UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (date of earliest event reported): October 7, 2025

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

26 Main Street, Chatham, New Jersey, 07928
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(862) 799-8599**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock	TNXP	The NASDAQ Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

Tonix Pharmaceuticals Holding Corp. (the "Company") updated its investor presentation, which is used to conduct meetings with investors, stockholders and analysts and at investor conferences, and which the Company intends to place on its website, which may contain nonpublic information. A copy of the presentation is filed as Exhibit 99.01 hereto and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

The Company intends to initiate a Phase 2 trial of its TNX-102 SL product candidate, which is already approved for the treatment of fibromyalgia, for the treatment of major depressive disorder in 2026. The Company intends to initiate an adaptive Phase 2/3 study of its TNX-4800 product candidate for the seasonal prevention of Lyme disease in 2027.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with the SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Corporate Presentation of the Company for October 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: October 7, 2025

By: /s/ Bradley Saenger
Bradley Saenger
Chief Financial Officer

Exhibit 99.01

Cautionary Note on Forward-Looking Statements

Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are “forward-looking statements” as defined by the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate” and “intend,” among others. These forward-looking statements are based on Tonix’s current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the failure to successfully market any of our products; risks related to the timing and progress of clinical development of our product candidates; risks related to the failure to successfully launch and commercialize Tonmya and any of our approved products; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by Tonix on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2024, as filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2025, and periodic reports and current reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.

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Our Mission

Committed to improving health by ***discovering, developing and delivering*** impactful solutions, through robust in-house capabilities and synergistic collaborations, to address important unmet needs in ***chronic pain, nociplastic pain, immunology / immuno-oncology, infectious disease and rare disease.***

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Fully Integrated Biotech: Key Commercial, Clinical, and Preclinical Programs

	Product*	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Approved
CNS	TONMYA™	Treatment of Fibromyalgia	TONMYA FDA Approved on August 15, 2025 — US Launch Planned Q4 2025				
	TNX-102 SL Cyclobenzaprine HCl Sublingual Tablets	Treatment of Acute Stress Disorder	Phase 2 Study Enrolling** — Topline Expected 2nd Half 2026				
	TNX-102 SL Cyclobenzaprine HCl Sublingual Tablets	Treatment of Major Depressive Disorder	Phase 2 Study Ready***				
	TOSYMRA®	Treatment of Acute Migraine					
	ZEMBRACE®	Treatment of Acute Migraine					
Immunology and Immuno-oncology	TNX-1500 Anti-CD40L mAb	Prevention of Organ Transplant Rejection/Treatment of Autoimmune Conditions	Phase 1 Study Completed — Topline Reported 1st Quarter 2025				
	TNX-1700 TFF2-HSA Fusion Protein	Treatment of Gastric and Colorectal Cancer	Preclinical				
Infectious disease	TNX-4800 Monoclonal Antibody	Seasonal Prevention of Lyme Disease	Phase 2/3 Study Planned				
	TNX-801 Live Virus Horsepox Vaccine	Prevention of Mpox or Smallpox	Preclinical				
	TNX-4200 Broad Spectrum Antiviral	Protection of the Warfighter From Viral Pathogens	Preclinical				
Rare disease	TNX-2900 Intranasal Potentiated Oxytocin With Magnesium	Treatment of Prader-Willi Syndrome	Ph 2 Study Planned for 2026				

*Tonix's unapproved product candidates (TNX-102 SL, TNX-1500, TNX-1700, TNX-4800, TNX-801, TNX-4200, and TNX-2900) are investigational new drugs or biologics; their safety and efficacy have not been established for the indications listed.
**Investigator-initiated study.
***Pending IND filing planned for Q4 2025.

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TONIX
PHARMACEUTICALS
Commercial
Portfolio
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Approved Medicines

	MEDICINE	INDICATION	AVAILABILITY
CNS Medicines	Tonmya™ (cyclobenzaprine HCl) sublingual tablets 2.8mg tonmya.com	Fibromyalgia in Adults	FDA approved on August 15, 2025; expected availability Q4 2025
	tosymra® (sumatriptan nasal spray) 10 mg tosymra-hcp.com	Acute Migraine With or Without Aura in Adults Who Have Been Diagnosed With Migraine	Available
	Zembrace® SYMTOUCH® (sumatriptan injection) 3 mg zembrace-hcp.com	Acute Migraine With or Without Aura in Adults Who Have Been Diagnosed With Migraine	Available

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Tonmya™ (cyclobenzaprine HCl) sublingual tablets 2.8mg

FDA Approved on August 15, 2025

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TONMYA is the First FDA-Approved Medicine for the Treatment of Fibromyalgia in Over 15 Years

First-in-class, First-line Medicine for Fibromyalgia
Unique, Sublingual, Proprietary Formulation of Cyclobenzaprine HCl Designed to Optimize Efficacy, Delivery and Absorption

- Two pivotal studies demonstrated durable reduction in fibromyalgia pain (primary endpoint)
- Non-opioid analgesic; not DEA scheduled
- Rapid drug exposure following once daily sublingual administration, at bedtime
- Reduced levels of norCyclobenzaprine (norCBP), the active major metabolite of cyclobenzaprine
  - norCBP is believed to reduce the effectiveness of swallowed cyclobenzaprine on pain relief
- Generally well tolerated
- Patent Protection / Exclusivity: Tonix owns worldwide rights to TONMYA with no royalties. In the US, issued composition of matter patent extending to 2034; pending method of use patents may extend exclusivity to 2044

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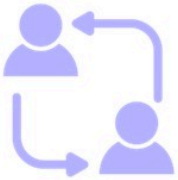
Fibromyalgia is a Large, Underserved and Dissatisfied Population

Chronic pain disorder, resulting from amplified sensory and pain signaling within the central nervous system - a serious condition comprised of the symptoms: chronic widespread pain, nonrestorative sleep, and fatigue

>10 million U.S. adults are affected– predominantly women[1,2]
Debilitating and life-altering condition
Significant economic impact

Patients have expressed dissatisfaction with currently available therapies[3,4]
85% of first-line treatments fail with patients, citing efficacy and tolerability issues[4]



High patient churn on currently available fibromyalgia treatments
Typical for patients to rotate between different therapies
79% of patients are on multiple therapies[4]

2.7 million patients diagnosed and treated annually[5]
~15 million prescriptions are written for the treatment of fibromyalgia (on- and off-label usage) each year[6]

No new FDA approved fibromyalgia therapies in over 15 years[4]

[1]Fibromyalgia. American College of Rheumatology. Accessed July 3, 2025. www.ACRPatientInfo.org
[2]Fibromyalgia prevalence. National Fibromyalgia Association. Accessed July 3, 2025.
[3]Robinson RL, et al. *Pain Med.* 2012 13(10):1366-76. doi: 10.1111; 85% received drug treatment
[4]EVERSANA primary physician research, May 2024; commissioned by Tonix
[5]EVERSANA analysis of claims database, May 2024, commissioned by Tonix.
[6]Symphony Market data, May 2025. Prescription data includes on-label FM prescriptions and patients with FM diagnoses who received commonly prescribed off-label therapies

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Conditions Commonly Comorbid with Fibromyalgia

- **Infection-Associated Chronic Conditions (IACCs)[1,2] – also known as Post-Acute Infection Syndromes (PAISs)[3]**
  - Long COVID - "The National Academies of Science, Engineering and Medicine (NASEM) concluded that fibromyalgia is a "diagnosable condition" in Long COVID (2024)[1]
  - Chronic Lyme - The NASEM report on Chronic Lyme found that fibromyalgia coexists in a subset of patients (2025)[2]
- **Autoimmune disease**
  - Systemic lupus erythematosus
  - Rheumatoid arthritis
- **Cancer and cancer chemotherapy**
- **Chronic Overlapping Pain Syndromes (COPCs)**
  - CFS/ME (chronic fatigue syndrome/myalgic encephalomyelitis)
  - Pelvic pain (cystitis)
  - Mild TBI / Post-concussive syndrome (PCS)[4]

[1]NASEM. 2024. A Long COVID Definition: A Chronic, Systemic Disease State with Profound Consequences. Washington, DC: The National Academies Press. https://doi.org/10.17226/27768.
[2]NASEM. 2025. Charting a Path Toward New Treatments for Lyme Infection-Associated Chronic Illnesses. Washington, DC: The National Academies Press. https://doi.org/10.17226/28578
[3]Choutka J, et al. *Nat Med.* 2022. 28(5):911-923. doi: 10.1038/s41591-022-01810-6.
[4]Kureshi S, et al. Healthcare (Basel). 2024. 2(3):289. doi: 10.3390/healthcare12030289.

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TONMYA Prescribing Information Highlights

TONMYA (cyclobenzaprine hydrochloride sublingual tablets)	
Indications and Usage	TONMYA is indicated for the treatment of fibromyalgia in adults
Dosage and Administration	The recommended dosage of TONMYA is 5.6 mg administered sublingually once daily at bedtime: • Starting dose: Days 1 to 14, administer 2.8 mg (1 sublingual tablet) once daily at bedtime • Target dose: Days 15 and thereafter, administer 5.6 mg (2 sublingual tablets) once daily at bedtime The recommended TONMYA dosage in geriatric patients and patients with mild hepatic impairment is 2.8 mg administered sublingually once daily at bedtime. TONMYA is not recommended in patients with moderate or severe hepatic impairment Pregnancy testing is recommended in females of reproductive potential prior to initiating treatment with TONMYA
Adverse Reactions	Most common adverse reactions (incidence ≥2% and at a higher incidence in TONMYA-treated patients compared to placebo-treated patients): oral hypoesthesia, oral discomfort, abnormal product taste, somnolence, oral paresthesia, oral pain, fatigue, dry mouth, and aphthous ulcer

For full prescribing information and safety information, please visit **www.tonmya.com**

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FDA Approval Based on Studies that Demonstrated Durable Improvement in Pain Intensity Scores in Fibromyalgia Patients

Primary Efficacy Endpoint: Mean Change from Baseline in Weekly Average of Daily 24-Hour Recall Pain Intensity Scores at Week 14 in Adult Subjects with Fibromyalgia (Trials 1 and 3)

Trial 1 (RELIEF Trial)

