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): **August 18, 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.

On August 18, 2025, at 8:30 a.m. Tonix Pharmaceuticals Holding Corp. (the "Company") will hold a webcast and conference call to discuss the U.S. Food and Drug Administration's ("FDA") approval of Tonmya™ (cyclobenzaprine HCl sublingual tablets), which was investigated as TNX-102 SL, for the treatment of fibromyalgia in adults. In connection with the webcast and conference call, the Company will be reviewing a presentation, a copy of which is furnished hereto as Exhibit 99.01, 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.

On August 18, 2025, at 8:30 a.m. the Company will hold a webcast and conference call to discuss the FDA's approval of Tonmya. In connection with the webcast and conference call to review the FDA's approval of Tonmya, the Company will be reviewing the presentation attached hereto as Exhibit 99.1, which is incorporated herein by reference.

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 launch, commercialization and 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	US Approval of Tonmya™ for the Treatment of Fibromyalgia
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.

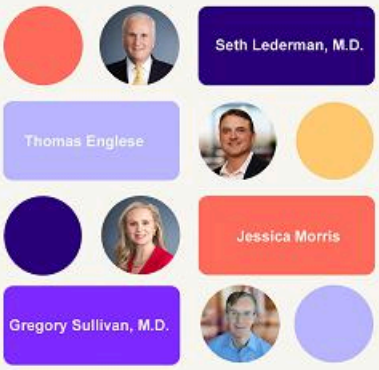
TONIX PHARMACEUTICALS HOLDING CORP.

Date: August 18, 2025

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

Exhibit 99.01

AGENDA + PARTICIPANTS



01 **Introduction, Fibromyalgia Overview & Tonmya™ Label**
Seth Lederman, M.D. – Chief Executive Officer and Chairman

02 **Commercial and Go-To-Market Strategy**
Thomas Englese – EVP, Commercial & President, Tonix Medicines

03 **Q&A**
Seth Lederman, M.D. – Chief Executive Officer and Chairman
Jessica Morris – Chief Operating Officer
Gregory Sullivan, M.D. – Chief Medical Officer
Thomas Englese – EVP, Commercial & President, Tonix Medicines

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," "expect", "plan", "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 the failure to successfully launch and commercialize Tonmya and any of our approved products; risks related to 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.

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.

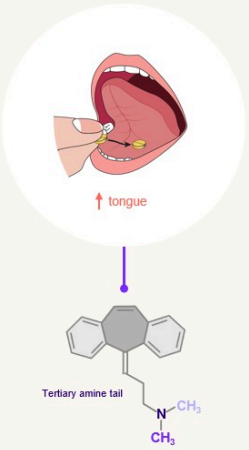

NOW APPROVED
Tonmya™
(cyclobenzaprine HCl)
sublingual tablets 2.8mg
4
TONIX PHARMACEUTICALS


Tonmya™ is the First FDA-Approved Medicine for the Treatment of Fibromyalgia in Over 15 Years
Fibromyalgia: >10M people in the US living with this serious, debilitating condition
Characterized by chronic widespread pain[1]
Approximately 80% are female
Tonmya is a first-in-class medicine, uniquely designed to treat fibromyalgia
Non-opioid analgesic. Not DEA[2] scheduled.
Demonstrated rapid and durable improvement in chronic widespread pain
Tonix is well positioned to support commercial launch, expected in Q4 2025
Commercial infrastructure in place
No debt; anticipated cash runway to support launch and other operations into Q3 2026
1. Bhargava J, Goldin J. Fibromyalgia. [Updated 2025 Jan 31]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK540974
2. U.S. Drug Enforcement Agency.
TONIX PHARMACEUTICALS

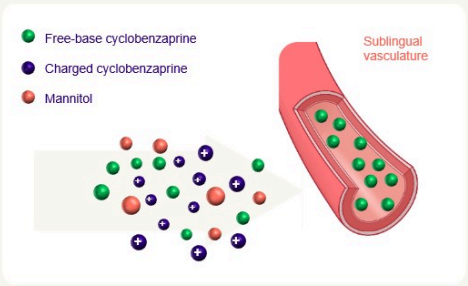
Tonmya™ is a Tertiary Amine Tricyclic that Bypasses First-Pass Liver Metabolism,

Leading to Faster Absorption and Reduced norCyclobenzaprine ("norCBP")

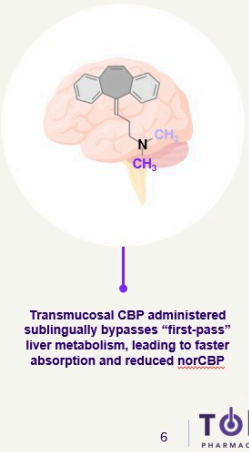
Tonmya™ is administered sublingually



- 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

Tonmya™

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 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

TONIX PHARMACEUTICALS

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**

TONIX PHARMACEUTICALS

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

	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

	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.

