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 8, 2023

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 Capital 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 2.02 Results of Operations and Financial Condition

On May 8, 2023, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter ended March 31, 2023. A copy of the press release that discusses these matters 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 of the Company, dated May 8, 2023
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: May 8, 2023

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

Exhibit 99.01

Tonix Pharmaceuticals Reports First Quarter 2023 Financial Results and Operational Highlights

Prioritizing Late-Stage Clinical CNS Programs in Fibromyalgia, Depression, Migraine, and Cocaine Intoxication

Topline Results Expected in Fourth Quarter 2023 for Potentially Confirmatory Phase 3 Trial of TNX-102 SL for Fibromyalgia

Potentially Pivotal Phase 2 Trial of TNX-601 ER for Major Depressive Disorder (MDD) Enrolling; TNX-601 ER Represents an Innovative Approach for MDD through Restoration of Neuroplasticity and Neurogenesis

Cash and Cash Equivalents of Approximately $72.0 Million at March 31, 2023

CHATHAM, N.J., May 8, 2023 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced financial results for the first quarter ended March 31, 2023, and provided an overview of recent operational highlights.

"With much achieved already, we expect 2023 will continue to serve as an important milestone year for Tonix," said Seth Lederman, M.D., Chief Executive Officer of Tonix. "The prioritization of key programs in our pipeline highlights our commitment to helping bring relief and value to patients suffering from diseases with limited or insufficient therapeutic options. We are pleased with the enrollment in our current RESILIENT Phase 3 study for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) in fibromyalgia. We are looking forward to topline results from the trial in the fourth quarter of this year. If successful, we believe it will be the second and final adequate and well-controlled efficacy trial required for filing a New Drug Application (NDA) for approval by the U.S. Food and Drug Administration (FDA). Moreover, we believe we have satisfied all the other clinical and non-clinical requirements for an NDA submission. In addition, we are excited to have initiated enrollment in the potentially pivotal UPLIFT Phase 2 study of TNX-601 ER (tianeptine hemioxalate extended release tablets) for major depressive disorder (MDD). TNX-601 ER represents a novel approach to treating depression in the U.S., since the active ingredient tianeptine restores neuroplasticity and neurogenesis rather than modulating neurotransmitter levels and activity."

Recent Highlights—Key Product Candidates*

Central Nervous System (CNS) Pipeline

TNX-102 SL: small molecule for the management of fibromyalgia (FM)

- In March 2023 at the *5th International Congress on Controversies in Fibromyalgia*, the Company presented positive efficacy and safety data from Phase 3 RELIEF Study of TNX-102 SL for the management of fibromyalgia. Titled "Efficacy and Safety of TNX-102 SL (Sublingual Cyclobenzaprine) for the Treatment of Fibromyalgia: Results from the Randomized, Placebo Controlled RELIEF Trial", the presentation displayed the data 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) in participants with fibromyalgia. In addition, TNX-102 SL was well tolerated with the most common adverse event associated with active treatment being oral numbness or hypoaesthesia, an administration site reaction that is typically transient, was never rated as severe, and led to only one discontinuation.

- The Company recently announced new plans to eliminate the interim analysis to streamline the ongoing Phase 3 RESILIENT trial and to provide topline data in the fourth quarter of 2023. Target enrollment for the TNX-102 SL fibromyalgia study remains approximately 470 participants.

TNX-102 SL for the treatment of Fibromyalgia-Type Long COVID, also known as Post-Acute Sequelae of COVID-19 (PASC)

- In April 2023, enrollment of 63 participants was completed in the PREVAIL study, a Phase 2 study of TNX-102 SL for fibromyalgia-type Long COVID.

- Topline results from the PREVAIL Phase 2 trial are expected in the third quarter of 2023.

