TONIX PHARMACEUTICALS

Investor Presentation
July 2026

NASDAQ: TNXP

PO6154 June 15, 2026 1671

Cautionary Note on Forward-Looking Statements

Certain statements in this presentation are forward-looking within the meaning of 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,” “expect,” 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, risks related to the failure to successfully launch and commercialize TONMYA® and any of our approved products; risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the timing and progress of clinical development of our product candidates; 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. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the Securities and Exchange Commission (the “SEC”) on March 12, 2026, and periodic 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. The information set forth herein speaks only as of the date thereof.

Innovating to Address Major Unmet Needs With Large Commercial Potential

Tonix is a commercial-stage biotechnology company committed to solving complex, chronic, and sometimes invisible conditions

Commercial Execution

Tonmya® (cyclobenzaprine HCl) sublingual tablets 2.8mg

- Launched Nov. 17, 2025
- First FDA-approved fibromyalgia treatment for adults in 15+ years[1]

Lyme Disease Human mAb

- Plan to initiate adaptive Ph. 2 field study of TNX-4800 for the prevention of Lyme disease in the U.S. in 1H'27[2]

Broad Opportunistic Pipeline

- Clinical and earlier-stage portfolio
- CNS, infectious disease, immunology, and rare disease expertise

~$185.5M cash and cash equivalents as of March 31, 2026, no debt; expected runway into early Q2'27

1. Tonix owns worldwide rights to TONMYA® with no royalty obligations. In the U.S., issued composition of matter patent extends to 2034; pending method of use patents may extend exclusivity to 2044.
2. Pending FDA agreement.

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Diversified Clinical Pipeline Represents Tonix's Breadth of Expertise

	MOLECULE*	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
CNS	**TNX-102 SL** Cyclobenzaprine HCl Sublingual Tablets	Treatment of Major Depressive Disorder	*Phase 2 Study Enrolling*			
		Treatment of Acute Stress Disorder/Acute Stress Reaction	*Phase 2 Topline Data Planned 2H'26***			
Infectious disease	**TNX-4800** Anti-*Borrelia* OspA Human Monoclonal Antibody (mAb)	Prevention of Lyme Disease in the U.S.	*Adaptive Phase 2 Field Study Planned 1H'27+*			
Immunology	**TNX-1500** Anti-CD40L mAb	Prevention of Organ Transplant Rejection	*Phase 2 Study Planned 2H'26**++*			
Rare disease	**TNX-2900** Intranasal Potentiated Oxytocin (OT) With Magnesium	Treatment of Prader-Willi Syndrome	*Phase 2 Study Planned 1Q'27*			
CNS	**TNX-1300** Recombinant Cocaine Esterase	Treatment of Cocaine Intoxication	*Mid-Phase 2*			

*All of Tonix Pharmaceuticals' product candidates, including TONMYA for unapproved indications, are investigational new drugs or biologics; their safety and efficacy have not been established for the listed indication.
**Investigator-initiated study.
+Pending FDA agreement.
++Pending FDA clearance of Investigational New Drug (IND) application.

TONMYA:
Uniquely Designed to Treat Fibromyalgia

TONMYA Targets a Large, Dissatisfied, and Underserved Population

About Fibromyalgia

- **Chronic pain disorder**
- **Results from amplified sensory and pain signaling in the CNS**
- **Core symptoms: chronic widespread pain, nonrestorative sleep, fatigue**
- **Causes significant economic impact[1]**

Patients and prescribers are dissatisfied with currently available therapies[2,3]

85% of first-line treatments fail with patients, citing efficacy and tolerability issues[3]

Patients

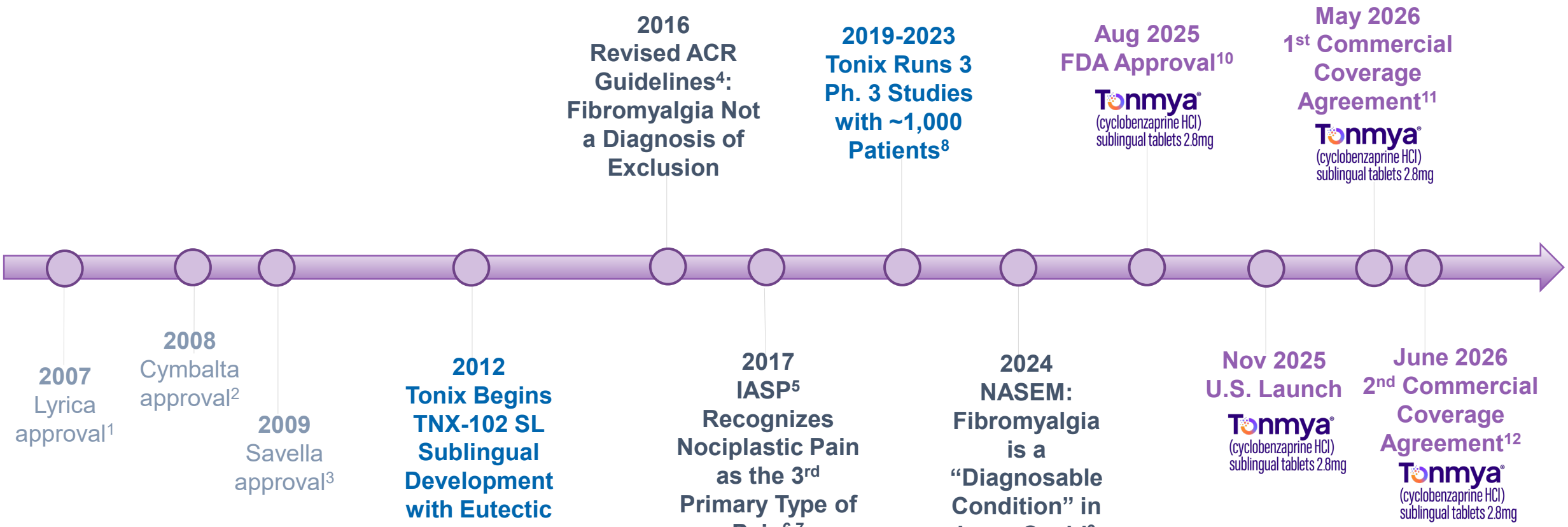
- More than 10 million patients in the U.S.[4]
- Only 2.7 million patients diagnosed and treated annually[5]
- ~6.42 years to official diagnosis from 1st complaint[6]
- Predominantly women
- 79% of patients are on multiple therapies[3]

Healthcare Providers

- ~15 million prescriptions are written (on- and off-label usage) each year[7]
- Whack-a-mole, trial and error approach[8]

1. National Fibromyalgia Association. https://www.fmaware.org/fibromyalgia-the-economic-burden/
2. Robinson RL, et al. *Pain Med*. 2012 13(10):1366-76. doi: 10.1111; 85% received drug treatment.
3. EVERSANA primary physician research, May 2024; commissioned by Tonix.
4. Fibromyalgia. American College of Rheumatology. www.ACRPatientInfo.org.
5. Fibromyalgia prevalence. National Fibromyalgia Association.
6.Gendelman O. et al. *Best Pract Res Clin Rheumatol.* 2018:32(4):489-499
7. Symphony Market data, May 2025. Prescription data includes on-label FM prescriptions and patients with FM diagnoses who received commonly prescribed off-label therapies.
8. Market research commissioned by Tonix, January 2025.