	Placebo		TONMYA	
Visit / Statistics	**Value**	**Change from baseline**	**Value**	**Change from baseline**
Trial 1				
Baseline				
N	255		248	
Mean (SD)	6.0 (1.08)		6.1 (1.06)	
(Minimum, Maximum)	(4, 9)		(4, 9)	
Week 14				
LS mean (SE)[1]	4.6 (0.12)	-1.5 (0.12)	4.2 (0.12)	-1.9 (0.12)
95% CI[1]	(4.3, 4.8)	(-1.7, -1.3)	(3.9, 4.4)	(-2.1, -1.7)
Difference in LS mean (SE)				-0.4 (0.16)
95% CI for difference in LS mean				(-0.7, -0.1)
p-value for difference				0.010

Trial 3 (RESILIENT Trial)

	Placebo		TONMYA	
Visit / Statistics	**Value**	**Change from baseline**	**Value**	**Change from baseline**
Trial 3				
Baseline				
N	225		231	
Mean (SD)	5.9 (1.08)		5.9 (1.05)	
(Minimum, Maximum)	(4, 9)		(4, 9)	
Week 14				
LS mean (SE)[1]	4.7 (0.12)	-1.2 (0.12)	4.1 (0.12)	-1.8 (0.12)
95% CI[1]	(4.5, 5.0)	(-1.4, -0.9)	(3.8, 4.3)	(-2.0, -1.6)
Difference in LS mean (SE)				-0.7 (0.16)[2]
95% CI for difference in LS mean				(-1.0, -0.3)
p-value for difference				<0.001

CI = confidence interval; LS = least squares; SD = standard deviation; SE = standard error
[1] LS means, differences and CIs were based on a mixed model for repeated measures with fixed, categorical effects of treatment, center, study week, and treatment-by-study week interaction, as well as the fixed covariates of baseline value and baseline value-by-study week interactions. An unstructured covariance matrix was used.
[2] Difference of -0.7 is due to a rounding effect: TONMYA: -1.82, placebo: -1.16, and the difference in LS mean is -0.66.

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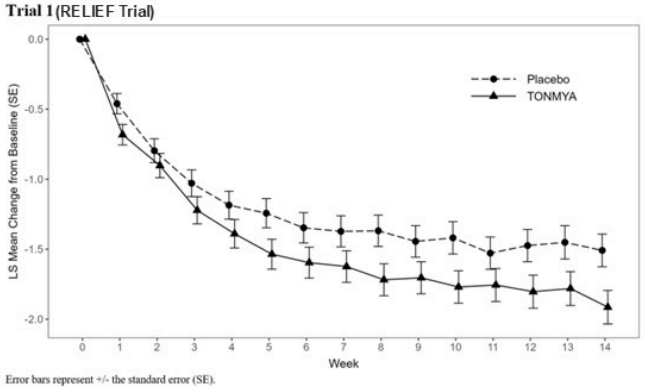
TONMYA Approval Based on Studies that Demonstrated Significant Improvement in Pain Intensity Scores in Fibromyalgia Patients

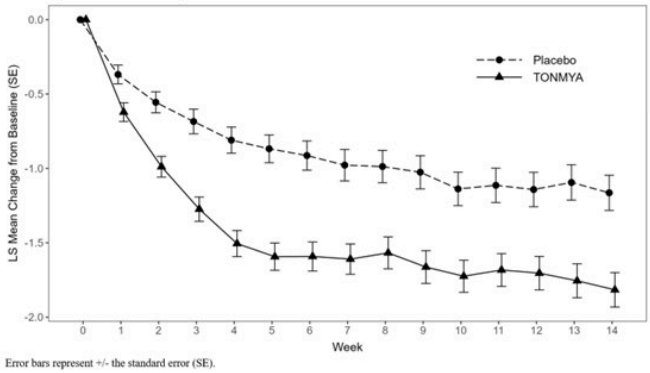
Pivotal Studies Included in Label Demonstrate Statistically Significant Mean Change from Baseline in Weekly Average of Daily 24-hour Recall Pain Intensity Scores at Week 14

Trial 1 (RELIEF Trial)



Error bars represent +/- the standard error (SE).

Trial 3 (RESILIENT Trial)



Error bars represent +/- the standard error (SE).

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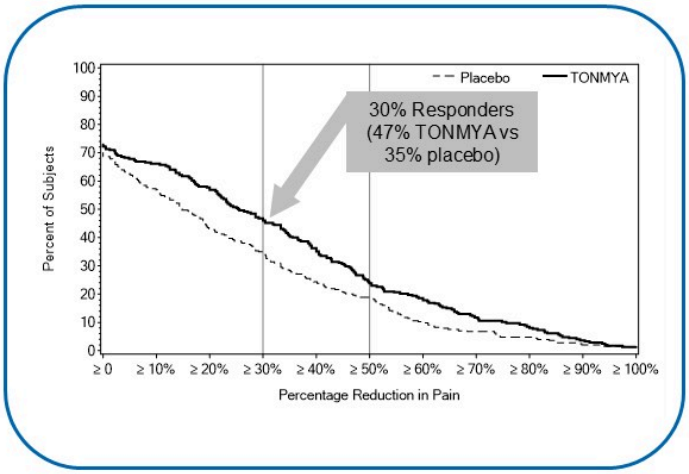
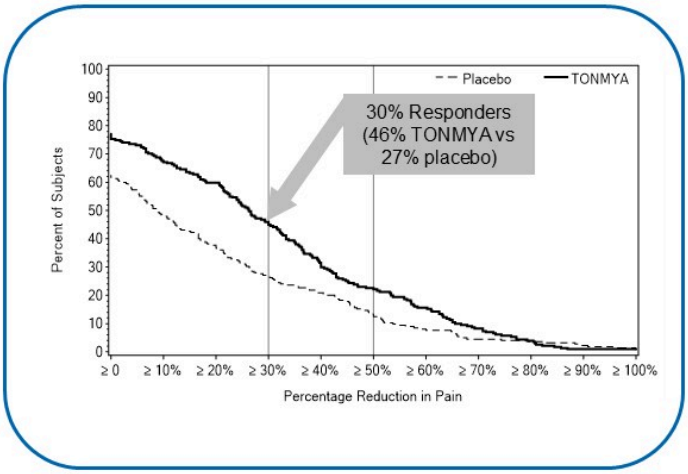
Greater Percentage of Study Participants Taking TONMYA Experienced a Clinically Meaningful (≥30%) Improvement in their Pain after Three Months, Compared to Placebo

Trial 1 (RELIEF Trial)*



Trial 3 (RESILIENT Trial)*



*The figures shows the percentage of patients in Trials 1 and 3 who achieved various degrees of improvement in the change from baseline to Week 14 in the weekly averages of daily diary pain scores. The figures are cumulative so that patients whose change from baseline is, for example, 30%, are also included at every level of improvement below 30%. Patients who did not complete the trial were assigned 0% improvement.

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Opportunities to Educate the Community about Fibromyalgia

- **Fibromyalgia is not a "Diagnosis of Exclusion" (ACR 2016 Criteria)**
  - "A diagnosis of fibromyalgia is valid irrespective of other diagnoses. A diagnosis of fibromyalgia does not exclude the presence of other clinically important illnesses."[1]

- **Tender Points are not required to diagnose fibromyalgia**
  - The 2016 ACR criteria specifically eliminated the 1990 requirement[2] for tender points

- **Changes in mean pain cannot be compared between different studies**
  - Mean pain changes vary between trials even for the same drug, same inclusion criteria and same statistical methods
  - TONMYA's registrational studies evaluated a different population of fibromyalgia patients (ACR 2016 criteria) than the prior approved products' studies (ACR 1990 criteria)
  - TONMYA also employed more rigorous analytic methods to account for "missing data" (earlier trials used single imputation methods; TONMYA Trials used multiple imputation)

- **Expert Consensus holds that "Clinically Meaningful" is a ≥ 30% reduction in pain from baseline[3,4]**

[1]Wolfe F, et al. *Semin Arthritis Rheum.* 2016. 46(3):319-329. doi: 10.1016/j.semarthrit.2016.08.012.
[2]Wolfe F, et al. *Arthritis Rheum.* 1990. 33(2):160-72. doi: 10.1002/art.1780330203.
[3]Dworkin RH, et al., *J Pain.* 2008. 9(2):105-21. doi: 10.1016/j.jpain.2007.09.005.
[4]Arnold LM, et al., Arthritis Rheum. 2012. 64(3):885-894. doi:10.1002/art.33360.

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Patients Identified by the 2016 ACR criteria More Representative of Current Fibromyalgia Treatment Paradigm

- **TONMYA's studies enrolled patients based on the ACR 2016 criteria, while the prior FDA approved products' studies used the ACR 1990 criteria**
  - The 1990 ACR criteria required physical exams and the presence of tender points.
  - The 2016 ACR criteria eliminated the requirement for physical exams and the presence of tender points

- **The fibromyalgia patient population identified by the 2016 ACR criteria are more representative of how fibromyalgia is diagnosed and treated today**
  - Physical exam and tender point exams are not necessary to diagnose fibromyalgia and are incompatible with, for example, telehealth
  - New ACR criteria achieved improved sensitivity by focusing on distribution of pain and the severity of other symptoms
  - Tender-point exams weren't reliable and did not reflect the full symptom burden

[1]Wolfe F, et al. *Semin Arthritis Rheum*. 2016 46(3):319-329. doi: 10.1016/j.semarthrit.2016.08.012.
[2]Wolfe F, et al. *Arthritis Rheum*. 1990. 33(2):160-72. doi: 10.1002/art.1780330203.
[3]Ablin JN, Wolfe F. *J Rheumatol*. 2017 Aug;44(8):1271-1276. doi: 10.3899/jrheum.170095.

