November 10, 2025

Tonix Pharmaceuticals Reports Third Quarter 2025 Financial Results and Operational Highlights

Tonmya™ (cyclobenzaprine HCl sublingual tablets) for the treatment of fibromyalgia set to launch in November

Tonmya is the first new FDA-approved medicine for fibromyalgia in more than 15 years

Cash and cash equivalents of $190.1 million reported as of September 30, 2025; current cash runway expected to fund operations into the first quarter of 2027

CHATHAM, N.J., Nov. 10, 2025 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully-integrated commercial biotechnology company today announced financial results for the third quarter ended September 30, 2025, and provided an overview of recent operational highlights.

"Following U.S. Food and Drug Administration (FDA) approval of Tonmya™, we are focused on execution of the U.S. launch later this month to bring the first new treatment option for fibromyalgia to patients and clinicians in more than 15 years," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "We have built the commercial infrastructure, market access capabilities, and brand awareness to position Tonmya for a strong launch and sustainable market presence."

Dr. Lederman continued, "Turning to our pipeline, we were excited to in-license TNX-4800, a Phase 2-ready, long-acting human monoclonal antibody for the seasonal prevention of Lyme disease, and to announce a collaboration with Massachusetts General Hospital to conduct an investigator-initiated Phase 2 study of TNX-1500 for the prevention of kidney transplant rejection. Our priorities are clear: launch Tonmya successfully, advance our pipeline strategically, and drive sustainable growth that benefits patients and shareholders."

Commercial Updates

Tonmya (cyclobenzaprine HCl sublingual tablets) 2.8 mg: a centrally acting, non-opioid analgesic for the treatment of fibromyalgia in adults

- In August, the FDA approved Tonmya, the first new fibromyalgia therapy in more than 15 years.
- In September, the Company established the wholesale acquisition cost (WAC) for Tonmya.
- In October, Tonix announced the commercial launch of Tonmya will commence before the end of November.

- 90 Tonmya sales representatives have been in the field for over a month, in preparation for the November launch.
- Tonix has contracted with its existing wholesalers and specialty pharmacies for the distribution of Tommya.
- Tonix has also contracted with companies to assist with prescription fulfillment and patient access.
- The Company strengthened its commercial organization with the appointment of Ganesh Kamath as Head of Market Access to lead pricing, payer strategy, and reimbursement for the Tonmya launch.

Tosymra® (sumatriptan nasal spray) 10 mg: approved treatment of acute migraine in adults

- Effective January 1, 2026, Tosymra has preferred exclusive placement on a payer formulary representing approximately 16 million covered lives.

Pipeline Updates

TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 2.8 mg: in development for major depressive disorder (MDD)

- In August, Tonix held a positive Type B Pre-Investigational New Drug (IND) meeting with the FDA regarding TNX-102 SL for MDD.
- In October, the Company filed the IND, and, upon receiving IND clearance, Tonix intends to initiate a Phase 2 study mid-year 2026.

TNX-1500 (dimeric Fc modified anti-CD40L, humanized monoclonal antibody [mAb]): third generation anti-CD40L under investigation for prophylaxis of kidney transplant rejection, with the potential to also be a treatment for autoimmune disorders.

- In October, Tonix presented an update at the *Japan Society for Transplantation* annual congress, highlighting Phase 1 safety and biomarker results and outlining next steps toward Phase 2 evaluation in allo-transplantation.
- In November, Tonix announced a collaboration with Massachusetts General Hospital to advance a Phase 2 open-label, investigator-initiated, clinical trial of TNX-1500 in kidney transplant recipients in 1H 2026.

