

**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 10, 2024

**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 7.01 Regulation FD Disclosure.**

On September 10, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced the appointment of Thomas Englese as Executive Vice President of Commercial Operations, effective immediately. The Company also provided an update on the timing of the filing of its New Drug Application with the U.S. Food and Drug Administration ("NDA") for its TNX-102 SL product candidate for fibromyalgia to October 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 10, 2024, the Company announced the appointment of Thomas Englese as Executive Vice President of Commercial Operations, effective immediately. The Company also provided an update on the timing of the filing of its NDA for TNX-102 SL to October 2024.

*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)	<b>Exhibit No.</b>	<b>Description</b>
	<a href="#">99.01</a>	Press Release of the Company, September 10, 2024
	104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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 10, 2024

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

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**Tonix Pharmaceuticals Announces Appointment of Thomas Englese as Executive Vice President of Commercial Operations**

*Thomas brings more than 20 years of commercial and operations experience in the biopharmaceutical industry to Tonix*

*Tonix is on track to submit an NDA for TNX-102 SL for fibromyalgia in October of 2024*

CHATHAM, N.J., September 10, 2024 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announced the appointment of Thomas (Tom) Englese as Executive Vice President of Commercial Operations, effective immediately. Mr. Englese brings significant leadership across several functions, including commercial operations, sales and marketing, and launching and managing major brands through all stages of commercialization.

“Tom brings extraordinary biopharmaceutical expertise as an industry leader with more than 20 years of commercial experience and a proven track record of launching and building commercial strategies and executing strategic growth planning,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “We expect to submit the NDA for TNX-102 SL for fibromyalgia, a critical milestone for this program, in October of this year. Tom will be a valuable addition to Tonix as we advance the fibromyalgia program toward launch, and further build out our existing commercial and marketing capabilities.”

Mr. Englese offers breadth and depth of knowledge across numerous therapeutic areas and in different leadership positions. Prior to joining Tonix, he was the Chief Commercial Officer at Tris Pharmaceuticals, where he managed all commercial aspects of the company and was responsible for the re-branding, growth, and launch strategies for the ADHD business. Prior to Tris, Mr. Englese was Chief Commercial Officer at Aziyo Biologics where he set the strategic direction for the commercial organization for a diverse range of therapeutic businesses. Previously, Mr. Englese spent 11 years in various roles at Mallinckrodt PLC (formerly Ikaria Inc.), culminating in serving as the Senior Vice President and General Manager of North America Hospital Therapies. At Mallinckrodt, he was responsible for setting strategic direction and objectives to ensure alignment to corporate objectives for a +\$1 billion North America franchise, and was accountable for the launch teams for several new products. Mr. Englese holds a Master of Business Administration in Finance from Pennsylvania State University and a Bachelor of Science in Marketing with a Minor in Communications from Villanova University. Mr. Englese succeeds the Company’s current EVP, Commercial Operations, Jim Hunter, who is stepping down to pursue retirement.

“I am excited to join Tonix at this important point in the Company’s growth,” said Mr. Englese. “I look forward to working with the Tonix leadership team to advance TNX-102 SL and if approved, help bring it to patients who could benefit from its differentiated activity and profile.”

**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 of 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<sup>®</sup> SymTouch<sup>®</sup> (sumatriptan injection) 3 mg and Tosymra<sup>®</sup> (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.

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines.

This press release and further information about Tonix can be found at [www.tonixpharma.com](http://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, 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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