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): **May 12, 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) 904-8182**

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 2.02 Results of Operations and Financial Condition

On May 12, 2025, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter ended March 31, 2025. A copy of the press release that discusses these matters is filed as Exhibit 99.01 to, and incorporated by reference in, this report.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	**Description.**
99.01	Press Release of the Company, dated May 12, 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: May 12, 2025

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

EXHIBIT 99.01

Tonix Pharmaceuticals Reports First Quarter 2025 Financial Results and Operational Highlights

FDA PDUFA goal date of August 15, 2025, for TNX-102 SL for the management of fibromyalgia; if approved, TNX-102 SL would become the first new drug for treating fibromyalgia in more than 15 years

Announced positive topline results from Phase 1 study of TNX-1500, a next generation anti-CD40L mAb candidate in development for prevention of kidney transplant rejection and treatment of autoimmune disorders

Cash and cash equivalents of $131.7 million reported as of March 31, 2025; Current cash sufficient to fund operations into the second quarter of 2026

CHATHAM, N.J., May12, 2025 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, today announced financial results for the first quarter ended March 31, 2025, and provided an overview of recent operational highlights.

"We believe TNX-102 SL (cyclobenzaprine HCl sublingual tablets)* is on track to become a new therapeutic option for patients suffering with fibromyalgia," said Seth Lederman, M.D., Chief Executive Officer of Tonix. "TNX-102 SL would be the first member of a new class of FDA approved drugs for fibromyalgia. TNX-102 SL is a non-opioid analgesic that targets fibromyalgia's characteristic disturbed sleep to improve the widespread pain of fibromyalgia, while also being well tolerated. Our focus continues to be on the upcoming U.S. Food and Drug Administration (FDA) Prescription Drug User Fee Act (PDUFA) goal date of August 15, 2025, for a decision on the market authorization on TNX-102 SL for the management of fibromyalgia. We are building out our commercial team for the anticipated product launch in the fourth quarter of this year. Tonix believes it has sufficient cash to fund operations beyond these key milestones."

Dr. Lederman continued, "Beyond TNX-102 SL for fibromyalgia, we are encouraged by the continued achievements in our pipeline, including positive Phase 1 results for TNX-1500, a next generation anti-CD40L Fc-modified humanized monoclonal antibody (mAb) in development for prevention of kidney transplant rejection and pre-clinical results for TNX-801, a live-virus vaccine in development for preventing mpox and smallpox. We look forward to providing additional updates to each of these promising programs in 2025."

Key Investigational Product Candidates* -- Recent Highlights

Central Nervous System (CNS) Pipeline

TNX-102 SL (cyclobenzaprine HCl sublingual tablets): 5.6 mg, once-daily at bedtime small molecule for the management of fibromyalgia (FM) – a centrally-acting, non-opioid analgesic.

- In March 2025, Tonix announced that FDA will not require an Advisory Committee meeting to discuss the Company's New Drug Application (NDA) for TNX-102 SL for the management of fibromyalgia. The FDA previously granted Fast Track designation to TNX-102 SL for the management of fibromyalgia in 2024, a designation intended to expedite FDA review of important new drugs to treat serious conditions and fill an unmet medical need.
- In December 2024, the NDA for TNX-102 SL for fibromyalgia was accepted by FDA with a PDUFA goal date of August 15, 2025. The NDA was based upon two Phase 3 studies of TNX-102 SL in fibromyalgia that showed statically significant reduction in the chronic, widespread pain associated with fibromyalgia. TNX-102 SL was generally well tolerated and has no known addictive properties. If approved by the FDA, TNX-102 SL would be the first member of a new class of tertiary amine tricyclic (TAT) non-opioid analgesic drugs for fibromyalgia and the first new drug available for treating fibromyalgia in more than 15 years. Fibromyalgia affects more than 10 million adults in the U.S., most of whom are women.

