Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

January 12, 2022
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: The Rise of Omicron Points to Deficiencies in Current Vaccination Strategy…

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL in fibromyalgia, TNX-1800, TNX-1900 and TNX-1300, TNXP is valued at $2.25/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 (01/12/22)	$0.33
Valuation	**$2.25**

OUTLOOK

The world is now two years into the COVID-19 pandemic and a new variant of SARS-CoV-2 is again making headlines. The Omicron variant was first detected in Botswana and South Africa in mid-November 2021 and since then has spread all across the world at an alarming rate. Currently, some jurisdictions are seeing testing positivity rates ≥25%. This is in spite of the fact that these same jurisdictions have very high (>75%) vaccination rates, indicating that the current vaccines are not providing the level of protection necessary to bring an end to the pandemic. While playing an important role earlier in the pandemic by providing personal protection from serious disease and death, the recent rise of Omicron points to the lack of sterilizing immunity from mRNA vaccines as a serious deficiency and supports the idea that additional vaccine technologies, including live virus vaccines that focus on T cell immunity, will be necessary to bring this pandemic to an end.

SUMMARY DATA

52-Week High	**$2.00**
52-Week Low	**$0.32**
One-Year Return (%)	**-64.71**
Beta	**1.10**
Average Daily Volume (sh)	**11,927,673**
Shares Outstanding (mil)	**496**
Market Capitalization ($mil)	**$162**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**19**
Insider Ownership (%)	**1**
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	**-1.8**
P/E using 2019 Estimate	**-1.8**

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)
2020	0 A	0 A	0 A	0 A	0 A
2021	0 A	0 A	0 A	0 E	0 E
2022					0 E
2023					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2020	-$0.37 A	-$0.23 A	-$0.09 A	-$0.10 A	-$0.55 A
2021	-$0.07 A	-$0.07 A	-$0.05 A	-$0.07 E	-$0.26 E
2022					-$0.16 E
2023					-$0.15 E

WHAT'S NEW

Business Update

Current COVID-19 Vaccination Strategy Not Sufficient

The world is now two years into the COVID-19 pandemic and a new SARS-CoV-2 variant is again making headlines. The Omicron variant, which was first isolated in Botswana and South Africa in mid-November 2021, is now spreading all over the world and becoming the dominant strain in most areas. The fact it has spread so quickly speaks to the inefficiency of the current vaccination strategy in bringing the pandemic to an end. Many jurisdictions are seeing SARS-CoV-2 test positivity rates ≥25% in spite of the fact that these same jurisdictions have vaccination rates ≥75%. This indicates that the mRNA vaccines are not offering sterilizing immunity to prevent forward transmission of the SARS-CoV-2 virus, which will likely be necessary to end the pandemic.

The fact that the mRNA vaccines do not offer sterilizing immunity, and vaccinated individuals are still able to transmit the virus, should come as no surprise as preclinical data from non-human primate studies showed the animals continued to have viral RNA detectable in their nasal passages after viral challenge (Corbett *et al*., 2020, Vogel *et al*., 2021). Multiple studies have shown the same lack of sterilizing immunity in fully vaccinated individuals:

- A study examining transmission risk in vaccinated and non-vaccinated individuals in the UK showed that while fully vaccinated individuals had a reduced risk of infection, those with breakthrough infections had similar peak viral loads to unvaccinated individuals and can efficiently transmit infection in a household setting (Singanayagam *et al*., 2021).

- A study of fully vaccinated medical workers in Israel found breakthrough infections in which 74% of infected individuals had a high viral load, meaning those individuals could transmit the virus (Bergwerk *et al*., 2021).

- A study on an outbreak of COVID-19 illnesses in a federal prison population in July 2021 showed a decreased risk of infection in vaccinated individuals, however vaccinated individuals with breakthrough infections had similar viral loads in their nasopharynx when compared to non-vaccinated individuals (Hagan *et al*., 2021).

- A study in California showed no difference in viral loads between vaccinated and unvaccinated individuals who had sought testing as part of a free asymptomatic testing program at UC Davis, including a substantial portion of asymptomatic, fully vaccinated individuals with high viral loads (Acharya *et al*., 2021).

The mRNA vaccines were a significant accomplishment and played an important role early on in the pandemic by providing personal protection against severe disease and death. However, the vaccines have not provided any public health protection, as is apparent from the Omicron surge. This is likely due to the emphasis on generating high titers of neutralizing antibodies and not focusing on generating a robust T cell response.

The importance of T cells in the immune response to SARS-CoV-2 was recently shown in a study out of South Africa (Keeton *et al*., 2021). Researchers tested the ability of T cells generated by vaccination with Ad26.CoV2.S (Johnson and Johnson), vaccination with BNT162b2 (Pfizer/BioNTech), or recovery from COVID-19 to react with the Omicron spike protein. The results showed that even though Omicron has an extensive number of mutations in the spike protein (as compared to other strains of SARS-CoV-2), approximately 70-80% of the T cell response to the spike protein was maintained across study groups. In addition, Omicron-infected hospitalized patients had comparable T cell responses to spike, nucleocapsid, and membrane proteins when compared with patients previously hospitalized by the Beta or Delta variants. These results highlight the importance of a robust T cell response against SARS-CoV-2 and how T cell immunity is likely to lead us to the end of the pandemic as it is not as sensitive to mutations in the viral genome.

