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): September 29, 2014

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 306, New York, New York 10022
(Address of principal executive offices) (Zip Code)

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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))

Item 8.01 Other Events.

On September 29, 2104, Tonix Pharmaceuticals Holding Corp. held a conference call to discuss the top line data results from its BESTFIT (BEdtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy) trial of TNX-102 SL for fibromyalgia.

A script of that conference call is attached hereto as Exhibit 99.01 to, and incorporated by reference in, this report. The information in this Current Report is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.01 Script of conference call, held September 29, 2014, by Tonix Pharmaceuticals Holding Corp.

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: September 29, 2014

By: */s/ SETH LEDERMAN*
Seth Lederman
Chief Executive Officer

Exhibit 99.01

LELAND GERSHELL - WELCOME

• Thank you, operator.

• On today's call we will review topline results of the BESTFIT phase 2b trial of TNX-102 SL for fibromyalgia, and provide a business update.

• Senior executives participating in the call with me today are Dr. Seth Lederman, our chief executive officer, and Dr. Don Kellerman, our senior vice president of clinical development and regulatory affairs.

• Before we begin, I would like to note that we will make forward-looking statements on this call, all of which involve certain assumptions, risks and uncertainties that are beyond our control and could cause our actual results to differ materially.

• Such forward-looking statements may include, but are not limited to, those involving:

  o regulatory actions, clinical, developmental and other matters related to TNX-102 SL and our other product candidates;

  o our business development and commercialization strategies; and

  o expectations of future growth, revenues and assessments of our competitive position.

• Please see our filings with the U.S. Securities and Exchange Commission for additional information on the risks that could cause our actual results to differ. Any forward-looking statements apply only as of today's date and we undertake no duty to update any of these statements after this call.

• I will now turn the call over to chief executive officer Seth Lederman.

SETH LEDERMAN – OPENING REMARKS

• Thank you, Leland, and good morning to everyone joining us. Today we are pleased to talk to you about an important milestone for the first product candidate in our pipeline which targets central nervous system disorders.

• Earlier this morning we announced top line results from our BESTFIT study, a phase 2b trial of TNX-102 SL in fibromyalgia. I'm going to provide some highlights of the preliminary data, and then Don Kellerman will provide additional details.

• While BESTFIT did not meet its primary endpoint, it did reach statistical significance on several key secondary measures.

• In addition, the daily pain data DID reach significance when analyzed by a responder analysis. Responders were defined as participants who had a 30% or greater reduction in their week 12 pain scores. It's important to note that this 30% responder analysis is an analysis method that has been accepted in the past by FDA for fibromyalgia drug approvals.

• In addition to the responder analysis on pain, we reached statistical significance on a number of key measures of fibromyalgia symptoms. All of the topline results favored the active treatment arm. This internal consistency across measures in the study strongly supports the activity of TNX-102 SL in fibromyalgia.

• TNX-102 SL also was generally well tolerated, and no serious adverse events were reported. Discontinuation rates were low for a study in fibromyalgia. In fact, 86% of participants in the active arm completed the full twelve week dosing period. This compared well to the 83% of participants in the placebo arm who completed. We are especially pleased by this participant retention, because when we listened to patients and doctors, we heard that they want a medicine that is not only effective but also well suited for long-term use.

• Common treatment-emergent adverse events are defined as occurring in greater than 3 percent of participants. The most common adverse events, tongue numbness and bitter taste, were local and related to dose administration. In almost all occurrences, the effect was transient and self-limited.

• Among systemic adverse events, the most common was somnolence, which occurred in 6.9% of the placebo group and 1.9% of the active group.

• No significant weight gain was observed with TNX-102 SL treatment. Not contributing to weight gain is a highly desirable characteristic for a medicine targeting this population.

• That's the extent of my highlights, and in a moment Don Kellerman will provide additional details about the BESTFIT results.

• As you may know, fibromyalgia is characterized by chronic, widespread pain, sleep problems and other symptoms. Non-restorative sleep is the particular sleep disturbance commonly reported by fibromyalgia sufferers.

• We designed TNX-102 SL to be a first-line treatment for fibromyalgia that targets non-restorative sleep. We are not developing another traditional analgesic. TNX-102 SL is designed to reduce pain and mitigate other symptoms in fibromyalgia by improving sleep quality.

• If TNX-102 SL is approved by FDA, we believe it will be the first therapeutic for fibromyalgia that targets non-restorative sleep.

• I'll now ask Don Kellerman, senior vice president of clinical development and regulatory affairs, to walk you through some of the details of the study and its outcome.

DON KELLERMAN – STUDY DETAILS

• Thank you, Seth, and good morning, everyone.

• You will recall that BESTFIT was a 12-week, randomized, double blind, placebo-controlled trial of TNX-102 SL, which is a fixed-dose sublingual tablet containing 2.8 mg of cyclobenzaprine hydrochloride.

