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): April 9, 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 7.0 Regulation FD Disclosure.

On April 9, 2025, Tonix Pharmaceuticals Holding Corp. (the "Company") announced a collaborative research agreement under which the Company and Makana Therapeutics, Inc. ("Makana") will study the Company's anti-CD40L (CD40 ligand, also called CD154) monoclonal antibody product candidate, TNX-1500, in combination with Makana's human-compatible organs and cells for the treatment of organ failure. A copy of the press release that 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

On April 9, 2025, the Company announced a collaborative research agreement under which the Company and Makana will study TNX-1500 in combination with Makana's human-compatible organs and cells for the treatment of organ failure. The preclinical research and development collaboration has the potential to span multiple Makana programs including kidney, heart and islet cell transplant. The goal of the preclinical studies is to support the submission of an investigational new drug application to the U.S. Food and Drug Administration to support compassionate use for patients undergoing xenotransplantation.

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, dated April 9, 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: April 9, 2025

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

Exhibit 99.01

Tonix Pharmaceuticals and Makana Therapeutics Announce Collaboration Combining Tonix's Anti-CD40L Monoclonal Antibody (TNX-1500) with Makana's Genetically Engineered Organs in Preclinical and Clinical Xenotransplantation Studies

Agreement includes the use of Tonix's TNX-1500, as part of an immunomodulatory regimen to reduce rejection of Makana's genetically engineered pig organs in xenotransplantation

Establishes framework for Makana's kidney, heart and islet cell programs to utilize TNX-1500 for preclinical studies in support of regulatory filings for potential use in human recipients

CHATHAM, N.J. and Miami, Fla., April 9, 2025 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), ("Tonix") a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, and Makana Therapeutics, Inc. ("Makana"), a global leader in the field of xenotransplantation, today announced a collaborative research agreement under which Tonix and Makana will study Tonix's anti-CD40L (CD40 ligand, also called CD154) monoclonal antibody candidate, TNX-1500, in combination with Makana's human-compatible organs and cells for the treatment of organ failure. The preclinical research and development collaboration has the potential to span multiple Makana programs including kidney, heart and islet cell transplant. The goal of the preclinical studies is to support the submission of an investigational new drug application (IND) to the U.S. Food and Drug Administration (FDA) to support compassionate use for patients undergoing xenotransplantation.

"We are excited to partner with Makana in support of our mutual goal to offer novel solutions for patients requiring organ or cellular transplantation," said Seth Lederman, M.D., Chief Executive Officer of Tonix. "We believe this strategic agreement is a promising step towards utilizing xenotransplantation in the clinic. Makana's novel genetically engineered (GE) pigs, which have deleted swine leukocyte antigen (SLA)^2, has shown improved human compatibility and several other advantages over other technologies including high rates of fertility and birthing, which potentially increases their ability to produce viable organs to satisfy a commercial market globally."

"Despite significant progress and momentum in the field of xenotransplantation, improving organ compatibility to prevent rejection remains an ongoing challenge," said Joseph Tector, M.D., Ph.D., Founder of Makana and a practicing transplant surgeon. "This collaboration provides Makana the opportunity to combine its novel GE pig organs with TNX-1500 in our ongoing and future preclinical studies. We view anti-CD40L as a critical part of an effective immunomodulatory regimen for successful xenotransplantation. This collaboration enables us to pursue co-development of our GE organs with the TNX-1500, which has shown best-in-class pharmacokinetics and pharmacodynamics in a human study after showing best-in-class results in preventing rejection in 6-month studies of allo- and xenotransplantation in animals. Our mutual goal is to obtain the best human results as soon as possible."

"We are thrilled with this collaboration utilizing TNX-1500 as an important element of our xenotransplant therapy. The collaboration with Tonix gives Makana the right product and the right partner to bring Makana toward clinical development," said Mark Platt, President and Chief Executive Officer of Makana. "Most organ-failure patients today will never receive a lifesaving/life-changing transplant. Our achievement in developing the SLA DR knockout pig has yielded encouraging results with preclinical kidney xenografts and positions us to deliver strong outcomes in clinical development."

TNX-1500 is an investigational, humanized Fc-modified IgG4 anti-CD40L antibody with high affinity for the CD40 ligand. CD40L is an attractive drug development target for transplant immunomodulation since the engagement of the CD40L plays a pivotal role in immune system activation by modulating both antibody and cellular immune responses.

