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## Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP)

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### BUY: Tonmya Reports Improvement in “Brain Fog” P=.001

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Tonix announced the presentation of additional efficacy data from RESILIENT, the second Phase 3 study evaluating Tonmya for the management of fibromyalgia, at the 6th International Congress on Controversies in Fibromyalgia in Brussels, Belgium, March 7-8, 2024. The data demonstrates that Tonmya successfully treats all the symptoms of fibromyalgia including pain, sleep quality, fatigue and brain fog – syndrome level.

### Investment Highlights

**Tonmya Effective at the Syndrome Level:** The study results show an improvement in cognitive dysfunction, or 'brain fog', measured by the change in the Fibromyalgia Impact Questionnaire-Revised (FIQ-R) memory item. The FIQ-R cognitive item showed nominal improvement in Tonmya-treated patients vs placebo-treated patients with a p=0.001 and effect size of 0.31. The impact of Tonmya on pain, sleep quality, fatigue and brain fog suggests a broad-spectrum activity to treat fibromyalgia at a syndromal level.

**The RESILIENT Study:** Recall that the study met its pre-specified primary endpoint, significantly reducing daily pain compared to placebo (p=0.00005) in participants with fibromyalgia. Tonix plans to submit a New Drug Application (NDA) to the FDA in H2 of 2024 and has scheduled a pre-NDA meeting with the FDA in Q2 of 2024.

**Tonmya – 505B2 – Low Risk, High Potential Reward.** The Fibromyalgia space represents 6-12 million adults, primarily women in the US. FDA-approved drugs include Lyrica, Cymbalta, and Savella (approved a decade plus) ago and re-purposed). A high failure rate (60%) has been reported with existing therapies, and all have known side effects. Tonmya has been evaluated in three Phase III trials, RELIEF, RALLY and RESILIENT. The RELIEF (2020) trial met its primary endpoint as did the RESILIENT trial (2023). RALLY missed as the trial was plagued by discontinuations because of the COVID effect. Tonix expects to file the NDA 2H-24 with an FDA decision by 2H25. We view the outcome as low risk as the drug, cyclobenzaprine, has been well-established (505b2 pathway) for skeletal muscle pain/injury. Additional indications beyond FM exist from Long COVID to Acute Street Reaction/Disorders but we do not factor them into our model.

**Valuation:** Our valuation for Tonix Pharmaceuticals is driven by Tonmya in Fibromyalgia. We project our model through 2030 and select a 30% discount rate. We assume a capital raise and out-year dilution (including all warrants are exercised). These assumptions flow through our FCFE, dEPS and SOP models which are averaged and rounded to the nearest whole number to derive our 12-month price target of \$3.00

**Risks to our thesis include:** 1. Regulatory Approvals; 2. Market Share Success and Pricing Assumptions; 3. Financing Risk; 4. Expense Control; 5. Human Capital; 6. Intellectual Property.

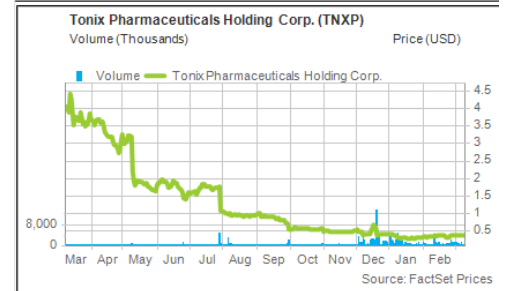
Current Price \$0.37  
Price Target \$3.00



Source: Tonix

#### Stock Data

52-Week Range	\$0.26	-	\$4.50
Shares Outstanding (mil.)	81		
Market Capitalization (mil.)	\$30		
Enterprise Value (mil.)	\$30		
Debt to Capital	0%		
Book Value/Share	\$62,876		
Price/Book	0.1		
Average Three Months Trading Volume (K)	2,273		
Insider Ownership	0.0%		
Institutional Ownership	20.8%		
Short interest (mil.)	0.0		
Dividend / Yield	\$0.00/0.0%		



**Exhibit 1. Does it work?** Three clinical trials are being submitted as part of the NDA in 2H-2024. The RESILIENT trial below shows a sharp separation between active and control groups with significance. Given the long and well-documented history of Cyclobenzaprine, we see low approval risk.