TNX-4800 (anti-OspA mAb): long-acting human mAb in development for the prevention of Lyme disease

- In September, Tonix announced in-licensing worldwide rights to TNX-4800, from UMass Chan Medical School. TNX-4800 is a fully human mAb that targets and kills *Borrelia burgdorferi* inside infected deer ticks when they have bitten treated animals and ingested their blood.
- Adaptive Phase 2/3 study will test whether TNX-4800 protects humans by killing B. burgdorferi inside infected deer ticks when they have bitten treated humans and ingested their blood.
- There are currently no FDA-approved vaccines or prophylactics to protect against Lyme Disease.
- Tonix plans to initiate the adaptive Phase 2/3 study during tick season in 2027.

TNX-2900 (intranasal potentiated oxytocin): in development for Prader-Willi syndrome

- In September, Tonix announced plans to initiate a Phase 2, randomized, double-blind, placebo-controlled trial in 2H 2026 in children and adolescents.
- TNX-2900 has Orphan Drug designation as well as Rare Pediatric Disease designation that could make Tonix eligible for a *Priority Review Voucher* upon approval.

Financials

As of September 30, 2025, Tonix had $190.1 million in cash and cash equivalents, compared with $98.8 million as of December 31, 2024. Net cash used in operations was approximately $60.2 million for the nine months ended September 30, 2025, compared to $46.3 million for the same period in 2024.

Based on its current operating plan, the Company believes its cash on hand as of September 30, 2025, together with $34.7 million in net proceeds received from equity offerings during the fourth quarter 2025, will fund planned operating and capital expenditures into the first quarter of 2027.

Third Quarter 2025 Financial Results

Net product revenue for the three months ended September 30, 2025 was approximately $3.3 million, compared to $2.8 million for the same period in2024; revenue reflected combined net sales of Zembrace® SymTouch® (sumatriptan injection) and Tosymra® (sumatriptan nasal spray). Cost of sales for the three months ended September 30, 2025 was approximately $1.4 million, compared to $1.6 million for the same period in 2024.

Research and development expenses for the three months ended September 30, 2025 were $9.3 million, compared to $9.1 million for the same period in 2024. The increase was predominately due to increased manufacturing expenses of $2.3 million, offset by a reduction in clinical expenses of $2.1 million, as a result of pipeline prioritization period over period.

Selling, general and administrative expenses for the three months ended September 30, 2025 were $25.7 million, compared to $7.7 million in 2024. The increase is predominately due to spending on sales and marketing relating to Tonmya.

Net loss available to common stockholders was $32.0 million, or $3.59 per share (basic and diluted), for the third quarter 2025, compared to a net loss of $14.2 million, or $22.68 per share, for the same period in 2024. The basic and diluted weighted-average common shares outstanding for the third quarter 2025 were 8,922,792, compared to 626,669 for the same period in 2024.

Tonix Pharmaceuticals Holding Corp.*
Tonix Pharmaceuticals is a fully-integrated biotechnology company with marketed products and a pipeline of development candidates. Tonix has received FDA approval for Tonmya ™, a first-in-class, non-opioid analgesic medicine for the treatment of fibromyalgia, a chronic pain condition that affects millions of adults. This marks the first approval for a new prescription medicine for fibromyalgia in more than 15 years. Tonix also markets two treatments for acute migraine in adults: Zembrace® SymTouch® and Tosymra®. Tonix's

development portfolio is focused on central nervous system (CNS) disorders, immunology, immuno-oncology, rare disease and infectious disease. TNX-102 SL is being developed to treat acute stress reaction and acute stress disorder under an Investigator-Initiated IND at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). TNX-102 SL is also in development for major depressive disorder. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is an Fc-modified humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. Tonix's rare disease portfolio includes TNX-2900, intranasal oxytocin potentiated with magnesium, in development for Prader-Willi syndrome. Tonix's infectious disease portfolio includes TNX-801, a vaccine in development for mpox and smallpox, as well as TNX-4800, a monoclonal antibody for the seasonal prevention of Lyme Disease. Finally, TNX-4200 for which Tonix has a contract with the U.S. DoD's Defense Threat Reduction Agency (DTRA) for up to $34 million over five years, is a small molecule broad-spectrum antiviral agent targeting CD45 for the prevention or treatment of high lethality infections to improve the medical readiness of military personnel in biological threat environments. Tonix owns and operates a state-of-the art infectious disease research facility in Frederick, Md.

