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): May 13, 2019

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 2.02 Results of Operations and Financial Condition

On May 13, 2019, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter ended March 31, 2019. A copy of the press release that discusses this matter is filed as Exhibit 99.01 to, and incorporated by reference in, this report.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	Description.
99.01	Press Release dated May 13, 2019, issued by the Company

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: May 13, 2019

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

Exhibit 99.01

Tonix Pharmaceuticals Reports First Quarter 2019 Financial Results and Operational Highlights

Phase 3 RECOVERY Trial of Tonmya® for the Treatment of PTSD is Enrolling; Topline Data Expected First Half of 2020

NEW YORK, May 13, 2019 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company developing pharmaceutical products to treat psychiatric and pain conditions, and biological products to improve biodefense, today announced financial results for the quarter ended March 31, 2019, and an overview of recent operational highlights. Tonix's lead program is TNX-102 SL, or Tonmya* (cyclobenzaprine HCl sublingual tablets), for the treatment of posttraumatic stress disorder (PTSD), which was granted Breakthrough Therapy designation, and which is currently being studied in a Phase 3 efficacy trial.

"We initiated the Phase 3 RECOVERY study of Tonmya for the treatment of PTSD in March, and we are pleased with the progress of enrollment thus far. We anticipate topline results in the first half of next year as previously guided," said Seth Lederman, M.D., President and Chief Executive Officer. "RECOVERY is different from our previous trials in PTSD in two important ways. First, RECOVERY is restricted to patients with PTSD resulting from trauma within 9 years of screening. Our prior studies in military-related PTSD have shown that PTSD is a potentially treatable condition, particularly if treatment is initiated within 9 years of trauma. Second, RECOVERY is recruiting civilians with PTSD in addition to those with military-related PTSD. Affecting approximately 12 million adults in the U.S., PTSD remains an area of high unmet medical need in both the civilian and military populations."

Recent Highlights

- Commenced enrollment in the Phase 3 RECOVERY study of Tonmya for the treatment of PTSD in March 2019. Topline data is expected in the first half of 2020.
- Received guidance and support from the U.S. Food and Drug Administration (FDA) to advance TNX-102 SL into Phase 3 clinical development for the treatment of fibromyalgia, using the 5.6 mg dose taken daily at bedtime. A lower dose of TNX-102 SL (2.8 mg) was studied previously in fibromyalgia in a Phase 2b study and a Phase 3 study. Both studies showed clinical benefits especially in the quality of sleep improvement, however, primary analyses on pain reduction were not statistically significant. The FDA also advised that the long-term safety exposure data from the Company's PTSD program may be used to support a New Drug Application (NDA) for the treatment of fibromyalgia. It is estimated that between 5-10 million adults in the U.S. are affected by fibromyalgia, of which approximately 3 million are diagnosed. Among those diagnosed, more than one-third have used opiates as a means of treatment. TNX-102 SL is a non-opioid, centrally-acting analgesic that would provide a new therapeutic option for fibromyalgia patients.
- Announced that Breakthrough Therapy designation (BTD) remains in effect for Tonmya for the treatment of PTSD and that the Company will meet with the FDA to address its "Intent to Rescind" Breakthrough Therapy designation notice, and to present additional data to support continuing Breakthrough Therapy designation.

**Tonmya has been conditionally accepted by the FDA as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.*

First Quarter 2019 Financial Results

Research and development expenses for the first quarter of 2019 totaled $3.9 million, compared to $5.2 million for the same period in 2018. This decrease is primarily due to a pharmacokinetic bridging study of TNX-102 SL that was conducted in the first quarter of 2018.

General and administrative expenses for the first quarter of 2019 totaled $2.4 million, compared to $1.8 million for the same period in 2018. This increase is primarily due to investor and public relations activities and an increase in insurance expenses due to higher premiums in 2019.

Net loss was $6.2 million, or $1.29 per share, for the first quarter of 2019, compared to net loss of $6.9 million, or $8.80 per share, for the first quarter of 2018. The weighted average common shares outstanding for the first quarter of 2019 was 4,848,199 shares. The weighted average common shares outstanding for the first quarter of 2018 was 787,900 shares.

At March 31, 2019, Tonix had $16.4 million of cash and cash equivalents, compared to $25.0 million as of December 31, 2018. Cash used in operations was $8.6 million for the three months ended March 31, 2019, compared to $6.8 million for the three months ended March 31, 2018. The increase in cash used in operations during the first quarter of 2019 is due primarily to non-recurring items, including close-out costs for the Phase 3 HONOR study and start-up costs related to the current Phase 3 RECOVERY study. Costs related to the RECOVERY study are expected to decrease on a quarterly basis going forward. Additionally, the Company's annual insurance premiums increased over the prior year, the payments of which occur in the first quarter.

About Tonix Pharmaceuticals Holding Corp.
Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat psychiatric and pain conditions, and biological products to improve biodefense through potential medical counter-measures. Tonix's lead program is the development of Tonmya (TNX-102 SL), which is in Phase 3 development as a bedtime treatment for PTSD. Tonmya for PTSD has been designated a Breakthrough Therapy by the FDA. Tonix is also developing TNX-102 SL as a bedtime treatment for fibromyalgia and agitation in Alzheimer's disease under separate Investigational New Drug applications (IND) to support potential pivotal efficacy studies. The fibromyalgia program is in Phase 3 development and the agitation in Alzheimer's program is Phase 2 ready. In fibromyalgia, TNX-102 SL acts as a non-opioid, centrally-acting analgesic that would provide a new therapeutic option for fibromyalgia patients. The agitation in Alzheimer's disease IND has been designated a Fast Track development program by the FDA. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but by a different mechanism from TNX-102 SL and designed for daytime dosing. TNX-601 is also in development for a potential indication - neurocognitive dysfunction associated with corticosteroid use. A Phase 1 clinical formulation selection pharmacokinetic study of TNX-601 will be conducted outside of the U.S. in 2019. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

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; 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, 2018, as filed with the Securities and Exchange Commission (the “SEC”) on March 18, 2019, 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.

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In Thousands, Except Share and Per Share Amounts)
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Costs and expenses		
Research and development	$ 3,896	$ 5,170
General and administrative	2,401	1,818
Total costs and expenses	6,297	6,988
Operating loss	(6,297)	(6,988)
Interest income, net	64	53
Net loss	$ (6,233)	$ (6,935)
Net loss per common share, basic and diluted	$ (1.29)	$ (8.80)
Weighted average common shares outstanding, basic and diluted	4,848,199	787,900

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In Thousands)
(Unaudited)

	March 31, 2019	**December 31, 2018[(1)]**
Assets		
Cash and cash equivalents	$ 16,448	$ 25,034
Prepaid expenses and other current assets	2,734	1,022
Total current assets	19,182	26,056
Other non-current assets	840	263
Total assets	$ 20,022	$ 26,319
Liabilities and stockholders' equity		
Total liabilities	$ 2,211	$ 2,655
Stockholders' equity	17,811	23,664
Total liabilities and stockholders' equity	$ 20,022	$ 26,319

(1) The condensed consolidated balance sheet for the year ended December 31, 2018 has been derived from the audited financial statements but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements

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