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 8, 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. ☐

Item 7.01 Regulation FD Disclosure.

On November 9, 2021, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing the poster presentation (the "Poster") of results from its Phase 1 clinical study of TNX-601 CR (tianeptine oxalate and naloxone controlled-release tablets) entitled "*TNX-601 CR*: a Once-Daily Formulation of Tianeptine in Development for the Treatment of Major Depressive Disorder"* at the CNS 2021 Summit. 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 November 8, 2021, the Company presented the Poster of results from its open-label, Phase 1 clinical study of TNX-601 CR (tianeptine oxalate and naloxone controlled-release tablets) for the treatment for major depressive disorder ("MDD") and post-traumatic stress disorder and neurocognitive dysfunction associated with corticosteroid use. The poster provides data related to the Phase 1 pharmacokinetic study in healthy subjects that assessed several novel modified-release ("MR") prototype formulations of tianeptine oxalate. The study showed that the selected TNX-601 MR1 demonstrated pharmacokinetics appropriate for once-daily dosing with minimal food effect, which is a potential treatment adherence advantage over three times per day dosing of immediate release tianeptine sodium. This MR prototype was selected in the development of the final formulation of TNX-601 CR as a once-daily treatment for MDD. The Company believes that these Phase 1 findings support its upcoming Phase 2 study of once-daily TNX-601 CR for MDD in the first half of 2022. Based on the Phase 1 results, the Company believes that with respect to plasma tianeptine and its primary metabolite, TNX-601 CR would meet the bioequivalence standard for daily dosing of these immediate release products. TNX-601 CR's proposed mechanism of action is distinct from any antidepressant approved in the U.S for chronic or long-term use. The Phase 2 study design is expected to be randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of TNX-601 CR monotherapy versus placebo in MDD. Treatment duration will be 6 weeks, preceded by up to 5 weeks in screening and followed by a 2-week safety follow-up period (total up to 13 weeks of participation). The Company plans to randomize approximately 260 individuals with MDD at a 1:1 ratio to two arms of 130 each for drug and placebo at approximately 25-30 US sites. The primary efficacy endpoint will be the change from Baseline to Week 6 in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score. Enrollment is estimated to start in the first half of 2022, pending Investigational New Drug Application clearance by the U.S. Food and Drug Administration.

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 1 clinical study of TNX-601 CR, 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	CNS 2021 Summit Poster Presentation
99.02	Press release of the Company, dated November 9, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 9, 2021