• TNX-102 SL is the first in our pipeline of novel therapeutic candidates that we are pursuing because they potentially will address large and growing demands by patients, their families, and their doctors for more effective medicines.

• In the BESTFIT trial, a total of 205 participants who met the 2010 American College of Rheumatology criteria for fibromyalgia were randomized, and 204 received either TNX-102 SL or placebo sublingual tablets. They were instructed to take one tablet daily at bedtime for twelve weeks.

• The primary efficacy endpoint of BESTFIT was the mean change from baseline in the daily diary pain score during week 12. Weekly pain values were calculated by averaging the daily pain scores for each week.

• I think it's interesting to note that in the responder analysis, TNX-102 SL demonstrated a significant improvement, where the p value was 0.03. Here a responder is defined as a "participant who successfully completed the 12-Week treatment program and also reported at least a 30% improvement in the daily Pain Numerical Rating Scale from baseline to week 12".

• Outcomes of several key secondary endpoints were statistically significant: Two of these were the Patient Global Impression of Change or PGIC, and the Fibromyalgia Impact Questionnaire–Revised or FIQ-R. We believe these measures are important, as these are widely accepted questionnaires and both are referenced in the package inserts of all three products currently approved by FDA for fibromyalgia.

• We also achieved statistically significant results on other highly relevant secondary analyses such as the PROMIS Sleep Disturbance Assessment and participants' daily sleep diaries. The study showed highly significant results on measures of sleep quality improvement, as well as significant improvement on several items of the FIQ-R: pain, sleep quality, anxiety, stiffness, sensitivity, and also the subdomain called overall symptom total.

• We are especially pleased by the robust outcomes in sleep, since TNX-102 SL is intended to reduce pain by improving sleep quality. You can see in the chart in our press release that all three sleep measures achieved statistically significant results, and two had a p value of less than 0.001.

• As a reminder, TNX-102 SL is a rapidly dissolving sublingual tablet. In pharmacokinetic studies during the development of the product, some volunteers experienced transient numbness on their tongues during administration of the product.

• Similar to this experience, in BESTFIT, approximately 40% of treated participants experienced some "local effect" at least once during the course of the study. The local effect was described as "tongue numbness" in 42% of treated participants versus 1.0% of placebo participants, and as "abnormal taste" in 7.8% of treated participants as compared to zero placebo participants.

• We'll continue to further analyze the overall dataset from BESTFIT, and we plan to present our comprehensive findings at a major medical conference.

• Lastly, we hear from physicians that the majority of fibromyalgia patients report unsatisfactory relief from currently available treatments. They have told us that many dissatisfied patients either haven't responded to other drugs, or have stopped responding, or discontinued their use due to side effects. Based on the results we saw from BESTFIT, we believe that TNX-102 SL could address this population's unmet needs. We are committed to further developing this product.

SETH LEDERMAN – FOLLOW-UP REMARKS

• I want to take a moment to thank the people who contributed to this clinical trial. We thank the participants and their families who gave their time and energy: They helped us evaluate this potential new therapy and their involvement provided valuable clinical and scientific information. I also want to congratulate the Tonix team that executed our plan so efficiently that we completed this trial ahead of schedule.

• This study was very supportive of our phase 3 program. TNX-102 SL showed broad efficacy across key fibromyalgia symptom domains, and it was very well tolerated in this population.

• These findings validate our approach in developing a new drug that reaches beyond analgesia. BESTFIT demonstrated that TNX-102 SL targets sleep quality and is associated with improvements in pain, quality of life and global improvement. We are gratified to see that these results cross-validate the paradigm that treating disturbed sleep can provide long-term benefits to fibromyalgia patients. The internal consistency of all of the topline results supports our belief that our medicine is active and could be an important treatment for this chronic disorder with multiple symptoms.

• We plan to meet with the Food and Drug Administration to review the BESTFIT results and to design our phase 3 program.

• In addition, I'd like to mention that we plan to initiate AtEase, a phase 2 trial of TNX-102 SL for Post-Traumatic Stress Disorder, in the fourth quarter. Patients with PTSD experience disturbed sleep and nightmares, and poor sleep correlates with severity. The strong sleep outcome data observed in BESTFIT suggest to us that bedtime TNX-102 SL may be well suited to treating PTSD. As with fibromyalgia, many PTSD patients remain dissatisfied with existing therapeutic options.

• With that, we would now like to take your questions.

// Q&A SESSION //

SETH LEDERMAN – CLOSING REMARKS

• Thank you, Operator. Thank you, everyone, for your time today, and for your ongoing support of our mission to develop innovative medications to address CNS disorders.

• We are motivated every day by the reality that, should TNX-102 SL be approved for use, it would be the first drug to treat fibromyalgia by targeting non-restorative sleep.

• We look forward to providing future updates on our progress. In fact, we are planning to host an event in late October to provide a deeper dive into our programs and the markets we are addressing. You can watch for details on the Investor section of our website.

• Operator, this brings us to the end of today's call. Thank you everyone.