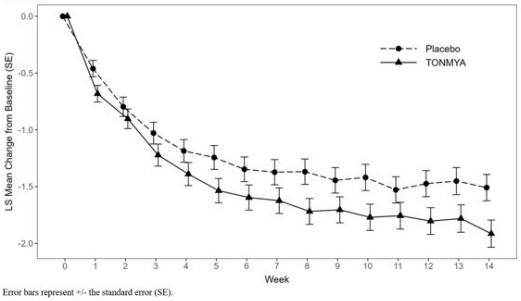
[2] Difference of -0.7 is due to a rounding effect: TONMYA: -1.82, placebo: -1.16, and the difference in LS mean is -0.66.

TONIX PHARMACEUTICALS

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

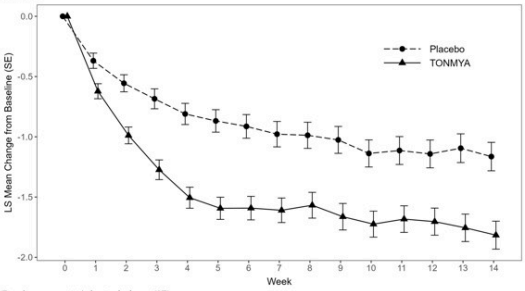
Pivotal Studies Included in Label Demonstrate Statistically Significant Mean Change from Baseline in Weekly Average of Daily 24-hour Recall Pain Intensity Scores at Week 14

Trial 1



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

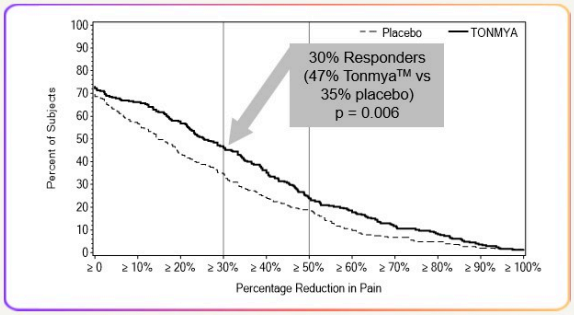
Trial 3



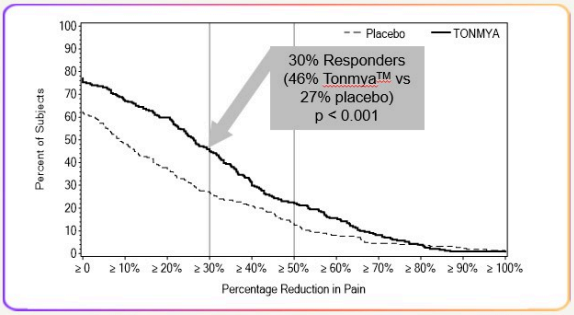
Error bars represent +/- the standard error (SE).

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

Trial 1

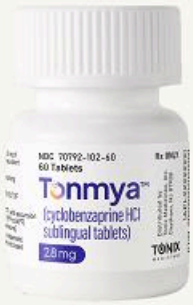


Trial 3



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 were similar to placebo
  - 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**