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Mean Pain Changes Cannot be Compared Between Studies

- **Mean pain changes vary between trials even for the same drug, same inclusion criteria and same statistical methods**

- **TONMYA's registrational studies evaluated a different population of fibromyalgia patients (ACR 2016 criteria) than the prior FDA approved products' studies (ACR 1990), which required tender points**[1,2]

- **TONMYA employed rigorous and conservative analytic methods to account for "missing data"**
  - The prior FDA approved products' studies used single imputation (i.e. last observation carried forward, LOCF) to account for missing data
  - LOCF assumes missing data are ignorable which can introduce bias and falsely enhance statistical precision[3]
  - The primary statistical analyses for the TONMYA registrational studies used multiple imputation, with missing values imputed drawing from baseline values when patients dropped out due to adverse events (AEs) or lack of efficacy[4]
  - Drugs with tolerability issues and high rates of drop-outs for AEs would be expected to be penalized by the modern missing data treatment requirements employed in TONMYA's registrational trials

[1]Wolfe F, et al. *Semin Arthritis Rheum*. 2016 46(3):319-329. doi: 10.1016/j.semarthrit.2016.08.012.
[2]Wolfe F, et al. *Arthritis Rheum*. 1990. 33(2):160-72. doi: 10.1002/art.1780330203.
[3]Woolley SB, et al. *Pharmacotherapy*. 2009. 29:1408-1416
[4]Drops-outs due to AEs or LOE are non-ignorable missing data

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“Clinically Meaningful” Defined by 30% Pain Reduction

- **Expert consensus holds that “Clinically Meaningful” in fibromyalgia is defined by a 30% or greater reduction in pain from baseline[1,2]**

Percentage of Patients with 30% or greater Reduction in Pain from Baseline to Week 14

Pre-specified Analyses

	TONMYA	Placebo	*p-value*[3]
Study 1 (RELIEF)	46.8%	34.9%	p=0.006
Study 2 (RESILIENT)	45.9%	27.1%	p<0.001

[1]Dworkin RH, et al., *J Pain*. 2008. 9(2):105-21. doi: 10.1016/j.jpain.2007.09.005.
[2]Arnold LM, et al., Arthritis Rheum. 2012. 64(3):885-894. doi:10.1002/art.33360.
[3]uncorrected p-value

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Generally Well Tolerated with an Established Safety Profile

- In Clinical Studies:
  - The most common adverse reactions (incidence ≥2% and at a higher incidence in TONMYA-treated patients compared to placebo-treated patients) were: oral hypoesthesia, oral discomfort, abnormal product taste, somnolence, oral paresthesia, oral pain, fatigue, dry mouth, and aphthous ulcer
  - Weight gain, and blood pressure for drug group were similar to placebo group at baseline and to the end of treatment
  - There were no reports of cognitive dysfunction or sexual dysfunction
  - No evidence of abuse potential
- Pregnancy testing is recommended in females of reproductive potential prior to initiating treatment with TONMYA
- Concomitant use of TONMYA with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), or tricyclic antidepressants, tramadol, bupropion, meperidine, verapamil, or MAO inhibitors increases the risk of serotonin syndrome

For full prescribing information and safety information, please visit **www.tonmya.com**

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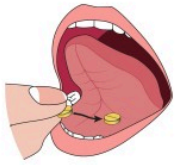
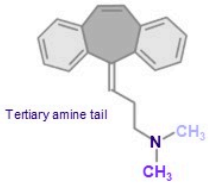
TONMYA is a Tertiary Amine Tricyclic that Bypasses First-Pass Liver Metabolism, Leading to Faster Absorption and Reduced norCyclobenzaprine ("norCBP")

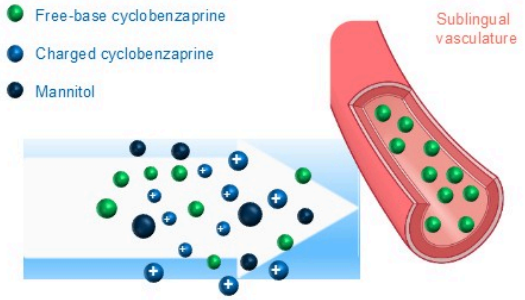
TONMYA is administered sublingually



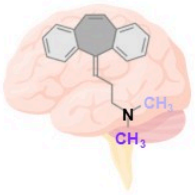
tongue



- The sublingual tablet rapidly disintegrates, dissolves, and releases solubilized cyclobenzaprine ("CBP") into the saliva adjacent to the mucosal membrane
- The base drives formation of CBP free-base, which enters the bloodstream across the mucosal membrane (transmucosal absorption)
- Tonix's proprietary formulation contains a basic ingredient which drives transmucosal absorption and a cyclobenzaprine-mannitol eutectic that results in a stable tablet with a 4-year shelf-life.



Sublingual CBP enters the bloodstream directly through the mucosal membrane



Transmucosal CBP administered sublingually bypasses "first-pass" liver metabolism, leading to faster absorption and reduced norCBP

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TONMYA: Patents and Patent Applications

- **U.S. Composition:***
  - A 75:25 cyclobenzaprine HCl - mannitol eutectic (dependent claims add a basifying agent).
    - 5 US Patents (Expire November 2034)
    - 1 Pending US Application (Would expire November 2034)
  - A composition of a cyclobenzaprine HCl and a basifying agent suitable for sublingual absorption.
    - 1 Pending US Application (Would expire June 2033)

- **U.S. Methods of Use* (Specific Indications):**
  - Fibromyalgia
    - Pain, Sleep Disturbance, Fatigue
      - 1 Pending US Application (Would expire December 2041)
    - Early Onset Response
      - 1 Pending US Provisional Application (Would expire December 2044)
    - Depressive Symptoms
      - 1 Pending US Application (Would expire March 2032)
  - Sexual Dysfunction
    - 1 Pending US Application (Would expire October 2041)
  - PASC
    - 1 Pending US Application (Would expire June 2043)
  - PTSD
    - 1 US Patent (Expires November 2030)
  - Agitation (Dementia)
    - 1 US Patent (Expires December 2038)
    - 1 Pending US Application (Would expire December 2038)
  - Alcohol Use Disorder
    - 1 Pending US Application (Would expire November 2041)

- **Foreign Filings**
  - Corresponding foreign patents have been filed and some have issued:
    - Composition (25 patents, 3 allowed applications, 16 pending applications)
    - Methods of Use (9 patents, 54 pending applications)

Patents based on TONMYA's eutectic composition and its properties have issued in the U.S., E.U., Japan, China and many other jurisdictions around the world and provide market protection into 2034.

The European Patent Office's Opposition Division maintained Tonix's European Patent EP 2 968 992 in unamended form after an Opposition was filed against it by a Sandoz subsidiary, Hexal AG. Hexal AG did not appeal that decision.

*US Patents: Issued: US Patent Nos. 9,636,408; 9,956,188; 10,117,936; 10,864,175; 11,839,594; 9,918,948; 11,826,321. Pending: US Patent Application Nos. 13/918,692; 18/385,468; 13/412,571; 18/265,525; 63/612,352; 18/382,262; 18/037,815; 17/226,058; 18/212,500.

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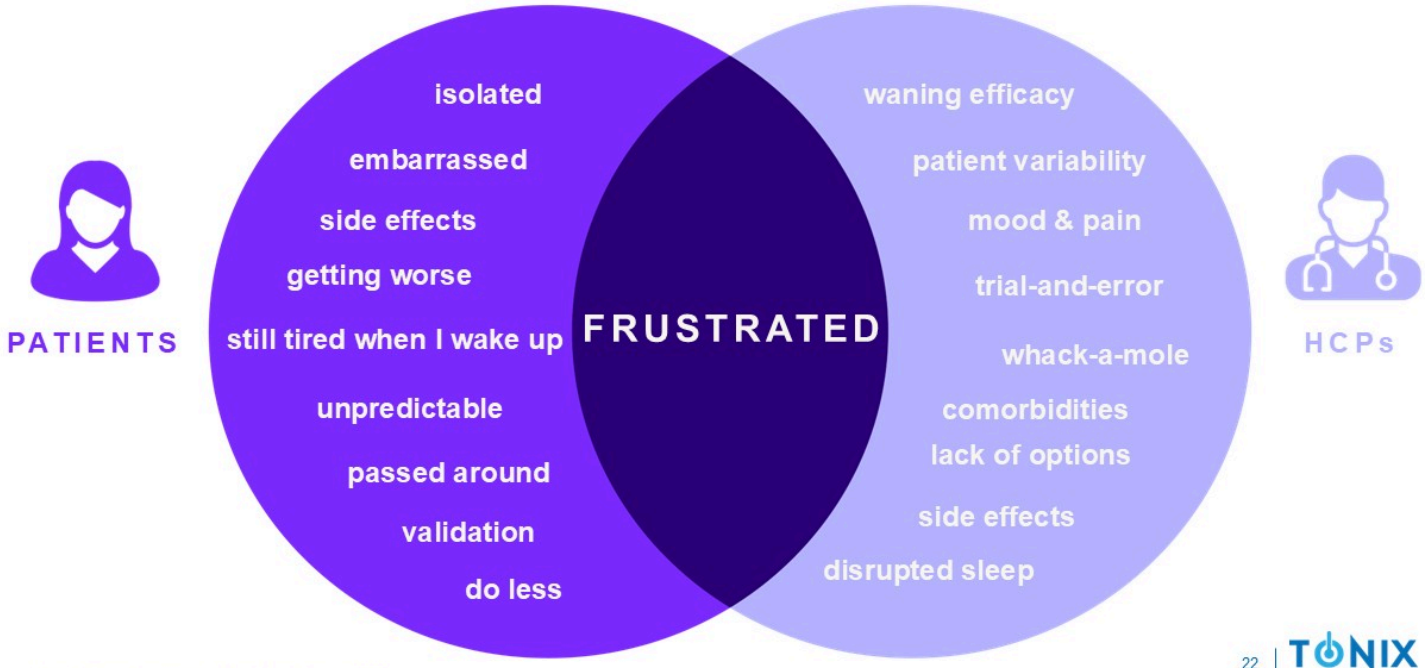
Both Patients and HCPs are Challenged by the Fibromyalgia Journey[1]