## Summary of Key Pre-Specified Secondary Outcome Measures

<u>Rating Scale</u>	<u>Week 14</u>	<u>Met**</u>
Patient Global Impression of Change (PGIC)	$p < 0.001$	✓
Fibromyalgia Impact Questionnaire - Symptoms	$p < 0.001$	✓
Fibromyalgia Impact Questionnaire - Function	$p = 0.001$	✓
PROMIS Sleep Disturbance	$p < 0.001$	✓
PROMIS Fatigue	$p < 0.001$	✓
Weekly average of daily Sleep Quality scores	$p < 0.001$	✓

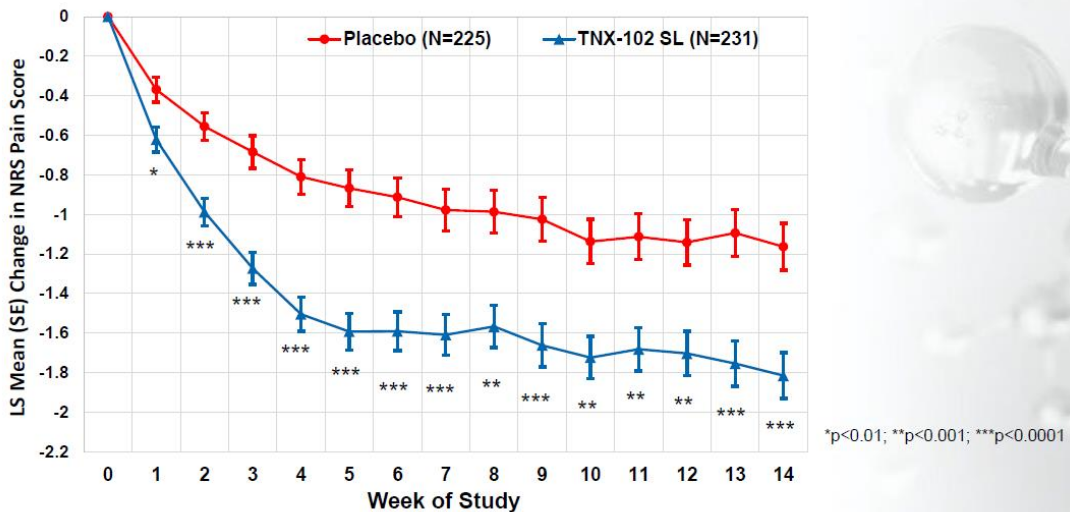
\*In order of statistical serial gate-keeping hierarchy (or, "waterfall") to control overall Type 1 error  
 \*\*Statistical significance met

Source: Tonix Pharmaceuticals

## RESILIENT Primary Outcome Measure Reduction in Widespread Pain



Weekly Average of Daily Diary NRS Ratings of Average Pain Over Prior 24 Hours



Week 14 LS mean (SE) change from baseline for TNX-102 SL -1.82 (0.12) and for placebo -1.16 (0.12); LSMD from placebo -0.65 (0.16);  $p=0.00005^{\#}$

<sup>#</sup>Based on Mixed Model Repeated Measures with Multiple Imputation, with fixed categorical effects of treatment, center, study week, and treatment by study week interaction, as well as baseline value and baseline value-by-study week interaction. Abbreviations: LS, least squares; LSMD, least squares mean difference; NRS, numerical rating scale; SE, standard error



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Source: Tonix Pharmaceuticals

**Exhibit 2. Warrants Outstanding Represent up to \$129 Million in Cash to the Company.** We assume dilution in our model for valuation purposes.

	Number of Warrants	Exercise Price	Cash upon exercise	Grant Date	Expiry	Shares outstanding if exercised
	9,000,000	\$0.50	\$4,500,000	10/3/2023	10/03/24	89,816,395
	81,081,081	\$0.555	\$45,000,000	12/22/2023	12/22/25 <sup>3</sup>	170,897,476
	9,000,000	\$0.50	\$4,500,000	10/3/2023	10/03/28	179,897,476
	81,081,081	\$0.85	\$68,918,919	12/22/2023	12/22/28	260,978,557
	7,000,000	\$1.00	\$7,000,000	8/1/2023	08/01/28	267,978,557
<b>Total</b>	<b>187,162,162</b>		<b>\$129,918,919</b>			

Source: Tonix Pharmaceuticals

### Model & Assumptions

1. We assume an actionable market prevalence of 6 million persons.
2. We assume an NDA filing in 2H24 followed by approval and launch in late 2025, with no related revenues in 2025.
3. We assume the sublingual formulation results in specialized pricing (above generics) for a \$5,000 annual cost of therapy with a low cost of goods of 10% initially and with volume, over time dropping to just 7%.
4. We assume a modest market share penetration of just 0.5% in 2026 rising to only 2.5% by 2030 coupled with annual pricing of \$5,000. Our pricing assumption could prove conservative however in a market where generic Cyclobenzaprine is available, we feel any higher pricing could hurt market share penetration.
5. Migraine Franchise: We assume the franchise will grow at 15% for the next two years and then moderate down to single digits for peak revenues of just \$43M by 2030.

