Zacks Small-Cap Research

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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: TNX-102 SL Given Breakthrough Therapy Designation for PTSD…

Based on our probability adjusted DCF model that takes into account potential future revenues from TNX-102 SL PTSD, TNXP is valued at $2/share. This model is highly dependent upon continued clinical success of TNX-102 SL in PTSD and will be adjusted accordingly based upon future clinical results.

Current Price (01/04/17)	$0.51
Valuation	**$2.00**

OUTLOOK

On December 19, 2016, Tonix Pharmaceuticals Holding Corp. (TNXP) announced that the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation (BTD) to TNX-102 SL for the treatment of posttraumatic stress disorder (PTSD). BTD comes with a host of benefits including priority review (six months vs. the standard 10 months) of the New Drug Application (NDA), rolling submission of portions of the NDA, and significant guidance from the FDA regarding clinical trial design. Following a successful "end of Phase 2" meeting with the FDA in the third quarter of 2016, Tonix is preparing to initiate a Phase 3 clinical trial, the HONOR study, in the first quarter of 2017.

SUMMARY DATA

52-Week High	**$7.67**
52-Week Low	**$0.37**
One-Year Return (%)	**-93.32**
Beta	**2.89**
Average Daily Volume (sh)	**3,070,789**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$20**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**10**
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 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**

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)
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 A	0 A	0 E	0 E
2017					0 E
2018					0 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$0.71 A	-$0.73 A	-$0.72 A	-$0.71 A	-$2.86 A
2016	-$0.74 A	-$0.50 A	-$0.29 A	-$0.19 E	-$1.52 E
2017					-$0.56 E
2018					-$0.57 E

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WHAT'S NEW

TNX-102 SL Granted Breakthrough Therapy Designation by FDA

On December 19, 2016, Tonix Pharmaceuticals Holding Corp. (TNXP) announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) to TNX-102 SL for the treatment of posttraumatic stress disorder (PTSD).

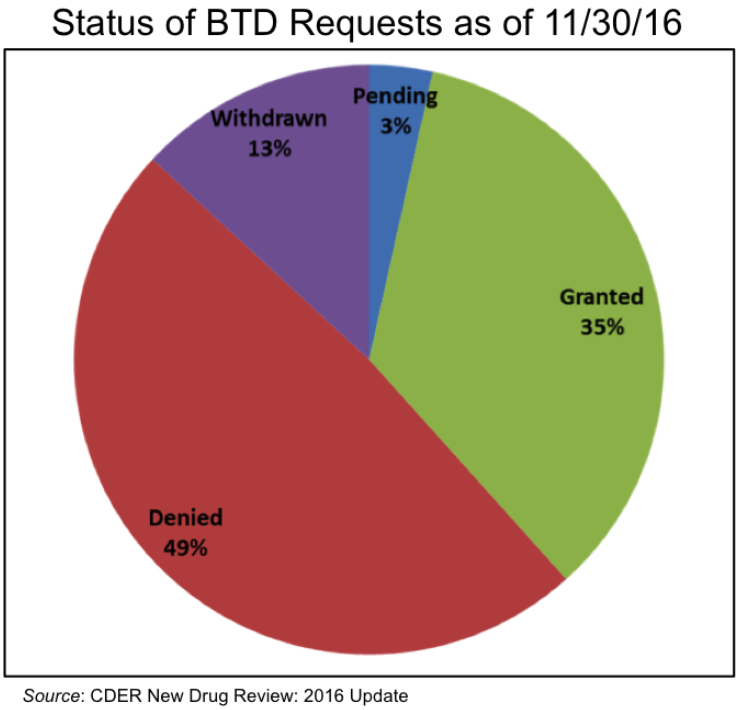
BTD was introduced in 2012 with the Food and Drug Administration Safety and Innovation Act (FDASIA). A breakthrough therapy is a drug:

1) Intended alone or in combination with one or more drugs to treat a serious or life threatening disease or condition; AND
2) Preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.