TNX-1800 Generates a Robust, Protective Immune Response to SARS-CoV-2

Tonix Pharmaceutical Holdings Corp. (TNXP) is developing TNX-1800, a live, replicating viral vaccine that expresses the SARS-CoV-2 spike protein. It is based on the company's horsepox vector platform. Orthopoxviruses are known to induce strong innate and adaptive immune responses along with long-lasting T cell immunity.

Tonix previously announced positive efficacy for TNX-1800 in non-human primates. The study was designed to compare TNX-1800 (modified horsepox virus encoding SARS-CoV-2 spike protein) to TNX-801 (horsepox virus) at two different doses with a control group receiving placebo. Four animals were included for each of the five groups.

Forty-one days following vaccination (or placebo), each animal was administered SARS-CoV-2 by intra-tracheal (1 x 10^6 $TCID_{50}$) and intra-nasal (1 x 10^6 $TCID_{50}$) administration. $TCID_{50}$ is a method for quantifying virus particles and represents a dilution that causes 50% of cells to display cytopathic effects. Six days after viral challenge, upper airway virus was examined through oropharyngeal swab and lower airway virus by tracheal lavage using qRT-PCR to quantitate the number of genome copies of SARS-CoV-2 present. The results showed that no samples (0/8) from animals vaccinated with TNX-1800 showed infection (defined as > 1,000 genome copies of SARS-CoV-2) in either the upper or lower airways. All animals vaccinated with TNX-801 (8/8) or placebo (4/4) showed infection in either the upper or lower airways. These data are particularly important as they differentiate TNX-1800 from the current mRNA COVID vaccines in the ability to provide sterilizing immunity in non-human primates, and presumably will elicit the same type of response in humans.

The company also disclosed that on Day 14 after vaccination, all (8/8) TNX-1800-vaccinated animals had anti-CoV-2 neutralizing antibodies (≥1:40 titer) while none of the TNX-801 (0/8) or placebo-vaccinated (0/4) developed anti-CoV-2 neutralizing antibodies (≤1:10 titer). Six days after challenge with SARS-CoV-2, TNX-1800-vaccinated animals showed neutralizing antibody titers (≥1:1280 titer), which was similar between the low and high dose TNX-1800 groups (1 x 10^6 PFU and 3 x 10^6 PFU, respectively). In addition, all vaccinated animals developed a 'take', which is a small lesion at the site of the immunization of a live, replicating virus vaccine that occurs approximately one week following dosing. The 'take' is a simple biomarker of a strong T cell immune response and is important as it is costly to measure the T cell response to a vaccine through *in vitro* studies. Thus, TNX-1800 elicits a complete immune response that stimulates the production of specific B cells, neutralizing antibodies, and T cells.

New Collaboration with Kansas State to Focus on Zinc Nanoparticle mRNA Vaccines

On January 4, 2022, Tonix announced an exclusive option agreement and research collaboration with Kansas State University to develop zinc nanoparticle mRNA vaccines. One of the drawbacks of the current mRNA COVID-19 vaccines is that they must be stored at -80°C. The zinc nanoparticle technology may increase the stability of mRNA vaccines across a wide range of temperatures, and the agreement with Kansas State will advance the preclinical development of a new zinc nanoparticle mRNA vaccine to protect against COVID-19 based on the spike protein of SARS-CoV-2. However, this does not mean that Tonix is abandoning or otherwise slowing the development of TNX-1800, as the collaboration with Kansas State will occur simultaneously along with the development of TNX-1800. mRNA vaccines offer the advantage of rapid development in the event of a pandemic, thus the reason Tonix is interested in developing an 'enhanced' mRNA vaccine technology, while second-generation vaccines such as TNX-1800 offering the advantage of potentially longer-lived immune protection and sterilizing immunity. Both technologies fit with the company's efforts to expand its portfolio of vaccines and vaccine platforms.