- In April 2025, Tonix presented data and analyses of TNX-102 SL treatment and effects on fibromyalgia at the American Academy of Pain Medicine (AAPM) 2025 Annual Meeting, held in Austin, Texas, in a poster presentation titled, "*Sublingual Cyclobenzaprine (TNX-102 SL) for Fibromyalgia: Efficacy and Safety in Two Randomized, Placebo-Controlled Trials.*"

- In March 2025, the Company presented data and analyses of TNX-102 SL treatment and effects on fibromyalgia at the 7 th International Congress on Controversies in Fibromyalgia, held in Vienna, Austria, in an oral presentation titled, "*Transmucosal Sublingual Cyclobenzaprine (TNX-102 SL) Treatment of Fibromyalgia at Bedtime to Target Non-Restorative Sleep Showed Durable Pain Reduction in Two Double-Blind Randomized Phase 3 Studies.*"

TNX-102 SL in development for the treatment of acute stress reaction (ASR) and acute stress disorder (ASD), and prophylaxis against development of posttraumatic stress disorder (PTSD)

- The U.S. Department of Defense-funded Optimizing Acute Stress Reaction Interventions (OASIS) trial will be conducted by the University of North Carolina under an investigator-initiated investigational new drug (IND) application. The OASIS trial will examine the safety and efficacy of TNX-102 SL to reduce adverse posttraumatic neuropsychiatric sequelae among patients in the emergency department (ED) after a motor vehicle collision. Fourteen days of bedtime TNX-102 SL will be dosed and tested in the immediate aftermath of motor vehicle collision. The study will test the potential for TNX-102 SL to target trauma-related sleep disturbance and its ability to facilitate recovery from ASR and to prevent PTSD. The program has the potential to provide military personnel with a new treatment option that improves warfighter performance and resilience when administered in the early aftermath of traumatic events in the war theater. The study is expected to be initiated in the second quarter of 2025.

TNX-1300 (recombinant double mutant cocaine esterase): under investigation for biologic for cocaine intoxication

- The National Institutes of Health (NIH)'s National Institute of Drug Abuse (NIDA) previously awarded Tonix a Cooperative Agreement grant for approximately $5 million to support development of TNX-1300.

- TNX-1300 has been granted Breakthrough Therapy designation by the FDA.

- The Company discontinued enrollment and terminated the Phase 2 CATALYST study of its TNX-1300 double-mutant cocaine esterase 200 mg, *i.v.* solution product candidate for the treatment of cocaine intoxication because enrollment in this emergency department-based study was slower than projected. The Company is evaluating new study designs and new endpoints for further development of TNX-1300. The CATALYST study was not discontinued for safety or efficacy reasons.

Immunology Pipeline

TNX-1500 (anti-CD40L Fc-modified humanized monoclonal antibody): third generation anti-CD40L monoclonal antibody under investigation for prophylaxis for organ transplant rejection and treatment of autoimmune disorders.

- In February 2025, Tonix announced positive topline results from its Phase 1, single ascending dose (SAD) first-in-human trial of TNX-1500 in healthy participants. The objectives of the Phase 1 trial were to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of intravenous TNX-1500, as well as to support dosing in a planned Phase 2 trial in kidney transplant recipients, pending alignment with the FDA. All objectives were met and support proceeding to a Phase 2 trial. TNX-1500 blocked the primary and secondary antibody responses to a test antigen at the 10 mg/kg and 30 mg/kg i.v. doses, showed mean half-life of 34-38 days for the 10 mg/kg and 30 mg/kg doses (supporting monthly dosing for future efficacy trials) and was generally well-tolerated with a favorable safety profile.

- The first proposed indication for TNX-1500 is prophylaxis of organ rejection in adult patients receiving a kidney transplant; but multiple additional indications are possible, including the treatment of autoimmune diseases. Preclinical studies have shown that TNX-1500 maintains the activity of first-generation monoclonal antibodies (mAbs), yet with reduced risk of thrombotic complications. Pharmacokinetic data support a monthly *i.v.* dosing regimen. This analysis together with TNX-1500's activity and tolerability in animal models, suggests that the protein engineering of TNX-1500's Fc region has achieved its design goals.