The benefits associated with BTD are intended to help expedite the development and review of drugs that are being developed for serious or life-threatening conditions, and include:

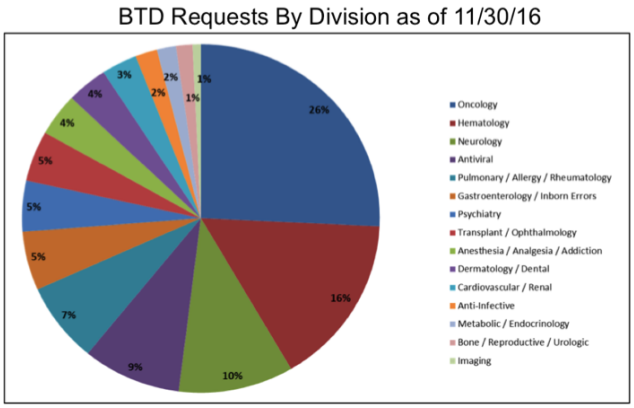
- ✓ Increased interaction with the FDA, including additional guidance on an efficient drug development program;
- ✓ An organizational commitment from the FDA involving senior managers;
- ✓ Eligibility for rolling submission of parts of the New Drug Application (NDA) and priority review (six months vs. the standard 10 months)

As of November 30, 2016, there have been 404 requests to the Center for Drug Evaluation and Research (CDER) for BTD. The following graph gives a breakdown for the outcome of those requests. Interestingly, almost half of the requests have been denied while only 1/3rd have been granted.

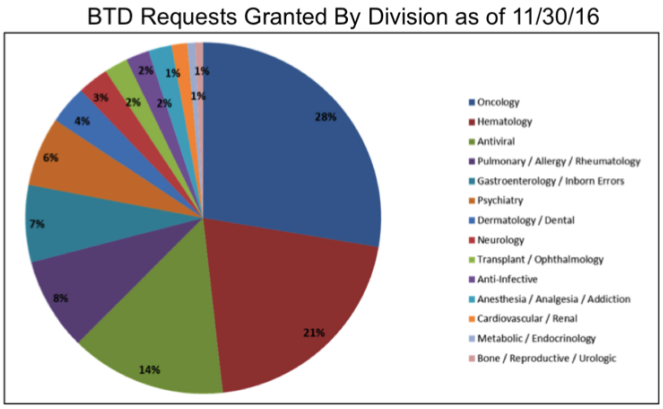


Source: CDER New Drug Review: 2016 Update

Over 50% of the BTD requests have been made to the divisions of Oncology, Hematology, and Neurology, while only 5% of requests have been in Psychiatry. For those requests granted, 28% have been in Oncology, 21% in Hematology, while 6% have been in Psychiatry.



Source: CDER New Drug Review: 2016 Update



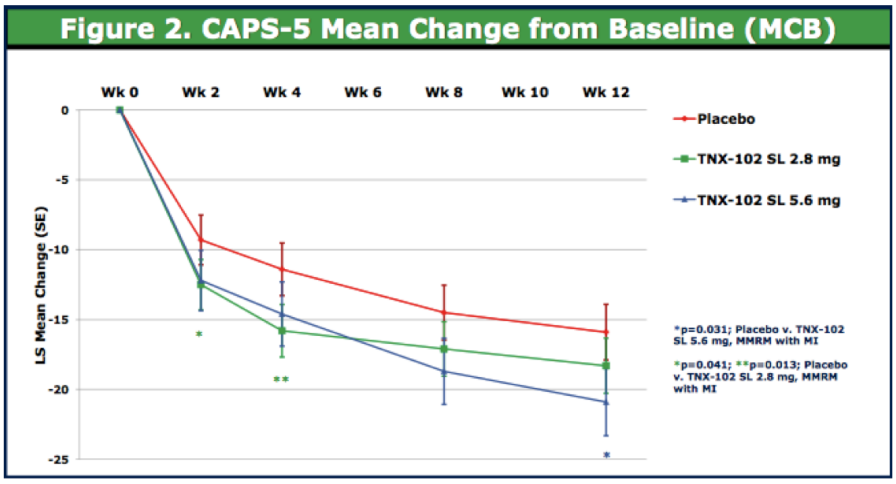
Source: CDER New Drug Review: 2016 Update