Conclusion

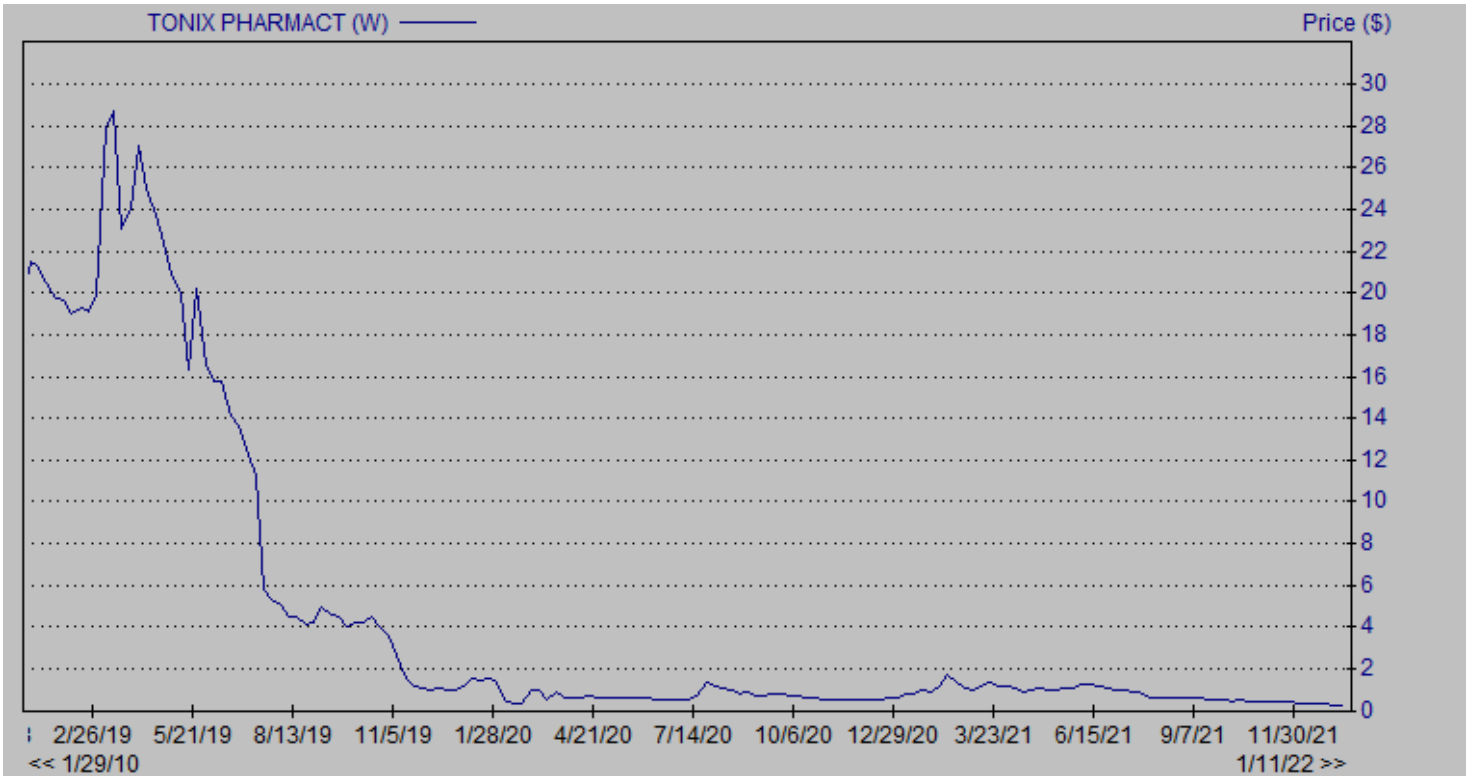
The increasingly rapid spread of the Omicron variant is proof that the world needs stronger vaccines that offer sterilizing immunity to finally bring an end to the COVID-19 pandemic, an idea that has been put forth by multiple individuals, including former health advisors to President Biden (Borio *et al*., 2022). The rapid development of the mRNA vaccines was an amazing accomplishment, however the persistent focus thus far on maximizing neutralizing antibody titers with little attention paid to T cell response is unfortunate as we are learning that however high the initial titers generated by the mRNA vaccines are they fade almost as fast. Unfortunately, without a strong T cell response the protection afforded by those vaccines decreases substantially after approximately 6 months. In addition, it is unfeasible to expect that we can re-vaccinate the world's population every 6 months in perpetuity, thus a new approach to vaccination is desperately needed. As discussed above, TNX-1800 has a number of properties that could make it the right vaccine to help bring the pandemic to an end, including generating a T cell focused response and sterilizing immunity, and we look forward to the company initiating Phase 1 studies in the second half of 2022.

PROJECTED FINANCIALS

Tonix Pharmaceuticals	2020 A	Q1 A	Q2 A	Q3 A	Q4 E	2021 E	2022 E	2023 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	$36.2	$15.3	$18.1	$13.1	$24.0	$70.5	$80.0	$90.0
SG&A	$14.4	$5.4	$5.4	$5.5	$6.0	$22.3	$13.5	$14.0
Operating Income	($50.5)	($20.7)	($23.6)	($18.5)	($30.0)	($92.8)	($93.5)	($104.0)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.0	$0.1	$0.0	$0.0	$0.0	$0.1	$0.2	$0.2
Pre-Tax Income	($50.5)	($20.7)	($23.6)	($18.5)	($30.0)	($92.7)	($93.3)	($103.8)
Preferred Stock Deemed Dividend	$1.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Warrant Deemed Dividend	$0.5	$0.0	$0.0	$0.0	$0.0	$0.0	$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	($52.2)	($20.7)	($23.6)	($18.5)	($30.0)	($92.7)	($93.3)	($103.8)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.55)**	**($0.07)**	**($0.07)**	**($0.05)**	**($0.07)**	**($0.26)**	**($0.16)**	**($0.15)**
YOY Growth	*-97.1%*	-	-	-	-	*-52.1%*	*115.4%*	*-43.9%*
Weighted Shares Outstanding	94.6	290.1	331.3	366.4	415.0	350.7	600.0	700.0

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

HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.