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

Exhibit 99.01

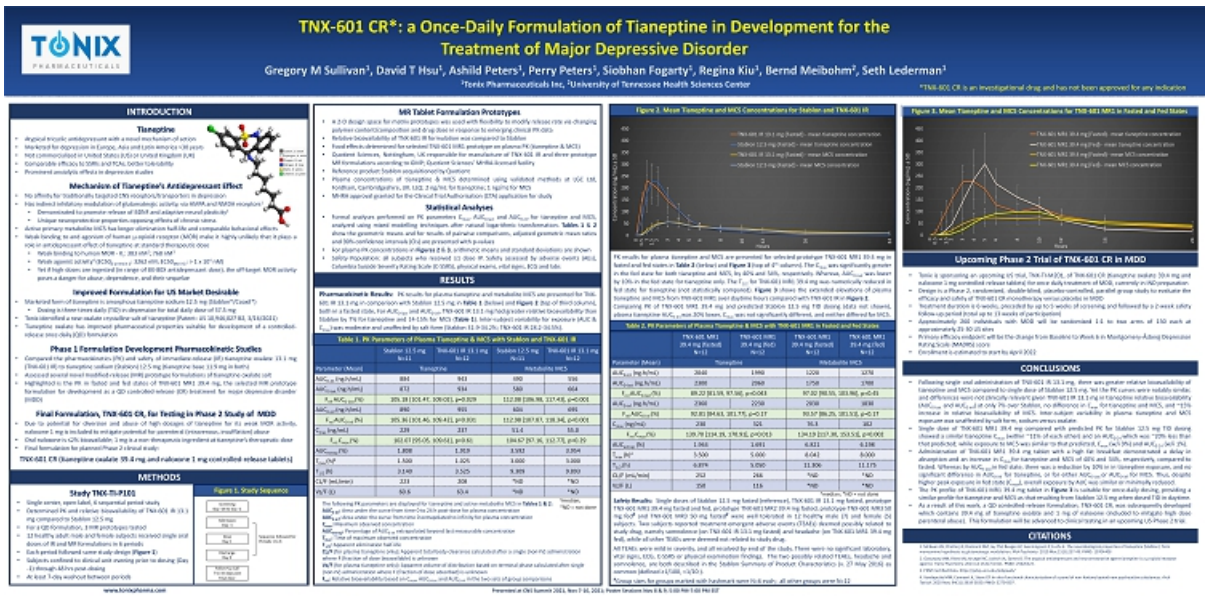

Exhibit 99.02

Tonix Pharmaceuticals Presents Phase 1 Formulation Development Data for TNX-601 CR in a Poster Presentation at CNS Summit 2021

Phase 2 Trial of TNX-601 CR for the Treatment of Major Depressive Disorder Expected to Start First Half 2022

CHATHAM, N.J., November 9, 2021 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced a poster presentation of results from its open-label, Phase 1 clinical study of TNX-601 CR (tianeptine oxalate and naloxone controlled-release tablets). Tonix is developing TNX-601 CR as a potential treatment for major depressive disorder (MDD) as well as post-traumatic stress disorder and neurocognitive dysfunction associated with corticosteroid use. A copy of the poster is available under the IR Events tab of the Investors section of the Tonix website at www.tonixpharma.com. CNS Summit 2021 is taking place November 7th – 10th in Boston, Mass. The poster presentations by Greg Sullivan, M.D., Chief Medical Officer of Tonix Pharmaceuticals, took place on November 8th and will also be presented on November 9th from 5:00 pm – 7:00 pm ET.

The poster, titled, "*TNX-601 CR*: a Once-Daily Formulation of Tianeptine in Development for the Treatment of Major Depressive Disorder"* provides data related to the Phase 1 pharmacokinetic study in healthy subjects that assessed several novel modified-release (MR) prototype formulations of tianeptine oxalate. The study showed that the selected TNX-601 MR1 demonstrated pharmacokinetics appropriate for once-daily dosing with minimal food effect, which is a potential treatment adherence advantage over three times per day dosing of immediate release tianeptine sodium. This MR prototype was selected in the development of the final formulation of TNX-601 CR as a once-daily treatment for MDD.

"We believe that these Phase 1 findings support our upcoming Phase 2 study of once-daily TNX-601 CR for MDD that we expect to initiate in the first half of 2022," said Seth Lederman, M.D., President and Chief Executive Officer of Tonix Pharmaceuticals. "Tianeptine products have been approved in Europe and other countries around the world and marketed as prescription drugs for the treatment of depression for more than three decades. Based on our Phase 1 results, we believe that with respect to plasma tianeptine and its primary metabolite, TNX-601 CR would meet the bioequivalence standard for daily dosing of these immediate release products. No tianeptine-containing product has been approved by the U.S. Food and Drug Administration (FDA). TNX-601 CR's proposed mechanism of action is distinct from any antidepressant approved in the U.S for chronic or long-term use."

Tonix previously completed a Phase 1 clinical trial for formulation development outside of the U.S. Based on this study, the final formulation of TNX-601 CR to be used in Phase 2 testing will be 39.4 mg tianeptine oxalate and 1 mg naloxone for once daily treatment of MDD. Naloxone is included in the formulation to mitigate the potential for high dose parenteral abuse. Tianeptine has weak off-target activity at the μ-opioid receptor that presents the potential for parenteral abuse with doses on the order of eight to 80 times the therapeutic daily dose for depression. The Phase 2 study design is expected to be a randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of TNX-601 CR monotherapy compared to placebo in MDD. Treatment duration will be six weeks, preceded by up to five weeks in screening and followed by a two-week safety follow-up period (total up to 13 weeks of participation). We plan to randomize approximately 260 individuals with MDD at a 1:1 ratio to two arms of 130 each for drug and placebo at approximately 25-30 U.S. sites. The primary efficacy endpoint will be the change from baseline to Week 6 in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score. Enrollment is estimated to start in the first half of 2022, pending clearance of the Investigational New Drug application.

