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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Positive Results for TNX-102 SL in Phase 3 RELIEF Trial…

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 $3.50/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 (12/15/20)	$0.58
Valuation	**$3.50**

OUTLOOK

On December 7, 2020, Tonix Pharmaceuticals Holding Corp. (TNXP) announced positive topline results for the Phase 3 RELIEF trial of TNX-102 SL (cyclobenzaprine HCl sublingual tablet). The trial met the pre-specified primary endpoint of significantly reducing daily pain compared to placebo in patients with fibromyalgia (*P*=0.01). The company is currently conducting a second Phase 3 clinical trial of TNX-102 SL in fibromyalgia patients, the RALLY trial, with an interim analysis expected in the second quarter of 2021 and topline results expected in the fourth quarter of 2021. Assuming positive results for the RALLY trial, Tonix will be in a position to file a New Drug Application (NDA) in 2022 as all other requirements for an NDA are ready.

SUMMARY DATA

52-Week High	**$1.73**
52-Week Low	**$0.40**
One-Year Return (%)	**-53.06**
Beta	**1.49**
Average Daily Volume (sh)	**15,089,949**
Shares Outstanding (mil)	**157**
Market Capitalization ($mil)	**$91**
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	**-1.7**

Risk Level	**Above Avg.**
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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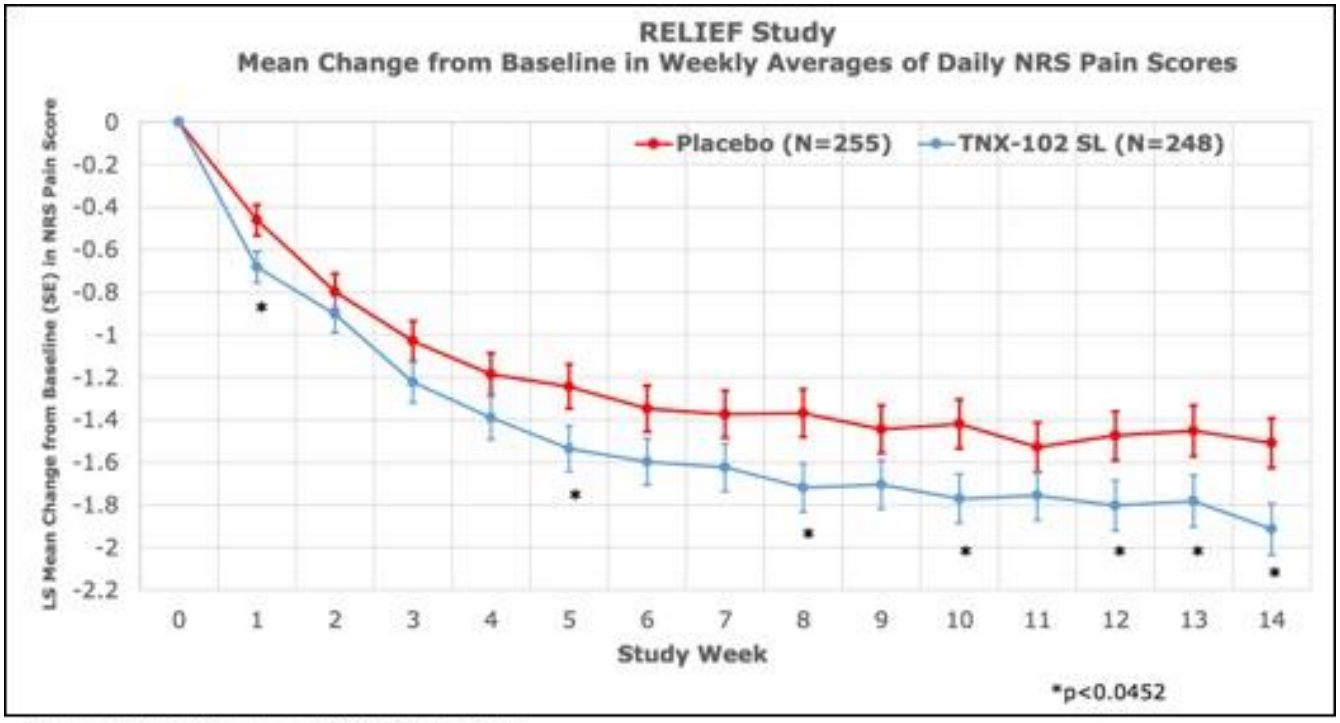
WHAT'S NEW

Business Update

Positive Results for TNX-102 SL in Phase 3 RELIEF Trial

On December 7, 2020, Tonix Pharmaceuticals Holding Corp. (TNXP) announced positive topline results for the Phase 3 RELIEF trial of TNX-102 SL 5.6 mg in patients with fibromyalgia (NCT04172831). This was a randomized, double blind, placebo controlled trial that enrolled 503 participants at 39 centers in the U.S. In September 2020, the company announced that at the interim analysis 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 at the time to complete the trial with the 503 enrolled participants.

