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 11, 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 2.02 Results of Operations and Financial Condition.

On August 11, 2025, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter ended June 30, 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 August 11, 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: August 11, 2025

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

Exhibit 99.01

Tonix Pharmaceuticals Reports Second Quarter 2025 Financial Results and Operational Highlights

FDA PDUFA goal date of August 15, 2025, for TNX-102 SL for fibromyalgia: if approved by FDA, TNX-102 SL would be the first new drug for fibromyalgia in more than 16 years

In June 2025, the Company was added to the Russell 3000® and Russell 2000® Indexes following the annual reconstitution

Phase 3 RESILIENT results published in peer-reviewed journal, Pain Medicine, including statistically significant reduction in fibromyalgia pain with once-nightly TNX-102 SL; generally well tolerated

Cash and cash equivalents of $125.3 million reported as of June 30, 2025; current cash runway expected to fund operations into the third quarter of 2026

CHATHAM, N.J., Aug 11, 2025 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) ("Tonix" or the "Company"), a fully-integrated biotechnology company with marketed products and a pipeline of development candidates, today announced financial results for the second quarter ended June 30, 2025, and provided an overview of recent operational highlights.

"With the U.S. Food and Drug Administration (FDA) Prescription Drug User Fee Act (PDUFA) goal date of August 15, for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for fibromyalgia, we are excited about the potential to make this important new therapy available to patients in the fourth quarter of this year," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "FDA considers fibromyalgia a serious condition and awarded TNX-102 SL Fast Track designation last year. There has been no new treatment for this debilitating condition approved in over 16 years. Additionally, our RESILIENT Phase 3 study results were recently published in the peer-reviewed journal, *Pain Medicine*."

Dr. Lederman continued, "Our pipeline momentum remains strong. In the second quarter, we dosed the first patient in the U.S. Department of Defense (DoD)-funded, investigator-initiated, OASIS trial of TNX-102 SL for acute stress reaction. We also presented new data for our live-virus vaccine, TNX-801, which demonstrated durable single-dose protection against mpox and rabbitpox in animal models. We previously reported positive Phase 1 safety and pharmacokinetic data for TNX-1500, advancing this next-generation anti-CD40L antibody toward a Phase 2 kidney-transplant study. We are well positioned to translate these milestones into meaningful value for patients and shareholders alike."

Key Investigational Product Candidates

Central Nervous System (CNS) Pipeline

TNX-102 SL (cyclobenzaprine HCl sublingual tablets 2.8 mg): two tablets (5.6 mg), once-daily at bedtime for fibromyalgia (FM) – a centrally-acting, non-opioid analgesic.

- In June 2025, Tonix presented a poster at the European Congress of Rheumatology (EULAR 2025) demonstrating that TNX-102 SL produced statistically significant, durable (14-week) pain reduction across two Phase 3 trials.
- In July 2025, Tonix announced online publication of full results from the confirmatory Phase 3 RESILIENT trial of TNX-102 SL in the peer-reviewed journal *Pain Medicine*, showing once-nightly 5.6 mg achieved a statistically significant reduction in fibromyalgia pain versus placebo and was well tolerated; the data confirm the earlier RELIEF study and support the ongoing New Drug Application (NDA) review with an August 15, 2025 PDUFA goal date.

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)

- In May 2025, the first patient was dosed in the Phase 2 investigator initiated OASIS trial evaluating a two week course of TNX102 SL 5.6 mg to reduce the severity of acute stress reaction (ASR) and the frequency of acute stress disorder (ASD); the study is sponsored by the University of North Carolina and supported by a $3 million U.S. Department of Defense grant, with topline results expected in the second half of 2026.

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 May 2025, Tonix reported positive topline data from a Phase 1 single-ascending-dose study in healthy volunteers: TNX-1500 met all safety, pharmacokinetic and pharmacodynamic goals, blocked primary and secondary antibody responses at 10 mg/kg and 30 mg/kg doses with intravenous (*i.v.*) administration, and showed a 34–38-day mean half-life that supports monthly *i.v.* dosing—supporting the path for a planned Phase 2 study to evaluate TNX-1500 for prevention of rejection in kidney allogeneic transplant.

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

- In April 2025, Tonix presented new preclinical data on TNX-801 at the World Vaccine Congress Washington 2025 showing a single subcutaneous (*s.c.*) dose protected animals from mpox and rabbitpox for at least six months, remained well tolerated even in immunocompromised models, and met key attributes in the WHO's preferred target product profile for mpox vaccines.