TONIX PHARMACEUTICALS

Tonix is Well Positioned to Support the Commercial Launch

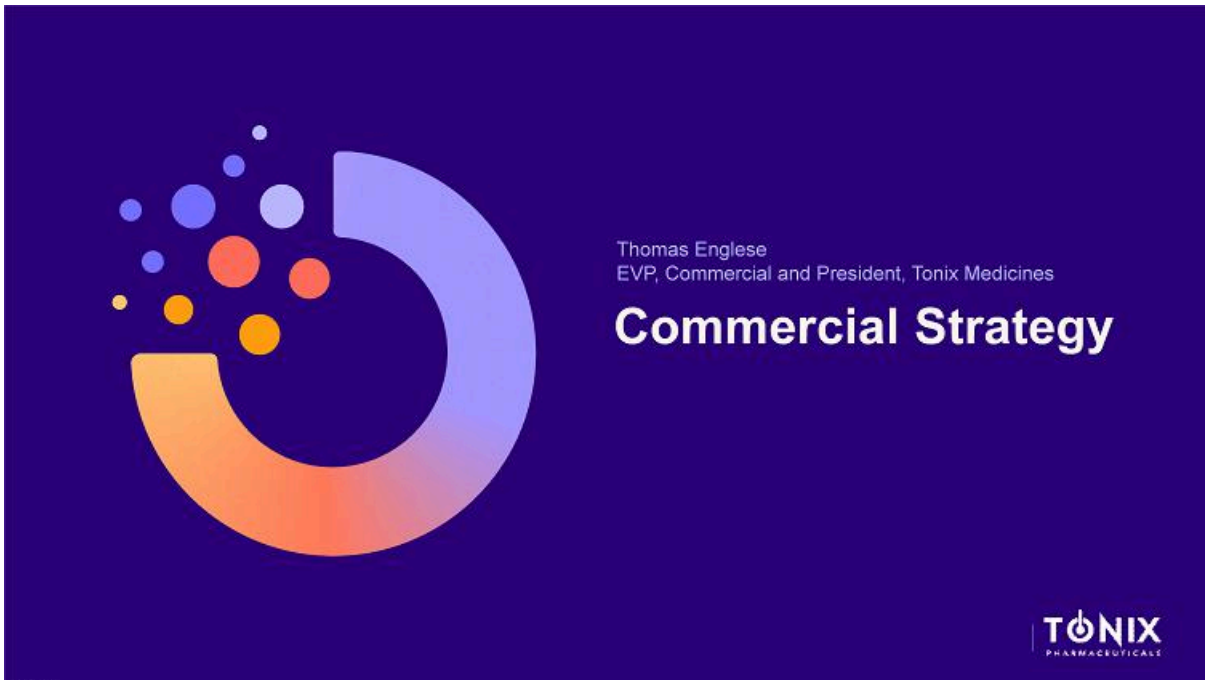
Tonix Medicines markets two FDA-Approved Rx migraine products and is prepared to launch Tonmya

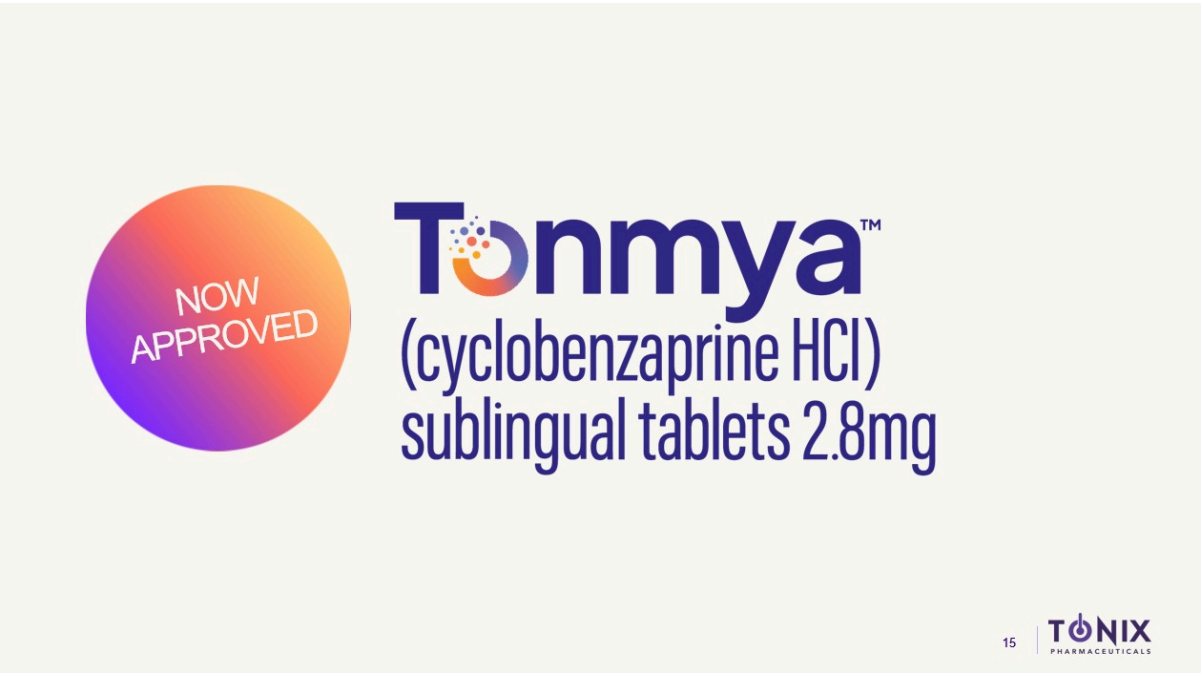
Ended Q2 2025 with ~$125 million in cash and cash equivalents

