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, 2024

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 13, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter ended March 31, 2024. 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, May 13, 2024
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 13, 2024

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

Exhibit 99.01

Tonix Pharmaceuticals Reports First Quarter 2024 Financial Results and Operational Highlights

On track to submit NDA in the second half of 2024 for Tonmya™ for fibromyalgia;
pre-NDA meeting with FDA scheduled for second quarter 2024

Commercial planning continues for U.S. launch of Tonmya, a potential new first-line, centrally-acting, non-opioid analgesic for the management of fibromyalgia

CHATHAM, N.J., May 13, 2024 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a fully-integrated biopharmaceutical company with marketed products and a pipeline of development candidates, today announced financial results for the first quarter ended March 31, 2024, and provided an overview of recent operational highlights.

"Our near-term priority continues to be the submission of our New Drug Application (NDA) for Tonmya™ (cyclobenzaprine HCl sublingual tablets) for the management of fibromyalgia, while continuing to build out our commercial strategy for the anticipated product launch in the event of FDA approval, which we currently estimate to occur in the second half of 2025," said Seth Lederman, M.D., Chief Executive Officer of Tonix.

Dr. Lederman added, "The well-known treatment-limiting side effects of the three currently approved drugs have led to widespread patient dissatisfaction, creating what we believe is a significant opportunity for a new therapeutic. Tonmya has a differentiated mechanism of action and is generally free of common side effects associated with the currently approved products, including weight gain, fatigue, insomnia, increased blood pressure, gastrointestinal issues or sexual dysfunction. As such, we believe Tonmya, if approved, could become the treatment of choice for the approximately 10 million people in the U.S. suffering the debilitating effects of fibromyalgia."

The Company is also advancing other key pipeline programs including those for immunology, obesity, eating disorders, infectious and rare diseases, many through a capital efficient strategy involving partnerships, grants and in-kind contributions.

Recent Highlights – Key Product Candidates*

Central Nervous System (CNS) Pipeline

Tonmya (also known as TNX-102 SL; cyclobenzaprine HCl sublingual tablets): a centrally-acting, non-opioid, small molecule analgesic taken once-daily at bedtime for the management of fibromyalgia (FM).

- In January 2024, Tonix presented additional safety and tolerability data from the pivotal Phase 3 RESILIENT study that showed Tonmya treatment was not associated with increases in systolic or diastolic blood pressure or body weight, nor were there any reported sexual side effects. The Company had previously announced in December 2023 that the Phase 3 RESILIENT study, a registration-quality, double-blind, placebo-controlled study evaluating Tonyma met its pre-specified primary endpoint in the second of two positive Phase 3 clinical trials, significantly reducing daily pain compared to placebo (p-value=0.00005) in participants with fibromyalgia. Statistically significant and clinically meaningful results were also seen in all pre-specified key secondary endpoints including those related to improving sleep quality, reducing fatigue, and improving patient global ratings and overall fibromyalgia symptoms and function. Tonmya was well tolerated with an adverse event profile comparable to prior studies and no new safety signals observed. In addition, Tonmya therapy showed activity on improving female sexual function relative to placebo with a nominal p-value=0.010 by the Changes in Sexual Functioning Questionnaire short-form, female version.

- Tonix plans to submit an NDA to the FDA in the second half of 2024 for Tonmya for the management of fibromyalgia. In February 2024, Tonix announced the engagement of Rho, Inc. as our contract research organization (CRO) to support NDA submission.

- In February 2024, Tonix announced statistically significant results from its clinical pharmacokinetic (PK) bridging study of Tonmya in healthy adult male and female ethnic Japanese and Chinese volunteers. Results indicate that key PK parameters of cyclobenzaprine are comparable in ethnic Japanese and Chinese volunteers to Caucasian volunteers from a prior PK study. Tonmya was generally well tolerated in the ethnic Japanese and Chinese healthy volunteers. The company expects these data to fulfill the requirement for a bridging study, and enables Tonix to rely on Phase 3 studies RESILIENT and RELIEF results to support regulatory filings for clinical studies in Japan and China where cyclobenzaprine is a new chemical entity (NCE). Tonix holds issued patents for market exclusivity rights of Tonmya in Japan, China, Hong Kong and Taiwan.

