat (ITR); RITR= right ITR.



Source: Tonix Pharmaceutical Holding Corp.

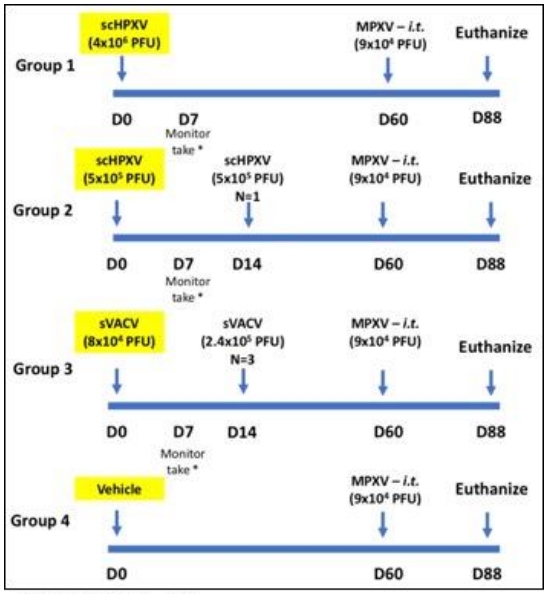
The construction of TNX-801 (scHPXV) has been previously described (Noyce *et al*., 2018). As a comparator for this study, synthetic VACV (sVACV) was constructed using similar techniques, and its sequence was deposited into Genbank (Accession #MN974381). The following table shows the experimental design, which included 4 animals per group, with "high dose" (4 x 10^6 PFU) and "low dose" (5 x 10^5 PFU) groups for scHPXV, a dose of 8 x 10^4 PFU for sVACV, or vehicle control.

Table 1. Experimental Design for scHPXV Dose-Range Finding Study in NHP.

Group	N	Vaccine (Day 0)	Vaccination Dose (PFU)*	Route of Vaccine Administration	IT Challenge Dose (Day 60)
1	4	scHPXV	$4x10^6$	Scarification	$9x10^4$ PFU
2	4	scHPXV	$5x10^5$	Scarification	$9x10^4$ PFU
3	4	sVACV	$8x10^4$	Scarification	$9x10^4$ PFU
4	4	Vehicle	N/A	Scarification	$9x10^4$ PFU

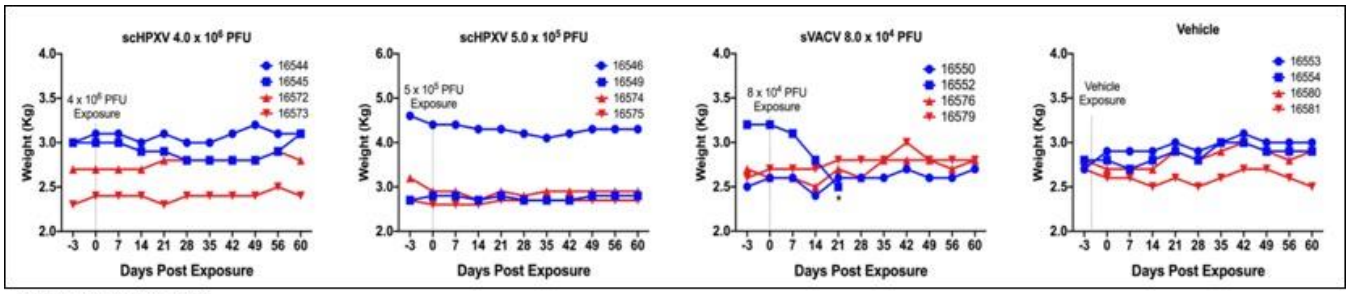
Source: Noyce *et al*., 2020

The following table shows the timeline for the study. Following the initial inoculation on Day 0, the "take" (discussed later in the report) was monitored by examination of the injection site and for those animals that did not show evidence of a take a second inoculation was performed on Day 7. This was followed by dosing of monkeypox virus on Day 60 at which point all animals were followed to Day 88 and then euthanized.



