UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (date of earliest event reported): September 27, 2024

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 7.01 Regulation FD Disclosure.

On September 27, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that the United States Patent and Trademark Office (the "U.S. PTO") issued U.S. Patent No. 12,097,183 (the "Patent") to the Company on September 24, 2024. 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 September 27, 2024, the Company announced that the U.S. PTO issued the Patent to the Company on September 24, 2024. The Patent, entitled "Pharmaceutical Composition for Treating Migraine", claims use of a pre-filled autoinjector comprising a composition of the Company's marketed Zembrace® SymTouch® drug product for treating migraines via subcutaneous administration. The Patent, excluding possible patent term extensions, is expected to provide protection into 2036.

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, September 27, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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

TONIX PHARMACEUTICALS HOLDING CORP.

Date: September 27, 2024

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

EXHIBIT 99.01

Tonix Pharmaceuticals Announces Issuance of U.S. Patent Covering the Subcutaneous Delivery of FDA-Approved *Zembrace® SymTouch®* to Treat Migraines

New patent expected to provide market exclusivity into 2036

Zembrace® SymTouch® (sumatriptan succinate injection) 10mg is indicated for the acute treatment of migraine in adults

CHATHAM, N.J., September 27, 2024 (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 that the United States Patent and Trademark Office issued U.S. Patent No. 12,097,183 to the Company on September 24, 2024. The patent, entitled "Pharmaceutical Composition for Treating Migraine", claims use of a pre-filled autoinjector comprising a composition of Zembrace® SymTouch® for treating migraines via subcutaneous administration. This patent, excluding possible patent term extensions, is expected to provide protection into 2036.

"We are excited to announce the issuance of this additional patent, providing additional protection for our exclusive marketing and sale of FDA-approved Zembrace® for the treatment of migraines," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "We believe Zembrace® is a compelling non-oral option for people who suffer with migraines."

Tonix recently launched a new educational campaign, "Does Your Migraine Pill Work Every Time?" The goal of the campaign is to educate patients and their healthcare providers on the benefits of non-oral migraine medications including nasal and injectable treatment options. Non-oral migraine medications, such as injectables and nasal sprays, do not rely on the digestive system to be absorbed and can offer the potential for faster relief from migraine symptoms in as little as 10 minutes.

Migraine often requires patients to advocate for themselves to develop an effective migraine treatment plan. Empowering patients to understand why they are experiencing delayed or inconsistent relief from oral medications and educating them on other migraine treatment options could ultimately improve their management of migraine symptoms and ultimately enhance their quality of life.

For example, gastroparesis is common before, during, and sometimes in between migraine attacks. Gastroparesis can slow or even block the absorption of oral medications causing delayed, incomplete, or no migraine symptom relief. Tonix will launch a new disease education website, www.gpmigraine.com, for patients who want to learn more about gastroparesis and migraine and why their oral medications do not work.

Dr. Lederman continued, "Tonix is dedicated to educating patients and their healthcare providers on gastroparesis and how non-oral medicines including nasal and injectable medications can help patients manage their migraines. We hope to inspire patients to optimize their migraine treatment plan with non-oral medications."

About Migraine

Nearly 40 million people in the United States suffer from migraine[1] and it has been recognized as the second leading cause of disability in the world[2,3]. Migraine is characterized by debilitating attacks lasting four to 72 hours with multiple symptoms, including pulsating headaches of moderate to severe pain intensity often associated with nausea or vomiting, and/or sensitivity to sound (phonophobia) and sensitivity to light (photophobia)[4].

[1] *Law, H. Z., Chung, M. H., Nissan, G., Janis, J. E., & Amirlak, B. (2020). Hospital Burden of Migraine in United States Adults: A 15-year National Inpatient Sample Analysis. Plastic and reconstructive surgery. Global open, 8(4), e2790. https://doi.org/10.1097/GOX.0000000000002790*

[2] *GBD 2016 Headache Collaborators. Global, regional, and national burden of migraine and tension-type headache, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet Neurol 2018;17(11):954-976.*

[3] *Steiner, T.J., Stovner, L.J., Jensen, R. et al. Lifting the Burden: the Global Campaign against Headache. Migraine remains second among the world's causes of disability, and first among young women: findings from GBD2019. J Headache Pain 21, 137 (2020).*

[4] *Headache Classification Committee of the International Headache Society (IHS). The international classification of headache disorders, 3rd edition. Cephalalgia. 2018;38(1):1–211.*

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully integrated biopharmaceutical company focused on transforming therapies for pain management and modernizing solutions for public health challenges. Tonix's development portfolio is focused on central nervous system (CNS) disorders, and its priority is to submit a New Drug Application (NDA) to the FDA in October 2024 for TNX-102 SL, a product candidate for which two statistically significant Phase 3 studies have been completed for the management of fibromyalgia. The FDA has 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. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic in Phase 2 development designed to treat cocaine intoxication that has Breakthrough Therapy designation. Tonix's immunology development portfolio consists of biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a 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 the areas of rare disease, including TNX-2900 for Prader-Willi syndrome, and infectious disease, including a vaccine for mpox, TNX-801. Tonix recently announced the U.S. Department of Defense (DoD), Defense Threat Reduction Agency (DTRA) awarded it a contract for up to $34 million over five years in an Other Transaction Agreement (OTA) 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, instrumental in progressing this development. 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 and have not been approved for any indication.