- In March 2024, Tonix announced the selection of two contract manufacturing organizations (CMOs), including Almac Pharma Services, as dual supply sources for the potential launch and commercialization of Tonmya in the U.S.

- In March 2024, Tonix selected EVERSANA, a leading provider of commercialization services to the global life sciences industry, to support the launch strategy and commercial planning of Tonmya in the U.S.

- Tonix presented additional efficacy data from RESILIENT at the 6th International Congress on Controversies in Fibromyalgia in Brussels, Belgium, March 7-8, 2024. The data showed that Tonmya treatment resulted in an improvement in cognitive dysfunction, or 'brain fog', measured by the change in the Fibromyalgia Impact Questionnaire-Revised (FIQ-R) memory item. The FIQ-R cognitive item showed nominal improvement in Tonmya-treated patients vs placebo-treated patients with a nominal p-value=0.001 and effect size of 0.31.

TNX-102 SL for the treatment of acute stress reaction (ASR) and acute stress disorder (ASD), and prophylaxis against development of posttraumatic stress disorder (PTSD)

- In February 2024, the Company announced the FDA cleared the Investigational New Drug (IND) application for the Phase 2 investigator-initiated OASIS trial to evaluate TNX-102 SL in reducing the severity of ASR and the frequency of ASD and PTSD. The trial is sponsored by the University of North Carolina Institute for Trauma Recovery and supported by a $3 million grant from the U.S. Department of Defense, which was awarded in September 2023. The proposed Phase 2, Optimizing Acute Stress Reaction Interventions with TNX-102 SL (OASIS) study will examine the safety and efficacy of TNX-102 SL to reduce adverse posttraumatic neuropsychiatric sequelae among patients presenting to the emergency department (ED) after a motor vehicle collision. The study will enroll approximately 180 trauma survivors at ED study sites in the U.S. Participants will be randomized in the ED to receive a two-week course of either TNX-102 SL 5.6 mg or placebo.

- Tonix anticipates the Phase 2 OASIS trial will initiate in the second quarter of 2024.

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

- In January 2024, the Company announced the online publication of a research paper in the Journal *Pain.* The article titled, "Chronic Overlapping Pain Conditions Increase the Risk of Long COVID Features, Regardless of Acute COVID Status," by Bergmans, et al. [1], found that patients with pre-existing chronic overlapping pain conditions (COPCs) had an increased risk of being diagnosed with symptoms of Long COVID[1]. Faculty at the University of Michigan directed the research. Commentary on the article titled, "A step towards better understanding chronic overlapping pain conditions" by Fitzcharles, et al,[2] is in the same issue of the journal. COPCs include fibromyalgia, chronic fatigue syndrome, migraine headache, irritable bowel syndrome, endometriosis and low back pain. These results contribute to a growing body of evidence that common symptoms of Long COVID in many patients are at least partly driven by central nervous system mechanisms.

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

- Tonix expects to initiate a Phase 2 clinical study of TNX-1300 for the treatment of cocaine intoxication in emergency rooms in the second quarter of 2024. In 2022, Tonix was awarded a Cooperative Agreement grant from the National Institutes of Health (NIH)'s National Institute of Drug Abuse (NIDA) to support development of TNX-1300.

- TNX-1300 has been granted Breakthrough Therapy designation by the FDA.

TNX-1900 (intranasal potentiated oxytocin): small peptide in development through investigator-initiated studies for adolescent obesity, binge eating disorder, bone health in autism and social anxiety disorder (SAD).