Path to Delivering 1st New Approved Treatment for Fibromyalgia in 15+ Years



1. Generic launched July 2019.
2. Generic launched December 2013.
3. Generic launched March 2026.
4. ACR = American College of Rheumatology.
5. IASP= International Association for the Study of Pain.
6. Kosek, E. et al. *Pain*. 2016;157(7):1382-1386.
7. Clauw DJ. *Ann Rheum Dis.* 2024;83(11):1421-1426.
8. Two pivotal Phase 3 studies demonstrated statistically significant improvement in pain compared with placebo; rapid onset of benefit, sustained efficacy, and known safety profile.
9. NASEM = National Academies of Sciences, Engineering, and Medicine. Ely EW. *N Engl J Med* 2024;391:1746-1753.
10. In the U.S., issued composition of matter patent extending to 2034; pending method of use patents may extend exclusivity to 2044.
11. With leading Group Purchasing Organization (GPO); effective 5/1/26.
12. With another leading GPO; effective, 6/1/26.

Delivering Much-Needed Innovation for the Treatment of Fibromyalgia

First-in-class, first-line, non-opioid medicine approved for the treatment of fibromyalgia in adults; designed for bedtime administration and long-term use

Patent-protected eutectic formulation[1] to provide the first and only sublingual medication for fibromyalgia

Two pivotal Phase 3 studies demonstrated statistically significant improvement in pain compared with placebo; rapid onset of benefit, sustained efficacy, and known safety profile[2]

FDA Approval: Aug 2025
U.S. Commercial Launch: Nov 2025

1. Tonix owns worldwide rights to TONMYA® with no royalties. In the U.S., issued composition of matter patent extends to 2034; pending method of use patents may extend exclusivity to 2044.
2. Most common adverse events were transient local oral reactions.

TONMYA is Distinct From Other Therapies and Oral Cyclobenzaprine

Tonix designed a unique, sublingual, proprietary formulation of cyclobenzaprine HCl intended to optimize efficacy, tolerability, delivery, and absorption

Tonmya® (cyclobenzaprine HCl) sublingual tablets 2.8mg

- ✓ Non-opioid analgesic designed for long-term, daily bedtime use
- ✓ Distinct mechanism of action vs. current therapies and oral cyclobenzaprine
- ✓ Improves multiple symptoms of fibromyalgia
- ✓ Avoids first-pass metabolism and reduces exposure to persistent active major metabolite, nCBP, as compared to oral cyclobenzaprine
- ✓ Rapid drug exposure
- ✓ Robust and durable efficacy
- ✓ Generally well tolerated
- ✓ Established safety profile

Other Treatment Options

- × High rate of patient and HCP dissatisfaction:
  - × Limited options with durability of efficacy
  - × Problematic side effects and poor tolerability
- × Off-label opioid use is detrimental to condition
- × Oral cyclobenzaprine was developed as a short-term (2-3) week treatment for acute muscle spasm and leads to accumulation of active major metabolite, nCBP
- × Do not fully address the interconnected symptom burden of fibromyalgia[1]

1. Giorgi V, et al. *Curr Pain Headache Rep*. 2024;28(12)-:1349-1363.

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High Rates of Opioid Use Despite Lacking Evidence of Effectiveness in Fibromyalgia[1,2]

Off-label opioids are commonly prescribed within 18 months of fibromyalgia diagnosis[3]

Nociplastic pain conditions such as **fibromyalgia** are **not responsive** to opioid therapy[4,5,6]

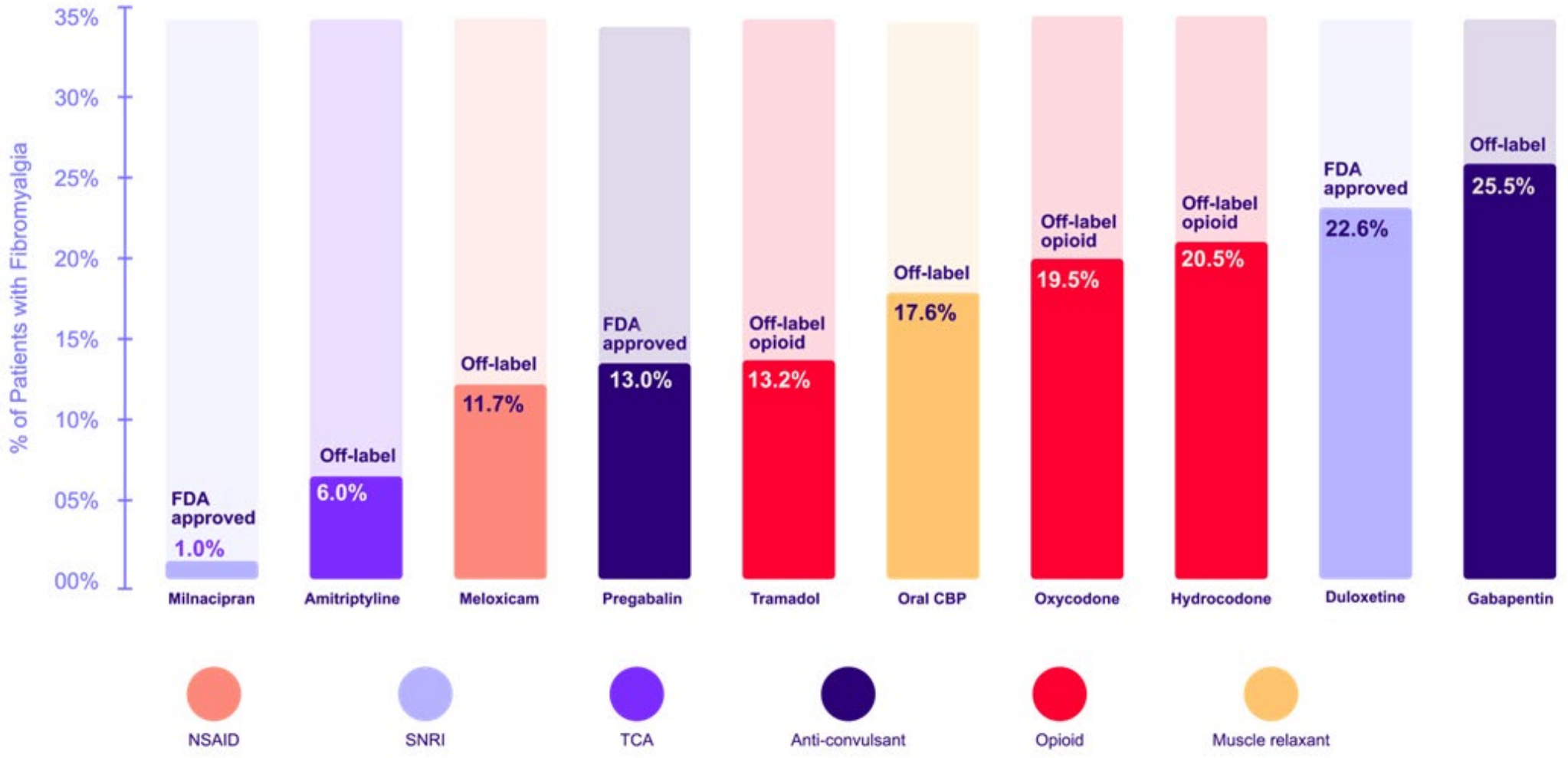
Long-term opioid use **may worsen pain sensitivity** via opioid-induced hyperalgesia in chronic pain conditions, including **fibromyalgia**[7,8]

Evidence-based consensus strongly discourages the use of opioids (e.g., oxycodone, hydrocodone) due to **risk of dependence** and **poor evidence of efficacy**[2,9]

1. Robinson RL, et al. *Pain Med.* 2013;14:1400-1415.
2. Macfarlane GJ, et al. *Ann Rheum Dis.* 2017;76(2):318-328.
3. Eversana analysis of claims database, May 2024.
4. Clauw DJ. *Ann Rheum Dis.* 2024;83(11):1421-1427.
5. Harris RE, et al. *J Neurosci.* 2007;27(37):10000-10006.
6. Peng X, et al. *Clin J Pain.* 2015;31(1):7-13.
7. Hooten EM, et al. *Pain.* 2015;156(6):1145-1152.
8. Clauw DJ. *JAMA.* 2014;311(15):1547-1555.
9. Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95.