- In February 2023 at a virtual event co-hosted by BIO and Solve M.E. titled, "Long COVID: What Will it Take to Accelerate Therapeutic Progress?", the Company presented its analysis that the majority of Long COVID patients present with a constellation of symptoms including multisite pain, fatigue, sleep disorders and cognitive dysfunction or brain fog. These symptoms overlap with fibromyalgia and chronic fatigue syndrome/myalgic encephalomyelitis (CFS/ME). Fibromyalgia-type Long COVID, like fibromyalgia and CFS/ME, appears to be one of several chronic overlapping pain conditions that have in common the neurological process called central sensitization.

TNX-601 ER: a once-daily orally-administered small molecule for the treatment of MDD, Posttraumatic Stress Disorder (PTSD), neurocognitive dysfunction associated with corticosteroid use and potentially Alzheimer's disease

- In March 2023, enrollment was initiated in the potentially pivotal Phase 2 'UPLIFT' Study for the treatment of MDD. Results from a planned interim analysis are expected to be released in the fourth quarter of 2023.

- TNX-601 ER represents a novel approach to treating depression in the U.S., since the active ingredient tianeptine induces a neuroprotective and resilient phenotype in both neurons and microglia under conditions of stress. The Phase 2 UPLIFT study is a double-blind, randomized, multicenter, placebo-controlled study to evaluate the efficacy and safety of TNX-601 ER taken orally once-daily for 6 weeks to treat MDD. It is a parallel design study with two arms, a TNX-601 ER 39.4 mg arm and a placebo arm. A total of 300 participants will be randomized in a 1:1 ratio into the two arms across approximately 30 U.S. sites, enrolling adult patients 18-65 years old. The primary efficacy endpoint is mean change from baseline in the Montgomery-Åsberg Depression Rating Scale (MADRS) total score at Week 6.

TNX-1900 (intranasal potentiated oxytocin): small peptide for migraine, craniofacial pain, insulin resistance and related disorders, and obesity-associated binge eating disorder

- In February 2023, enrollment began in the Phase 2 PREVENTION study of TNX-1900 for the prevention of migraine headache in chronic migraineurs. The double-blind, placebo-controlled study has a target enrollment of 150 participants at approximately 25 sites across the U.S, with topline results expected in the fourth quarter of 2023.

- In January 2023, data from clinical and nonclinical studies were presented at the *16th Annual Headache Cooperative of the Pacific (HCOP) Winter Conference* by collaborator Professor David Yeomans. The oral presentation titled, "Primary vs Secondary Sex Hormones and Migraine," includes research sponsored and licensed by Tonix. Preliminary results from a positron emission tomography study in humans showed that intranasal delivery of a radioisotope of magnesium-potentiated oxytocin is delivered to the trigeminal ganglia, which have known roles in migraine headaches. In addition, preliminary results of data collected from isolated human trigeminal ganglia neurons *in vitro* show co-expression of oxytocin receptors and calcitonin gene-related peptide, which are believed to represent the first observation of oxytocin receptors in human trigeminal ganglia. Furthermore, the presentation highlights data which suggest a sex difference in oxytocin potency.

TNX-1300 (recombinant double mutant cocaine esterase): biologic for life-threatening cocaine intoxication

- Tonix expects to initiate a potentially pivotal, Phase 2 clinical study of TNX-1300 for the treatment of cocaine intoxication in the third quarter of 2023.
- As previously disclosed, in 2022, Tonix received a Cooperative Agreement grant from the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), to support development of TNX-1300.
- TNX-1300 has been granted Breakthrough Therapy designation by the FDA.

Rare Disease Pipeline

TNX-2900 (intranasal potentiated oxytocin): small peptide for the treatment of Prader-Willi syndrome (PWS)

- TNX-2900 has been granted Orphan Drug designation from the FDA for the treatment of PWS.
- In March 2023, Tonix delivered a presentation titled, "TNX-2900 (Intranasal Oxytocin + Magnesium) in Development for the Treatment of Hyperphagia in Adolescents and Young Adults with Prader-Willi Syndrome" at the Rare Disease Innovation and Partnership Summit. The presentation displayed data showing the enhancing effects of magnesium (Mg^{2+}) on the activation of oxytocin receptors. The Mg^{2+} enhanced formulation of intranasal oxytocin is the basis for TNX-2900, in development to treat hyperphagia, or pathological over-eating, in children and young adult patients with PWS.