* Tonix's product development candidates are investigational new drugs or biologics; their efficacy and safety have not been established and have not been approved for any indication.

This press release and further information about Tonix can be found at www.tonixpharma.com.

Forward Looking Statements

Certain statements in this press release 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, 2024, as filed with the Securities and Exchange Commission (the "SEC") on March 18, 2025, 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.

TONIX PHARMACEUTICALS HOLDING CORP.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Dollars In Thousands Except Per Share Amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
REVENUE:				
Product revenues, net	$ 3,290	$ 2,822	$ 7,717	$ 7,512
COSTS AND EXPENSES:				
Cost of sales	1,367	1,555	5,582	6,582
Research and development	9,289	9,114	27,545	31,675
General and administrative	25,701	7,707	52,007	24,519
Asset impairment charges	-	-	-	58,957
Total operating expenses	36,357	18,376	85,134	121,733
Operating Loss	(33,067)	(15,554)	(77,417)	(114,221)
Grant income	982		2,941	1,668
(Loss) gain on change in fair value of warrant liabilities	-	1,668	-	6,150
Loss on Extinguishment	-	-	(2,092)	-
Interest income, net	1,231	18	2,802	21
Interest expense	-	(301)	(89)	(954)
Other expense, net	(1,156)	(44)	(3,256)	(592)
Net loss available to common stockholders	$ (32,010)	$ (14,213)	$ (77,111)	$ (107,928)
Net loss per common share, basic and diluted	$ (3.59)	$ (22.68)	$ (10.42)	$ (466.17)
Weighted average common shares outstanding, basic and diluted	8,922,792	626,669	7,403,400	231,523

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In Thousands)
(Unaudited)

	September 30, 2025	December 31, 2024[1]
Assets		
Cash and cash equivalents	$ 190,055	$ 98,776
Accounts receivable, net	3,481	3,683
Inventory	5,729	8,408
Prepaid expenses and other	8,806	8,135
Total current assets	208,071	119,002
Other non-current assets	44,369	43,888
Total assets	$ 252,440	$ 162,890
Liabilities and stockholders' equity		
Total liabilities	$ 21,297	$ 23,332
Stockholders' equity	231,143	139,558
Total liabilities and stockholders' equity	$ 252,440	$ 162,890

[1]The condensed consolidated balance sheet for the year ended December 31, 2024 has been derived from the audited financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

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INDICATION
TONMYA is indicated for the treatment of fibromyalgia in adults.
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.

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.

Indication and Usage

Zembrace® SymTouch® (sumatriptan succinate) injection (Zembrace) and Tosymra® (sumatriptan) nasal spray are prescription medicines used to treat acute migraine

headaches with or without aura in adults who have been diagnosed with migraine.
Zembrace and Tosymra are not used to prevent migraines. It is not known if Zembrace or Tosymra are safe and effective in children under 18 years of age.

Important Safety Information

Zembrace and Tosymra 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 and Tosymra are 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 or 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
- 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, or dihydroergotamine. Ask your provider for a list of these medicines if you are not sure.
- 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 or Tosymra

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.
Zembrace and 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.
Zembrace and 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 Zembrace or 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.
- 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 Zembrace and Tosymra include: pain and redness at injection site (Zembrace only); 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; application site (nasal) reactions (Tosymra only) and throat irritation (Tosymra only).

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 and Tosymra. For more information, ask your provider.

This is the most important information to know about Zembrace and Tosymra but is not comprehensive. For more information, talk to your provider and read the Patient Information and Instructions for Use. You can also visit https://www.tonixpharma.com or call 1-888-869-7633.

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

TONIX PHARMACEUTICALS

Source: Tonix Pharmaceuticals Holding Corp.