Of the 141 BTD requests granted, 30 of those drugs have gone on to be approved. Thus far, the only BTD drug in Psychiatry that has been approved is NUPLAZID™ (pimavanserin) for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.

Tonix Phase 3 Program in PTSD Set to Get Underway in 1Q17

Tonix's lead product, TNX-102 SL, is currently being developed for the treatment of PTSD. TNX-102 SL is a small, rapidly disintegrating tablet of cyclobenzaprine (CBP) for sublingual administration and transmucosal absorption. CBP is the active ingredient of two products that are FDA approved in the U.S. for the treatment of muscle spasms. These products are sold as immediate-release tablets and extended-release capsules. The sublingual formulation has a differentiated pharmacokinetic profile from the oral immediate-release CBP tablet as exemplified by a 154% higher bioavailability, 338% higher plasma levels during the first hour after dosage, and substantially lower production of norcyclobenzaprine due to the decrease in first-pass hepatic metabolism.

In May 2016, Tonix announced positive results from the AtEase Phase 2 clinical trial of TNX-102 SL in patients with military-related PTSD. The three-arm trial enrolled 231 participants, who were randomized to receive either 2.8 mg of TNX-102 SL (n=90), 5.6 mg of TNX-102 SL (n=49), or placebo (n=92) taken sublingually at bedtime daily for 12 weeks. The primary endpoint of the trial was the week 12 mean change from baseline in the total CAPS-5 score, which is shown in the following graph.



Source: Sullivan *et al*., 2016

On December 8, 2016, the company presented additional data from the Phase 2 study showing the potential for TNX-102 SL to treat combat-related PTSD patients, who are typically the most difficult to treat. Combat-related PTSD represented the majority of index traumas in the Phase 2 study (85%, n=197). This sub-group was analyzed according to baseline CAPS-5 score of either ≥ 33 or the whole population with a baseline CAPS-5 score of ≥ 29. The following table shows a significantly greater improvement in CAPS-5 total score, CAPS-5 clusters in intrusion (Cluster B) and hyperarousal (Cluster E), and in certain measures (e.g., sleep quality) in the 5.6 mg TNX-102 SL group.

Table 4. Week 12 Outcome Measures for TNX-102 SL 5.6 mg v. Placebo in Combat-Only PTSD for Both Entry Thresholds				
	PBO N=74, 5.6mg N=46; CAPS-5 ≥ 29		PBO N= 64, 5.6mg N=35; CAPS-5 ≥ 33	
Outcome Measure	ES[1]	p-value[2]	ES[1]	p-value[2]
CAPS-5				
Total score	0.42	*0.037	0.57	*0.013
Cluster B (intrusion)	0.26	0.183	0.50	*0.031
Cluster C (avoidance)	0.04	0.824	0.11	0.570
Cluster D (mood/cognition)	0.41	*0.035	0.42	0.061
Cluster E (arousal and reactivity)	0.40	*0.036	0.57	*0.012
E6 (Sleep item)	0.58	*0.003	0.58	*0.010
E2 (Reckless/Self Destruct)	0.15	0.178	0.30	*0.019
CGI–I (responders)	2.15	*0.049	2.12	0.082
SDS				
Total Score	0.41	*0.039	0.47	*0.032
Work/School item	0.40	*0.026	0.40	*0.015
Social/Leisure item	0.50	*0.013	0.51	*0.028
Family Life/Home Responsibilities item	0.19	0.328	0.22	0.274

