

**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): **June 12, 2025**

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-36019
(Commission
File Number)

26-1434750
(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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(d) Effective as of June 12, 2025, the Board of Directors (the "Board") of Tonix Pharmaceuticals Holding Corp. (the "Company"), on the recommendation of its Nominating and Corporate Governance Committee, appointed James Hunter as a member of the Board. Based on his prior employment with the Company, the Board has determined that Mr. Hunter is not independent under the NASDAQ corporate governance listing standards and Item 407(a) of Regulation S-K.

Mr. Hunter was the Company's Executive Vice President, Commercial Operations, from June 2023 to December 2024, and was the founder and Chief Executive Officer of Validus Pharmaceuticals LLC, a privately-held pharmaceutical company, from January 2007 to June 2018. Mr. Hunter's commercial, sales, marketing and market access experience were instrumental in his selection as a member of the Board.

Mr. Hunter will be compensated in accordance with the Company's standard non-employee director compensation plan and received a stock option grant on June 12, 2025, of 7,740 options, having an exercise price of \$34.54, and which vests on the day of the Company's 2026 annual shareholder meeting.

Transactions with Related Parties

In connection with his employment with the Company, Mr. Hunter received approximately \$25,000 in consulting fees during the period beginning January 1, 2025 and ending June 1, 2025, and approximately \$215,000 in compensation during the year ended December 31, 2024.

Item 8.01 Other Events

On June 13, 2025, the Company issued a press release announcing Mr. Hunter's appointment to the Board. A copy of the press release that discusses this matter is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

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	Description.
	No.	
	<u>99.01</u>	<u>Press Release of the Company, June 13, 2025</u>
	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: June 13, 2025

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

Tonix Pharmaceuticals Announces Appointment of Commercial Industry Veteran, James “Jim” Hunter, to Board of Directors

Mr. Hunter brings more than 40 years of experience building and leading commercial organizations in the biopharmaceutical industry, including leadership roles at Validus Pharmaceuticals, Relialab and Novartis

Led launch of Tonix Medicines, acquisition of migraine assets Zembrace® SymTouch® and Tosymra®, and recruitment of commercial leadership team

Appointment strengthens commercial strategy and governance as Tonix prepares for potential launch of TNX-102 SL for fibromyalgia this year

CHATHAM, N.J., June 13, 2025 – 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 the appointment of James “Jim” Hunter to its Board of Directors, effective June 12, 2025. Mr. Hunter most recently served as Executive Vice President, Commercial at Tonix, where he was responsible for building the Company’s commercial subsidiary, Tonix Medicines, and successfully executing its entry into the migraine market.

“Jim’s appointment to our Board comes at a pivotal moment as we continue to expand our commercial footprint and intensify our pre-commercial efforts for the potential launch of TNX-102 SL for fibromyalgia later this year,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “Having successfully built Tonix Medicines from the ground up, Jim brings a unique operational perspective and deep commercial expertise that will be invaluable as we advance our commercial strategy and long-term growth.”

In his role as Executive Vice President of Commercial Operations at Tonix Pharmaceuticals and President of Tonix Medicines from June 2023 to December 2024, Mr. Hunter was responsible for managing all aspects of Tonix’s commercial efforts, including sales, marketing, market access and other operational and strategic initiatives. In addition to its ongoing commercial activities with respect Tosymra and Zembrance, Tonix Medicines is actively involved in TNX-SL 102 pre-launch activities including launch strategy, market analysis, product positioning, and market access initiatives.

Previously, Mr. Hunter was CEO and Co-founder of Validus Pharmaceuticals from 2007 to 2018, where he was responsible for more than two dozen successful product acquisitions from companies such as Shire, Roche, Novartis and Sanofi. Jim was also Co-Founder of Relialab, a diagnostics company focused on CLIA-waived, point-of-care psychiatric testing. Prior to these ventures, Mr. Hunter was Executive Director of Neuroscience Sales at Novartis Pharmaceuticals, where he launched and supported products in schizophrenia, epilepsy, migraine, Parkinson’s and Alzheimer’s. Mr. Hunter also served as Executive Director of the Northeast Business Unit at Ciba Geigy Pharmaceuticals, where he was responsible for the General Practice and hospital sales force and Regional Managed Care. Mr. Hunter received his B.S. at Seton Hall University and earned his M.B.A at Fairleigh Dickinson University.

“I’m honored to join Tonix’s Board at such an exciting juncture,” said Mr. Hunter. “It’s been a privilege to help build Tonix Medicines and launch the Company’s commercial capabilities. I look forward to continuing to support Tonix’s mission as a member of the Board and contributing to its next phase of growth.”

“I’m grateful to Jim for creating and building our commercial department which has positioned us well to launch TNX-102 SL for the management of fibromyalgia,” said Thomas Englese, EVP of Commercial Operations and leader of Tonix Medicines. “Jim’s continued strategic involvement as we prepare for the launch and continue to build our commercial infrastructure will be incredibly valuable.”

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 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.

Zembrance 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.