Raised ~$50 million in Q3 2025 through August 11, 2025 via equity sales

Strong balance sheet: no debt; expected cash runway into Q3 2026

TONIX PHARMACEUTICALS


Thomas Englese
EVP, Commercial and President, Tonix Medicines
Commercial Strategy
TONIX
PHARMACEUTICALS


NOW APPROVED
Tonmya™
(cyclobenzaprine HCl)
sublingual tablets 2.8mg
15
TONIX PHARMACEUTICALS


Tonix Medicines' Commercial Team has
Extensive Commercial and Launch Expertise
AMGEN
gsk
MERCK
Allergan
AstraZeneca
Eisai
axsome
Ironwood
Insmed
Baxter
Tris
PHARMA
Otsuka
Incyte
endo
Mallinckrodt
Pharmaceuticals

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]

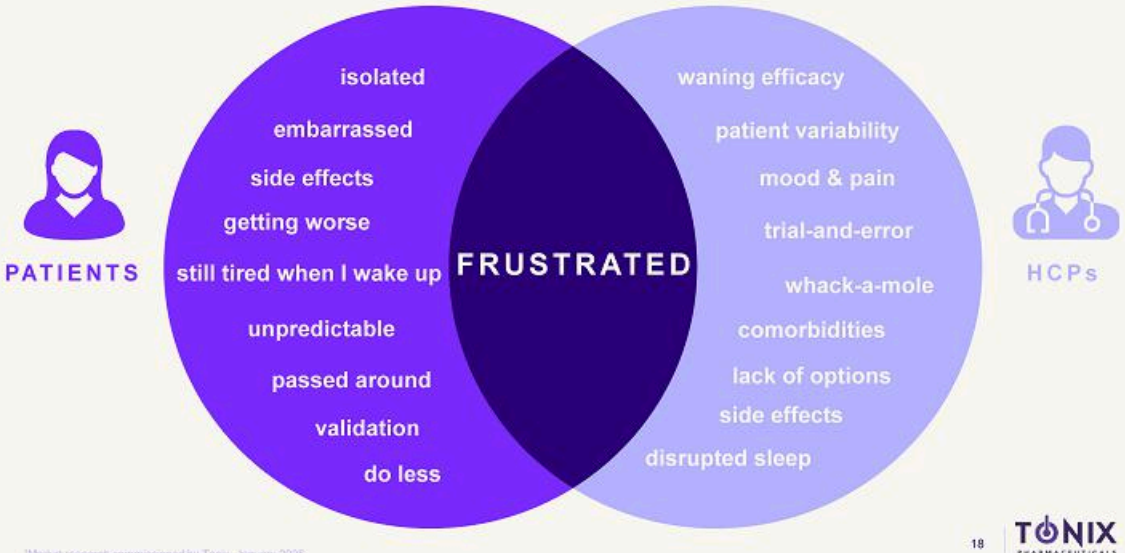
2.7 million patients diagnosed and treated annually[5]
~15 million prescriptions are written for the treatment of fibromyalgia (on- and off-label usage) each year[6]

