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# Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

***TNXP: 50% Enrollment Reached in Phase 3 RELIEF Trial of TNX-102 SL in Fibromyalgia; Interim Analysis in Sep. 2020…***

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL in fibromyalgia, TNXP is valued at $2.25/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 (06/12/20) | $0.68 |
| **Valuation** | **$2.25** |

## OUTLOOK

In April 2020, Tonix Pharmaceuticals Holding Corp. (TNXP) announced that the Phase 3 RELIEF Trial of TNX-102 SL (cyclobenzaprine HCL sublingual tablet) has achieved 50% enrollment. An interim analysis of the first 50% of randomized participants is anticipated following their completion of the 12-week treatment period. We estimate the results of the interim analysis will be available in Sep. 2020. The potential outcomes of the interim analysis are: 1) stop the study for success; 2) continue to enroll the trial as planned; 3) continue to enroll with an increase in the total number of participants; or 4) stop the study for futility. Thus far, the coronavirus pandemic has not affected enrollment in the trial and we currently estimate for full results of the study to be available in the first quarter of 2021, pending the outcome of the interim analysis.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$17.90** |
| **52-Week Low** | **$0.40** |
| **One-Year Return (%)** | **-95.86** |
| **Beta** | **1.18** |
| **Average Daily Volume (sh)** | **8,758,863** |
| **Shares Outstanding (mil)** | **52** |
| **Market Capitalization ($mil)** | **$36** |
| **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** | **-0.6** |
| **P/E using 2019 Estimate** | **-0.9** |

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|---|---|
| **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 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 | -$12.90 A | -$9.50 A | -$5.69 A | -$2.86 A | -$19.33 A |
| 2020 | -$0.37 A | -$0.21 E | -$0.21 E | -$0.21 E | -$0.92 E |
| 2021 | | | | | -$0.57 E |
| 2022 | | | | | -$0.53 E |

## WHAT'S NEW

**Business Update**

*Phase 3 RELIEF Trial 50% Enrolled; Results of Interim Analysis in Sep. 2020*

On April 24, 2020, Tonix Pharmaceuticals Holding Corp. (TNXP) announced that the Phase 3 RELIEF trial of TNX-102 SL 5.6 mg for the treatment of fibromyalgia is 50% enrolled. There will be an interim analysis performed once the first 50% of enrolled patients are evaluable for efficacy, with results likely in Sep. 2020. There are four potential outcomes from the interim analysis:

1) Stop the study early for success
2) Continue to enroll the study as planned
3) Continue to enroll the study but increase the total number of participants
4) Stop the study for futility

The RELIEF trial is a randomized, double blind, placebo controlled trial and is expected to enroll approximately 470 participants at approximately 40 sites in the U.S. (NCT04172831). 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. Topline results, assuming the target population remains 470 participants, are expected in the first quarter of 2021. For a discussion of prior data for TNX-102 SL at 2.8 mg per day in fibromyalgia, see our previous report.

*Multiple COVID-19 Vaccines in Development*

In February 2020, Tonix announced a research collaboration with Southern Research to develop a vaccine (TNX-1800) against the novel coronavirus, SARS-CoV-2, and in May 2020 a collaboration with the University of Alberta was announced for three new vaccines (TNX-1810, TNX-1820, TNX-1830) targeting SARS-CoV-2. Each of the vaccines are based on the company's horsepox vector platform. TNX-1800 is designed to elicit a predominantly T cell response to the SARS-CoV-2 spike protein. TNX-1810, TNX-1820, and TNX-1830 are designed to elicit an almost purely T cell response and express different SARS-CoV-2 antigens than the spike protein. On June 1, 2020, Tonix announced an agreement whereby FUJIFILM Diosynth Biotechnologies will manufacture the clinical trial supply of TNX-1800.