### Exhibit 3. Market Model TNX-102 SL for Fibromyalgia

TNX-102 SL for Fibromyalgia	2025E	2026E	2027E	2028E	2029E	2030E
Fibromyalgia Prevalence - Active Seeking	5,960,000	6,120,000	6,280,000	6,440,000	6,600,000	6,760,000
Increase in Incidence	160,000	160,000	160,000	160,000	160,000	160,000
<b>Market Penetration</b>	<b>0.00%</b>	<b>0.50%</b>	<b>1.00%</b>	<b>1.75%</b>	<b>2.00%</b>	<b>2.50%</b>
Total Patients Treated	-	30,600	62,800	112,700	132,000	169,000
Annual Cost of Treatment	\$ 5,308	\$ 5,361	\$ 5,414	\$ 5,468	\$ 5,523	\$ 5,578
Increase in Cost	1%	1%	1%	1%	1%	1%
<b>Total Revenue ('000)</b>	<b>\$ -</b>	<b>\$ 164,037</b>	<b>\$ 340,017</b>	<b>\$ 616,292</b>	<b>\$ 729,051</b>	<b>\$ 942,740</b>

Source: Dawson James.

**Risk Analysis**

1. **Clinical Risk.** There can be no assurances that the company's lead product will be submitted on time and if submitted and accepted will be approved.
2. **Market Share Risk.** There can be no assurances that the company's lead product will be successful at penetrating the marketplace.
3. **Pricing Risk:** There can be no assurances that our pricing assumption is accurate, especially when one considers the availability of generic versions, and oral formulations of the drug, which are "cheaper".
4. **Financing Risk.** There can be no assurances that the company can successfully raise capital to continue current operations and that the existing warrants will be successfully exercised.
5. **Expense Control.** There can be no assurances that our assumption that the company reduces expenses in the out-years is accurate.
6. **Human Capital.** There can be no assurance that the current management team remains in place and that the company is successfully building the required sales infrastructure to support its product offerings.
7. **Intellectual Property.** There can be no assurance that the company's current IP protections will work around its lead products and not be overturned or penetrated.

Please see the company's disclosures in the annual report for additional associated risks.