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

TONIX PHARMACEUTICALS

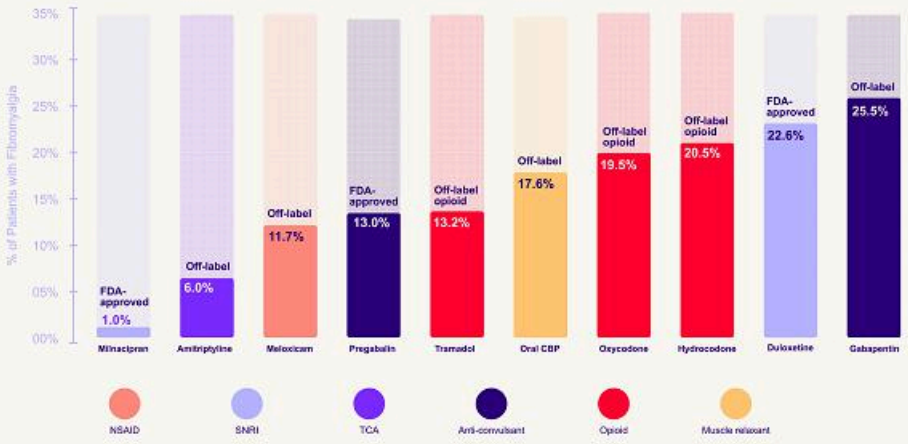
Both Patients and HCPs are Challenged by the Fibromyalgia Journey[1]



[1]Market research commissioned by Tonix, January 2025

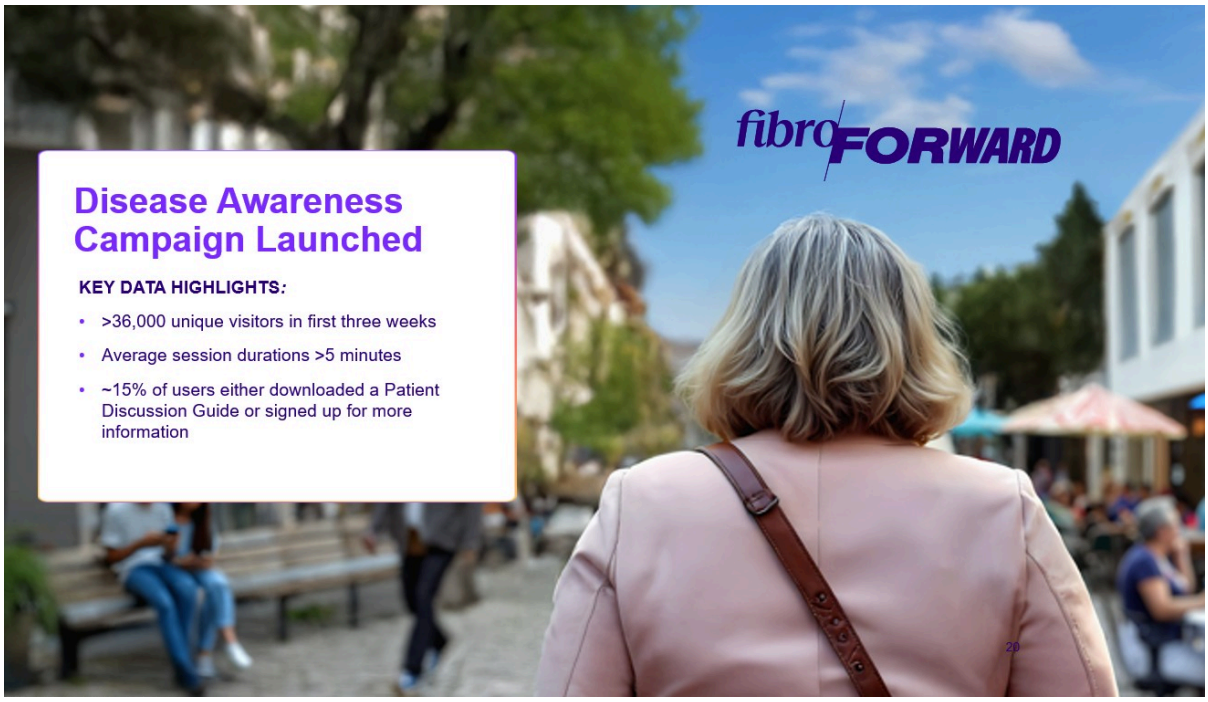
Patient and HCP Dissatisfaction has Led to Significant Off-label Use

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.
Evernana analysis of claims database, May 2024.

