**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 3, 2021**

# 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 Global 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. ☐

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**Item 7.01 Regulation FD Disclosure.**

On June 3, 2021, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing the poster presentation (the "Poster") of positive results from the Phase 3 RELIEF study of TNX-102 SL for the management of fibromyalgia at the 2021 American Society of Clinical Psychopharmacology ("ASCP") Annual Meeting. Copies of the Poster and press release which discusses this matter are furnished hereto as Exhibits 99.01 and 99.02, respectively, and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.01 and 99.02 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 June 3, 2021, the Company announced the Poster presentation of positive results from the Phase 3 RELIEF study of TNX-102 SL for the management of fibromyalgia at the 2021 ASCP Annual Meeting. The Poster, titled, " *Efficacy and Safety of TNX-102 SL (Sublingual Cyclobenzaprine) for the Treatment of Fibromyalgia in the RELIEF Study: Positive Results of a Phase 3 Randomized, Double-Blind, Placebo-Controlled Multicenter Trial"* shows that TNX-102 SL met its pre-specified primary endpoint in the Phase 3 RELIEF trial, significantly reducing daily pain compared to placebo ($p=0.01$) and was associated with a higher rate than placebo of ≥30% pain responders in participants with fibromyalgia ($p=0.006$). TNX-102 SL at the 5.6 mg dose also showed activity in key secondary endpoints measuring improvements in sleep quality, mitigation of fatigue, and fibromyalgia-specific functional recovery. TNX-102 SL was well tolerated and not associated with side-effects seen with other approved oral fibromyalgia treatments, including weight gain, insomnia, nausea, or sexual dysfunction.

The Company believes that the results of the Phase 3 RELIEF trial validate the mechanism that improved sleep quality can lead to syndromal effects on fibromyalgia, improving pain, sleep and fatigue. The Company believes that the results of the RELIEF study provide evidence that 5.6 mg is the right dose for the targeted patient population. Interim analysis results for the confirmatory Phase 3 study, RALLY, are expected in the third quarter of 2021, followed by topline data in the first quarter of 2022.

*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 results of the Phase 3 RELIEF study, 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 | Poster Presentation |
| 99.02 | Press release of the Company, dated June 3, 2021 |

**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 3, 2021

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

**Exhibit 99.01**

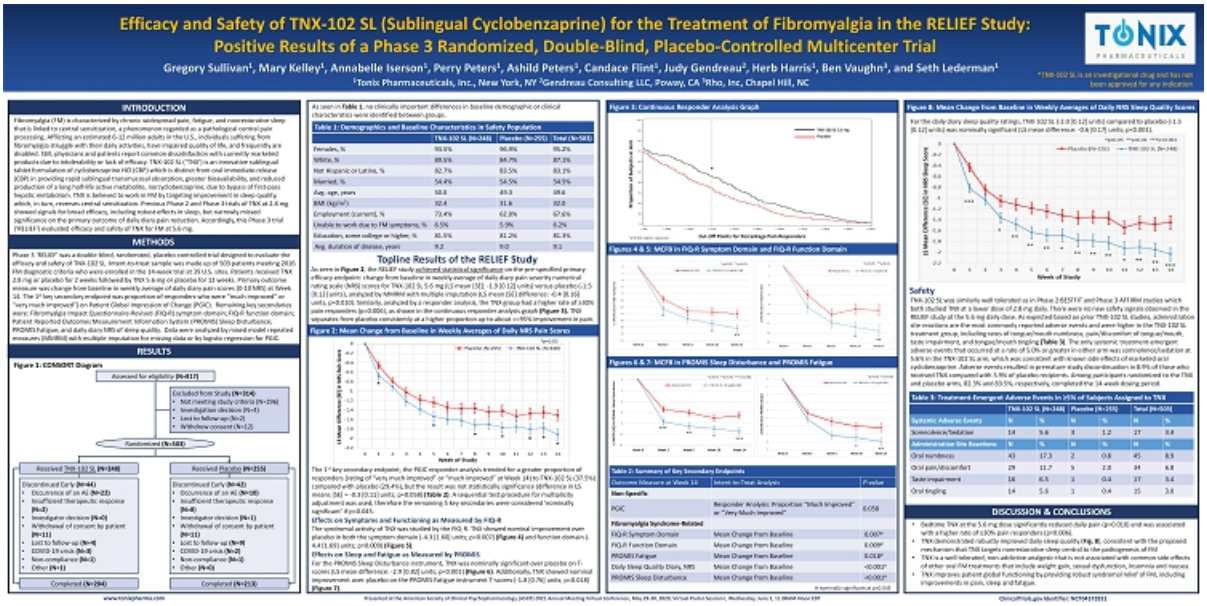

**Exhibit 99.02**

# Tonix Pharmaceuticals Presents Positive Results from Phase 3 RELIEF Study of TNX-102 SL for the Management of Fibromyalgia at the 2021 American Society of Clinical Psychopharmacology (ASCP) Annual Meeting

*Confirmatory Phase 3 Study, RALLY, Ongoing with Interim Analysis Expected in Third Quarter 2021*

CHATHAM, N.J., June 2, 2021 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the poster presentation of positive results from its Phase 3 clinical study, RELIEF, of TNX-102 SL for the management of fibromyalgia. A copy of the poster will be made available under the IR Events tab of the Investors section of the Tonix website at www.tonixpharma.com.