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

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.

Focused on Driving Uptake With Highly Targeted, Multi-Strategy Approach

TONMYA has 100% share of voice as the only marketed fibromyalgia prescription drug[1]

Data-Driven HCP Targeting

- ~5% of 470K fibromyalgia diagnosing HCPs write ~70% of prescriptions[1]
- Targeting these 25K HCPS initially
- Rheumatology, primary care, pain management, neurology

Experienced Sales Team

- ~100 TONMYA reps[2] in the field since Oct. 2025
- Commercial infrastructure from TOSYMRA, ZEMBRACE
- Extensive CNS commercial and launch expertise

Patient Access and Support

- TONMYA savings card, copay assistance, and prior authorization support
- Digital and traditional pharmacy savings programs
- Intended to reduce patient access barriers

Managed Care Engagement

- Two commercial coverage agreements secured
- TONMYA covered by Medicare in nearly all states
- Ongoing engagement with commercial payers, Medicare, and Medicaid on value proposition and coverage

Medical Affairs Education

- Drive diagnosis with 2016 ACR criteria
- Build understanding for TONMYA's unique MOA
- Continue evidence generation, medical congress visibility, and KOL engagements/symposia

Omni-Channel Marketing

- Move Fibro Forward disease awareness campaign
- Patient and HCP targeted reach
- Speaker training and peer-to-peer HCP programs; congress presentations, symposia, and booths

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

Omnichannel Marketing Campaigns and Messaging Building Brand Awareness and Activation Among Target Audiences

Summary of Branded Ecosystems

Patients

- Welcome kit
- Influencer program
- Paid search
- Patient testimonials
- Digital media
- Website
- Social ads
- AI optimization

HCPs

- KOL programming
- HCP emails
- Social/digital ads
- Website
- Field leave behind materials
- Paid search

TONMYA Together™ Provides Robust Patient Access and Support Services[1]

We are committed to offering product support to appropriate patients and their HCPs

Payer Education and Engagement

- Two commercial coverage agreements with leading GPOs; total commercial coverage now ~52 million lives (29% of ~177 mil commercial lives in U.S.)
- TONMYA is now available in most states under Medicaid representing in total ~75 million lives
- Ongoing dialogue to expand access[3]

Digital Pharmacy Experience

- Bridge programs
- Streamlined enrollment
- Enhanced prior authorization support
- Refill and consultative services
- Free home delivery, enhancing convenience and access

Traditional Pharmacy Savings Program

- Copay support and savings program for eligible patients
- Digital and text enrollment

1. Programs are for patients after their HCP has determined TONMYA is appropriate for them.
2. GPO = Group Purchasing Organization.
3. With commercial payers, Medicare, and Medicaid.

Growing Momentum for TONMYA: Net Sales and Key Metrics

Net Sales

1Q'26
$3.7 million

Nov 17, 2025[1]-Mar 31, 2026
$5.1 million

Metrics

1Q'26

- **2,145** unique HCPs
- **3,588** unique patients
- **~5,400** prescriptions[2]

Nov 17, 2025-Apr 24, 2026

- **2,700+** unique HCPs
- **~5,618** unique patients

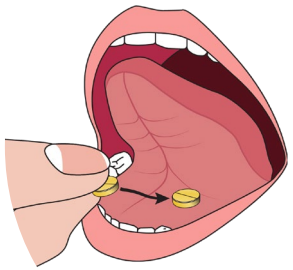
Nov 17, 2025-May 1, 2026

- **~11,016** prescriptions[2]

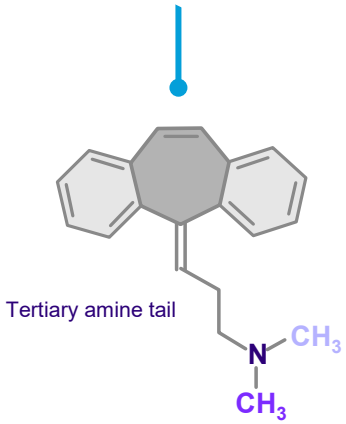
1. TONMYA launched on November 17, 2025.
2. Includes bridge prescriptions.

Tonix Created TONMYA's Formulation to Deliver the Tertiary Amine Tricyclic by Transmucosal Absorption, Bypassing First-Pass Liver Metabolism

TONMYA is administered sublingually



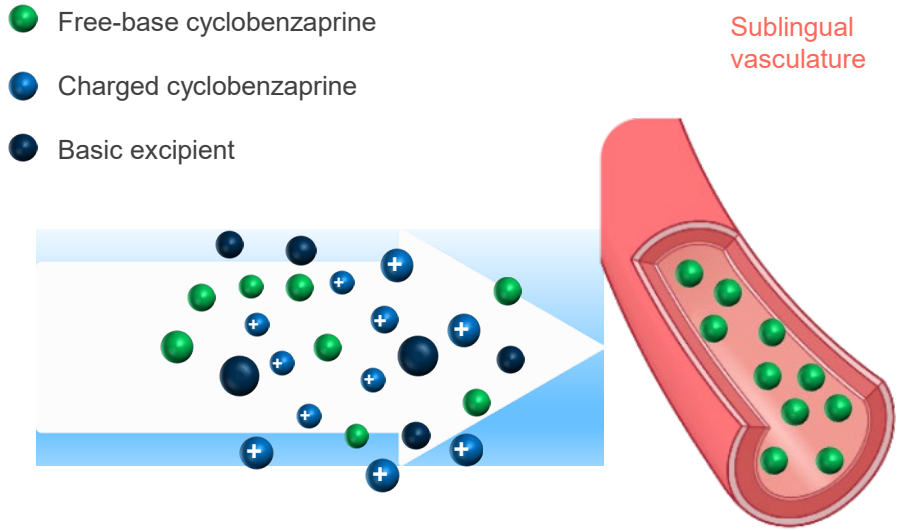
tongue



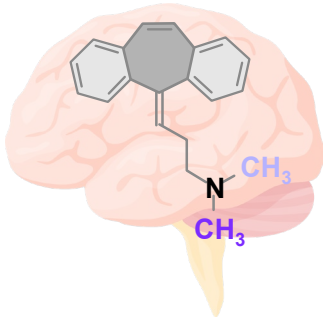
The sublingual tablet rapidly disintegrates, dissolves, and releases solubilized cyclobenzaprine ("CBP") into the saliva adjacent to the mucosal membrane

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.