[1]Market research commissioned by Tonix, January 2025

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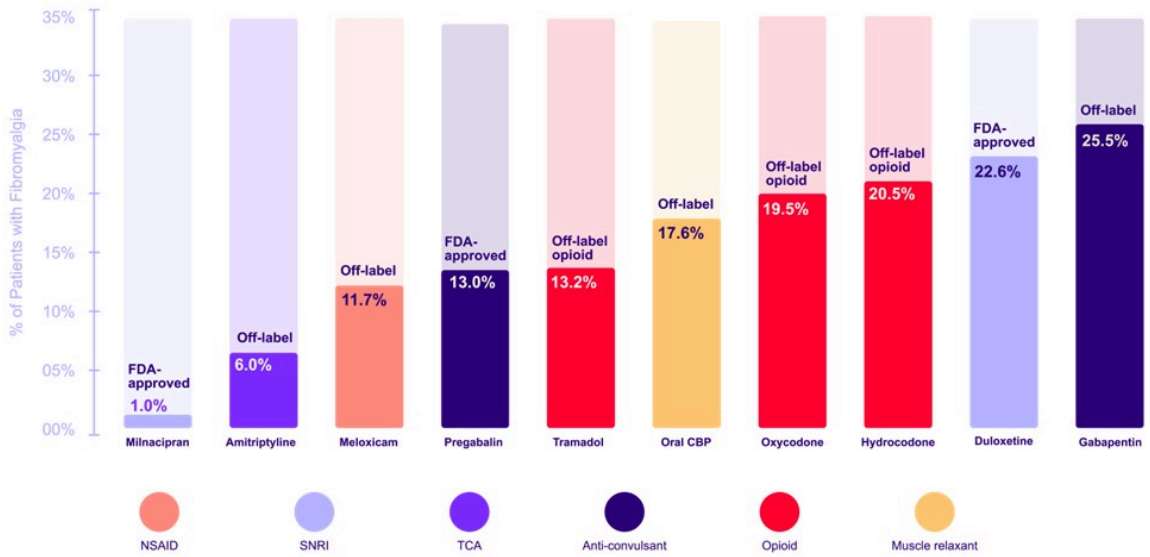
Patient and HCP Dissatisfaction has Led to Significant Off-label Use

Off-label Opioids are Commonly Prescribed within 18 Months of Fibromyalgia Diagnosis



CBP, cyclobenzaprine; NSAID, nonsteroidal anti-inflammatory drug; SNRI, serotonin norepinephrine reuptake inhibitor; TCA, tricyclic antidepressant.
Eversana analysis of claims database, May 2024.

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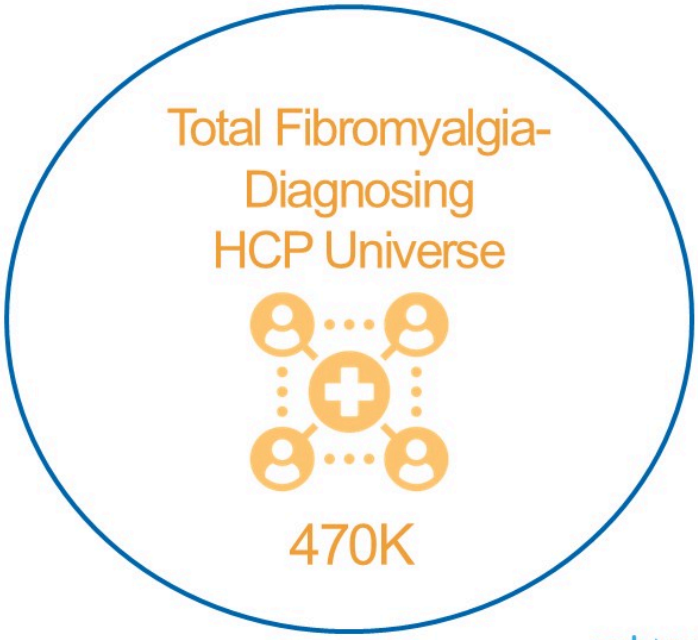
~5% of Fibromyalgia-Diagnosing HCPs Write ~70% of Fibromyalgia Prescriptions[1,2]

WE WILL GO FROM:

Traditional specialty-based decile targeting

TO:

Hyper-focused 1:1 HCP targeting based on ideal patient types → **~25K HCPs**



[1,2] Paid Rx (APLD) in the recent 12 months (Feb'24 to Jan'25); Rx (FACT) in the recent 12 months (Feb'24 to Jan'25); FBM DX 2020-2025. This 5% also diagnoses 70% of fibromyalgia patients.

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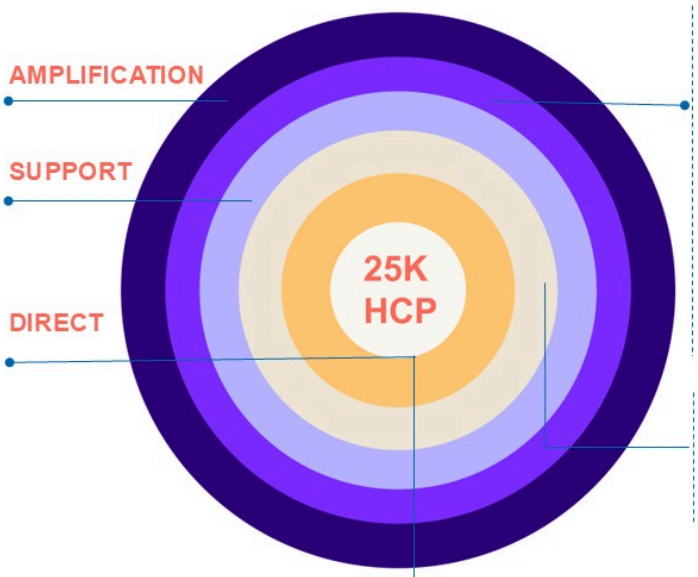
Using our Omnichannel Approach to Empower Reps and Engage Top-prescribing HCPs



- Earned Media
- Corporate Communications
- Influencer Marketing
- Owned Social Channels
- Reputation Management
- KOL Engagement
- Search Engine Optimization
- Digital Media
- Paid Social
- Machine Learning

Sales Force[1] (~90 Reps initially)

[1] Tonix has engaged Inizio, a leading contract sales organization, to provide the majority of its sales force.

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Robust Patient Access & Support Services On Track to be in Place at Launch

ACCESS PATHWAYS[1]

Payer Education & Engagement

Payer Research and Value Analysis

Pre-Approval Information Exchange Meetings

Burden of Disease & Payer Value Proposition

Digital Pharmacy Experience

Bridge Program

Streamlined Enrollment & Enhanced Prior Authorization Support

Free Home Delivery, Enhancing Convenience and Access

Traditional Pharmacy Savings Program

Copay Support for Eligible Patients Digital & Text Enrollment

Prior Authorization Support

[1] Programs are for patients after their HCP has determined TONMYA is appropriate for them.

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TONMYA will Join Tonix Medicine's Two Existing Proprietary CNS Drugs: Both are Non-Oral Formulations of Sumatriptan

Tonix Medicines Commercial Subsidiary: Complete Commercialized Capabilities & Infrastructure

- Trade, Managed Care & Government contracting
- Team of professionals including Sales, Marketing, and Medical Affairs personnel
- Manage supply chain and contract manufacturers
- Distribution

- TOSYMRA® and ZEMBRACE® are each indicated for the ***treatment of acute migraine with or without aura in adults***
- Sumatriptan remains the acute migraine 'gold standard' treatment for many patients and continues to represent the largest segment of the market in terms of unit sales[3]
- Each may provide migraine ***pain relief in as few as 10 minutes*** for some patients[1,2,4,5]
- Patents to 2036 (ZEMBRACE) and 2031 (TOSYMRA)

TOSYMRA®
(sumatriptan nasal spray) 10 mg[2]

ZEMBRACE® SymTouch®
(sumatriptan injection) 3 mg[1]

[1]ZEMBRACE SymTouch [package insert]. For more information, talk to your provider and read the Patient Information and Instructions for Use. – Important Safety Information is provided in the appendix
[2]TOSYMRA [package insert]. For more information, talk to your provider and read the Patient Information and Instructions for use– Important Safety Information is provided in the appendix
[3]Tonix Medicines, Inc.; Data On File, 2023

[4]Mathew NT, et al. Dose ranging efficacy and safety of subcutaneous sumatriptan in the acute treatment of migraine. US Sumatriptan Research Group. Arch Neurol. 1992;49(12):1271-1276.
[5]Wendt J, et al. A randomized, double-blind, placebo-controlled trial of the efficacy and tolerability of a 4-mg dose of subcutaneous sumatriptan for the treatment of acute migraine attacks in adults. Clinical Therapeutics. 2006;28(4):517-526.

ZEMBRACE SymTouch and TOSYMRA are registered trademarks of Tonix Medicines, Inc. Intravail is a registered trademark of Aegis Therapeutics, LLC, a wholly owned subsidiary of Neurelis, Inc.

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TONIX
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Pre-Clinical and
Clinical Pipeline
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Key Clinical and Preclinical Programs

	MOLECULE*	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
CNS	**TNX-102 SL** Cyclobenzaprine HCl Sublingual Tablets	Treatment of Acute Stress Disorder		Phase 2 Study Enrolling**	Topline Expected 2nd Half 2026	
	TNX-102 SL Cyclobenzaprine HCl Sublingual Tablets	Treatment of Major Depressive Disorder		Phase 2 Study Ready***		
Immunology and immuno-oncology	**TNX-1500** Anti-CD40L mAb	Prevention of Organ Transplant Rejection/ Treatment of Autoimmune Conditions		Phase 1 Study Completed	Topline Reported 1st Quarter 2025	
	TNX-1700 TFF2-HSA Fusion Protein	Treatment of Gastric and Colorectal Cancer	Preclinical			
Infectious disease	**TNX-4800** Monoclonal Antibody	Seasonal Prevention of Lyme Disease		Phase 2/3 Study Planned		
	TNX-801 Live Virus Horsepox Vaccine	Prevention of Mpox or Smallpox	Preclinical			
	TNX-4200 Broad Spectrum Antiviral	Protection of the Warfighter From Viral Pathogens	Preclinical			
Rare disease	**TNX-2900** Intranasal Potentiated Oxytocin (OT) With Magnesium	Treatment of Prader-Willi Syndrome		Phase 2 Study Planned 2026		

*All of Tonix Pharmaceuticals' product candidates are investigational new drugs or biologics; their safety and efficacy have not been established for the listed indication.
**Investigator-initiated study.
***Pending IND filing planned for Q4 2025.