TONIX PHARMACEUTICALS


fibroFORWARD
Disease Awareness Campaign Launched
KEY DATA HIGHLIGHTS:
• >36,000 unique visitors in first three weeks
• Average session durations >5 minutes
• ~15% of users either downloaded a Patient Discussion Guide or signed up for more information
20

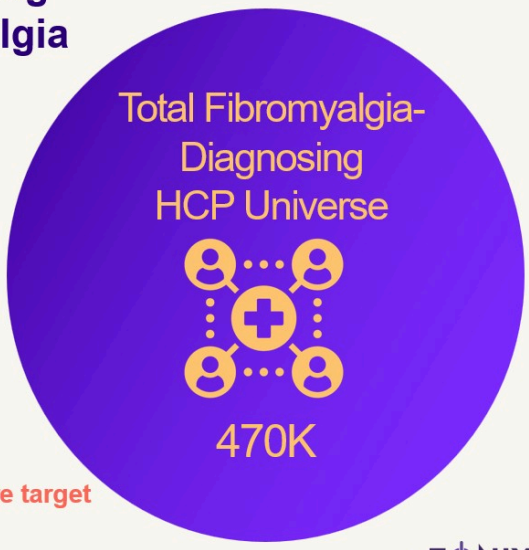
~5% of Fibromyalgia-Diagnosing HCPs Write ~70% of Fibromyalgia Prescriptions[1,2]

WE WILL GO FROM:

Traditional specialty-based decile targeting

TO:

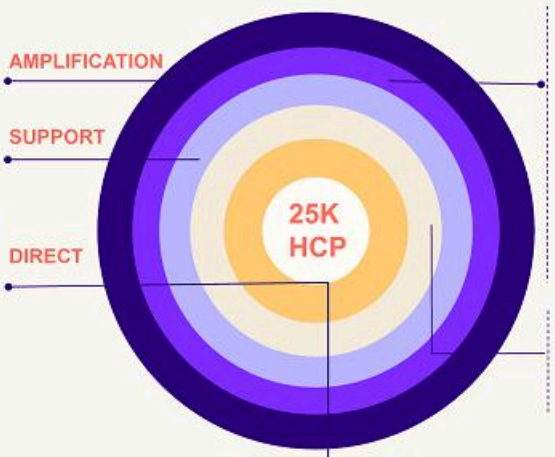
Hyper-focused 1:1 HCP targeting based on ideal patient types → ~25K HCPs



Our *precision strategy* will drive who and how we target

[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.

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

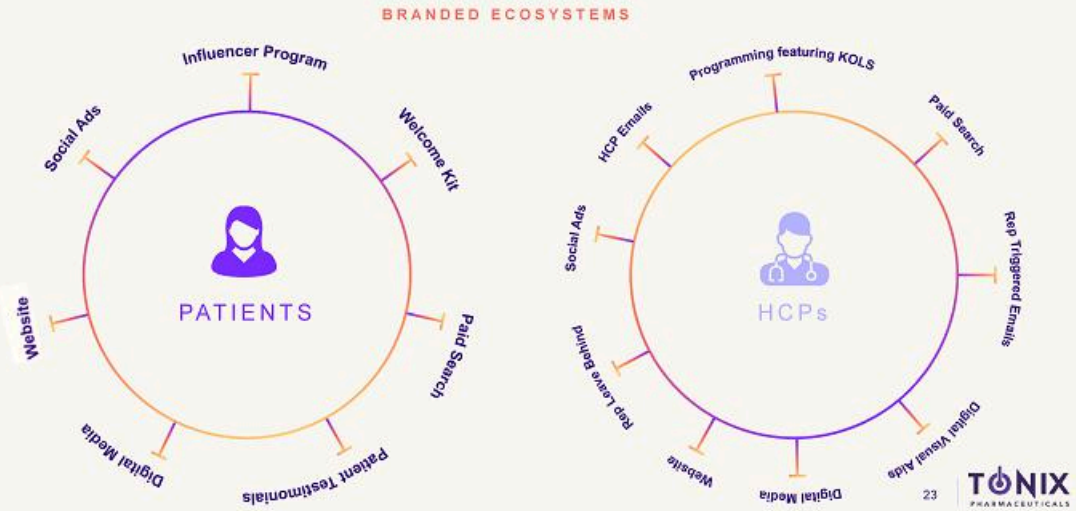
Paid Social

Machine Learning

Sales Force (~90 Reps initially)

TONIX PHARMACEUTICALS

Omnichannel Marketing & Messaging Campaign
Planned to Maximize Reach Within the Retail and Specialty Channels



TONIX PHARMACEUTICALS

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 whom their HCP has determined Tonmya™ is appropriate for them.

