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): July 2, 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 July 2, 2025, Tonix Pharmaceuticals Holding Corp. (the "Company") announced a publication of a paper titled "A CXCR4 Partial Agonist, Improves Immunotherapy by Targeting Immunosuppressive Neutrophils and Cancer-Driven Granulopoiesis" in a peer-review journal, Cancer Cell. A copy of the press release which discusses this matter 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 July 2, 2025, the Company announced a publication in a peer-reviewed journal, Cancer Cell, that represents a collaboration between scientists at the Company and Columbia University's Medical School and presents data demonstrating that treatment with murine TNX-1700 (mTNX-1700) increased survival and decreased metastases in animal models of gastric cancer. The Company believes the published data support further development of TNX-1700 as an approach to overcome resistance to anti-PD-1 immunotherapy, in the treatment of gastric cancer and other tumors. The published studies examined mTNX-1700, which is a fusion protein of murine trefoil factor-2 (mTFF2) and murine serum albumin (MSA). The human version, TNX-1700 is a fusion protein of human TFF2 (hTFF2) and human serum albumin (HSA) that is under development for the treatment of gastric and colorectal cancers.

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 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	Press Release of the Company, July 2, 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: July 2, 2025

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Peer-Reviewed Publication in *Cancer Cell* Journal Highlighting Positive Preclinical Data of mTNX-1700 in Gastric Cancer Animal Models

Combination treatment of mTNX-1700 (mTFF2-MSA fusion protein) with anti-PD1 antibody was associated with increased survival and decreased metastases in animal models of gastric cancer relative to anti-PD1 treatment alone

mTNX-1700 treatment was associated with activation of cancer-killing CD8+ T Cells and limiting neutrophil-mediated immune evasion

TNX-1700 (hTFF2-HSA fusion protein) is in preclinical development for gastric and colorectal cancers

CHATHAM, N.J., July 2, 2025 – 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 the publication of a paper entitled, "A CXCR4 Partial Agonist, Improves Immunotherapy by Targeting Immunosuppressive Neutrophils and Cancer-Driven Granulopoiesis,"[1] in the peer-reviewed journal *Cancer Cell*, that represents a collaboration between scientists at Tonix and Columbia University's Medical School and presents data demonstrating that treatment with murine TNX-1700 (mTNX-1700) increased survival and decreased metastases in animal models of gastric cancer. The manuscript can be accessed here: www.sciencedirect.com/science/article/pii/S1535610825002569.

"Addressing the root causes of resistance to immunotherapy in solid tumors is a hurdle for the successful application of immuno-oncology to anti-PD-1 resistant cancers," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "The combination therapy of mTFF2-MSA with anti-PD1 treatment shows significant promise in reducing the ability of tumors to evade anti-PD-1 therapy in animal models. We believe the published data support further development of TNX-1700 as an approach to overcome resistance to anti-PD-1 immunotherapy in the treatment of gastric cancer and other tumors."

The published studies examined mTNX-1700, which is a fusion protein of murine trefoil factor-2 (mTFF2) and murine serum albumin (MSA). The human version, TNX-1700 is a fusion protein of human TFF2 (hTFF2) and human serum albumin (HSA) that is under development for the treatment of gastric and colorectal cancers.

Dr. Lederman added, "The study showed that in several mouse models, mTNX-1700 plus anti-PD-1 shrank primary tumors, cut liver and lung metastases, and increased survival compared to anti-PD-1 alone. These data show that fine-tuned modulation of CXCR4 can dismantle neutrophil-driven immune suppression and revive checkpoint efficacy without compromising normal myelopoiesis. We are excited, through our collaboration with Columbia University, to continue studies to identify potential clinical biomarkers through preclinical models while enhancing our understanding of the relationship between the role of TFF2 in overcoming resistance to anti-PD1 therapy in the tumor microenvironment (TME)."

Immunosuppressive neutrophils, also known as polymorphonuclear myeloid-derived suppressor cells (PMN-MDSCs), are a major component in solid tumors that significantly hinder anti-tumor activity[2,3]. Despite being short-lived, the continuous replenishment of PMN-MDSCs from the bone marrow sustains

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their potent immunosuppression in the TME[4]. Stromal cells in the TME promote immunosuppression by recruiting MDSCs via secretion of CXCL12. Trefoil Factor 2 (TFF2), a secreted peptide of the trefoil factor family, has displayed activity as a partial agonist of CXCR4[5,6]. The *Cancer Cell* publication describes data demonstrating that TFF2-MSA selectively reduces immunosuppressive neutrophils and cancer-driven granulopoiesis. Treatment with TFF2-MSA, in combination with an anti-PD1 antibody, induced robust anti-tumoral CD8+ T cell responses, inhibiting tumor invasion. This combination of the mTNX-1700 with anti-PD1 therapy has been shown to reduce tumor size and increase survival in these animal models. TFF2 reduction correlated with elevated PMN-MDSCs in gastric cancer patients, highlighting the potential negative correlation between TFF2 and PMN-MDSCs levels while promoting a T-cell rich microenvironment and inducing an increase in CD8+ T cells in the tumor.

About Trefoil Factor Family Member 2 (TFF2)

Human TFF2 is a secreted protein, encoded by the TFF2 gene in humans, that is expressed in gastrointestinal mucosa where it functions to protect and repair mucosa. TFF2 is also expressed at low levels in splenic immune cells and is now appreciated to have intravascular roles in the spleen and in the tumor microenvironment. In gastric cancer, TFF2 is epigenetically silenced, and TFF2 is suggested to be protective against cancer development through several mechanisms. Tonix is developing TNX-1700 for the treatment of gastric and colorectal cancers under a license from Columbia University. The inventor of the core technology at Columbia is Dr. Timothy Wang, who is an expert in the molecular mechanisms of carcinogenesis whose research has focused on the carcinogenic role of inflammation in modulating stem cell functions. Dr. Wang demonstrated that knocking out the mTFF2 gene in mice leads to faster tumor growth and that overexpression of TFF2 markedly suppresses tumor growth by curtailing the homing, differentiation, and expansion of MDSCs to allow activation of cancer-killing CD8+ T cells. He went on to show that a novel engineered form of recombinant murine TFF2 (mTFF2-CTP) had an extended half-life *in vivo* and was able to suppress MDSCs and tumor growth in an animal model of colorectal cancer. Later, he showed in gastric cancer models that suppressing MDSCs using chemotherapy enhances the effectiveness of anti-PD1 therapy and significantly reduces tumor growth. Dr. Wang proposed the concept of employing recombinant TFF2 in combination with other therapies in cancer prevention and early treatment.

[1]Qian, J. et al. *Cancer Cell*. 2025. on-line: https://doi.org/10.1016/j.ccell.2025.06.006.
[2]Kim W, et al. *Gastroenterology*. 2021. 160(3):781-796
[3]Veglia F, et al. *J Exp Med*. 2021. 218(4):e20201803.
[4]Colligan SH, et al. *J Clin Invest*. 2022. 132(23):e158661.
[5]Dubeykovskaya Z, et al. *J Biol Chem*. 2009. 284(6):3650-62.
[6]Dubeykovskaya Z, et al. *Nat Commun*. 2016. 7:10517.

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 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. The FDA has also granted Fast Track designation to TNX-102 SL for the management of fibromyalgia. TNX-102 SL is

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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.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. All other marks are property of their respective owners.

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.

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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.