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Tonix's scientific expertise validated by numerous mutually beneficial government and academic collaborations

- Reduces internal spend
- Increases number of trials
- Potentially speeds time to market
- Grants, contracts, cost-sharing or "in-kind" arrangements

TNX-102 SL: ACUTE STRESS DISORDER

U.S. Department of Defense | THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

TNX-2900: PRADER-WILLI SYNDROME

InsermTransfert | CHU de Toulouse | Aix*Marseille université

TNX-4200: BROAD-SPECTRUM ANTIVIRAL

U.S. Department of Defense | DTRA Defense Threat Reduction Agency

TNX-1500: ALLOGRAFT REJECTION

MASSACHUSETTS GENERAL HOSPITAL | HARVARD MEDICAL SCHOOL

TNX-4800: SEASONAL LYME PREVENTION

UMass Chan MEDICAL SCHOOL

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Tonix Research and Development Center (RDC)

- Supports expanding infectious disease pipeline by accelerating internal discovery and development of vaccines and antiviral drugs
- Located in Frederick, MD (close to Fort Detrick/ USAMRIID)
- 48,000 square foot facility
- Main building is BSL-2 with certain areas designated BSL-3
- At full capacity, the RDC can employ up to 100 scientists and technical support staff

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TNX-102 SL

For Acute Stress Reaction (ASR) / Acute Stress Disorder (ASD)

ASR/ASD are acute stress conditions resulting from trauma which can affect both civilian and military populations.

Status: Phase 2 Investigator Initiated Study ("OASIS") currently enrolling patients

OASIS trial will build upon infrastructure developed through the UNC-led, $40M AURORA initiative, a major national research initiative to improve the understanding, prevention, and recovery of individuals who have experienced a traumatic event

Large unmet need:

- According to National Center for PTSD, about 60% of men and 50% of women in the US are exposed least one traumatic experience in their lives[1]
- In the US alone, one-third of emergency department visits (40-50 million patients per year) are for evaluation after trauma exposures[2]

Current standard of care:

- No medications are currently available at or near the point of care to treat patients suffering from acute traumatic events and support long-term health

Phase 2 Trial in Partnership with:

U.S. Department of Defense

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

[1]National Center for PTSD. How Common is PTSD in Adults? https://www.ptsd.va.gov/understand/common/common_adults.asp
[2]Wisco et al. *J Clin Psychiatry.* 2014.75(12):1338-46

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TNX-102 SL

For Major Depressive Disorder (MDD)

TNX-102 SL is believed first-in-class for targeting the disturbed sleep associated with depression

Status: Successful pre-IND meeting; planning to submit IND in 4Q 2025. Plan to pursue a supplemental new drug application (sNDA) for MDD for TNX-102 SL, which is already FDA-approved for treating fibromyalgia

Evidence: TNX-102 SL showed activity on the Beck Depression Inventory-II (BDI) in the Phase 3 RESILIENT study in fibromyalgia patients with an uncorrected p-value < 0.05. The BDI-II was a pre-specified exploratory endpoint. The biological relationship between depressive symptoms in fibromyalgia and those in major depressive disorder is not clear

Large unmet need:

- Depression is a problem/remains an unmet need despite multiple approved drugs[1]
- ~21 million U.S. adults annually experience at least one major depressive episode[2]

Current standard of care:

- SSRIs, SNRIs, dextromethorphan/bupropion
- Secondary amine tricyclic antidepressants
- Tertiary amine tricyclic antidepressants
  - Swallowed pill formulations, that are largely metabolized by first-pass to longer-lived secondary amine tricyclics, are active in treating depression at doses which can adversely impact weight, blood pressure/heart rate, cognition, and sexual function

Potential Pivotal Phase 2 Trial planned: double-blind, placebo-controlled study in Major Depressive Disorder (MDD), targeting moderate-to-severe depression, including in older adults, with the 5.6 mg dose. Plan to initiate enrollment in 2026

[1]Rush, et al Am J Psychiatry. 2006 Nov;163(11):1905-17; Garcia-Marin et al. Annals of General Psychiatry (2023) 22:49
[2]www.nimh.nih.gov/health/statistics/major-depression

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TNX-102 SL: Phase 3 *RESILIENT* Study Design

RESILIENT Study

CNS PORTFOLIO

General study characteristics:

- Randomized, double-blind, multicenter, placebo-controlled study in fibromyalgia
- 33 U.S. sites enrolled 457 participants with fibromyalgia as defined by 2016 Revisions to the 2010/2011 FM Diagnostic Criteria[1]

Primary Endpoint:

- Change from baseline to Week 14 (TNX-102 SL vs. placebo) in weekly averages of daily diary average pain severity score
- ***Primary Endpoint, p-value = 0.00005***

*Two-week run-in at 2.8 mg dose at bedtime followed by 12 weeks at 5.6 mg dose

ClinicalTrials.gov Identifier: **NCT05273749**

Study Title: A Phase 3 Study to Evaluate the Efficacy and Safety of TNX-102 SL Taken Daily in Patients With Fibromyalgia (RESILIENT)

Trial ID: TNY-CY-F307 ('RESILIENT')

[1]Wolfe F, Clauw DJ, Fitzcharles MA, Goldenberg DL, Häuser W, Katz RL, Mease PJ, Russell AS, Russell IJ, Walitt B. 2016 Revisions to the 2010/2011 fibromyalgia diagnostic criteria. Semin Arthritis Rheum. 2016; 46(3):319-329.

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RESILIENT: FIQR Individual Items[1]

Affective Symptoms, Sensory Sensitivity, Cognition, and Energy

Pre-specified exploratory endpoints

RESILIENT Study

CNS PORTFOLIO

Selected Fibromyalgia Impact Questionnaire-Revised Symptoms Domain Item Scores

Pre-specified exploratory endpoints

FIQ-R Item **Please rate your level of...** (past 7 days)	Week 14 LS Mean (SE) Difference from Placebo[#]	95% Confidence Interval[#]	P-value^	Effect Size
Depression	-0.8 (0.21)	-1.2, -0.6	<0.001	0.35
Anxiety	-0.8 (0.24)	-1.2, -0.3	0.001	0.30
Sensitivity to…*	-0.6 (0.24)	-1.0, -0.1	0.020	0.22
Memory problems	-0.8 (0.23)	-1.2, -0.3	0.001	0.31
Energy	-0.8 (0.23)	-1.2, -0.3	<0.001	0.31

*…loud noises, bright lights, odors, and cold

[1]FIQR=Fibromyalgia Impact Questionnaire- Revised
[#]Mixed model repeated measures analysis (no imputation); fixed categorical effects of treatment, site, study week, and treatment x study week interaction; fixed covariates of baseline value and baseline value x study week interaction
^Uncorrected for multiple comparisons

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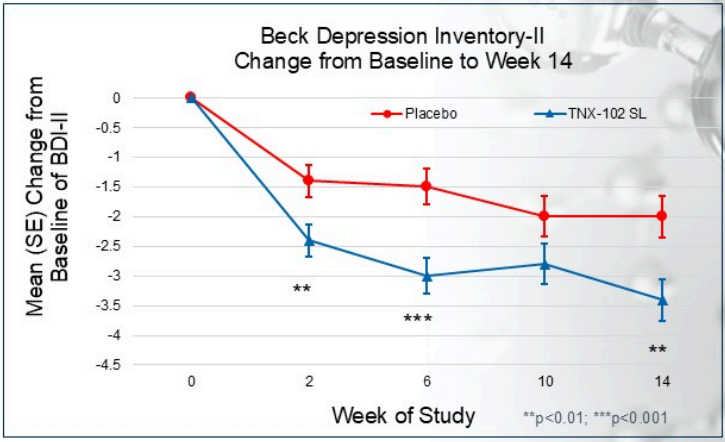
RESILIENT: Beck Depression Inventory-II
Pre-specified Exploratory Endpoint

RESILIENT Study

CNS PORTFOLIO

	Placebo Mean (SD)	Placebo LS MCFB (SE)	TNX Mean (SD)	TNX LS MCFB (SE)	Difference in LS Means (SE)	95% CI for Difference	P-value	Effect Size
Baseline	10.0 (6.72)		9.6 (6.32)					
Week 14		-2.0 (0.35)		-3.4 (0.35)	-1.4 (0.49)	-2.3, -0.4	0.005#	0.27

- Greater reduction in total BDI-II score in TNX-102 SL group over placebo at Week 14 with p=0.005#, effect size of 0.27
  - Also separated, with p<0.01#, at Week 2 when on TNX-102 SL 2.8 mg first two weeks
  - And separated, with p<0.001#, at Week 6



#Uncorrected for multiple comparisons
SE=standard error; SD=standard deviation

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RESILIENT: Summary of Baseline Depression BDI-II and FIQR Item

RESILIENT Study

CNS PORTFOLIO

- **While the rate of current MDE diagnosis was ~2% of the ITT, ~25% ITT had experienced a lifetime MDE, and ~47% reported depression during prior 6 months on FM Dx***
- **Also, about 25% of the ITT enrolled on concomitant antidepressant or buspirone**
- **By end of treatment (Week 14), there was a greater reduction in depression severity by total BDI-II score in TNX-102 SL group compared with placebo (p=0.005)**
  - And greater reduction in FIQR items for depression (p<0.001), anxiety (p=0.001), and sensory sensitivity (p=0.020) in the TNX-102 SL group compared with placebo
  - The FIQR memory item, a measure of cognitive impairment in FM, was more improved in the TNX-102 SL group than placebo (p=0.001)
  - The FIQR energy item, another indicator of less fatigue in FM, was also more improved in the TNX-102 SL group than placebo (p<0.001)
- **Cohen's *d* effect sizes were between 0.27 and 0.35 for all Week 14 outcomes above except sensory sensitivity**

Abbreviations: BDI-II, Beck Depression Inventory-II; Dx, diagnosis; FIQR, Fibromyalgia Impact Questionnaire-Revised; FM, fibromyalgia; ITT, Intention-to-Treat

*Wolfe F, et al. 2016 Revisions to the 2010/2011 fibromyalgia diagnostic criteria. Semin Arthritis Rheum. 2016; 46(3):319-329.