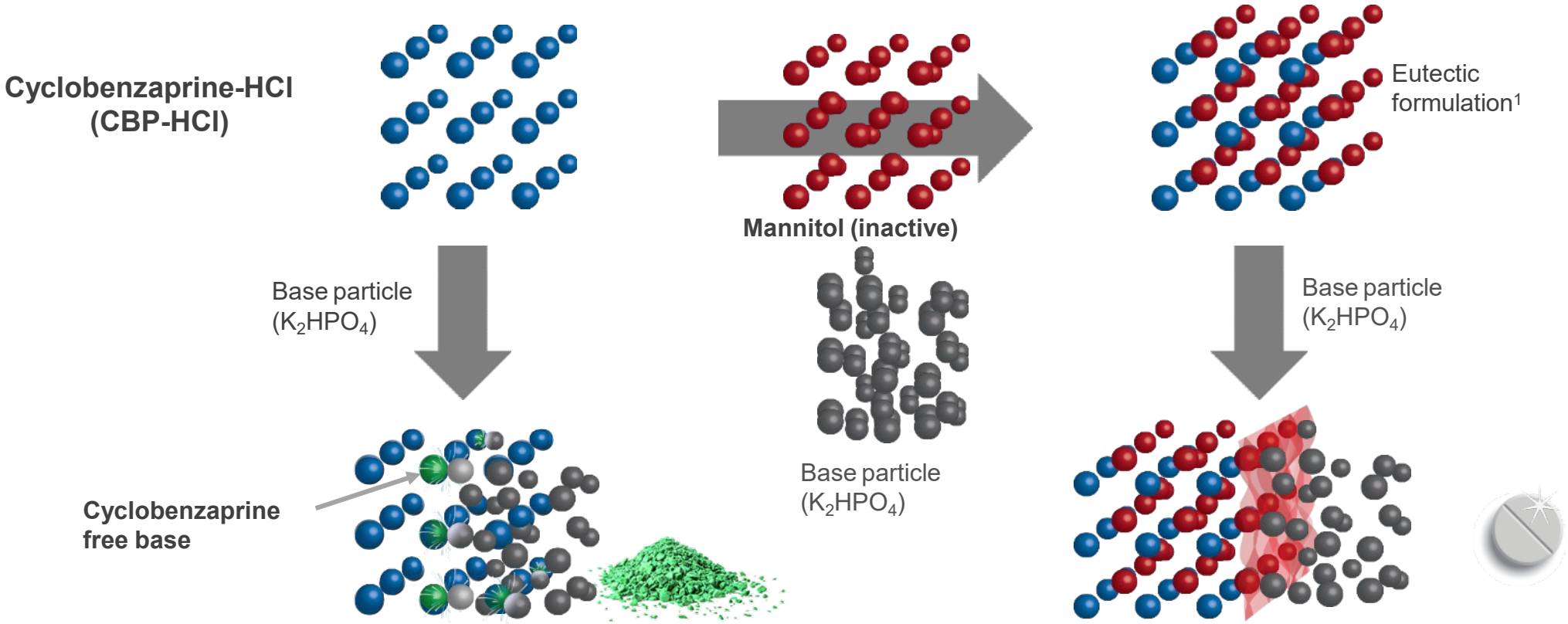
Sublingual CBP enters the bloodstream directly through the mucosal membrane



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

TNX-102 SL: Proprietary Eutectic Formulation

Proprietary Cyclobenzaprine HCl Eutectic Mixture Stabilizes Sublingual Tablet Formulation



1. U.S. Patent issued May 2, 2017.

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 (Studies 1 and 3)

Study 1 (RELIEF)

	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

Study 3 (RESILIENT)

	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

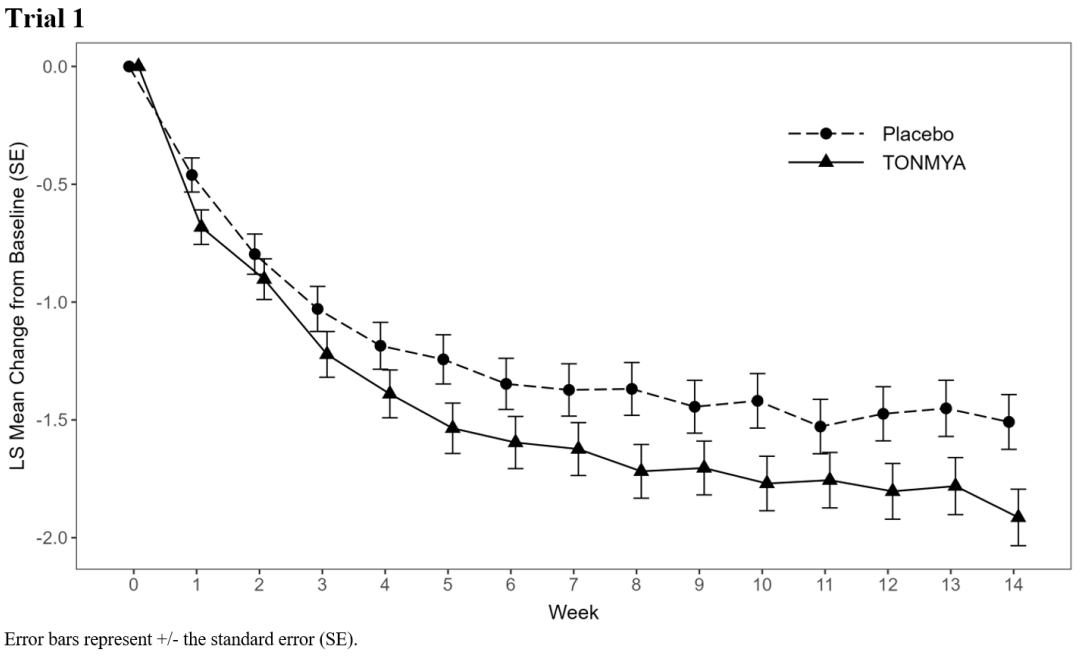
CI = confidence interval; LS = least squares; SD = standard deviation; SE = standard error

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.

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

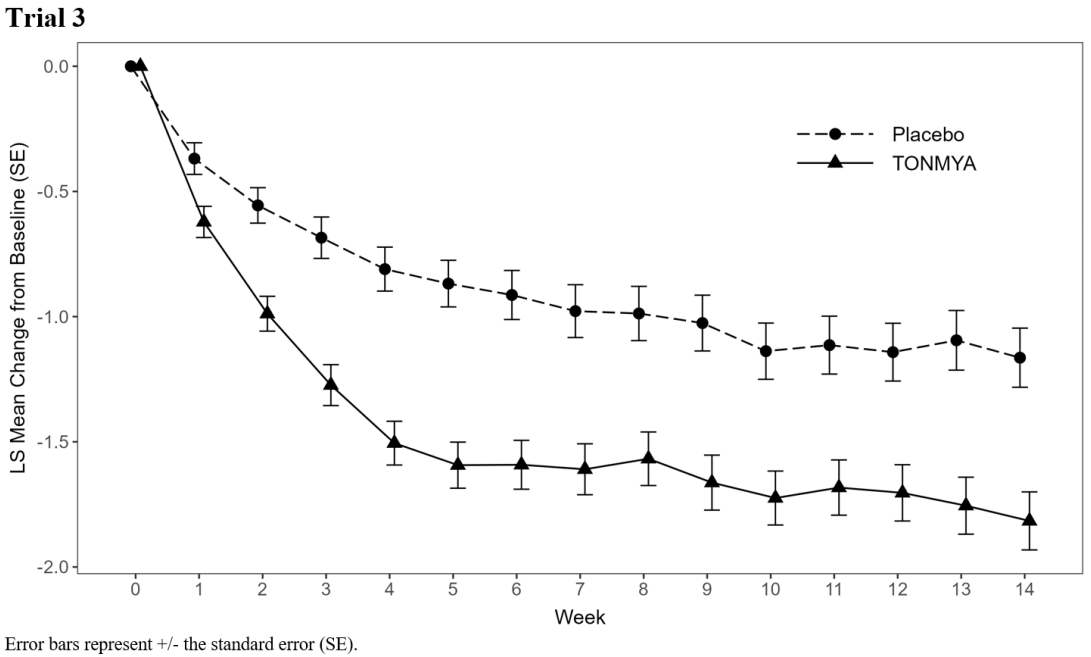
Pivotal Studies Included in Label Demonstrate Statistically Significant Mean Change from Baseline in Weekly Average of Daily 24-hour Recall Pain Intensity Scores at Week 14