A recent publication examined the T cell response in patients who have recovered following infection with SARS-CoV-2 (Grifoni *et al*., 2020). CD8+ and CD4+ T cells responsive to SARS-CoV-2 peptide epitopes were identified in approximately 70% and 100% of patients, respectively. The CD4+ T cell responses to spike protein were robust, with the M and N proteins being other major targets. Less common responses were seen to nsp3, nsp4, ORF3a, and ORF3. For CD8+ T cells, spike and M protein were major targets along with at least eight other viral proteins. Surprisingly, CD4+ T cells that reacted to SARS-CoV-2 were found in approximately 40-60% of unexposed individuals, which could represent cross-reactivity between T cells that react to 'common cold' coronaviruses and SARS-CoV-2. These results point to the importance of a T cell response in combating SARS-CoV-2 and why vaccines to prevent COVID-19 should focus on generating a robust T cell response.

Tonix is one of the few companies developing a SARS-CoV-2 vaccine utilizing a live, replicating viral vector that is designed to generate a predominant T cell response and the only company utilizing the horsepox vector. Orthopoxviruses are known to induce strong innate and adaptive immune responses along with long-lasting T cell immunity, which the data discussed above leads us to believe will be an important feature of a successful SARS-CoV-2 vaccine. In addition, Merck recently announced the acquisition of Themis, a privately-held company developing a SARS-CoV-2 vaccine that utilizes a modified measles vaccine virus (live replicating) as a vector. We view Merck's acquisition as an important validation of the use of a live, replicating vector for development of a SARS-CoV-2 vaccine.

Multiple COVID-19 vaccines have initiated clinical trials, and two of them have recently announced results from Phase 1 trials. While the results shown thus far are encouraging regarding safety and tolerability, there are a number of questions regarding efficacy and immunological response.

- **CanSino Biologics Inc**. – Replication defective Adenovirus 5 (Ad5) vector expressing the spike protein. The company recently reported results from a Phase 1 clinical trial examining a single administration of three different doses ($5 \times 10^{10}$, $1 \times 10^{11}$, $1.5 \times 10^{11}$) of an Ad5 vectored COVID-19 vaccine (Zhu *et al*., 2020). The vaccine was safe and well tolerated with the most common adverse events being injection site pain, fever, fatigue, headache, and muscle pain. A positive antibody response was defined as a four-fold increase in antibody titer post vaccination, which was noted against the receptor binding domain of the spike protein in 97%, 94%, and 100% of participants in the low, mid, and high dose groups, respectively. However, a neutralizing antibody titer with a geometric mean titer (GMT) of only 34.0 was noted in the high dose group, 16.2 in the mid-dose group, and 14.5 in the low dose group. This is potentially a cause for concern because the FDA recommends a neutralizing antibody titer of 160 for convalescent plasma (source). Thus, while the vaccine appears to elicit a robust antibody response, the neutralizing antibody titer may not be sufficient to confer long-lasting, effective immunity. The paper also reported T cell responses, which ranged from 83-97% across the dose groups. However, it was noted that a high baseline Ad5 neutralizing antibody titer, which was found in 50%, 53%, and 47% of those in the low, mid, and high dose groups, respectively, reduced the peak of post-vaccination T cell responses. We believe this high background of neutralizing antibodies to the adenovirus vector could present a problem for their use as that may prevent a robust, effective immune response to the vaccine from developing in a significant portion of the population.

- **Moderna Inc**. – mRNA-1273; mRNA encoding for a prefusion stabilized form of the spike protein. The company reported interim Phase 1 data following two doses of the 25 μg and 100 μg dose levels and one dose at the 250 μg level. The company reported that dose dependent increases in immunogenicity were seen across all dose levels and the levels of neutralizing antibodies at Day 43 were "at or above levels generally seen in convalescent sera." However, the actual levels of neutralizing antibodies were not disclosed and thus we are unsure how these levels compare to the FDA recommendation for neutralizing antibody titers in convalescent plasma.