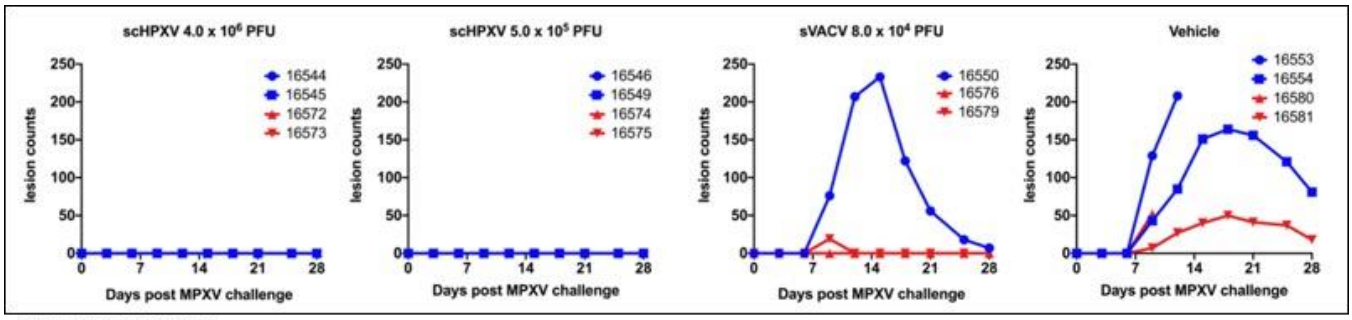
Source: Noyce *et al.*, 2020

The safety of TNX-801 was exhibited by stable weights and body temperatures for the treated animals. The following figure shows how weights were relatively stable for 60 days following dosing for each of the animals, regardless of whether they were treated with scHPXV, sVACV, or vehicle. Similar results were seen with body temperature during the experiment. One animal treated with sVACV had to be euthanized for reasons not pertaining to the vaccine.



Source: Noyce *et al.*, 2020

Regarding efficacy, the following charts show that no animals immunized with scHPXV developed lesions, while two animals immunized with sVACV developed lesions. However, due to the fact that the sVACV dose was lower than the scHPXV dose, a comparison of the efficacy between scHPXV and sVACV is not possible. We believe the important conclusion to draw is that scHPXV can provide protective immunity against monkeypox with no lesions while also being safe and well tolerated.



Source: Noyce *et al.*, 2020

In summary, scHPXV virus shares a high degree of homology with VACV vaccines, and it is possible that the lack of "deletions" compared to the VACV genome could result in enhanced immunity as those regions of the genome may contain additional antigenic proteins. In addition, both doses of scHPXV exhibited safety and tolerability comparable

to low-dose sVACV. Lastly, scHPXV induced immunity against monkeypox in all immunized animals with no lesions. This is very important, as lesion development indicates the host is contagious, and in an outbreak scenario the absence of lesions would help with containment efforts.

Smallpox Vaccines in the News

A couple of news items pertaining to smallpox vaccines were announced in September 2019, which we believe show the continued relevance of developing an improved smallpox vaccine:

- On September 24, 2019, the U.S. FDA announced the approval of Jynneos®, the first live, non-replicating vaccine (modified vaccinia Ankara, MVA) for the prevention of smallpox and monkeypox in adults aged 18 years and older who are at high risk for smallpox and monkeypox infection. The vaccine will also be a part of the Strategic National Stockpile (SNS), which the U.S. Government keeps in the event of a public health emergency. Bavarian Nordic, the developer of Jynneos®, was also awarded a material threat medical countermeasure (MCM) priority review voucher.

- On September 3, 2019, Emergent BioSolutions announced a 10-year contract with the U.S. Department of Health and Human Services for the continued supply of ACAM2000® into the U.S. SNS. The contract is valued at approximately $2 billion, which includes a one-year base period of performance, valued at approximately $170 million, followed by nine option years.

These announcements show that: 1) there is still an opportunity for improved versions of the smallpox vaccine, as shown by the approval of Jynneos®; and 2) the U.S. government is continuing to take the threat of a smallpox outbreak seriously, as shown by the continued stockpiling of ACAM2000® and the addition of Jynneos® into the SNS.