Study 1 (RELIEF) n=503



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

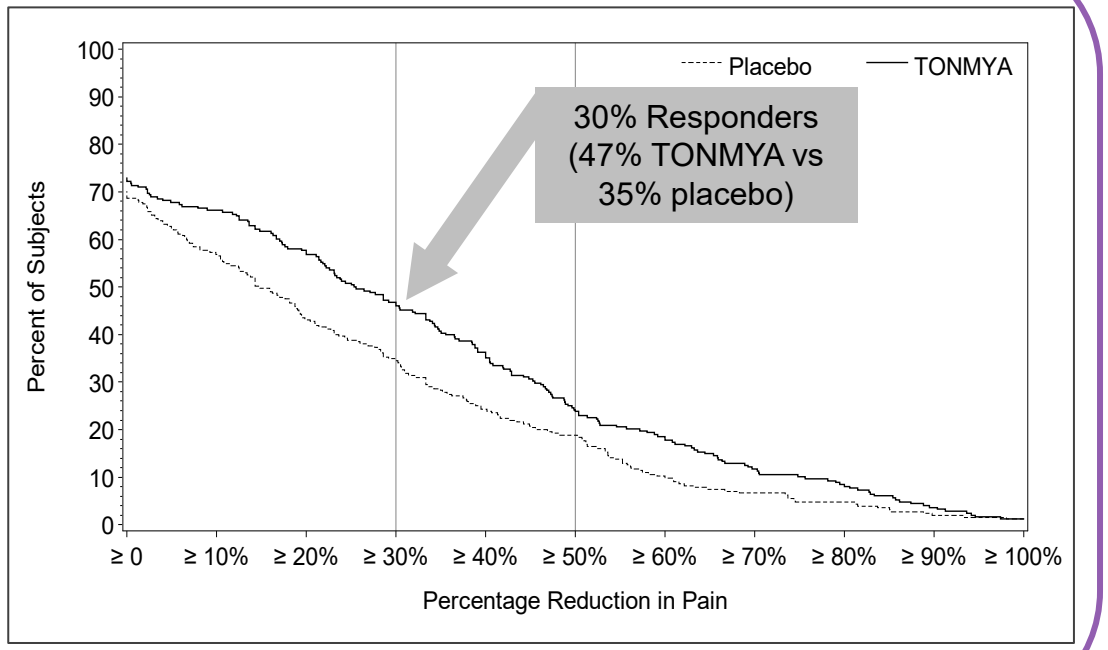
Study 3 (RESILIENT) n=457



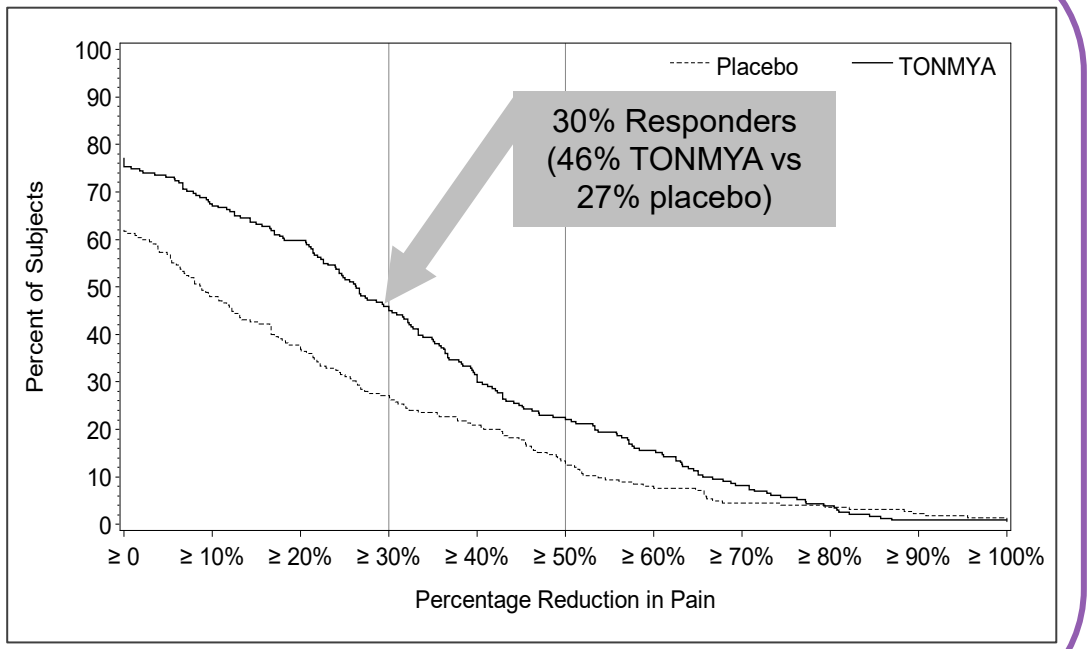
Error bars represent +/- the standard error (SE).

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

Study 1 (RELIEF)* n=503



Study 3 (RESILIENT)* n=457



*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.

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
- No reports of cognitive dysfunction or sexual dysfunction
- No evidence of abuse potential
- Pregnancy testing recommended in females with reproductive potential
- 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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Robust Mid-Stage Clinical Portfolio

TNX-102 SL[1] for Major Depressive Disorder (MDD)

TNX-102 SL

- Potentially first-in-class for targeting the disturbed sleep associated with depression
- Showed activity on the Beck Depression Inventory-II (BDI) in two Phase 3 studies in fibromyalgia patients with an uncorrected p-value < 0.05

IND Cleared: Phase 2 Horizon Study

- 6-week, randomized, double-blind, placebo-controlled study of TNX-102 SL 5.6 mg as a first-line monotherapy in adults with MDD
- About 360 patients will be enrolled at ~30 U.S. sites
- Eligible participants are 18 years or older and currently experiencing a moderate to severe major depressive episode

Overview

MOA

- Unique pharmacological profile of TNX-102 SL is designed to target the disturbed sleep (often associated with depression)

Unmet Need/Current Standard of Care

- Depression is an unmet need, despite many approved drugs[2]
- Standard of care includes SSRIs, SNRIs, tricyclic antidepressants, and dextromethorphan/bupropion
- Current antidepressants can cause side effects like weight gain, sleep disruption, and sexual disfunction

Population

- ~21 million U.S. adults experience at least one major depressive episode annually[3]

Upcoming Milestone

- **Phase 2 HORIZON study is enrolling patients**

1. TNX-102 SL has not been approved for MDD.
2.Rush, et al. *Am J Psychiatry*. 2006 Nov;163(11):1905-17; Garcia-Marin et al. *Annals of General Psychiatry* (2023) 22:49.
3.www.nimh.nih.gov/health/statistics/major-depression.

