

**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): October 1, 2026

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.)

200 Connell Drive, Suite 3100, Berkeley Heights, New Jersey 07922
(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 Global Select 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 8.01 Other Events.

On October 1, 2026, Tonix Pharmaceuticals Holding Corp. (the "Company") received a notice (the "Notice") from Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") stating that DRL filed an Abbreviated New Drug Application ("ANDA") containing a Paragraph IV patent certification with the U.S. Food and Drug Administration ("FDA") for a generic version of the Company's drug, TONMYA® (cyclobenzaprine hydrochloride) sublingual tablets, 2.8 mg. The Notice states that the Paragraph IV patent certification was made with respect to U.S. Patent Nos. 9636408, 9956188, 10117936 and 10864175 listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. A Paragraph IV patent certification is a certification by a generic applicant that, in the opinion of that applicant, the patent listed in the Orange Book for a branded product is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the generic product. Under the Federal Food, Drug, and Cosmetic Act and the FDA's implementing regulations, the filing of a patent infringement lawsuit within 45 days of the receipt of notice of a Paragraph IV patent certification automatically prevents the FDA from approving the ANDA until the earliest of the expiration of a 30-month period beginning on the receipt of the Notice by the patent owner, the expiration of the patents, the entry of a settlement order or consent decree stating that the patents are invalid or not infringed, a decision in the infringement case that is favorable to the ANDA applicant, or such shorter or longer period as the court may order. The Company intends to vigorously enforce its intellectual property rights relating to TONMYA against infringement, but cannot predict the outcome of this matter or guarantee the outcome of any litigation. TONMYA is protected by four patents, all of which are listed in the Orange Book.

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, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, including those relating to the Company's review of the Notice, the Company's intention to enforce its intellectual property rights relating to TONMYA, the timing and outcome of any patent infringement litigation, the potential stay of FDA approval of the ANDA, the scope, validity and enforceability of the Company's patents, the potential timing of generic competition for TONMYA, and other statements 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 the Company operates 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 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, including risks related to the outcome of any patent litigation, the possibility that one or more of the Company’s patents may be found invalid, unenforceable or not infringed, the possibility that the FDA may approve the ANDA or other generic applications, the costs and management attention associated with litigation, and the impact of generic competition on sales of TONMYA. Such factors also include those set forth in the Company’s filings with the Securities and Exchange Commission (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 Current Report on Form 8-K. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

SIGNATURE

Pursuant to the requirements 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: October 2, 2026

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