Source: Sullivan *et al.*, 2016

Phase 3 Development Plan

Tonix is currently developing a Phase 3 program for the 5.6 mg dose of TNX-102 SL in PTSD. Following a successful end-of-Phase 2 meeting with the FDA, the company announced that the meeting minutes indicated that positive results from two adequate, well-controlled Phase 3 efficacy and safety studies and long-term (six- and 12-month) safety exposure studies would support the registration of 5.6 mg TNX-102 SL for the treatment of PTSD. Importantly, the same primary endpoint that was used in the Phase 2 study will be used for both upcoming Phase 3 studies. Importantly, the company has already produced all of the TNX-102 SL for the Phase 3 studies.

The first Phase 3 clinical trial will be in military-related PTSD and be similar to the recently completed Phase 2 study. The trial is likely to begin in the first quarter of 2017 and we anticipate enrollment of approximately 550 patients divided evenly between placebo and 5.6 mg TNX-102 SL treatment. We expect topline data to be available in the fourth quarter of 2018. The company will be performing up to two planned interim analyses to test for efficacy or sample size adjustment: the first will be conducted when approximately 30% (~180 patients) of the total planned enrollment is evaluable for efficacy and the second analysis after 50% (~270 patients) of the total planned enrollment is eligible for efficacy. The study will be limited to those patients with a CAPS-5 score ≥33 (indicating moderate to severe PTSD). The primary endpoint will be the mean change from baseline in total CAPS-5 at Week 12 between those treated with TNX-102 SL 5.6 mg and placebo.

The second Phase 3 study will involve individuals with any type of PTSD. The reason for this is because the company will need to show efficacy in a broad population of patients with PTSD in order for a label of treating PTSD, not just military-related PTSD. In addition, since the military-related PTSD studies have predominantly male subjects, the FDA will require data in a larger female PTSD population. The second Phase 3 study will also be limited to those with a CAPS-5 score ≥33 and will likely enroll approximately 550 patients. The primary endpoint will be the mean change from baseline in total CAPS-5 at Week 12 between those treated with TNX-102 SL 5.6 mg and placebo.

Conclusion

Attaining BTD for TNX-102 SL is an important milestone for Tonix, particularly since it allows for increased interaction with the FDA and the potential for priority review. The company is planning to receive comments from the FDA regarding the Phase 3 study protocol and interim analysis plan. We expect the first Phase 3 clinical trial to initiate in the first quarter of 2017, with the first interim analysis likely taking place near the end of 2017. Upon approval, we estimate for peak sales of TNX-102 SL of $650 million. Using an 18% discount rate and a 50% probability of approval, our current valuation is $2.00 per share.

PROJECTED FINANCIALS

Tonix Pharmaceuticals Holding Corp.
Income Statement

Tonix Pharmaceuticals	2015 A	Q1 A	Q2 A	Q3 A	Q4 E	2016 E	2017 E	2018 E
TNX-102 SL (FM)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
TNX-102 SL (PTSD)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Research & Collaborations	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
CoGS	$0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D	$35.5	$10.7	$7.5	$5.5	$5.0	$28.7	$17.0	$20.0
SG&A	$12.7	$3.3	$2.3	$2.1	$2.2	$10.0	$8.0	$8.5
Operating Income	($48.2)	($14.0)	($9.8)	($7.6)	($7.2)	($38.7)	($25.0)	($28.5)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($48.1)	($14.0)	($9.8)	($7.6)	($7.2)	($38.7)	($25.0)	($28.5)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($48.1)	($14.0)	($9.8)	($7.6)	($7.2)	($38.7)	($25.0)	($28.5)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($2.86)**	**($0.74)**	**($0.50)**	**($0.29)**	**($0.19)**	**($1.52)**	**($0.56)**	**($0.57)**
YOY Growth	*3.5%*	-	-	-	-	*-46.9%*	*-63.5%*	*2.6%*
Weighted Shares Outstanding	16.8	18.9	19.7	26.1	37.0	25.4	45.0	50.0

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

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