Infectious Disease Pipeline

TNX-801 (recombinant horsepox virus, minimally replicative live vaccine): potential vaccine to protect against mpox and smallpox.

- In April 2025, the company presented data on TNX-801 in an oral presentation at the World Vaccine Congress Washington 2025, held in Washington, D.C. The presentation titled "*A Novel Single-Dose, Attenuated Live, Minimally Replicative Mpox Vaccine*" highlighted positive preclinical efficacy data, demonstrating that TNX-801 protected animals from mpox and rabbitpox and was well tolerated, even in immunocompromised animals. Durable protection of rabbits from lethal rabbitpox infection was present six months after vaccination. In September 2024, Tonix announced that the WHO's preferred target product profile (TPP), released at the WHO sponsored Mpox Research and Innovation Scientific Conference, aligns with the characteristics of TNX-801.

- In March 2025, Tonix announced it was awarded a grant from the Medical CBRN Defense Consortium (MCDC) to support the development of TNX-801. The grant will allow Tonix to develop a commercialization plan for TNX-801.

Corporate and Partnerships – Recent Highlights*

- In April 2025, the Company announced it has entered into a collaborative research agreement with Makana Therapeutics, a global leader in the field of xenotransplantation, to study Tonix's anti-CD40L (CD40 ligand, also called CD154) monoclonal antibody candidate, TNX-1500, in combination with Makana's human-compatible pig organs and cells for the treatment of organ failure. TNX-1500 is an investigational, humanized Fc-modified IgG4 anti-CD40L antibody with high affinity for CD40L. The preclinical research and development collaboration has the potential to span multiple Makana programs including kidney, heart and islet cell xenotransplant.

- In April 2025, Tonix announced the launch of TONIX ONE ™, a fully-integrated digital platform designed to provide resources to help patients better understand and manage their migraine condition. TONIX ONE provides an intuitive, comprehensive journey for patients by offering educational resources about migraine and the limitations of oral medications which can sometimes lead to delayed or ineffective symptom relief. The platform also connects patients directly to independent migraine specialists via telehealth services and e-prescription requests, simplifying and accelerating access to treatment.

- During the first quarter of 2025, the Company announced the promotion of Siobhan Fogarty to Chief Technical Officer and the appointment of Gary Ainsworth as its new Vice President, Market Access.

Financial - Recent Highlight

As of March 31, 2025, Tonix had $131.7 million of cash and cash equivalents, compared to $98.8 million as of December 31, 2024. Net cash used in operations was approximately $16.6 million for first quarter 2025, compared to net cash used in operations of $17.6 for the same period in 2024.

On July 30, 2024, the Company entered into a Sales Agreement with AGP pursuant to which the Company may issue and sell, from time to time, shares of the Company's common stock having an aggregate offering price of up to $250.0 million in at-the-market sales. During the three months ended March 31, 2025, the Company sold approximately 2.7 million shares of common stock for net proceeds of approximately $59.8 million. Subsequent to March 31, 2025, the Company sold 0.6 million shares of common stock under the Sales Agreement, for net proceeds of approximately $9.9 million.

The Company believes that its cash resources at March 31, 2025, along with the net proceeds of $9.9 million raised from equity offerings in the second quarter of 2025, will meet its planned operating and capital expenditure requirements into the second quarter of 2026.

Subsequent to March 31, 2025, the Company repurchased 150,000 of its shares of common stock outstanding under a share repurchase program, for a gross aggregate cost of approximately $2.9 million.

First Quarter 2025 Financial Results

Net product revenue for the first quarter 2025 was approximately $2.4 million compared to $2.5 million for the same period in 2024. Net product revenue consisted of combined net sales of Zembrace® SymTouch® and Tosymra®. Cost of Sales for the first quarter 2025 was approximately $0.9 million compared to $1.7 million for the same period in 2024.