Questions Regarding Jynneos® Data

Jynneos (MVA) was approved based upon the results of a Phase 3 study in which a total of 440 patients were randomized 1:1 to receive either two doses of MVA followed by one dose of ACAM2000 or a single dose of ACAM2000 (Pittman *et al*., 2019). The primary endpoints were noninferiority of the MVA vaccine to ACAM2000 in regards to peak serum neutralizing antibodies and the attenuation of ACAM2000-associated major cutaneous reaction (the "take") by previous MVA vaccination (NCT01913353). The trial met the primary endpoints through MVA exhibiting noninferiority to ACAM2000 when measuring geometric mean titer of neutralizing antibodies as well as an attenuation of the major cutaneous reaction to ACAM2000.

The "take", or the reaction observed after an inoculation of smallpox vaccine, 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 vaccinia virus, and it is the immune response to clear the virus that results in the small lesion. This reaction is a simple biomarker that correlates with long-lasting immunity to smallpox and other orthopoxviruses. MVA does not induce a take since it is an attenuated virus that only goes through one round of replication in mammalian cells (i.e., it's a non-replicating virus), however the presence of neutralizing antibodies and an ability to prevent the take to ACAM2000 is indirect evidence of its efficacy. It should be noted that live, replicating vaccines are only intended for healthy, immunocompetent, and non-pregnant adults. A non-replicating vaccine can be utilized in populations unable to be administered a replicating vaccine (e.g., children, pregnant females, and those that are immunocompromised).

While the presence of neutralizing antibodies is indicative of short-term protection against variola, there is no evidence for sustained long-term immunity in the aforementioned article on Jynneos that would be the result of a cell-mediated immune response. Thus, our belief is that the results of the MVA Phase 3 trial may be over-estimated, that long-term immunity may not be achieved for everyone dosed with MVA, and that there is room for an improved smallpox vaccine such as TNX-801.

Put another way, the trade-off of efficacy vs. safety for Jynneos means that it is an appropriate vaccine for a 'post-eradication of smallpox' world, while TNX-801 (and other replicating viruses such as ACAM2000) are appropriate vaccines for a 'post-re-introduction of smallpox' world. This means that while smallpox is currently not present it is fine to vaccinate with a potentially safer but unproven vaccine such as Jynneos. Were an outbreak of smallpox to occur, we don't believe Jynneos would be used for mass vaccination of healthy, immunocompetent, non-pregnant adults as it does not have the proven efficacy of replicating vaccines to prevent a widespread outbreak. While ACAM2000 likely has the requisite efficacy for mass vaccination, it has known safety issues. Thus, while it would

certainly be utilized were smallpox to be reintroduced, it leaves open the potential for a safer vaccine with similar efficacy, like TNX-801.

Topline Results for PTSD Trial Still Expected in 2Q20 Following Enrollment Halt

On February 5, 2020, Tonix announced the outcome of the planned interim analysis for the ongoing Phase 3 RECOVERY trial of TNX-102 SL in patients with posttraumatic stress disorder (PTSD). Based on the interim analysis, which occurred after the first 50% of patients enrolled were evaluable for efficacy, the independent data monitoring committee (IDMC) recommended stopping the trial for futility as it is unlikely that TNX-102 SL will demonstrate a statistically significant improvement in the primary endpoint of overall change from baseline in the severity of PTSD symptoms as measured by the Clinician Administered PTSD Scale for DMS-5 (CAPS DSM-5) when compared to placebo.

The company has not stopped the trial but has ceased enrolling additional patients. All patients currently enrolled in the trial will be followed to completion of the study, at which point a full analysis of the unblinded data will be performed to determine potential next steps. It is important to note that there were no safety concerns in the decision to stop further enrollment. We anticipate the topline data being reported in the second quarter of 2020.

As opposed to the previous PTSD trials with TNX-102 SL, which were restricted to current or former members of the military, the RECOVERY trial allowed for enrollment of both civilians and military personnel, however there was a restriction that the trauma had to occur within the past nine years. Thus, we would expect the majority of those enrolled in the RECOVERY trial to be civilians, particularly since major military combat operations occurred greater than nine years ago and thus a large number of military personnel would likely be excluded from the trial. While we won't know the reason the trial performed worse than expected until the unblinded results are released, a large proportion of civilian enrollees could have contributed to the unexpectedly poor outcome. Regardless, we anticipate the company will meet with the FDA following the full data analysis to receive guidance on a potential path forward for TNX-102 SL in PTSD.