Immunology Pipeline

TNX-1500 (anti-CD40L monoclonal antibody): third generation anti-CD40L monoclonal antibody for prophylaxis of organ transplant rejection and treatment of autoimmune disorders.

- In May 2023, the IND for prevention of organ rejection in patients receiving a kidney transplant was cleared by FDA. A First-in-Human Phase 1 study is expected to initiate in the third quarter of 2023.The first indication for TNX-1500 will be prophylaxis of organ rejection in adult patients receiving a kidney transplant, but multiple additional indications are possible, including autoimmune diseases.
- Tonix announced a research agreement with Boston Children's Hospital to study TNX-1500 for the prevention of graft-versus-host diseases (GvHD) after hematopoietic stem cell transplantation (HCT) in animals. HCT from unrelated donors is a component of the treatment protocol for several hematologic malignancies, but GvHD complicates treatment and limits the success of engraftment after HCT. In April 2023, the Company announced the online publication of two papers in the *American Journal of Transplantation* by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital (MGH) in collaboration with Tonix Pharmaceuticals[1,2]. The publications include data demonstrating that TNX-1500 showed activity in preventing organ rejection and was well tolerated in non-human primates. To date, there has not been a humanized anti-CD40L antibody that can effectively prevent transplant rejections with an acceptable level of safety.

Infectious Disease Pipeline

TNX-801 (live horsepox virus vaccine for percutaneous administration): vaccine to protect against smallpox and monkeypox (mpox) designed as a single-administration vaccine to elicit T cell immunity.

- As previously announced, a Phase 1 study is expected to start in the second half of 2023.
- In January 2023, the Company appointed Zeil Rosenberg, M.D., M.P.H., as Executive Vice President, Medical for Infectious Disease programs. Dr. Rosenberg is responsible for leading the Company's clinical development efforts for vaccines, including TNX-801.
- A publication describing the activity of TNX-801 to protect non-human primates against a lethal challenge with intra-tracheal monkeypox was published in the peer-reviewed journal, *Viruses*[3].

**All of Tonix's product candidates are investigational new drugs or biologics and none has been approved for any indication.*

[1]Lassiter, G., et al. (2023). TNX-1500, a crystallizable fragment–modified anti-CD154 antibody, prolongs non-human primate renal allograft survival.*American Journal of Transplantation*. https://doi.org/10.1016/j.ajt.2023.03.022

[2]Miura, S., et al. (2023). TNX-1500, a crystallizable fragment–modified anti-CD154 antibody, prolongs non-human primate cardiac allograft survival.*American Journal of Transplantation*. https://doi.org/10.1016/j.ajt.2023.03.025

[3]Noyce RS, et al. (2023). Single Dose of Recombinant Chimeric Horsepox Virus (TNX-801) Vaccination Protects Macaques from Lethal Monkeypox Challenge.*Viruses*. 15(2):356. doi: 10.3390/v15020356

Recent Highlights—Corporate and Other

- In April 2023, Tonix announced it is reallocating resources and cash to streamline its pipeline and focus on its mid- and late-stage clinical programs within its core CNS portfolio. The pipeline realignment prioritizes key near-term value drivers, reduces investment in several longer-term programs, particularly COVID-19-related studies, and delays the start of a PTSD study in Kenya.

Recent Highlights—Financial

As of March 31, 2023, Tonix had $72.0 million of cash and cash equivalents, compared to $120.2 million as of December 31, 2022. Net cash used by financing activities was approximately $11.5 million for first quarter 2023, compared to net cash provided by financing activities of $13.1 million for the same period in 2022.