About Makana's Genetically Engineered (GE) Pigs

Makana began developing pigs for xenotransplantation in 2010. Makana's 2013 creation of the Triple Knockout (TKO) Pig, lacking three key glycans responsible for hyperacute and acute organ rejection in humans, resulted in the first 1-year preclinical xeno-kidney survivor in animals[1]. This discovery revitalized the xeno-field and today Makana's TKO genetics are employed across the xenotransplantation field.

Realizing that the first clinical xenografts failed because of antibody mediated rejection, Makana deferred rushing to the clinic and employed the same stepwise scientific approach to show that these early clinical failures occur because of the development of antibodies against SLA. The final result is that Makana has developed the new TKO plus SLA DR KO pig that eliminates the next barrier to clinical success. Now Makana is poised to achieve longer term clinical success.

Makana has achieved the field's longest and most consistent preclinical survival without the need to insert human transgenes into its pig genetics. Rejection continues as a barrier to survival in the limited number of emergency IND human transplants performed with transgenic pigs, further supporting Makana's focus on antigen discovery and deletion in lieu of relying on inserted transgenes to evade the human immune response.

Without the need for transgenes, the future commercialization of Makana's xeno-organs through breeding will be straightforward. When compared to transgenic animals, Makana's knockout-only pigs will breed with greater efficiency and eliminate the challenge of retaining transgenic expression. This is an important consideration, reducing both the cost of therapy and the complexity of GE pig production.

Makana's preclinical successes with SLA-deleted pig kidneys in animal xenotransplantation has depended on the co-administration of primatized 5c8 anti-CD40L monoclonal antibody. Tonix's TNX-1500 is an Fc-modified version of humanized 5c8, which maintains the activity of 5c8, while improving tolerability.

About TNX-1500

TNX-1500 (Fc-modified humanized anti-CD40L mAb) is a humanized monoclonal antibody that binds and functionally inhibits the CD40-ligand (CD40L), also known as CD154 or 5c8 Ag.[4] The combining sites of TNX-1500 are derived from humanized 5c8 or ruplizumab, which showed promise in treating systemic lupus erythematosus.[5] Chimeric primatized 5c8 showed promise in preventing rejection of organ rejection in animals.[6] TNX-1500 is being developed for the prevention of allograft and xenograft rejection, for the prevention of graft-versus-host disease (GvHD) after hematopoietic stem cell transplantation (HCT) and for the treatment of autoimmune diseases. TNX-1500 prevents rejection, prolongs survival and preserves graft function as a single agent or in combination with other drugs in non-human primate renal and heart allografts and renal xenografts.[7-9]

---

*TNX-1500 is an investigational new biologic and is not approved for any indication

Citations

1. Estrada JL, et al. *Xenotransplantation*. 2015;22(3):194-202.
2. Reyes LM, et al. *J Immunol*. 2014;193(11):5751-7.
3. Lederman S, et al, *J Exp Med.* 1992;175(4):1091-101. doi: 10.1084/jem.175.4.1091. PMID: 1348081; PMCID: PMC2119166.
4. Boumpas DT, et. al. *Arthritis Rheum*. 2003;48(3):719-27. doi: 10.1002/art.10856. PMID: 12632425.
5. Pierson RN 3rd, et al. *Transplantation*. 1999;68(11):1800-5. doi: 10.1097/00007890-199912150-00026. PMID: 10609959.
6. Lassiter G, et al. *Am J Transplant.* 2023;23(8):1171-1181. doi: 10.1016/j.ajt.2023.03.022.
7. Miura S, et al. *Am J Transplant.* 2023;23(8):1182-1193. doi: 10.1016/j.ajt.2023.03.025.
8. Anand, R.P., et al *Nature.* 622, 393–401 (2023). https://doi.org/10.1038/s41586-023-06594-4

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. 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 CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has FDA Breakthrough Therapy designation, and its development is supported by a grant from the U.S. National Institute on Drug Abuse. 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 also has product candidates in development in infectious disease, including a vaccine for mpox, TNX-801. Tonix recently announced a contract with the U.S. DoD's Defense Threat Reduction Agency (DTRA) for up to $34 million over five years to develop TNX-4200, small molecule broad-spectrum antiviral agents 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.

About Makana Therapeutics

Founded in 2009, Makana Therapeutics is focused on developing swine with reduced xenoantigen expression, making human transplantation of cells, tissues and organs from these animals possible. Makana's focus on scientifically validated genetics, optimized pig cloning techniques and careful patient selection is expected to streamline product development and result in safer more efficacious products. For more information on Makana, please visit www.makanatherapeutics.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.

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

For Makana:

Mark Leonard
Next Level Agency
mark@reachthenextlevel.com
847-651-9682

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.