Building a Market Leader

Q3 2025

- Sales force onboarding
- HCP & Patient Omnichannel education and awareness campaign launch

Q4 2025

- Commercial and sample availability
- Sales representatives in field & tele-sales campaign initiated

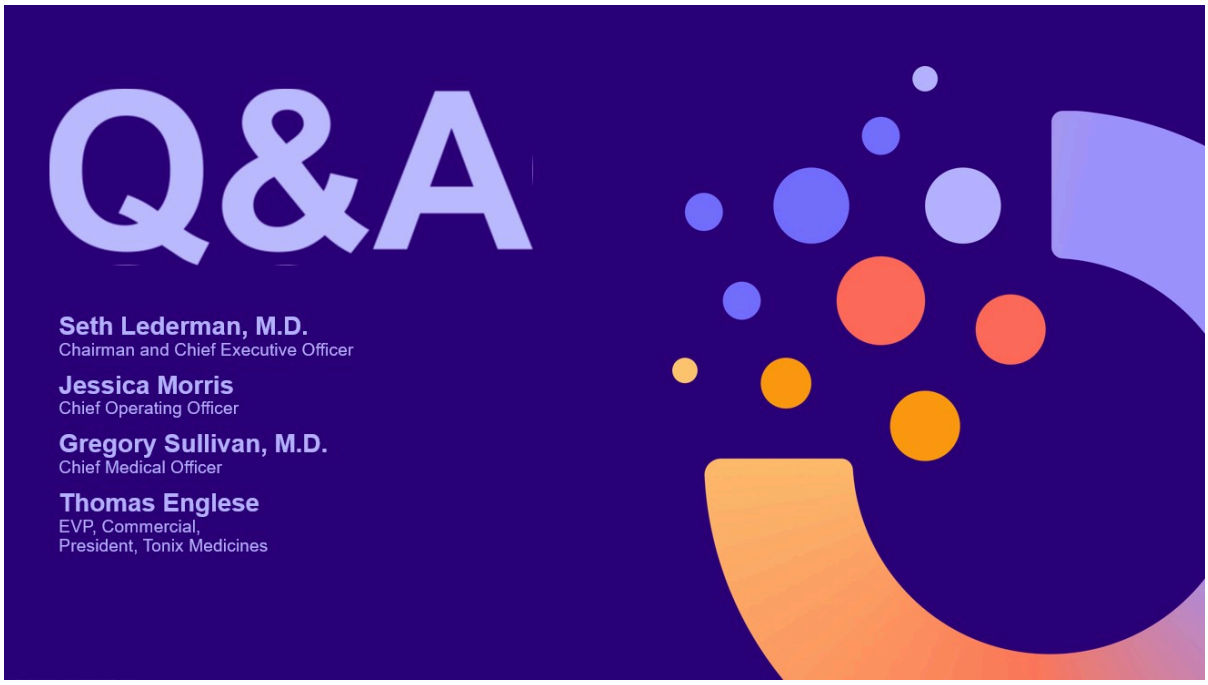
Q1 2026

- Plan to expand commercial access
- Ramp up of educational speaker programs

Q2 2026

- Expect increased access
- Launch broader digital advertising campaign


Tonmya™
Unlocking Transformational Potential in Treating Fibromyalgia
First FDA-approved medicine for the treatment of fibromyalgia in over 15 years
First-in-class medicine; non-opioid analgesic
Demonstrated rapid and durable improvement in chronic widespread pain and was generally well tolerated
Large market opportunity with significant unmet need
10M potential patients; 2.7M diagnosed and treated patients
High level of patient and HCP dissatisfaction with current therapies
Prepared and poised for commercial launch targeted for Q4 2025
Commercial activities underway
No debt; anticipated cash runway to support launch and other operations, into Q3 2026
TONIX PHARMACEUTICALS


Q&A
Seth Lederman, M.D.
Chairman and Chief Executive Officer
Jessica Morris
Chief Operating Officer
Gregory Sullivan, M.D.
Chief Medical Officer
Thomas Englese
EVP, Commercial,
President, Tonix Medicines

TONMYA™ (cyclobenzaprine hydrochloride sublingual tablets)

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

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.

TONIX PHARMACEUTICALS

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.

TONIX PHARMACEUTICALS