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): November 13, 2026

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.)**

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.

As previously disclosed, 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. 9,636,408, 9,956,188, 10,117,936 and 10,864,175 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.

On November 13, 2026, the Company filed a complaint for patent infringement (the "Complaint") against DRL in the United States District Court for the District of New Jersey. The Complaint alleges that by filing the ANDA, DRL has infringed certain of the Company's Orange Book-listed patents, and seeks an order that the effective date of FDA approval of the ANDA shall be a date no earlier than the expiration of the last to expire of the asserted patents. The timely filing of the Complaint triggers a statutory stay of final FDA approval of DRL's ANDA for up to 30 months, subject to applicable exceptions and court orders.

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 intention to enforce its intellectual property rights relating to TONMYA, the anticipated timing and outcome of the patent infringement litigation, the duration of the stay of final 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, except as required by law.

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: November 13, 2026

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