
**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): September 8, 2026

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-36019
(Commission
File Number)

26-1434750
(IRS Employer
Identification No.)

200 Connell Drive, Suite 3100, Berkeley Heights, New Jersey 07922
(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 Global Select 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 8.01 Other Events.

On September 8, 2026, Tonix Pharmaceuticals Holding Corp. (the “Company”) announced the appointment of Thomas Englese as the Company’s Chief Commercial Officer, effective immediately.

Item 9.01 Financial Statements and Exhibits.

(d)	Exhibit	
	No.	Description.
	99.01	Press Release of the Company, September 8, 2025
	104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

TONIX PHARMACEUTICALS HOLDING CORP.

Date: September 8, 2026

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



Tonix Pharmaceuticals Promotes Thomas Englese, MBA, to Chief Commercial Officer

Mr. Englese's leadership of Tonix's commercial organization since 2024 has included the go-to-market strategy and U.S. launch of TONMYA[®], with growth across sales, managed care, and patient access

BERKELEY HEIGHTS, N.J., **September 8, 2026** (GLOBE NEWSWIRE) — Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully integrated, commercial-stage biopharmaceutical company, today announced the promotion of Thomas Englese to Chief Commercial Officer, effective immediately. Mr. Englese has served as Tonix's Executive Vice President, Commercial Operations, since September 2024. He will continue to direct sales, marketing, market access, and commercial operations for TONMYA (cyclobenzaprine HCl sublingual tablets) for the treatment of fibromyalgia in adults, and Zembrace[®] SymTouch[®] (sumatriptan injection) and Tosymra[®] (sumatriptan nasal spray) for the treatment of acute migraine in adults.

"Tom has been instrumental to the formation of Tonix's commercial organization and launch of TONMYA, a first-in-class, non-opioid analgesic for the treatment of fibromyalgia," said Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals. "Tom's vision and leadership have shaped a high-performing, patient-centric team at Tonix. Promoting Tom to serve as our first Chief Commercial Officer is an important milestone for the Company. We believe we are well positioned to bring TONMYA as a treatment option to more fibromyalgia patients and create stakeholder value."

Thomas Englese, MBA, Chief Commercial Officer of Tonix Pharmaceuticals, added, "I am honored to be promoted to Chief Commercial Officer of Tonix as we expand the launch of TONMYA more broadly to new healthcare providers and more deeply to current prescribers. I believe our exceptional team has the potential to achieve Tonix's mission of making a difference for patients with fibromyalgia and migraine patients. We have had an encouraging start to our launch as patients are introduced to and prescribed TONMYA. I am proud of our team's progress with our access wins and increased awareness of TONMYA and fibromyalgia, and encouraging trends across our launch key performance indicators. Our launch priorities remain clear, and we will continue to focus on expanding access, growing patients and prescribers, and increasing sales."

Mr. Englese brings extensive industry experience building and scaling large global commercial organizations, overseeing strategy and P&Ls for multi-million- and billion-dollar products across therapeutic areas, launching products, and supporting cross-organizational business functions. Prior to Tonix, Mr. Englese served as Chief Commercial Officer of Tris Pharmaceuticals, where he was responsible for the ADHD global brand business, and Aziyo, where he was responsible for the cardiac and soft tissue business and serving on the initial public offering (IPO) leadership team. At Mallinckrodt plc, formerly Ikaria Inc., Mr. Englese served as Senior Vice President and General Manager of North America Hospital Therapies, Vice President and General Manager of Global Critical Care, and Vice President of Customer Operations, responsible for the North America franchise. Earlier in his career, he was Senior Director of Business Operations, Global Analytics, and a Finance Manager at Baxter Healthcare International, and he held positions at Pfizer and Wells Fargo. Mr. Englese received an MBA in finance from Pennsylvania State University and a B.S. in marketing from Villanova University.

Tonix Pharmaceuticals Holding Corp.

Tonix Pharmaceuticals* is a fully integrated, commercial-stage biopharmaceutical company focused on central nervous system (CNS) disorders, infectious diseases, and immunology conditions with high unmet medical needs. TONMYA[®] (cyclobenzaprine HCl sublingual tablets 2.8mg), the Company's flagship internally conceived and developed medicine, is the first treatment for fibromyalgia in more than 15 years. Tonix's CNS commercial infrastructure supports its marketed products, including its acute migraine products, Zembrace[®] SymTouch[®] (sumatriptan injection 3 mg) and Tosymra[®] (sumatriptan nasal spray 10 mg). Tonix is extending the science behind TONMYA in Phase 2 clinical studies to evaluate the potential of TNX-102 SL in major depressive disorder and acute stress disorder/acute stress reaction. Tonix is also advancing a pipeline of infectious disease programs, including Phase 2-ready monoclonal antibody TNX-4800 (anti-OspA mAb) for Lyme disease prevention in the U.S. and TNX-801 (horsepox, live virus vaccine), a vaccine in development for the prevention of mpox and smallpox. Within immunology, TNX-1500 (anti-CD40L mAb) is a Phase 2-ready, third-generation CD40 ligand inhibitor for the prevention of kidney transplant rejection. To learn more, visit www.tonixpharma.com.

**Tonix's product development candidates, including TNX-102 SL for new, unapproved indications, are investigational new drugs or biologics. Their efficacy and safety have not been established and have not been approved for any indication.*

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. TONMYA is a registered trademark of Tonix Pharma Limited. All other marks are property of their respective owners.

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. 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 in the Company’s Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 12, 2026, and periodic reports filed with the SEC on or after the date thereof. Tonix does not undertake an obligation to update or revise any forward-looking statement. 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.

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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 $\geq 2\%$ 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.