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RESILIENT Safety Summary

Among participants randomized to TNX-102 SL and to placebo, 81.0% and 79.6%, respectively, completed the study

TNX-102 SL was generally well tolerated with an adverse event (AE) profile comparable to prior fibromyalgia studies

- No new safety signals were observed
- AE-related study discontinuations occurred in 6.1% and 3.6% of patients in the TNX-102 SL and placebo groups, respectively
- Events rated as mild or moderate made up 97.2% of AEs on placebo and 99.1% on TNX-102 SL
- As observed in prior studies with TNX-102 SL, oral administration site AEs were higher in TNX-102 SL than placebo, 42.9% and 10.2%, respectively
  - Most common oral AEs were oral hypoaesthesia, product taste abnormal, oral paraesthesia, and tongue discomfort (see table on next slide)
  - Nearly all of these common oral AEs were temporally related to dosing and typically lasted <60 minutes
- Serious Adverse Events (SAEs)
  - Three placebo participants experienced an SAE:
    - 1. Pneumonia, 2. Muscular weakness, and 3. Hypertension/Angina/Coronary Artery Disease
  - Two TNX-102 SL participants experienced an SAE
    - 1. Renal carcinoma deemed not related to study drug
    - 2. Acute pancreatitis with onset 14 days after completion of treatment phase, deemed 'possibly related'* to study drug
      - Outcome: 'Recovered/Resolved'

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RESILIENT Safety

RESILIENT Study

CNS PORTFOLIO

Treatment-Emergent Adverse Events (TEAEs) at Rate of ≥ 3% in Either Treatment Group

System Organ Class Preferred Term	TNX-102 SL N=231	Placebo N=226	Total* N=457
Systemic Adverse Events			
COVID-19	10 (4.3%)	7 (3.1%)	17 (3.7%)
Somnolence	7 (3.0%)	3 (1.3%)	10 (2.2%)
Headache	7 (3.0%)	4 (1.8%)	11 (2.4%)
Oral Cavity Adverse Events			
Hypoaesthesia oral	55 (23.8%)	1 (0.4%)	56 (12.3%)
Product taste abnormal	27 (11.7%)	2 (0.9%)	29 (6.3%)
Paraesthesia oral	16 (6.9%)	2 (0.9%)	18 (3.9%)
Tongue discomfort	16 (6.9%)	0 (0.0%)	16 (3.5%)

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TNX-1500[1]

Next (Third) Generation α-CD40 Ligand (CD40L) Antibody

The CD40-CD40L pathway is a pivotal immune system modulator and a well-established and promising treatment target

Differentiators: Expected to deliver efficacy without compromising safety

First Generation: Development halted due to thromboembolic (TE) complications—blood clots—traced to Fc gamma receptor (FcγR)

Second Generation: Eliminated the FcγR TE complication but potency and half life was reduced, limiting utility

Third Generation (TNX-1500): Re-engineered to better modulate the binding of FcγR.

[1]TNX-1500 has not been approved for any indication. Patents filed.

Prevention of Allograft and Bone Marrow Transplant Rejection

Status: Phase 1 study – completed

Collaborations ongoing with Mass General Hospital on heart and kidney transplantation in non-human primates

- Collaboration with Boston Children's on bone marrow transplantation in non-human primates

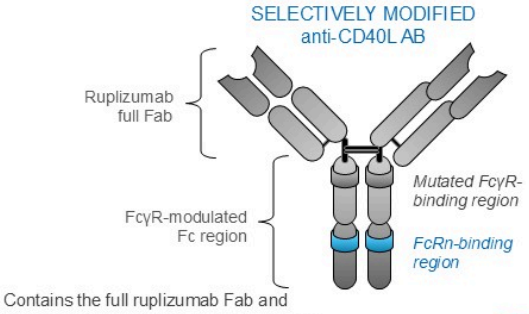
Next Steps: Initiate Phase 2 study in Kidney Transplant Recipients

Autoimmune Diseases

Status: Potential future indications include:

Sjögren's Syndrome, Systemic Lupus Erythematosus

- These indications require large studies, but represent large target markets



Contains the full ruplizumab Fab and the engineered Fc region that modulates FcγR-binding, while preserving FcRn function.

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TNX-1500 Phase 1 Topline Results and Conclusions

Phase 1: single ascending dose study in healthy participants to evaluate safety and pharmacokinetics/pharmacodynamics (PK/PD)

- At total of 26 participants were enrolled in three cohorts (3 mg/kg, 10 mg/kg, and 30 mg/kg *i.v.*)

Topline results

- **Pharmacodynamics (PD):** TNX-1500 blocked the primary and secondary antibody responses to a test antigen (KLH) at the 10 and 30 mg/kg *i.v.* doses
- **Pharmacokinetics (PK)**: mean half-life ($t_{1/2}$) for the 10 mg/kg and 30 mg/kg doses of 34-38 days
- **TNX-1500 was generally well-tolerated with a favorable safety profile**
- **Tolerability:** TNX-1500 was generally well-tolerated with a favorable safety and tolerability profile. The only TEAE occurring in ≥ 3 participants among all TNX-1500 groups was Aphthous ulcer, occurring in one participant each in the 3 mg/kg, 10 mg/kg, and 30 mg/kg groups; all were rated as mild, possibly related, and resolved in 2-10 days.

Conclusions

- Results support proceeding to develop Phase 2 trial for the prevention of kidney transplant rejection
- Fc modifications we engineered to TNX-1500 for safety did not attenuate the potency of TNX-1500 relative to humanized 5c8 (hu5c8, ruplizumab, BG9588)[1-3]
- We believe the results of this study and our prior animal studies[4,5] indicate that TNX-1500 is potentially best-in-class among anti-CD40L mAbs in development

[1]Lederman S, et al, *J Exp Med.* 1992 Apr 1;175(4):1091-101. doi: 10.1084/jem.175.4.1091. PMID: 1348081; PMCID: PMC2119166.
[2]Boumpas DT, et. al. *Arthritis Rheum.* 2003;48(3):719-27. doi: 10.1002/art.10856. PMID: 12632425.
[3]Pierson RN 3rd, et al. *Transplantation.* 1999;68(11):1800-5. doi: 10.1097/00007890-199912150-00026. PMID: 10609959.
[4]Lassiter G, et al. *Am J Transplant.* 2023;23(8):1171-1181. doi: 10.1016/j.ajt.2023.03.022.
[5]Miura S, et al. *Am J Transplant.* 2023;23(8):1182-1193. doi: 10.1016/j.ajt.2023.03.025.

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TNX-1700[1]

Gastric and Colorectal Cancers Recombinant Trefoil Factor 2 (hTFF2) Fusion Protein

mTNX-1700 (mTFF2) has effects on cancer by altering the tumor micro-environment

Differentiator: No product yet identified consistently augments PD1 effects on cold tumors

Mechanism of Action: suppresses myeloid-derived suppressor cells and activates anti-cancer CD8+ T cells

Potential synergies with anti-PD-1 or antil-PD-L1 monoclonal antibodies (mAbs)

Licensed from Columbia University: developing in partnership under sponsored research agreement. Patents filed.

Preclinical Evidence for Inhibiting Growth of Cancer Cells

- Data showed that mTFF2-CTP augmented the efficacy of mAb anti-PD-1 therapy. Anti-PD-1 in combination with mTFF2-CTP showed greater anti-tumor activity in PD-L1-overexpressing mice

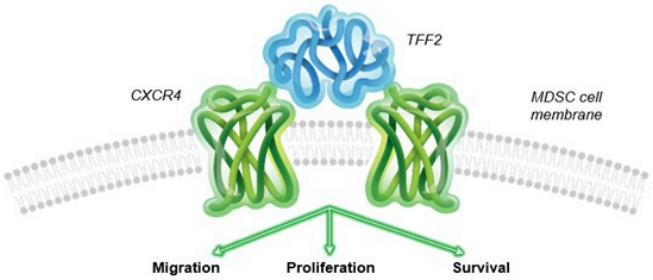
Status:

- Preclinical, progressing to IND

Market Entry:

- Immuno-oncology, combination therapy with PD1 blockers for gastric and colorectal cancer

TFF2 Modulates MDSC Function via CXCR4 Signaling[2-4]



[1]TNX-1700 is in the pre-IND stage of development and has not been approved for any indication.
[2]Dubeykovskaya Z, et al. J Biol Chem. 2009;284(6):3650-3662.
[3]Balkwill F. Semin Cancer Biol. 2004;14(3):171-179.
[4]Teixidó J, et al. Int J Biochem Cell Biol. 2018;95:121-131.

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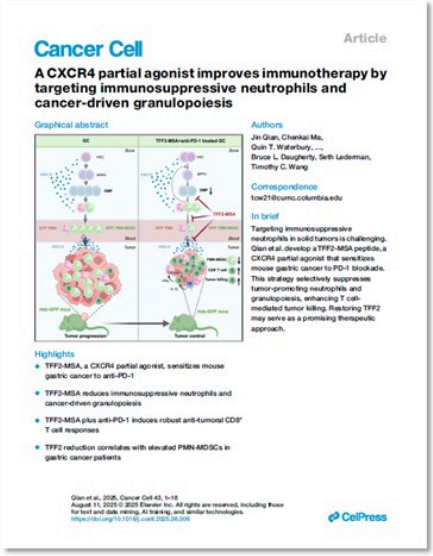
TNX-1700 – Recent Publication in *Cancer Cell*[1]

- *Combination treatment of mTNX-1700 (mTFF2-MSA fusion protein) with anti-PD1 antibody was associated with increased survival and decreased metastases in animal models of gastric cancer relative to anti-PD1 treatment alone*
- *mTNX-1700 treatment was associated with activation of cancer-killing CD8+ T Cells and limiting neutrophil-mediated immune evasion*



Cancer Cell

Article

A CXCR4 partial agonist improves immunotherapy by targeting immunosuppressive neutrophils and cancer-driven granulopoiesis

Graphical abstract

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In brief

Targeting immunosuppressive neutrophils in solid tumors is challenging. Qian et al. develop a TFF2-MSA peptide, a CXCR4 partial agonist that sensitizes mouse gastric cancer to PD-1 blockade. This strategy selectively suppresses tumor-promoting neutrophils and granulopoiesis, enhancing T cell-mediated tumor killing. Restoring TFF2 may serve as a promising therapeutic approach.

Highlights

- TFF2-MSA, a CXCR4 partial agonist, sensitizes mouse gastric cancer to anti-PD-1
- TFF2-MSA reduces immunosuppressive neutrophils and cancer-driven granulopoiesis
- TFF2-MSA plus anti-PD-1 induces robust anti-tumoral CD8+ T cell responses
- TFF2 reduction correlates with elevated PMN-MDSCs in gastric cancer patients

Qian et al., 2025, Cancer Cell 43, 1–16
August 11, 2025 © 2025 Elsevier Inc. All rights reserved, including those for text and data mining, AI training, and similar technologies.
https://doi.org/10.1016/j.ccell.2025.06.006

CellPress

[1]Qian J, et al. Cancer Cell. 2025. 43(8):1512-1529.e11. doi: 10.1016/j.ccell.2025.06.006.