Financial Update

On March 24, 2020, Tonix announced financial results for the fourth quarter and full year 2019. As expected, the company did not report any revenues for the fourth quarter or full year 2019. Net loss for the fourth quarter of 2019 was $11.2 million, or $2.86 per share, compared to a net loss of $10.9 million, or $59.85 per share, for the fourth quarter of 2018. We remind investors that the weighted average common shares outstanding for the fourth quarter of 2019 were approximately 3.9 million compared to 0.2 million for the fourth quarter of 2018 due to the 1-for-10 reverse stock split effective Nov. 1, 2019.

R&D expenses for the fourth quarter of 2019 were $5.7 million, compared to $5.1 million for the same period in 2018. The increase was primarily due to work related to TNX-601 CR and the pipeline. G&A expenses in the fourth quarter of 2019 were $3.0 million, compared to $2.6 million for the fourth quarter of 2018. The increase was primarily due to increased patent expenses.

For 2019, net loss was $31.1 million, or $19.33 per share, compared to a net loss of $29.4 million, or $259.85, for full year 2018. R&D expenses for 2019 were $18.2 million, compared to $17.6 million in 2018. The increase was primarily due to work related to TNX-601 along with expenses related to pipeline development. G&A expenses in 2019 were $10.6 million, compared to $8.8 million for the same period in 2018. The increase was primarily due to higher insurance premiums and an increase in legal fees.

Tonix exited 2019 with approximately $11.2 million in cash and cash equivalents. Subsequent to the end of the year, the company raised net proceeds of approximately $29 million through equity financings and warrant exercises. We estimate the company currently has sufficient capital to fund operations through the end of 2020. As of March 23, 2020, Tonix had approximately 49.4 million shares outstanding and when factoring in reasonably priced warrants and stock options a fully diluted share count of approximately 54 million.

Conclusion

We are excited to see initial preclinical results for TNX-1800 and are confident that it will induce an immunological response sufficient to be advanced as a vaccine candidate against SARS-CoV-2. The initial results should be available in the second quarter of 2020.

The results presented by Tonix regarding TNX-801 are highly encouraging as the vaccine offers protection from monkeypox with no lesions while exhibiting a favorable safety and tolerability profile. We believe the questions surrounding long-term immunity with Jynneos® offers the opportunity for an improved smallpox vaccine to be added to the SNS. We anticipate Tonix discussing the regulatory path forward for TNX-801 with the FDA later this year and providing an update on anticipated timelines.

We were disappointed with the outcome for the interim analysis for the Phase 3 RECOVERY trial and we look forward to release of the unblinded data so we can evaluate what led to the negative outcome. We anticipate the company meeting with the FDA at some point in the second half of 2020 to determine if there is a path forward for TNX-102 SL in PTSD. As a reminder, we anticipate the result of an interim analysis for the Phase 3 RELIEF trial in patients with fibromyalgia in the third quarter of 2020.

We have removed PTSD from our model and are now valuing the company only based on the potential for TNX-102 SL in fibromyalgia pending the full data analysis from the RECOVERY trial. After accounting for the most recent financing our valuation is now $2 per share.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2019 A	Q1 E	Q2 E	Q3 E	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	$7.8	$8.0	$8.1	$8.2	$32.1	$34.0	$35.0
SG&A	$10.6	$2.8	$2.8	$3.0	$3.0	$11.6	$12.0	$13.0
Operating Income	($28.8)	($10.6)	($10.8)	($11.1)	($11.2)	($43.7)	($46.0)	($48.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.2	$0.1	$0.1	$0.1	$0.1	$0.4	$0.4	$0.4
Pre-Tax Income	($28.6)	($10.5)	($10.7)	($11.0)	($11.1)	($43.3)	($45.6)	($47.6)
Preferred Stock Deemed Dividend	$2	$0	$0	$0	$0	$0	$0	$0
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($31.1)	($10.5)	($10.7)	($11.0)	($11.1)	($43.3)	($45.6)	($47.6)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($19.33)**	**($0.21)**	**($0.21)**	**($0.22)**	**($0.16)**	**($0.79)**	**($0.57)**	**($0.53)**
YOY Growth	*-92.8%*	-	-	-	-	*-95.9%*	*-27.9%*	*-7.2%*
Weighted Shares Outstanding	1.6	49.0	50.0	50.0	70.0	54.8	80.0	90.0

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

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