This press release and further information about Tonix can be found atwww.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, 2023, as filed with the Securities and Exchange Commission (the “SEC”) on April 1, 2024, 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/Limitations of Use

ZEMBRACE® SymTouch® (sumatriptan succinate) and TOSYMRA® (sumatriptan spray) are indicated for the acute treatment of migraine with or without aura in adults. ZEMBRACE SymTouch and TOSYMRA should only be used where a clear diagnosis of migraine has been established. ZEMBRACE SymTouch and TOSYMRA are not indicated for the prevention of migraine attacks or for the treatment of cluster headache.

Important Safety Information CONTRAINDICATED IN PATIENTS WITH:

- Ischemic coronary artery disease (CAD) or coronary artery vasospasm, including Prinzmetal’s angina
- Wolff-Parkinson-White syndrome or arrhythmias associated with other cardiac accessory conduction pathway disorders
- History of stroke, transient ischemic attack (TIA), or hemiplegic or basilar migraine
- Peripheral vascular disease
- Ischemic bowel disease
- Uncontrolled hypertension
- Recent (i.e., within 24 hours) use of ergotamine-containing or ergot-type medication, or another 5-HT$_1$ agonist
- Concurrent or recent (within 2 weeks) use of a MAO-A inhibitor
- Hypersensitivity to sumatriptan (angioedema and anaphylaxis seen)
- Severe hepatic impairment

WARNINGS AND PRECAUTIONS

- Myocardial ischemia/infarction, Prinzmetal’s angina: These events may occur even in patients without known cardiovascular disease. Perform cardiac evaluation in triptan-naïve patients with multiple risk factors and, if satisfactory, administer first dose of ZEMBRACE SymTouch and TOSYMRA in a medically-supervised setting
- Arrhythmias: Life-threatening disturbances of cardiac rhythm, including ventricular tachycardia and ventricular fibrillation leading to death, have been reported within a few hours following the administration of 5-HT$_1$ agonists. Discontinue ZEMBRACE SymTouch and TOSYMRA if these disturbances occur
- Sensations of chest/throat/neck/jaw pain, tightness, pressure, or heaviness: Commonly occur after treatment with 5-HT$_1$ agonists and are usually non-cardiac in origin. Perform a cardiac evaluation in patients with cardiac risk
- Cerebrovascular Events: Cerebral hemorrhage, subarachnoid hemorrhage, and stroke have occurred in patients treated with 5-HT$_1$ agonists, and some have resulted in fatalities. Discontinue ZEMBRACE SymTouch and TOSYMRA if a cerebrovascular event occurs. Before treating headaches in patients not previously diagnosed as migraineurs, and in migraineurs who present with atypical symptoms, exclude other potentially serious neurological conditions
- Other Vasospasm Reactions: 5-HT$_1$ agonists, including ZEMBRACE SymTouch and TOSYMRA, may cause non-coronary vasospastic reactions, such as peripheral vascular ischemia, gastrointestinal vascular ischemia and infarction, splenic infarction, and Raynaud’s syndrome. In patients who experience symptoms or signs suggestive of a vasospastic reaction following the use of any 5-HT$_1$ agonist, rule out a vasospastic reaction before using ZEMBRACE SymTouch and TOSYMRA
- Medication Overuse Headache: Overuse of acute migraine drugs may lead to exacerbation headache (medication overuse head- ache). Detoxification of patients, including withdrawal of the overused drugs, and treatment of withdrawal symptoms may be necessary

- Serotonin Syndrome: May occur with triptans, including ZEMBRACE SymTouch and TOSYMRA, particularly during co-administration with selective serotonin reuptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), and monoamine oxidase inhibitors (MAOIs). The onset of symptoms usually occurs within minutes to hours of receiving a new or greater dose of a serotonergic medication. Discontinue ZEMBRACE SymTouch and TOSYMRA if serotonin syndrome is suspected
- Increases in Blood Pressure: Significant elevation in blood pressure, including hypertensive crisis with acute impairment of organ systems, has been reported in patients treated with 5-HT_1 agonists. Monitor blood pressure in patients treated with ZEMBRACE SymTouch and TOSYMRA
- Hypersensitivity Reactions: Hypersensitivity reactions, including angioedema and anaphylaxis, have occurred in patients receiv- ing sumatriptan. Such reactions can be life threatening or fatal. ZEMBRACE SymTouch and TOSYMRA are contraindicated in patients with a history of hypersensitivity reaction to sumatriptan
- Seizures: Seizures have been reported following administration of sumatriptan, with or without predisposing factors. ZEMBRACE SymTouch and TOSYMRA should be used with caution in patients with a history of epilepsy or conditions associated with a lowered seizure threshold
- Local Irritation (TOSYMRA only): Local irritative symptoms were reported in approximately 46% of patients with TOSYMRA in an open-label trial which allowed repeated use of TOSYMRA over the course of 6 months. The most common of which were application site reaction (eg., burning sensations in the nose), dysgeusia, and throat irritation. Approximately 0.5% of the cases were reported as severe.

ADVERSE REACTIONS

The most common adverse reactions (≥5% and > placebo) were injection site reactions (ZEMBRACE SymTouch only), tingling, dizziness/vertigo, warm/hot sensation, burning sensation, feeling of heaviness, pressure sensation, flushing, feeling of tightness, and numbness/paresthesia.
To report SUSPECTED ADVERSE REACTIONS, contact TONIX Medicines, Inc, at 1-888-869-7633 or FDA at 1-800-FDA-1088 orwww.fda.gov/medwatch.

Please see the full Prescribing Information, including Instructions for Use, for ZEMBRACE SymTouch and TOSYMRA.