On April 8, 2020, the Company entered into a sales agreement (the "Sales Agreement") with AGP of up to $320.0 million in at-the-market offerings ("ATM") sales. During the quarter ended March 31, 2023, the Company sold approximately 3.2 million shares of common stock under the Sales Agreement, for net proceeds of approximately $2.0 million. Subsequent to March 31, 2023, the Company has sold 0.9 million shares of common stock under the Sales Agreement, for net proceeds of approximately $0.5 million.

In January 1, 2023, the Company repurchased 16,700,269 shares of common stock under its share repurchase programs at an average price per share of $0.82 for a gross aggregate cost of approximately $13.6 million.

Cash used in operations was approximately $32.9 million for the first quarter ended March 31, 2023, compared to $31.0 million for the first quarter ended March 31, 2022.

Cash used by investing activities for the first quarter ended March 31, 2023, and 2022 was approximately $3.8 million and $20.2 million, respectively, related to the purchase of property and equipment.

First Quarter 2023 Financial Results

R&D expenses for the first quarter 2023 were $26.5 million, compared to $18.4 million for the same period in 2022. As planned, R&D expenses will be increasing during 2023 as we move our clinical development programs forward and invest in our development pipeline.

G&A expenses for the first quarter 2023 were $7.4 million, compared to $8.0 million for the same period in 2022. The decrease is primarily due to decreased employee-related and financial reporting expenses.

Net loss was $33.0 million, or $0.52 per share, basic and diluted, for the first quarter 2023, compared to net loss of $26.4 million, or $1.61 per share, basic and diluted, for the same period in 2022. The basic and diluted weighted average common shares outstanding for the first quarter 2023 was 63,352,898 compared to 16,445,010 shares for the same period in 2022.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix'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 (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with topline data expected in the fourth quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Enrollment in a Phase 2 study has been completed, and topline results are expected in the third quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), in development for chronic migraine, is currently enrolling with topline data expected in the fourth quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets), a once-daily formulation being developed as a treatment for major depressive disorder (MDD), is also currently enrolling with interim data expected in the fourth quarter of 2023. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the third quarter of 2023. Tonix's rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the third quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox, for which a Phase 1 study is expected to be initiated in the second half of 2023. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases. The infectious disease portfolio also includes TNX-3900 and TNX-4000, classes of broad-spectrum small molecule oral antivirals.

** All of Tonix's product candidates are investigational new drugs or biologics and none has 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 the 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, 2022, as filed with the Securities and Exchange Commission (the "SEC") on March 13, 2023, 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,	
	2023	**2022**
COSTS AND EXPENSES:		
Research and development	$ 26,511	$ 18,422

General and administrative	7,391	8,014
	33,902	26,436
Operating loss	(33,902)	(26,436)
Interest income	897	19
Net loss	$ (33,005)	$ (26,417)
Net loss per common share, basic and diluted	$ (0.52)	$ (1.61)
Weighted average common shares outstanding, basic and diluted	63,352,898	16,445,010

See the accompanying notes to the condensed consolidated financial statements

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

	March 31, 2023	December 31, 2022[1]
Assets		
Cash and cash equivalents	$ 71,975	$ 120,229
Prepaid expenses and other	11,751	10,548
Total current assets	83,726	130,777
Other non-current assets	95,362	94,913
Total assets	$ 179,088	$ 225,690
Liabilities and stockholders' equity		
Total liabilities	$ 13,661	$ 18,508
Stockholders' equity	165,427	207,182
Total liabilities and stockholders' equity	$ 179,088	$ 225,690

[1]The condensed consolidated balance sheet for the year ended December 31, 2022 has been derived from the audited financial statements but do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 904-8182

Maddie Stabinski (media)
Russo Partners
madeline.stabinski@russopartnersllc.com
(212) 845-4273

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