The poster, titled, "*Efficacy and Safety of TNX-102 SL (Sublingual Cyclobenzaprine) for the Treatment of Fibromyalgia in the RELIEF Study: Positive Results of a Phase 3 Randomized, Double-Blind, Placebo-Controlled Multicenter Trial"* shows that TNX-102 SL met its pre-specified primary endpoint in the Phase 3 RELIEF trial, significantly reducing daily pain compared to placebo (p=0.01) and was associated with a higher rate than placebo of ≥30% pain responders in participants with fibromyalgia (p=0.006). TNX-102 SL at 5.6 mg also showed activity in key secondary endpoints measuring improvements in sleep quality, mitigation of fatigue, and fibromyalgia-specific functional recovery. In addition, TNX-102 SL was well tolerated and was not associated with side-effects seen with other approved oral fibromyalgia treatments, including weight gain, insomnia, nausea, or sexual dysfunction.

"We believe the results of the Phase 3 RELIEF trial validate the mechanism that improved sleep quality can lead to syndromal effects on fibromyalgia, improving not only pain but also sleep and fatigue. The sublingual formulation of TNX-102 SL for transmucosal absorption showed promise at the 2.8 mg dose in prior fibromyalgia studies, but we believe RELIEF provides evidence that 5.6 mg is the right dose for this patient population," said Seth Lederman, M.D., President and Chief Executive Officer. "We expect interim analysis results for the confirmatory Phase 3 study, RALLY, in the third quarter of this year, followed by topline data in the first quarter of next year."

**About Fibromyalgia**

Fibromyalgia is a chronic pain disorder that is understood to result from amplified sensory and pain signaling within the central nervous system. Fibromyalgia afflicts an estimated 6-12 million adults in the U.S., approximately 90% of whom are women. Symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled. Physicians and patients report common dissatisfaction with currently marketed products.

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**About TNX-102 SL**

TNX-102 SL is a patented sublingual tablet formulation of cyclobenzaprine hydrochloride which provides rapid transmucosal absorption and reduced production of a long half-life active metabolite, norcyclobenzaprine, due to bypass of first-pass hepatic metabolism. As a multifunctional agent with potent binding and antagonist activities at the serotonin$_{2A}$, $\alpha_1$-adrenergic, histaminergic-$H_1$, and muscarinic-$M_1$ receptors, TNX-102 SL is in clinical development as a daily bedtime treatment for fibromyalgia, PTSD, alcohol use disorder and agitation in Alzheimer's disease. The U.S. Patent and Trademark Office (USPTO) has issued United States Patent No. 9636408 in May 2017, Patent No. 9956188 in May 2018, Patent No. 10117936 in November 2018, Patent No. 10,357,465 in July 2019, and Patent No. 10736859 in August 2020. The Protectic™ protective eutectic and Angstro-Technology™ formulation claimed in these patents are important elements of Tonix's proprietary TNX-102 SL composition. These patents are expected to provide TNX-102 SL, upon NDA approval, with U.S. market exclusivity until 2034/2035.

**About the Phase 3 RELIEF Study**

The RELIEF study has been completed and TNX-102 SL achieved a statistically significant benefit as measured by the primary, prespecified endpoint of improvement over placebo in daily pain. The RELIEF study was a double-blind, randomized, placebo-controlled Phase 3 trial designed to evaluate the efficacy and safety of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the management of fibromyalgia. The two-arm trial targeted enrollment of 470 participants, at approximately 40 U.S. sites. RELIEF completed final enrollment of 503 participants. The first two weeks of treatment were a run-in period in which participants start on TNX-102 SL 2.8 mg (1 tablet) or placebo. After the first two weeks, all participants had the dose increased to TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for 12 weeks. The primary endpoint was daily diary pain severity score change (TNX-102 SL 5.6 mg vs. placebo) from baseline (using the weekly averages of the daily numerical rating scale scores), analyzed by mixed model repeated measures with multiple imputation.

Additional details about the completed RELIEF study are available at clinicaltrials.gov (NCT04172831), and study results are detailed in the poster presentation at ASCP (available under the IR Events tab of the Investors section of the Tonix website at www.tonixpharma.com).

**About the Phase 3 RALLY Study**

The ongoing RALLY study is also a double-blind, randomized, placebo-controlled Phase 3 trial designed to evaluate the efficacy and safety of TNX-102 SL (cyclobenzaprine HCl sublingual tablets). The trial design and endpoints are essentially the same as the RELIEF study; however, the RALLY study is targeting to enroll 200 more participants than the RELIEF study, for a total of 670 participants at approximately 40 U.S. sites. RALLY has already enrolled more than 335 participants for the interim cohort. RALLY will have a planned interim analysis based on the first approximately 335 recruited participants in which an independent data monitoring board (IDMB) will make recommendations to the company to stop early for success, continue as planned, add more participants, or stop for futility. The interim analysis results expected in the third quarter of 2021 followed by topline data in the first quarter of 2022.

Additional details about the ongoing RALLY study are available at clinicaltrials.gov (NCT04508621).

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**Tonix Pharmaceuticals Holding Corp.**

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The Company's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL[1], is in mid-Phase 3 development for the management of fibromyalgia, with positive data from the Phase 3 RELIEF study reported in December 2020. The Company expects interim data from the second Phase 3 study, RALLY, in the third quarter of 2021 and topline data in the first quarter of 2022. Tonix's immunology portfolio includes vaccines to prevent infectious

diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. Tonix's lead vaccine candidate, TNX-1800[2], is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix reported positive efficacy data from animal studies of TNX-1800 in the first quarter of 2021. TNX-801[2], live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

[1] *TNX-102 SL is an investigational new drug and has not been approved for any indication.*

[2] *TNX-1800 and TNX-801 are investigational new biologics and have not been approved for any indication.*

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 failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; 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, 2020, as filed with the Securities and Exchange Commission (the "SEC") on March 15, 2021, and periodic reports filed with the SEC on or after the date thereof. All 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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