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TNX-801[1]
Recombinant Pox Vaccine (RPV) Platform Using Live Virus Technology

Cloned version of horsepox[2] purified from cell culture

Differentiators: Live virus vaccines are the most established vaccine technology. Prevents forward transmission and effective in eliciting durable or long-term immunity

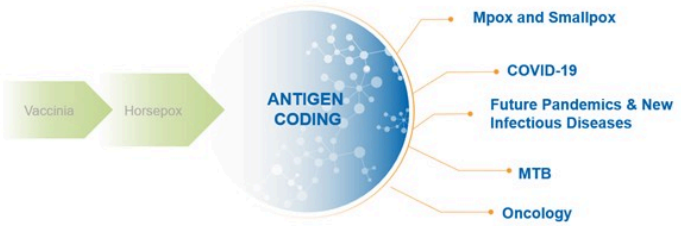
Economical to manufacture at scale: low dose because replication amplifies dose in vivo single administration

Standard refrigeration for shipping and storage: believed to be stable without freezing (thermostable) in ultimate lyophilized formulation

[1]TNX-801 is in the pre-IND stage of development and has not been approved for any indication.
[2]Noyce et al., 2018. *PLoS One.* 13(1):e0188453.
[3]Noyce RS, et al. *Viruses.* 2023 5(2):356. Doi: 10.3390/v15020356. PMID: 36851570; PMCID: PMC9965234
[4]Bavari, S. July 10, 2025. Presentation: World Congress on Vaccines (Vienna). "TNX-801, a single-dose live vaccine platform for Mpox and other emerging viral diseases: Safety, Immunogenicity, and Efficacy"

Attenuated, minimally replicative, live virus
- Based on synthetic horsepox-vector, believed related to first smallpox vaccine used by Dr. Edward Jenner in 1796[3]
- Single-dose subcutaneous[3,4]
- Expected durable T-cell immunity similar to 19th Century vaccinia

Design supports potential real-world effectiveness
- One-dose vaccine, allows for ring vaccination strategy and eliminates dropouts between doses
- Working to develop microneedle one-dose delivery to drive local accessibility



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TNX-4800[1]

Monoclonal antibody prophylaxis for Lyme Disease

Long Acting anti-OspA monoclonal antibody[2-4] to block *Borrelia Burgdorferi* transfer

Differentiators: Immediate protection

Advantages of TNX-4800 relative to vaccines in development: provides protection after first dose, does not require a host immune response

Phase 1 data showed prolonged levels of TNX-4800 consistent with protection throughout the tick season: from Spring to Fall in the U.S.

Plan to initiate an adaptive Phase 2/3 trial in 2027

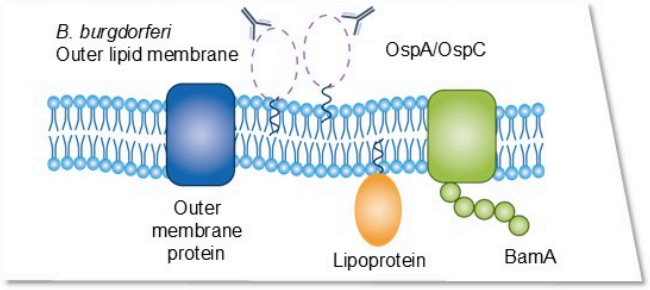
[1]TNX-4800 has not been approved for any indication.
[2]Schiller ZA, al. *J Clin Invest.* 2021;131(11):e144843.
[3]de Silva AM, et al. *J Exp Med.* 1996;183(1):271-275.
[4]Radolf JD, et al. *Nat Rev Microbiol.* 2012;10(2):87-99.

Monoclonal Antibody Attacks Borrelia

- When the tick bites a human host who has been given TNX-4800, the anti-OspA antibodies will enter the tick midgut, binding to OspA proteins on the outer lipid membrane of *B. burgdorferi*[3,4]
- Once OspA has been targeted, the bacteria cannot migrate from the tick's midgut to the tick's salivary glands or then to the human host[2]

Long-Acting Antibody: Seasonal Duration

- A mutation in the Fc region of the TNX-4800 antibody extends its half-life, allowing a single administration to provide protection throughout the months of greatest infection risk



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TNX-4200[1]

Broad-spectrum Host-directed Therapeutics: CD45 Inhibitor as Antiviral

Small molecule therapeutics that reduce endogenous levels of CD45, a protein tyrosine phosphatase

Differentiators: Reduction in CD45 has potential to protect against many viruses.

Department of Defense Contract: awarded Tonix a $34M contract over five years to advance development of TNX-4200 for medical countermeasures

Broad antiviral application: objective of this program is to find an orally available small molecule inhibitor of CD45 activity and show protection against multiple viral infections

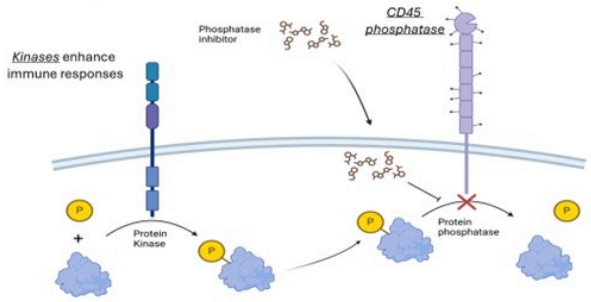
[1]TNX-4200 is in the pre-IND stage of development and has not been approved for any indication.
[2]Panchal RG, et al., Cell Host Microbe. 2009 6(2):162-73. doi: 10.1016/j.chom.2009.07.003. PMID: 19683682.
[3]Panchal RG, et al. J Biol Chem. 2009 284(19):12874-85. doi: 10.1074/jbc.M809633200

Department of Defense Contract

- Represents a move away from "one drug, one bug" approach. Broad antiviral application has potential to protect against multiple viruses ("one drug, multiple bugs").
- Program is expected to establish physicochemical properties, pharmacokinetics, and safety attributes to support an IND submission and to fund a first-in-human Phase 1 clinical study

Enhances viral immunity by inhibiting CD45 phosphatase

- CD45 is a transmembrane protein tyrosine phosphatase (PTPase) expressed on most hematopoietic cells, including T lymphocytes
- CD45 regulates receptor signaling pathways, particularly T cell activation
- Dephosphorylates the negative regulatory tyrosine kinases (e.g., lck and src)
- Decreased levels of CD45 enhance antiviral[2] and antibacterial immunity in animals[3]



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TNX-2900[1]
Intranasal Potentiated Oxytocin (OT) with Magnesium

In development for Prader-Willi Syndrome, a rare disease.

Differentiators: Tonix's patented potentiated OT formulation is believed to increase activity of OT at OT receptors (OXTR)

Prader-Willi Syndrome: is the most common genetic cause of life-threatening childhood obesity
- Rare disease occurring in 1 in 10,000 to 1 in 30,000 births
- Symptoms include lack of suckling as infants, poor muscle strength, and constant hunger (hyperphagia) in adolescents and young adults

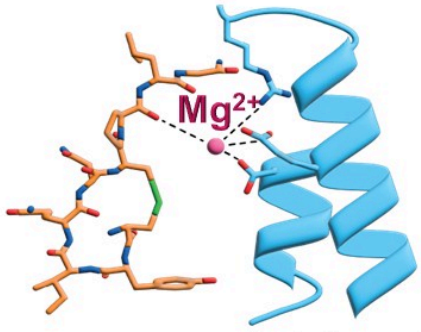
In animal models: Oxytocin has improved suckling and suppressed hunger

[1]TNX-2900 has not been approved for any indication

Market Entry:
- Treatment of children and adolescents with Prader-Willi Syndrome

Status & Next Steps
- Granted Orphan Drug Designation and Rare Pediatric Disease Designation by FDA
- Received IND clearance for Phase 2 trial from FDA
- Plan to Initiate Phase 2 Trial in 2026

Oxytocin Requires Magnesium for Receptor Binding



Oxytocin Oxytocin receptor

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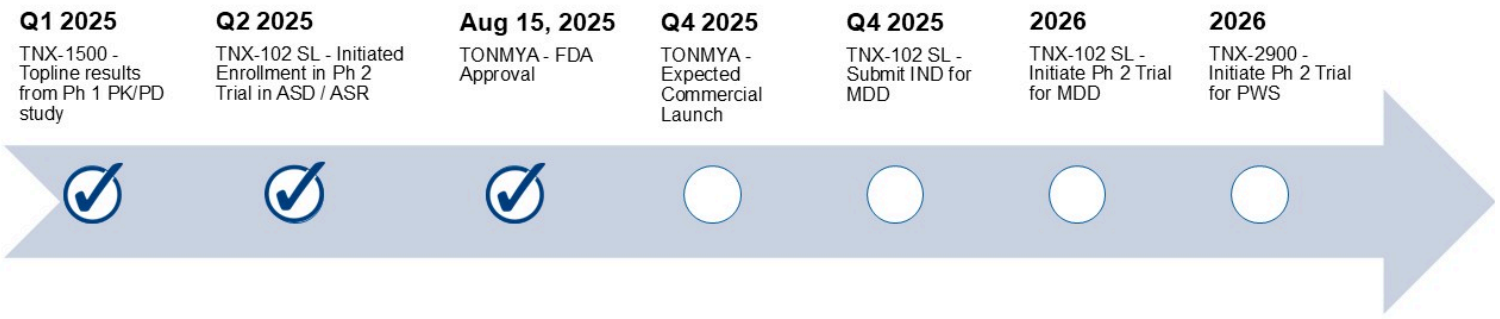
Milestones: Recently Completed and Targeted



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THANK YOU

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TONMYA (cyclobenzaprine hydrochloride sublingual tablets)
INDICATION: TONMYA is indicated for the treatment of fibromyalgia in adults.
Important Safety Information (1 of 2)

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
TONMYA is contraindicated:

In patients with hypersensitivity to cyclobenzaprine or any inactive ingredient in TONMYA. Hypersensitivity reactions may manifest as an anaphylactic reaction, urticaria, facial and/or tongue swelling, or pruritus. Discontinue TONMYA if a hypersensitivity reaction is suspected.

With concomitant use of monoamine oxidase (MAO) inhibitors or within 14 days after discontinuation of an MAO inhibitor. Hyperpyretic crisis seizures and deaths have occurred in patients who received cyclobenzaprine (or structurally similar tricyclic antidepressants) concomitantly with MAO inhibitors drugs.