Research and development expenses for the first quarter 2025 were $7.4 million, compared to $12.9 million for the same period in 2024. This decrease is predominantly due to decreased clinical, non-clinical, manufacturing and employee-related expenses.

Selling, general and administrative expenses for the first quarter 2025 were $10.1 million, compared to $9.3 for the same period in 2024. The increase was primarily due to an increase in sales and marketing expenses offset by a decrease in employee-related expenses resulting from a reduction in workforce in earlier 2024.

Net loss available to common stockholders was $16.8 million, or $2.84 per share, basic and diluted, for the first quarter 2025, compared to net loss of $14.9 million, or $535.72 per share, basic and diluted, for the same period in 2024. The basic and diluted weighted average common shares outstanding for the first quarter 2025 was 5,927,231 compared to 27,886 shares for the same period in 2024.

About Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully integrated biopharmaceutical company focused on transforming therapies for pain management and vaccines for public health challenges. Tonix's development portfolio is focused on central nervous system (CNS) disorders. Tonix's priority is to advance TNX-102 SL, a product candidate for the management of fibromyalgia, for which an NDA was submitted based on two statistically significant Phase 3 studies for the management of fibromyalgia and for which a PDUFA (Prescription Drug User Fee act) goal date of August 15, 2025 has been assigned for a decision on marketing authorization. In March 2025 the FDA guided that no Advisory Committee Meeting will be required for this NDA. The FDA has also granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction and acute stress disorder under a Physician-Initiated IND at the University of North Carolina in the OASIS study funded by the U.S. Department of Defense (DoD). 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 infectious disease portfolio includes TNX-801, a vaccine in development for mpox and smallpox, as well as TNX-4200 for which Tonix has a contract with the U.S. Department of Defense's (DoD's) Defense Threat Reduction Agency (DTRA) for up to $34 million over five years. TNX-4200 is a small molecule broad-spectrum antiviral agent targeting CD45 for the prevention or treatment of 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 Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

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* 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 obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the failure to successfully market any of our products; risks related to the timing and progress of clinical development of our product candidates; 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
(In Thousands, Except Share and Per Share Amounts)
(unaudited)

	Three months ended March 31,	
	2025	**2024**
REVENUES:		
Product revenue, net	$ 2,429	$ 2,482
COSTS AND EXPENSES:		
Cost of sales	943	1,660
Research and development	7,436	12,863
General and administrative	10,104	9,310
Total operating expenses	18,483	23,833
Operating loss	(16,054)	(21,351)
Grant income	923	—
Gain on change in fair value of warrant liabilities	—	7,005
Loss on extinguishment of debt	(2,092)	—
Other income (expense), net	394	(593)
Net loss available to common stockholders	$ (16,829)	$ (14,939)
Net loss to common stockholders per common share, basic and diluted	$ (2.84)	$ (535.72)
Weighted average common shares outstanding, basic and diluted	5,927,231	27,886

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

	March 31, 2025	**December 31, 2024[1]**
Assets		
Cash and cash equivalents	$ 131,716	$ 98,776
Accounts receivable, net	3,312	3,683
Inventory	8,136	8,408
Prepaid expenses and other	6,409	8,135
Total current assets	149,573	119,002
Other non-current assets	43,297	43,888
Total assets	$ 192,870	$ 162,890
Liabilities and stockholders' equity		
Total liabilities	$ 12,474	$ 23,332
Stockholders' equity	180,396	139,558
Total liabilities and stockholders' equity	$ 192,870	$ 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.

Investor Contact

Jessica Morris
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 799-8599

Peter Vozzo
ICR Healthcare
peter.vozzo@icrhealthcare.com
(443) 213-0505

Media Contact

Ray Jordan
Putnam Insights
ray@putnaminsights.com
(949) 245-5432

About Zembrace SymTouch and Tosymra

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. Visitwww.fda.gov/medwatch, or call 1-800-FDA-1088.