** TNX-601 CR is an investigational new drug and has not been approved for any indication.*

About Depression

According to the National Institute of Mental Health, approximately 17 million adults in the U.S.[1] have had at least one major depressive episode. Depression is a condition characterized by symptoms such as a depressed mood or loss of interest or pleasure in daily activities most of the time for two weeks or more, accompanied by appetite changes, sleep disturbances, motor restlessness or retardation, loss of energy, feelings of worthlessness or excessive guilt, poor concentration, and suicidal thoughts and behaviors. These symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning. The majority of people who suffer from depression do not respond adequately to initial antidepressant therapy.[2]

[1] National Institute of Mental Health. (2017). Major Depression. Retrieved from http://www.nimh.nih.gov/health/statistics/major-depression.shtml
*[2] \Rush AJ, et al. (2007) Am J. Psychiatry 163:11, pp. 1905-1917 (STAR*D Study).*

About TNX-601 CR

TNX-601 CR is a novel oral formulation of tianeptine oxalate designed for once-daily daytime dosing that is in development for the treatment of MDD. Tianeptine sodium (amorphous) immediate release was first marketed for depression in France in 1989 and has been available for decades in Europe, Russia, Asia, and Latin America for the treatment of depression. Tianeptine sodium has an established safety profile from decades of use in these jurisdictions. Currently there is no tianeptine-containing product approved in the U.S. and no controlled-release tianeptine product approved in any jurisdiction. Tonix discovered a novel oxalate salt of tianeptine that may provide improved stability, consistency, and manufacturability compared to known forms of tianeptine. Tianeptine is believed to work in depression as a modulator of the glutamatergic system. Tianeptine modulates the glutamatergic system indirectly since it does not directly bind to NMDA, AMPA or kainate receptors. In animals, tianeptine has been shown to reverse the adverse neuroplastic changes that are observed during periods of stress and elevated corticosteroid exposure. Tianeptine and its MC5 metabolite are weak μ-opioid receptor agonists. Tonix has added naloxone to the TNX-601 CR tablet to mitigate potential for parenteral abuse as tianeptine has been linked to illicit misuse at higher doses than the reported therapeutic dose in the treatment of MDD. Neither tianeptine nor MC5 have been shown to bind other neurotransmitter receptors. Tianeptine's reported pro-cognitive and anxiolytic effects as well as its ability to attenuate the neuropathological effects of excessive stress responses suggest that it may also be used to treat post-traumatic stress disorder by a different mechanism of action than TNX-102 SL.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and diagnostics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of immunology and central nervous system (CNS) product candidates. Tonix's immunology portfolio includes COVID-19-related product candidates to prevent and treat COVID-19, to treat Long COVID as well as to detect functional T cell immunity to SARS-CoV-2. 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] (cyclobenzaprine HCl sublingual tablets), is in mid-Phase 3 development for the management of fibromyalgia. TNX-1300[2] is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial before year end. Tonix's lead vaccine candidate for COVID-19, TNX-1800[3], is a live replicating vaccine based on Tonix's recombinant pox vaccine (RPV) platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects to start a Phase 1 study in humans in the second half of 2022. Tonix is developing TNX-2100[4], an *in vivo* diagnostic to measure the presence of functional T cell immunity to SARS-CoV-2 and intends to initiate a first-in-human clinical study in the fourth quarter of 2021, pending IND clearance. TNX-3500[5] (sangivamycin) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-IND stage of development. Finally, TNX-102 SL is a small molecule drug being developed to treat Long COVID, a chronic post-COVID condition, and is also in the pre-

IND stage. Tonix expects to conduct a Phase 2 study in Long COVID in the first half of 2022. Tonix's immunology portfolio also includes biologics to address immunosuppression, cancer, and autoimmune diseases.

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

[2] *TNX-1300 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.*

[3] *TNX-1800 is an investigational new biologic and has not been approved for any indication. TNX-1800 is based on TNX-801, live horsepox virus vaccine for percutaneous administration, which is in development to protect against smallpox and monkeypox. TNX-801 is an investigational new biologic and has not been approved for any indication.*

[4] *TNX-2100 is an investigational new biologic and has not been approved for any indication.*

[5] *TNX-3500 is an investigational new drug at the pre-IND stage of development and has not been approved for any indication.*

This press release and further information about Tonix can be found atwww.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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