**Exhibit 4. Income Statement.**

Tonix Pharmaceuticals: Income Statement (\$000)																	
YE December 31	2022A	1Q23A	2Q23A	3Q23A	4Q23E	2023E	2024E	1Q25E	2Q25E	3Q25E	4Q25E	2025E	2026E	2027E	2028E	2029E	2030E
<b>Revenue:</b>																	
TNX-102 for Fibromyalgia	-	-	-	-	-	-	-	-	-	-	-	-	164,037	340,017	616,292	729,051	942,740
Migraine Franchise - Zembrace & Tosmyra	-	-	-	-	-	-	-	6,900	7,200	7,800	8,100	30,000	34,500	39,675	41,659	42,492	43,342
TNX-102 Other Indications - Long Covid & Acute Stress Disorder	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
TNX-1300 (Cocaine Esterase) - Cocaine Intoxication	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
TNX-2900 (Intranasal Oxycotin) - Prader Willy Syndrome	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
TNX-1500 (Anti-CD40L.mAb) - Organ Rejection	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Antiviral Discovery Platform	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Net revenue</b>	-	-	-	3,989	-	-	-	6,900	7,200	7,800	8,100	30,000	198,537	379,692	657,950	771,543	986,082
<b>Collaborative revenue:</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Collaborative Revenue</b>	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Revenue</b>	-	-	-	3,989	-	-	-	6,900	7,200	7,800	8,100	30,000	198,537	379,692	657,950	771,543	986,082
<b>Expenses:</b>																	
Costs of Goods Sold	-	-	-	2,374	-	-	-	690	720	780	810	3,000	19,854	34,172	52,636	54,008	69,026
Research and Development	81,876	26,511	21,976	21,050	20,000	89,537	89,537	15,445	16,117	16,788	18,803	67,153	50,365	30,000	30,600	31,212	31,836
General and Administrative	30,215	7,391	7,026	8,712	8,000	31,129	31,129	10,740	11,206	11,673	13,074	46,694	70,040	70,741	50,000	50,500	51,005
<b>Total Expenses</b>	112,091	33,902	29,002	32,136	28,000	120,666	120,666	26,875	28,043	29,242	32,687	116,846	140,258	134,913	133,236	135,720	151,867
<b>Operating Income (Loss)</b>	(112,091)	(33,902)	(29,002)	(28,147)	(28,000)	(120,666)	(120,666)	(19,975)	(20,843)	(21,442)	(24,587)	(86,846)	58,278	244,779	524,714	635,823	834,215
Interest Income	1,873	897	646	172	-	1,715	-	-	-	-	-	-	-	-	-	-	-
<b>Total Other Income</b>	-	897	646	172	-	1,715	-	-	-	-	-	-	-	-	-	-	-
<b>Pre-tax Income</b>	(110,218)	(33,005)	(28,356)	(27,975)	(28,000)	(118,951)	(120,666)	(19,975)	(20,843)	(21,442)	(24,587)	(86,846)	58,278	244,779	524,714	635,823	834,215
Warrant deemed dividend	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Preferred stock deemed dividend	6,659	-	-	-	-	-	-	(1,997)	(2,084)	(2,144)	(2,459)	(8,685)	8,742	61,195	157,414	197,105	266,949
Taxes on income	-	-	-	-	-	-	-	10%	10%	10%	10%	10%	15%	25%	30%	31%	32%
<b>Tax Rate</b>	-	-	-	-	-	-	-	10%	10%	10%	10%	10%	15%	25%	30%	31%	32%
<b>GAAP Net Income (Loss)</b>	116,877	(33,005)	(28,356)	(27,975)	(28,000)	(117,336)	(120,666)	(17,977)	(18,759)	(19,297)	(22,128)	(78,162)	49,536	183,584	367,300	438,718	567,266
<b>Total comprehensive loss</b>	116,877	(33,005)	(28,356)	(27,975)	(28,000)	(117,336)	(120,666)	(17,977)	(18,759)	(19,297)	(22,128)	(78,162)	49,536	183,584	367,300	438,718	567,266
<b>GAAP-EPS</b>	3.27	(0.52)	(2.68)	(1.83)	(1.83)	(4.49)	(0.91)	(0.12)	(0.12)	(0.13)	(0.15)	(0.52)	0.33	1.21	2.41	2.87	3.69
GAAP-EPS (Dil)	3.27	(0.22)	(0.95)	(0.70)	(0.09)	(4.49)	(0.39)	(0.06)	(0.06)	(0.06)	(0.07)	(0.25)	0.16	0.59	1.17	1.40	1.80
Wgtd Avg Shrs (Bas) - '000s	35,739	63,353	10,587	15,327	15,342	26,152	132,813	150,450	150,601	150,752	150,902	150,676	151,280	151,886	152,494	153,105	153,719
Wgtd Avg Shrs (Dil) - '000s	35,739	150,000	30,000	40,000	307,000	26,152	307,768	308,538	308,847	309,155	309,465	309,001	310,239	311,482	312,730	313,982	315,240

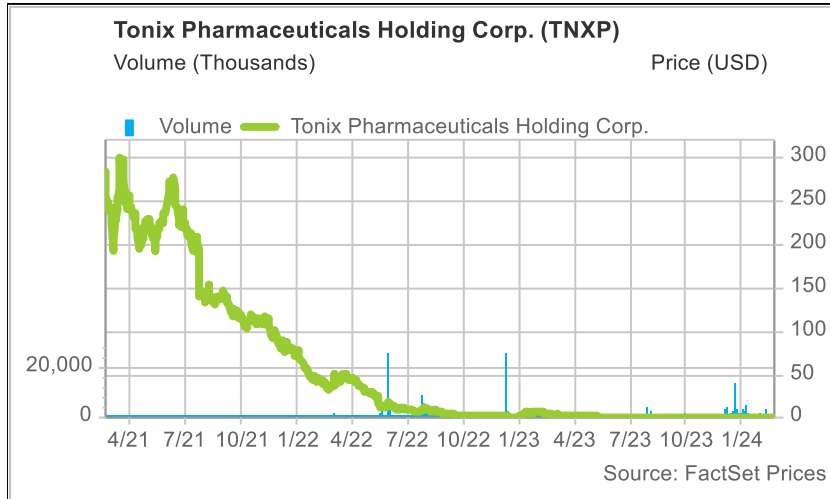
Source: Dawson James estimates.

Companies mentioned in this report:

Tonix Pharmaceuticals Holding Corp.

Important Disclosures:

**Price Chart:**



Price target and ratings changes over the past three years:

Initiated – Buy – February 28, 2024 – Price Target \$3.0  
Update Report – March 11, 2024 – Price Target \$3.0

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Current as of 27-Feb-24

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<b>Ratings Distribution</b>	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	20	57.14%	4	11.43%
Market Perform (Neutral)	15	42.86%	2	5.71%
Market Underperform (Sell)	0	0%	0	0.00%
<b>Total</b>	<b>35</b>	<b>100%</b>	<b>6</b>	<b>17.14%</b>

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