Corporate and Partnerships

- In May 2025, Tonix appointed Joseph Hand, Esq. as General Counsel and Executive Vice President of Operations, adding more than two decades of legal and operational expertise as the Company prepares for potential TNX-102 SL commercialization.
- In June 2025, Tonix announced that commercial veteran James Hunter joined its Board of Directors, bringing forty years of go-to-market experience to strengthen strategy and governance ahead of the expected TNX-102 SL launch.
- In June 2025, the Company was added to the Russell 3000® and Russell 2000® Indexes following the annual reconstitution, broadening visibility among institutional investors as Tonix approaches key regulatory milestones.

Financials

As of June 30, 2025, Tonix had $125.3 million in cash and cash equivalents, compared with $98.8 million as of December 31, 2024. Net cash used in operations was approximately $31.4 million for the six months ended June 30, 2025, compared to $27.5 million for the same period in 2024.

The Company believes that, based on its current operating plan, its cash on hand at June 30, 2025, together with $51.5 million in net proceeds received from equity offerings during the third quarter 2025, will fund planned operating and capital expenditures into the third quarter of 2026.

Second Quarter 2025 Financial Results

Net product revenue for the three months ended June 30, 2025 was approximately $2.0 million, compared to $2.2 million for the same period in 2024; revenue again reflected combined net sales of Zembrace® SymTouch® and Tosymra®. Cost of sales for the three months ended June 30, 2025 was approximately $3.3 million, compared to $3.4 million for the same period in 2024.

Research and development expenses for the three months ended June 30, 2025 were $10.8 million, compared to $9.7 million for the same period in 2024. The increase was predominately due to increased clinical expenses, nonclinical expenses and manufacturing expenses, reflecting spend on pipeline priorities.

Selling, general and administrative expenses for the three months ended June 30, 2025 were $16.2 million, compared to $7.5 million in 2024. The increase is predominately due to spend on sales and marketing to progress pre-launch activities related to the potential FDA approval of TNX-102 SL for fibromyalgia.

Net loss available to common stockholders was $28.3 million, or $3.86 per share (basic and diluted), for the second quarter 2025, compared to a net loss of $78.8 million, or $1,920.85 per share, for the same period in 2024. The basic and diluted weightedaverage common shares outstanding for the second quarter 2025 were 7,327,257 compared to 41,011 for the same period in 2024.

Tonix Pharmaceuticals Holding Corp.*
Tonix is a fully-integrated biotechnology 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 fibromyalgia, for which an NDA was submitted based on two statistically significant Phase 3 studies for fibromyalgia and for which a PDUFA goal date of August 15, 2025 has been assigned for a decision on marketing authorization. The FDA had also granted Fast Track designation to TNX-102 SL for 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. 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.

* 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
(Dollars In Thousands Except Per Share Amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
REVENUE:				
Product revenues, net	$ 1,998	$ 2,208	$ 4,427	$ 4,690
COSTS AND EXPENSES:				
Cost of sales	3,272	3,367	4,215	5,027
Research and development	10,820	9,698	18,256	22,561
General and administrative	16,202	7,502	26,306	16,812
Asset impairment charges	—	58,957	—	58,957
Total operating expenses	30,294	79,524	48,777	103,357
Operating Loss	(28,296)	(77,316)	(44,350)	(98,667)
Grant income	1,036		1,959	
(Loss) gain on change in fair value of warrant liabilities	—	(855)	—	6,150
Loss on Extinguishment	—	—	(2,092)	—
Interest income, net	943	—	1,571	—
Other expense, net	(1,955)	(605)	(2,189)	(1,198)
Net loss available to common stockholders	$ (28,272)	$ (78,776)	$ (45,101)	$ (93,715)
Net loss per common share, basic and diluted	$ (3.86)	$ (1,920.84)	$ (6.80)	$ (2,720.43)
Weighted average common shares outstanding, basic and diluted	7,327,257	41,011	6,631,111	34,449

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

	June 30, 2025	December 31, 2024[1]
Assets		
Cash and cash equivalents	$ 125,331	$ 98,776
Accounts receivable, net	2,320	3,683
Inventory	5,986	8,408
Prepaid expenses and other	9,898	8,135
Total current assets	143,535	119,002
Other non-current assets	43,824	43,888
Total assets	$ 187,359	$ 162,890
Liabilities and stockholders' equity		
Total liabilities	$ 19,358	$ 23,332
Stockholders' equity	168,001	139,558
Total liabilities and stockholders' equity	$ 187,359	$ 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
investor.relations@tonixpharma.com
(862) 799-8599

Brian Korb
astr partners
(917) 653-5122
brian.korb@astrpartners.com

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

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.