TNX-102 SL[1] for Acute Stress Disorder (ASD)/Acute Stress Reaction (ASR)

Phase 2 OASIS Investigator-Initiated Study

$40M AURORA initiative, a national research program to improve the understanding, prevention, and recovery of people who have experienced a traumatic event

U.S. Department of Defense

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

Overview

About ASD/ASR

- Acute stress conditions resulting from trauma which can affect both civilian and military populations

Unmet Need

- No medications are available at or near the point of care for acute traumatic events and that support long-term health

Population

- ~60% of men and ~50% of women in the U.S. are exposed to at least one traumatic experience in their lifetime[2]
- In the U.S., 1/3 of emergency dept. visits (40-50 million patients per year) are for trauma exposures[3]

Upcoming Milestone

- **Topline data expected 1Q'27**

1.TNX-102 SL has not been approved for the ASR indication.
2. National Center for PTSD. How Common is PTSD in Adults? https://www.ptsd.va.gov/understand/common/common_adults.asp.
3. Wisco et al. *J Clin Psychiatry*. 2014.75(12):1338-46.

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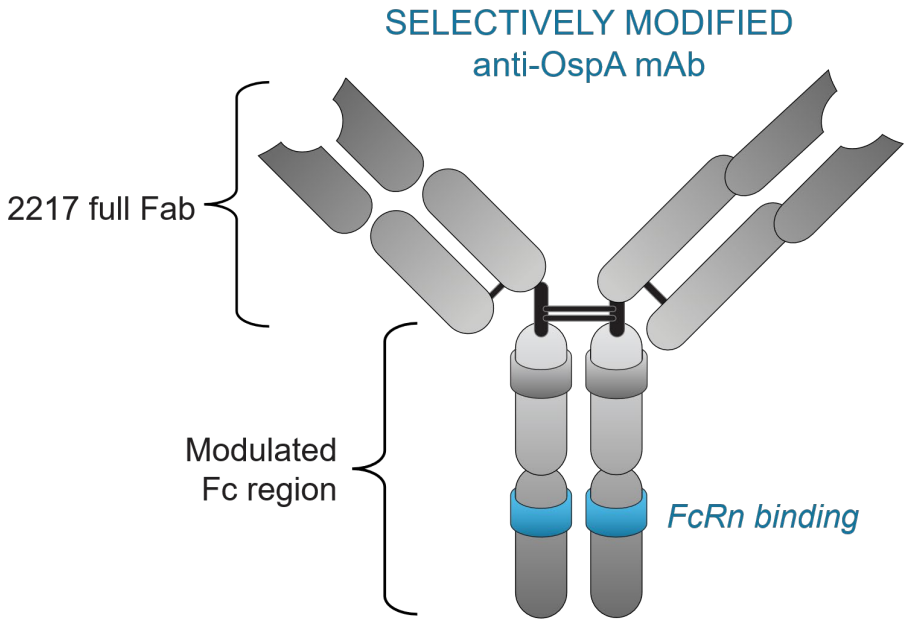
TNX-4800[1]: Phase 2-Ready, Intended to Address a Major Unmet Need and Public Health Challenge in the U.S.

TNX-4800[1]

Long-acting borreliacidal, human monoclonal antibody (mAb) with an engineered FC domain for an extended half-life that targets OspA of *Borrelia burgdorferi*[2,3]



LS substitutions maintain C1q binding and function and augment FcRn binding for extended half-life

Overview

Unmet Need

- No currently marketed U.S. FDA-approved vaccines or prophylactics to protect against Lyme disease

Population

- 87 million people in the U.S. are at high risk of contracting the disease because they live, work, or travel to an endemic area[2]