The data generated thus far from the early COVID-19 vaccine candidates have been encouraging from a safety standpoint but thus far there is not much to indicate if any of them will be efficacious in preventing SARS-CoV-2 infection in a large population. In addition, neutralizing antibody levels, at least for the Ad5-based vaccine, do not appear very promising. Thus, while Tonix may not be the first into the clinic with a COVID-19 vaccine candidate, we believe that the early candidates are unlikely to be efficacious. We look forward to updates regarding TNX-1800 and believe that initial preclinical data could be available in the fourth quarter of 2020.

**Financial Update**

On May 12, 2020, Tonix announced financial results for the first quarter of 2020. As expected, the company did not report any revenues for the first quarter of 2020. Net loss available to common stockholders for the first quarter of 2020 was $9.0 million, or $0.37 per share, compared to $6.2 million, or $12.76 per share, for the first quarter of 2019. R&D expenses for the first quarter of 2020 were $4.7 million, compared to $3.9 million for the first period of 2019. The increase was primarily due to increased expenses related to the Phase 3 trials of TNX-102 SL and the beginning of the COVID-19 vaccine work. G&A expenses for the first quarter of 2020 were $2.6 million, compared to $2.4 million for the first quarter of 2019. The increase was primarily due to increased legal fees, patent prosecution, and maintenance costs.

The company exited the first quarter of 2020 with approximately $30.7 million in cash and cash equivalents. During the first quarter of 2020 the company raised net proceeds of approximately $28.8 million through equity financings and warrant exercises. We estimate the company currently has sufficient capital to fund operations through the end of 2020. In addition, the company entered into an at-the-market offerings (ATM) agreement with AGP in which Tonix may sell up to $50 million in common stock.

As of May 11, 2020, Tonix had approximately 52.3 million shares outstanding and when factoring in reasonably priced warrants and stock options a fully diluted share count of approximately 57.7 million.

**Conclusion**

We look forward to the results of the interim analysis for TNX-102 SL in fibromyalgia in September 2020. While we don't anticipate the trial being stopped early for efficacy, based upon the previous results the company saw with the 2.8 mg dose we are confident that the trial will be successful using the 5.6 mg dose.

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 from animal experiment should be available in the fourth quarter of 2020.

We have added TNX-1800 to our model, although the situation is still incredibly fluid and likely to change a number of times over the next year as other companies report data for various vaccine candidates. At this point we model for TNX-1800 to generate $1 billion in revenue in 2024 as the vaccine would presumably be sold to the government. Using a 10% probability of approval and a 16% discount rate leads to an NPV of $55 million. This increases our valuation to $2.25.

## PROJECTED FINANCIALS

| Tonix Pharmaceuticals | 2019 A | Q1 A | 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 | $4.7 | $8.0 | $8.1 | $8.2 | $29.0 | $34.0 | $35.0 |
| SG&A | $10.6 | $2.6 | $2.8 | $3.0 | $3.0 | $11.4 | $12.0 | $13.0 |
| Operating Income | ($28.8) | ($7.3) | ($10.8) | ($11.1) | ($11.2) | ($40.4) | ($46.0) | ($48.0) |
| *Operating Margin* | - | - | - | - | - | - | - | - |
| Interest & Other Income | $0.2 | $0.0 | $0.1 | $0.1 | $0.1 | $0.3 | $0.4 | $0.4 |
| Pre-Tax Income | ($28.6) | ($7.3) | ($10.7) | ($11.0) | ($11.1) | ($40.1) | ($45.6) | ($47.6) |
| 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) | ($10.7) | ($11.0) | ($11.1) | ($41.8) | ($45.6) | ($47.6) |
| *Net Margin* | - | - | - | - | - | - | - | - |
| **Reported EPS** | **($19.33)** | **($0.37)** | **($0.21)** | **($0.21)** | **($0.21)** | **($0.92)** | **($0.57)** | **($0.53)** |
| *YOY Growth* | *-92.8%* | - | - | - | - | *-95.2%* | *-38.1%* | *-7.2%* |
| Weighted Shares Outstanding | 1.6 | 24.0 | 52.0 | 52.5 | 53.0 | 45.4 | 80.0 | 90.0 |

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

## HISTORICAL STOCK PRICE


Source: Zacks Small Cap Research

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