The following graph shows the results for the primary efficacy endpoint of the trial, the mean change from baseline in weekly averages of the daily diary pain numerical rating scale (NRS) scores. At week 14, participants on TNX-102 SL had a LS mean change from baseline of -1.9 units compared to -1.5 units for participants on placebo (*P*=0.01). The graph shows that a statistically significant separation between TNX-102 SL-treated and placebo-treated participants appears intermittently at Week 5, Week 8, and Week 10 and continues consistently from Week 12 to Week 14.



Source: Tonix Pharmaceuticals Holding Corp.

The analysis of the efficacy endpoints involved a sequential test procedure being applied to the primary endpoint and six key secondary endpoints such that each endpoint had to meet statistical significance (*P*<0.0452) in order for the subsequent endpoints to be considered statistically significant. As explained above, the primary endpoint was statistically significant. The key secondary endpoints examined, in sequential order, were:

1) Patient Global Impression of Change (PGIC)
2) FIQ-R symptom domain score
3) FIQ-R function domain score
4) PROMIS sleep disturbance instrument T-score
5) PROMIS fatigue instrument T-score
6) Daily diary NRS assessment of sleep quality

The PGIC analysis was not statistically significant (37.5% vs. 29.4%; *P*=0.058), thus due to the sequential test waterfall, the rest of the secondary endpoints could only be considered nominally significant at best even though all of the P values were <0.0452, as shown in the following table.

Outcome Measure at Week 14	Intent-to-Treat Analysis	P-value[1]
Primary Endpoint		
Daily Pain Diary, NRS	Mean Change (Primary Analysis)[2]	0.010*
Key Secondary Endpoints		
Non-specific		
Patient Global Impression of Change	Proportion "Much" or "Very Much Improved"	0.058 (LR)
Fibromyalgia Syndrome-Related		
FIQ-R Symptom Domain	Mean Change	0.007#
FIQ-R Function Domain	Mean Change	0.009#
PROMIS Fatigue	Mean Change	0.018#
Daily Sleep Quality Diary, NRS	Mean Change	<0.001#
PROMIS Sleep Disturbance	Mean Change	<0.001#

Abbreviations: FIQ-R = Fibromyalgia Impact Questionnaire - Revised; PROMIS = Patient-Reported Outcomes Measurement Information System; LR = Logistic Regression (missing data considered non-responders);
NRS = Numeric Rating Scale
* statistically significant at p<0.0452
# nominally significant at p<0.0452

[1]*Analysis by Mixed Model Repeated Measures with Multiple Imputation unless otherwise indicated.*
[2]*Primary endpoint analysis for FDA approvals of Cymbalta® and Lyrica® in fibromyalgia.*

Source: Tonix Pharmaceuticals Holding Corp.

What is interesting about the PGIC results is that in two prior studies of TNX-102 SL 2.8 mg in fibromyalgia patients, PGIC was statistically significant in both. One explanation for the lack of significance in PGIC in the RELIEF trial could be due to the fact that the trial took place during the COVID-19 pandemic. Since PGIC is not particular to fibromyalgia symptoms, the current environment of uneasiness and uncertainty for everyone may have affected the PGIC results.

In regards to safety, TNX-102 SL was well tolerated similarly to what had been shown previously in the Phase 2 BESTFIT and Phase 3 AFFIRM trials, which both tested TNX-102 SL at 2.8 mg daily. Similar numbers of participants in the TNX-102 SL and placebo arms finished the 14-week dosing period (82.3% vs. 83.5%). The most common adverse events for the TNX-102 SL group were focused on administration site reactions, including tongue/mouth numbness, tongue/mouth pain/discomfort, taste impairment, and tongue/mouth tingling. The only systemic adverse event that occurred in ≥5% of patients was somnolence/sedation at 5.6% in the TNX-102 SL arm. This is consistent with known side effects of cyclobenzaprine, however the rate (5.6%) was lower than reported in previous trials of TNX-102 SL.

Table 2. Treatment-Emergent Adverse Events at Rate of 5% or Greater in Either Treatment Arm

	TNX-102 SL (N=248)		Placebo (N=255)		Total (N=503)	
Administration Site Reactions	**N**	**%**	**N**	**%**	**N**	**%**
Oral numbness	43	17.3	2	0.8	45	8.9
Oral pain/discomfort	29	11.7	5	2.0	34	6.8
Taste impairment	16	6.5	1	0.4	17	3.4
Oral tingling	14	5.6	1	0.4	15	3.0
Systemic Adverse Events	**N**	**%**	**N**	**%**	**N**	**%**
Somnolence/Sedation	14	5.6	3	1.2	17	3.4

Source: Tonix Pharmaceuticals Holding Corp.

Conclusion

We were very glad to see the positive results from the Phase 3 RELIEF trial. The company had previously failed a Phase 3 trial in fibromyalgia with TNX-102 SL 2.8 mg, however the 5.6 mg dose delivered a successful outcome with no apparent difference in the AE profile, in fact systemic AEs such as somnolence were lower in the RELIEF trial than in previous trials. We look forward to updates on enrollment of the RALLY trial and we anticipate results from an interim analysis in the second quarter of 2021 and topline results in the fourth quarter of 2021. Based on the positive results from the RELIEF trial we have raised our probability of approval for TNX-102 SL in fibromyalgia to 70%, which has increased our valuation to $3.50.

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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HISTORICAL STOCK PRICE



Source: Zacks Small Cap Research

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