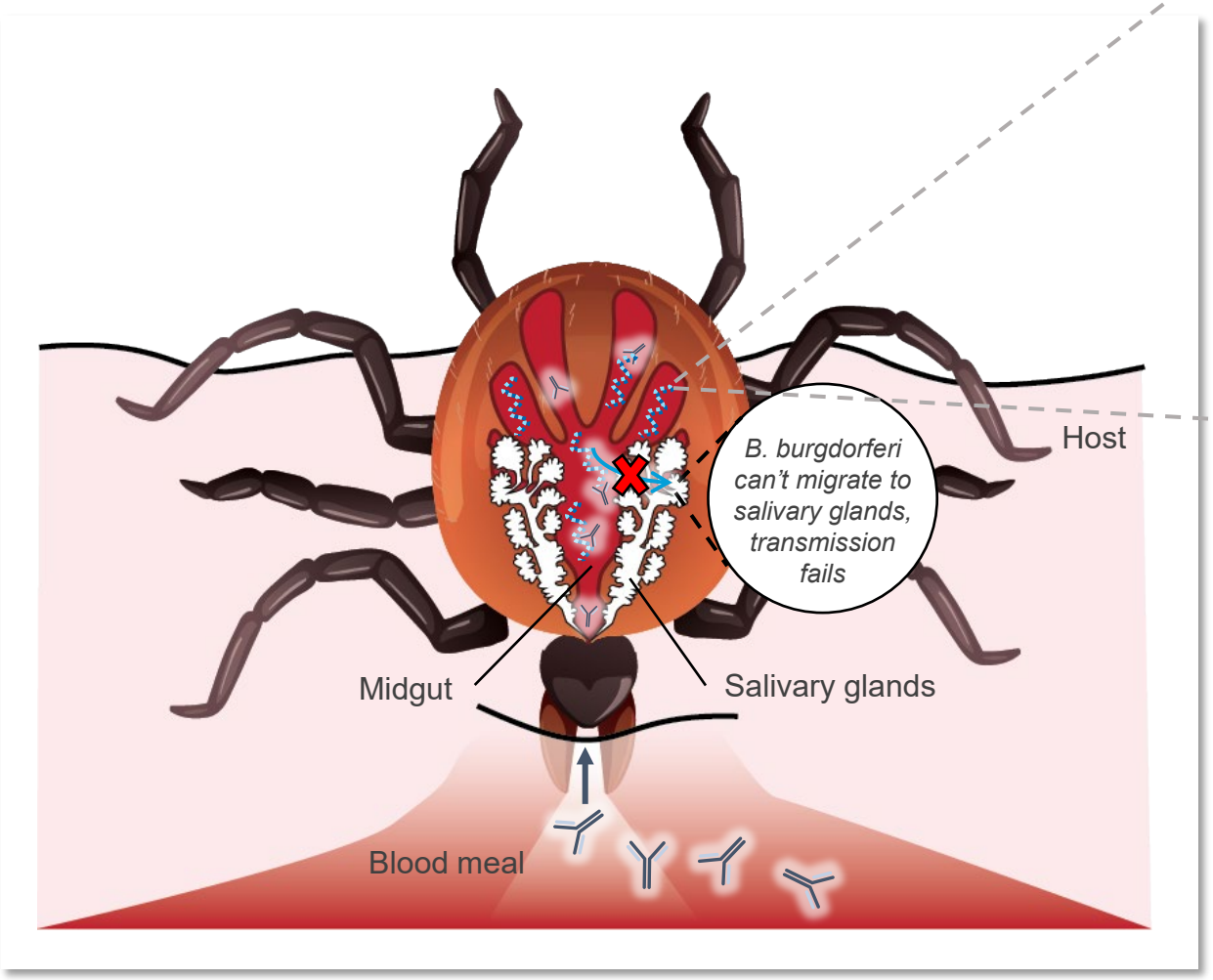
Upcoming Milestones

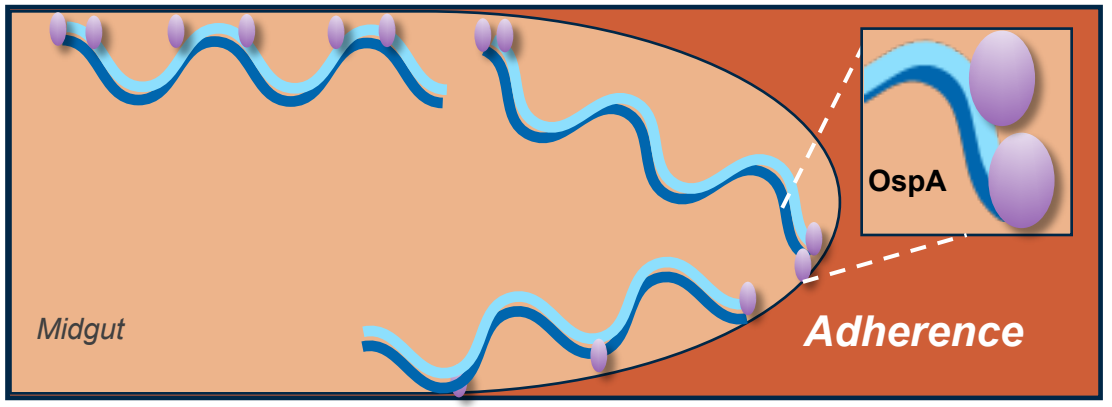
- **Manufacturing GMP material for human studies currently on track: early ’27**
- **Type C meeting scheduled with the FDA to discuss adaptive Phase 2 study design: early 3Q’26**
- **Plan to initiate adaptive Phase 2 field study, pending FDA agreement: 1H’27**

1. TNX-4800 is an investigational new biologic and has not been approved for any indication.
2. Kugeler KJ, et al. *Emerg Infect Dis.* 2021;27(2):616-619.
3. Wang Y, et al. *J Infect Dis.* 2016;214(2):205-211.

GMP = Good Manufacturing Process

Circulating Anti-OspA Monoclonal Antibody (TNX-4800) Ingested by Tick Blocks *B. burgdorferi* Transmission From Tick to Human[1]





- TNX-4800 is a human monoclonal antibody against OspA[1]
- TNX-4800 is designed to kill *Borrelia* and prevent the bacteria from reaching the tick's salivary glands, and protects from infection in animal challenge studies[2]1
- An Fc region mutation in TNX-4800 extends its half-life: a single administration at the beginning of tick season provides protection during the months of high infection risk
- If a tick bites a human immunized with TNX-4800, anti-OspA antibodies enter the tick midgut and bind to OspA on *B. burgdorferi* spirochetes[2,3]
- After TNX-4800:OspA binding, bacteria are killed or fail to migrate from the midgut to salivary glands, preventing transmission to the human host[2]

1 Schiller ZA, et al. *J Clin Invest*. 2021;131(11):e144843.
2. de Silva AM, et al. *J Exp Med*. 1996;183(1):271-275.
3. Radolf JD, et al. *Nat Rev Microbiol*. 2012;10(2):87-99.

Bam=β-barrel assembly machinery; Fc=fragment crystallizable; Osp=outer surface lipoprotein.

Potential Advantages of TNX-4800 Relative to Vaccines in Development

TNX-4800

- ✓ Provides protection within two days after one dose
- ✓ Does not require a host immune response
- ✓ Avoids onerous immunization regimen

	TNX-4800	VLA15	mRNA-1975	mRNA-1982
Sponsor	Tonix	Pfizer/Valneva	Moderna	Moderna
Status	Phase 2 ready	Phase 3	Phase 1/2	Phase 1/2
Type	Monoclonal Antibody	Vaccine – alum adjuvant	mRNA	mRNA
Immunity	Passive	Active	Active	Active
Target Market	U.S.	EU + U.S.	U.S.	EU + Asia
***Borrelia* targeted**[1-4]	*B. burgdorferi* (U.S.)	*B. burgdorferi* (U.S.) *B. afzelii* (Europe) *B. garinii** (Europe) *B. Bavariensis* (Europe)	*B. burgdorferi* (U.S.)	*B. burgdorferi* (U.S.) *B. afzelii* (Europe) *B. garinii* (Europe) *B. bavariensis* (OspA type 4)(Europe) B. *garinii* (OspA type 5 and 6 variants)(Asia) B. *spielmanii*

1. Marques AR, et al. *Emerg Infect Dis.* 2021. 27(8):2017-2024.
2. Pritt BS, et al. *Lancet Infect Dis.* 2016. 6(5):556-564..
3. Lemieux JE, et al. *PLoS Pathog*. 2023.19(8):e1011243.
4. Comstedt P, et al. *PLoS One*. 2014 9(11):e113294.

*VLA15 contains 3 OspA's from different garinii genospecies.

Phase 1 Clinical Study Summary Results

TNX-4800 was studied in randomized, double-blind, sequential dose-escalation study (NCT04863287) to evaluate its safety, tolerability, pharmacokinetics, and immunogenicity

- 44 healthy adult subjects randomized and 41 completed study; subjects received a single subcutaneous (SC) administration of placebo or TNX-4800 at 0.5, 1.5, 5, or 10 mg/kg
- Peak serum concentration (C_{max}) increased by ~25-fold for a 20-times increase in dose
- Serum TNX-4800 measurable at earliest sampling time of 2 days, indicating rapid systemic absorption
- TNX-4800 levels remained quantifiable for >200 days in 80% of subjects at lowest dose and for up to 350 days in majority of participants at higher doses (i.e., ≥ 1.5 mg/kg)
- Mean half-life ranged from 62–69 days across TNX-4800 groups; serum concentrations quantifiable for up to 12 months in most subjects; mean exposure for 10 mg/kg group <17% of the highest exposures in a nonclinical toxicology study
- Anti-drug antibodies (ADA) detected in <10% of treated subjects, with no impact on pharmacokinetics
- Most adverse events were mild or moderate[1]
- TNX-4800 found to be generally safe and well tolerated

1. One serious adverse event deemed unrelated to study drug.

Planned Phase 2 Field Study: To Be Discussed with FDA Early in Third Quarter 2026

TNX-4800 is intended to be studied in an adaptive randomized, double-blind, placebo-controlled field study, pending FDA agreement

- **Primary Efficacy Endpoint*:** Incidence of a first confirmed case of Lyme disease, caused by *B. burgdorferi* within the period of 2 days post administration up through Week 16 following first administration
- **Primary Efficacy Objective:** Evaluate the efficacy of TNX-4800 in preventing the first occurrence of confirmed Lyme disease during the primary efficacy surveillance period from Day 2 after the first administration up to Week 16 following the first administration
- **Primary Safety Objective:** Evaluate the safety and tolerability of TNX-4800 over a 24-week period

- **Inclusion:** Adolescents and adults[1] 16 years of age and older from U.S. Lyme-endemic areas
- **Dosing:** Two total doses; one 450 mg SC dose or placebo at Day 1, and one 450 mg SC dose or placebo 12 weeks later at Day 85
- **Administration:** Each 450 mg SC dose or placebo will be divided into two injections that each have 1.5 mL volume with 225 mg
- **Rationale:** Efficacy relevant threshold based on Phase 1 pharmacokinetic results and nonclinical protection models against *B. burgdorferi* transmission

Key secondary efficacy endpoint at 24 weeks.