During the acute recovery phase of myocardial infarction, and in patients with arrhythmias, heart block or conduction disturbances, or congestive heart failure.

In patients with hyperthyroidism.

WARNINGS AND PRECAUTIONS
Embryofetal toxicity: Based on animal data, TONMYA may cause neural tube defects when used two weeks prior to conception and during the first trimester of pregnancy. Advise females of reproductive potential of the potential risk and to use effective contraception during treatment and for two weeks after the final dose. Perform a pregnancy test prior to initiation of treatment with TONMYA to exclude use of TONMYA during the first trimester of pregnancy.

Serotonin syndrome: Concomitant use of TONMYA with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, tramadol, bupropion, meperidine, verapamil, or MAO inhibitors increases the risk of serotonin syndrome, a potentially life-threatening condition. Serotonin syndrome symptoms may include mental status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms. Treatment with TONMYA and any concomitant serotonergic agent should be discontinued immediately if serotonin syndrome symptoms occur and supportive symptomatic treatment should be initiated. If concomitant treatment with TONMYA and other serotonergic drugs is clinically warranted, careful observation is advised, particularly during treatment initiation or dosage increases.

Tricyclic antidepressant-like adverse reactions: Cyclobenzaprine is structurally related to TCAs. TCAs have been reported to produce arrhythmias, sinus tachycardia, prolongation of the conduction time leading to myocardial infarction and stroke. If clinically significant central nervous system (CNS) symptoms develop, consider discontinuation of TONMYA. Caution should be used when TCAs are given to patients with a history of seizure disorder, because TCAs may lower the seizure threshold. Patients with a history of seizures should be monitored during TCA use to identify recurrence of seizures or an increase in the frequency of seizures.

Atropine-like effects: Use with caution in patients with a history of urinary retention, angle-closure glaucoma, increased intraocular pressure, and in patients taking anticholinergic drugs.

CNS depression and risk of operating a motor vehicle or hazardous machinery: TONMYA monotherapy may cause CNS depression. Concomitant use of TONMYA with alcohol, barbiturates, or other CNS depressants may increase the risk of CNS depression. Advise patients not to operate a motor vehicle or dangerous machinery until they are reasonably certain that TONMYA therapy will not adversely affect their ability to engage in such activities.

Oral mucosal adverse reactions: In clinical studies with TONMYA, oral mucosal adverse reactions occurred more frequently in patients treated with TONMYA compared to placebo. Advise patients to moisten the mouth with sips of water before administration of TONMYA to reduce the risk of oral sensory changes (hypoesthesia). Consider discontinuation of TONMYA if severe reactions occur.

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TONMYA (cyclobenzaprine hydrochloride sublingual tablets)
INDICATION: TONMYA is indicated for the treatment of fibromyalgia in adults.
Important Safety Information (2 of 2)

IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS
The most common adverse reactions (incidence ≥2% and at a higher incidence in TONMYA-treated patients compared to placebo-treated patients) were oral hypoesthesia, oral discomfort, abnormal product taste, somnolence, oral paresthesia, oral pain, fatigue, dry mouth, and aphthous ulcer.

DRUG INTERACTIONS
MAO inhibitors: Life-threatening interactions may occur.

Other serotonergic drugs: Serotonin syndrome has been reported.

CNS depressants: CNS depressant effects of alcohol, barbiturates, and other CNS depressants may be enhanced.

Tramadol: Seizure risk may be enhanced.

Guanethidine or other similar acting drugs: The antihypertensive action of these drugs may be blocked.

USE IN SPECIFIC POPULATIONS
Pregnancy: Based on animal data, TONMYA may cause fetal harm when administered to a pregnant woman. The limited amount of available observational data on oral cyclobenzaprine use in pregnancy is of insufficient quality to inform a TONMYA-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Advise pregnant women about the potential risk to the fetus with maternal exposure to TONMYA and to avoid use of TONMYA two weeks prior to conception and through the first trimester of pregnancy. Report pregnancies to the Tonix Medicines, Inc., adverse-event reporting line at 1-888-869-7633 (1-888-TNXPMED).

Lactation: A small number of published cases report the transfer of cyclobenzaprine into human milk in low amounts, but these data cannot be confirmed. There are no data on the effects of cyclobenzaprine on a breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for TONMYA and any potential adverse effects on the breastfed child from TONMYA or from the underlying maternal condition.

Pediatric use: The safety and effectiveness of TONMYA have not been established.

Geriatric patients: Of the total number of TONMYA-treated patients in the clinical trials in adult patients with fibromyalgia, none were 65 years of age and older. Clinical trials of TONMYA did not include sufficient numbers of patients 65 years of age and older to determine whether they respond differently from younger adult patients.

Hepatic impairment: The recommended dosage of TONMYA in patients with mild hepatic impairment (HI) (Child Pugh A) is 2.8 mg once daily at bedtime, lower than the recommended dosage in patients with normal hepatic function. The use of TONMYA is not recommended in patients with moderate HI (Child Pugh B) or severe HI (Child Pugh C). Cyclobenzaprine exposure (AUC) was increased in patients with mild HI and moderate HI compared to subjects with normal hepatic function, which may increase the risk of TONMYA-associated adverse reactions.

Please see additional safety information in the full Prescribing Information.

To report suspected adverse reactions, contact Tonix Medicines, Inc. at 1-888-869-7633, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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ZEMBRACE® Important Safety Information (1 of 2)

ZEMBRACE SymTouch (ZEMBRACE) can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop use and get emergency help if you have any signs of a heart attack:

- Discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back; severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw; pain or discomfort in your arms, back, neck, jaw or stomach; shortness of breath with or without chest discomfort; breaking out in a cold sweat; nausea or vomiting; feeling lightheaded

ZEMBRACE is not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam shows no problem.

Do not use ZEMBRACE if you have:

- History of heart problems; narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease); uncontrolled high blood pressure; hemiplegic or basilar migraines. If you are not sure if you have these, ask your provider.
- Had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation; severe liver problems; taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, dihydroergotamine; are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure.
- An allergy to sumatriptan or any of the components of ZEMBRACE.

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

ZEMBRACE can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

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ZEMBRACE® Important Safety Information (2 of 2)

ZEMBRACE may cause serious side effects including:

- Changes in color or sensation in your fingers and toes; sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever; cramping and pain in your legs or hips; feeling of heaviness or tightness in your leg muscles; burning or aching pain in your feet or toes while resting; numbness, tingling, or weakness in your legs; cold feeling or color changes in one or both legs or feet; increased blood pressure including a sudden severe increase even if you have no history of high blood pressure; medication overuse headaches from using migraine medicine for 10 or more days each month. If your headaches get worse, call your provider.
- Serotonin syndrome, a rare but serious problem that can happen in people using ZEMBRACE, especially when used with anti-depressant medicines called SSRIs or SNRIs. Call your provider right away if you have: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
- Hives (itchy bumps); swelling of your tongue, mouth, or throat
- Seizures even in people who have never had seizures before

The most common side effects of ZEMRACE include: pain and redness at injection site; tingling or numbness in your fingers or toes; dizziness; warm, hot, burning feeling to your face (flushing); discomfort or stiffness in your neck; feeling weak, drowsy, or tired.

Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of ZEMBRACE. For more information, ask your provider.

This is the most important information to know about ZEMBRACE but is not comprehensive. For more information, talk to your provider and read the Patient Information and Instructions for Use. For full Prescribing Information, visit: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6e5b104f-2b9e-416e-92fb-ef1bdaea867d

You are encouraged to report adverse effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

ZEMBRACE is a prescription medicine used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.

ZEMBRACE is not used to prevent migraines. It is not known if it is safe and effective in children under 18 years of age.

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TOSYMRA® Important Safety Information (1 of 2)

TOSYMRA® can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop TOSYMRA and get emergency medical help if you have any signs of heart attack:

- Discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back; severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw; pain or discomfort in your arms, back, neck, jaw, or stomach; shortness of breath with or without chest discomfort; breaking out in a cold sweat; nausea or vomiting; feeling lightheaded

TOSYMRA is not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam is done and shows no problem.

Do not use TOSYMRA if you have:

- History of heart problems; narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease); uncontrolled high blood pressure; severe liver problems; hemiplegic or basilar migraines. If you are not sure if you have these, ask your healthcare provider.
- Had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation; taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, or dihydroergotamine. Ask your provider if you are not sure if your medicine is listed above
- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure
- An allergy to sumatriptan or any ingredient in TOSYMRA

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements. TOSYMRA can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

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TOSYMRA® Important Safety Information (2 of 2)

TOSYMRA may cause serious side effects including:

- Changes in color or sensation in your fingers and toes; sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever; cramping and pain in your legs or hips, feeling of heaviness or tightness in your leg muscles, burning or aching pain in your feet or toes while resting, numbness, tingling, or weakness in your legs, cold feeling or color changes in one or both legs or feet; increased blood pressure including a sudden severe increase even if you have no history of high blood pressure; medication overuse headaches from using migraine medicine for 10 or more days each month. **If your headaches get worse, call your provider**.
- Serotonin syndrome, a rare but serious problem that can happen in people using TOSYMRA, especially when used with anti-depressant medicines called SSRIs or SNRIs. **Call your provider right away if you have**: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
- Seizures even in people who have never had seizures before

The most common side effects of TOSYMRA include:

tingling, dizziness, feeling warm or hot, burning feeling, feeling of heaviness, feeling of pressure, flushing, feeling of tightness, numbness, application site (nasal) reactions, abnormal taste, and throat irritation.
Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of TOSYMRA. For more information, ask your provider.
This is the most important information to know about TOSYMRA but is not comprehensive. For more information, talk to your provider and read the Patient Information and Instructions for use. For full Prescribing Information, visit: https://dailymed.nlm.nih.gov/dailymed/druginfo.cfm?setid=015a5cf9-f246-48bc-b91e-cd730a53d8aa.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.
TOSYMRA is a prescription medicine used to treat acute migraine headaches with or without aura in adults.
TOSYMRA is not used to treat other types of headaches such as hemiplegic or basilar migraines or cluster headaches.
TOSYMRA is not used to prevent migraines. It is not known if TOSYMRA is safe and effective in children under 18 years of age.

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