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 26, 2020

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.)**

509 Madison Avenue, Suite 1608, New York, New York 10022
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (212) 980-9155

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))

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. ☐

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

Item 5.07. Submission of Matters to a Vote of Security Holders.

On June 26, 2020, Tonix Pharmaceuticals Holding Corp., a Nevada corporation (the "Company"), held a special meeting of shareholders (the "Meeting"). Shareholders representing 32,017,555 shares, or 64.87%, of the Company's common stock outstanding as of the May 5, 2020 record date were represented at the Meeting by proxy. The proposals are described in detail in the Company's proxy statement (the "Proxy") filed with the Securities and Exchange Commission on May 15, 2020, pursuant to Section 14(a) of the Securities Exchange Act of 1934, as amended. At the Meeting, the Company's shareholders voted in favor of Proposal 2 to adjourn the Meeting in the event that the number of shares of common stock present in person or represented by proxy at the Meeting and voting "FOR" the adoption of any proposal specified in the Proxy was insufficient to adopt such proposal. As an insufficient number of votes was cast in favor of Proposal 1 to approve an amendment to the Company's articles of incorporation, as amended, to increase the authorized shares of common stock from 150,000,000 to 400,000,000 ("Proposal 1"), the Meeting was adjourned to allow additional time for the Company's shareholders to vote on Proposal 1. The record date for the Meeting will be reset and the Company will reschedule the Meeting.

Set forth below are the final voting results for the proposal to adjourn the meeting:

Votes For	Votes Against	Votes Abstained
9,223,312	3,310,128	830,216

Item 8.01. Other Events.

On June 29, 2020, the Company updated guidance on the timing of topline results for the Phase 3 RELIEF trial, a potentially pivotal study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg in fibromyalgia. A copy of the press release that discusses this matter is attached hereto as Exhibit 99.01, and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press Release of the Company, dated June 29, 2020

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 29, 2020

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Enrollment of Phase 3 RELIEF Trial of TNX-102 SL for Management of Fibromyalgia is Ahead of Schedule

Topline Results Expected Fourth Quarter 2020 Due to Faster than Previously Projected Enrollment

Completion of Trial Enrollment Anticipated Early Third Quarter 2020

Interim Results from the First 50 Percent of Participants Continue to be Expected in September 2020

NEW YORK, June 29, 2020 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that due to faster-than-expected enrollment, the Company anticipates topline Phase 3 RELIEF results in the fourth quarter of 2020, rather than the first quarter of 2021 as previously guided. RELIEF is a potential pivotal study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg, a non-opioid, centrally acting analgesic, taken daily at bedtime for the management of fibromyalgia. An optional interim analysis of the first 50 percent of randomized participants that are evaluable for efficacy will be conducted, with results expected in September 2020.

“We are pleased to announce that we will achieve our recruitment goal ahead of schedule. We have worked diligently to ensure the safe and timely recruitment of the RELIEF trial before and during the COVID-19 pandemic.” said Seth Lederman, M.D., Chief Executive Officer of Tonix. “Fibromyalgia affects millions of adults globally and we believe that TNX-102 SL has the potential to offer a new, non-addictive treatment option for patients seeking relief from this disorder.”

About the Phase 3 RELIEF Study

The RELIEF study is a double-blind, randomized, placebo-controlled adaptive design trial designed to evaluate the efficacy and safety of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg in fibromyalgia. The trial is expected to enroll approximately 470 participants across approximately 40 U.S. sites. For the first two weeks of treatment, there is 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 have 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 is daily diary pain severity score change from baseline to Week 14 (using the weekly averages of the daily numerical rating scale scores), analyzed by mixed model repeated measures with multiple imputation.

Additional details about the RELIEF study are available at www.theRELIEFstudy.com or clinicaltrials.gov (NCT04172831).

About 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 immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead vaccine candidate, TNX-1800*, is based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects data from animal studies of TNX-1800 in the fourth quarter of 2020. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox and serves as the vector platform on which TNX-1800 is based. Tonix's lead CNS candidate, TNX-102 SL**, is in Phase 3 development for the management of fibromyalgia. The Company expects results from an unblinded interim analysis in September 2020 and topline data in the fourth quarter of 2020. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). The agitation in Alzheimer's disease program is Phase 2 ready with FDA Fast Track designation, and the development program for AUD is in the pre-Investigational New Drug (IND) stage. Tonix's programs for treating addiction conditions also include TNX-1300* (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution), which is in Phase 2 development for the treatment of cocaine intoxication and has FDA Breakthrough Therapy designation. TNX-601 CR (tianeptine oxalate controlled-release tablets) is another CNS program, currently in Phase 1 development as a daytime treatment for depression while TNX-1900, intranasal oxytocin, is in development as a non-addictive treatment for migraine and cranio-facial pain. Tonix's preclinical pipeline includes TNX-1600 (triple reuptake inhibitor) , a new molecular entity being developed as a treatment for PTSD, TNX-1500 (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions, and TNX-1700 (rTFF2), a biologic being developed to treat gastric and pancreatic cancers.

*TNX-1800, TNX-801 and TNX-1300 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is an investigational new drug and has 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 partices; 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, 2019, as filed with the Securities and Exchange Commission (the "SEC") on March 24, 2020, 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.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(212) 688-9421

Travis Kruse (media)
Russo Partners
travis.kruse@russopartnersllc.com
(212) 845-4272

Peter Vozzo (investors)
Westwicke
peter.vozzo@westwicke.com
(443) 213-0505