TONIX PHARMACEUTICALS

TNX-1500[1] for the Prevention of Organ Transplant Rejection

Phase 1 Topline Results

- Pharmacokinetic results showed mean half-life for the 10 mg/kg and 30 mg/kg dose groups of 34-38 days, consistent with monthly dosing
- In healthy volunteers, TNX-1500 was generally well-tolerated with a favorable safety profile

Phase 2 Investigator-Initiated Study

- Led by Massachusetts General Hospital (MGH)
- Designed to assess the safety, tolerability, and activity of TNX-1500 in preventing kidney transplant rejection while significantly minimizing the dose of conventional immunosuppressive drugs, which are associated with infection, cancer, cardiovascular side effects, and various metabolic derangements

Overview

MOA

- Humanized monoclonal antibody directed against CD40-ligand, or CD40L (also known as CD154), engineered to modulate binding to Fc receptors

Unmet Need/Current Standard of Care

- Organ transplant rejection occurs when the immune system of the organ recipient attacks the new organ as if it were an infection or tumor
- Often transplantation is the last resort for most end-stage organ failure patients
- Mismatched or not closely matched organs trigger an immune reaction that leads to rejection
- Organ donations are in limited supply

Upcoming Milestone

- **MGH investigator-initiated Phase 2 study in kidney transplant expected to initiate in the 2nd half of 2026[2]**

1. TNX-1500 has not been approved for any indication. Patents filed.
2. Pending FDA clearance of MGH's IND.

TNX-1500: Expected to Deliver Efficacy Without Compromising Safety

First Generation

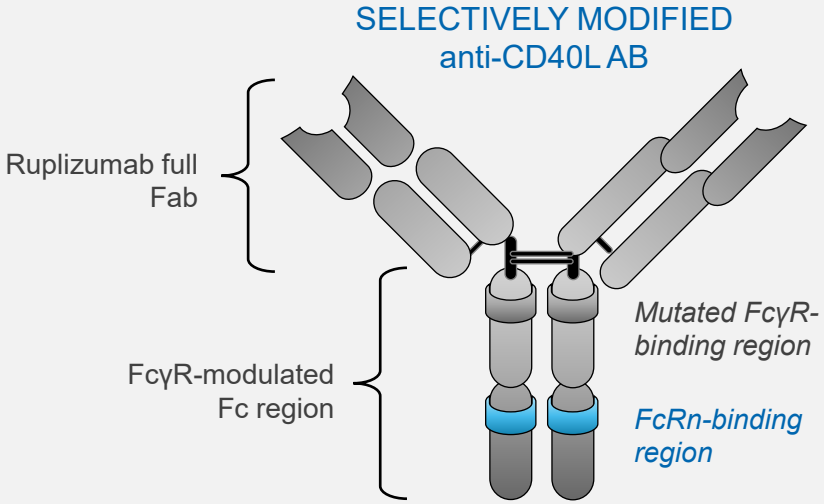
- Development halted due to thromboembolic (TE) complications—blood clots—traced to Fc gamma receptor (FcγR)

Second Generation

- Eliminated the FcγR TE complication, but potency and half life were reduced

Third Generation: TNX-1500

- Re-engineered to better modulate the binding of FcγR



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

TNX-2900[1,2] for Prader Willi Syndrome (PWS)

TNX-2900

- Treatment of children and adolescents with PWS
- Orphan Drug and Rare Pediatric Disease designations in the U.S.; eligible for transferable Priority Review Voucher upon approval
- IND cleared by FDA

Phase 2 Study

- Randomized, double-blind, placebo-controlled, parallel-design study to evaluate the safety, tolerability, and efficacy of TNX-2900 in male and female participants with PWS, ages 8 to 17.5 years
- Eligible participants will be randomized to receive 12-weeks of treatment with TNX-2900 at one of three dose levels, or placebo, in a 1:1:1:1 ratio
- Primary efficacy endpoint: change from baseline in the validated Hyperphagia Questionnaire for Clinical Trials (HQ-CT); Secondary objectives: assessments of behavior, caregiver burden, and quality of life measures, as well as safety and tolerability outcomes

Overview

MOA

- Intranasal potentiated oxytocin (OT) with magnesium
- Patented potentiated OT formulation is believed to increase activity of OT at OT receptors (OXTR)

Unmet Need

- Current interventions are difficult to sustain and often inadequate

Population

- Rare genetic disorder occurring in 1 in 10,000 to 1 in 30,000 births in the U.S.
- Infants often present with poor muscle tone and feeding difficulties
- Children and adolescents develop hyperphagia, behavioral challenges, and severe obesity and metabolic disease

Upcoming Milestone

- **Plan to initiate enrollment for Phase 2 study in 1Q’27**

1. TNX-2900 has not been approved for any indication. Patents filed.
2. Formulation technology was acquired from Trigemina, Inc. and licensed from Stanford University in 2020. Therapeutic technology was licensed from Inserm, the French National Institute of Health and Medical Research.

TNX-1300[1] for Cocaine Intoxication

Cocaine Intoxication

- With the continued use of cocaine, intense cocaine cravings occur, resulting in a high potential for abuse and addiction, or dependence, as well as the risk of cocaine intoxication
- Cocaine intoxication refers to the deleterious effects on other parts of the body, especially those involving the cardiovascular system

CocE Rapidly Inactivates Cocaine

Overview

MOA

- CocE is a recombinant protein that degrades cocaine in the bloodstream
- Rapidly reverses physiologic effects of cocaine
- Drops plasma exposure by 90% in two minutes

Unmet Need

- No other product currently on the market for this indication

Population

- ~505,000 emergency room visits for cocaine abuse each year in the U.S., of which 61,000 require detoxification services
- According to the National Institute on Drug Abuse, cocaine-involved deaths rose nearly 54% from 2019 to 2021, resulting in over 24,486 deaths total

Upcoming Milestone

- **Intend to meet with FDA in 2026 to inform the clinical design of next Phase 2 study (Phase 2a study completed)**

1. TNX-1300 has not been approved for any indication. Patents filed.

Tonix is Strategically Executing for the Future

2026 Priorities

Execute on TONMYA launch

Advance mid-stage clinical programs

Drive sustainable growth to create value for all shareholders

Upcoming Milestones

Early 3Q 2026
Type C FDA Meeting to Discuss Ph. 2 Study of TNX-4800 for Lyme Disease in U.S.[3]

2H 2026
Initiate IIT Ph. 2 Study of TNX-1500 for Kidney Transplant[1]

1Q 2027
Topline Data for Ph. 2 IIT Study of TNX-102 SL for ASD/ASR[2]

1Q 2027
Initiate Ph. 2 Study of TNX-2900 for Prader Willi Syndrome

1H 2027
Initiate Adaptive Ph. 2 Field Study of TNX-4800 for Lyme Disease in U.S.[3]

1. IIT = Investigator-Initiated Trial. With MGH, pending FDA clearance.
2. IIT = Investigator-Initiated Trial. With University of North Carolina.
3. Pending FDA agreement.

Appendix

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.

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.

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.

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.

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.

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.