- TNX-1900 continues to be studied in four ongoing investigator-initiated Phase 2 studies as follows: Massachusetts General Hospital (MGH): (1) Phase 2 study for binge-eating disorder (BED); (2) Phase 2 study for adolescent obesity; (3) Phase 2 study for improving bone health in children with autism spectrum disorder (BOX); and at University of Washington, (4) Phase 2 study for social anxiety disorder (SAD). The BED study and the adolescent obesity study will investigate whether TNX-1900 has effects on eating behaviors in specialized populations.

Rare Disease Pipeline

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

- In March 2024, Tonix announced that it received Rare Pediatric Disease designation from the FDA for TNX-2900 for the treatment of PWS. Tonix has an IND to support clinical development of TNX-2900 to treat PWS in children and adolescents. The planned Phase 2 study is a dose-finding study involving approximately 36 PWS patients divided into four groups with approximately nine per group. One group will receive placebo and three groups will receive different dosage regimens of TNX-2900. TNX-2900 for the treatment of PWS was granted Orphan Drug designation by the FDA in 2022. PWS is a genetic disorder that affects several body systems, with cognitive and behavioral symptoms including pathological over-eating beginning in childhood and leading to severe metabolic sequelae.

Immunology Pipeline

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

- The first proposed indication for TNX-1500 is prophylaxis of organ rejection in adult patients receiving a kidney transplant; but multiple additional indications are possible, including autoimmune diseases. Two peer reviewed publications described the work with TNX-1500 at the Massachusetts General Hospital (MGH) on allogeneic transplants in animals.[3,4]

- Preclinical studies have shown that TNX-1500 maintains the activity of first-generation monoclonal antibodies (mAbs), yet with reduced risk of thrombotic complications.[3-5] Modeling studies from animal pharmacokinetic data[3] predict a half-life of greater than three weeks for TNX-1500 in humans, which supports a monthly *i.v.* dosing regimen. This analysis together with TNX-1500's activity and tolerability in animals, suggests that the protein engineering of TNX-1500's Fc region has achieved its design goals.

- In February 2024, Tonix announced the completion of the clinical stage of its Phase 1 single ascending dose study of TNX-1500 in healthy volunteers. The primary objectives of the study are to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of intravenous TNX-1500. This first-in-human study is intended to support dosing in a planned Phase 2 trial in kidney transplant recipients.

- In March of 2024, the MGH announced the first transplant of a genetically modified pig kidney into a living patient in collaboration with eGenesis, which produced the pig donors and used an anti-CD40L mAb from another company.[5] Some of the pre-clinical work that supported the living human transplant was performed in collaboration with Tonix and used TNX-1500.[6] The patient was able to return home after the transplant, but died after approximately two months.[7]

Marketed Products – Recent Highlights

- As of April 1, 2024, Tonix completed the transition to becoming a fully integrated pharmaceutical company. Tonix Pharmaceuticals has implemented personnel, systems and contracts required to support a commercial organization and has assumed responsibility for distribution, selling and marketing of Zembrace SymTouch and Tosymra, as well as supply chain, regulatory and quality control of the two products.

Facilities – Recent Highlights

- In the fourth quarter of 2023, Tonix engaged CBRE, an international real estate brokerage firm, to potentially find a strategic partner for, or buyer of, its Advanced Development Center (ADC) to align with the Company's current business objectives and priorities. At this time, the Company does not have a commitment in place to sell the building. ADC, located in the New Bedford business park in Dartmouth, Massachusetts, isan approximately 45,000 square foot BSL-2 facility intended for clinical scale manufacturing of live-virus vaccines and biologics.

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

Tonmya™ is conditionally accepted by the U.S. Food and Drug Administration (FDA) as the tradename for TNX-102 SL for the management of fibromyalgia. Tonmya has not been approved for any indication.

[1] Bergmans RS, et al. *PAIN*. 2023. DOI: 10.1097/j.pain.0000000000003110.

[2] Fitzcharles M-A, et al. *PAIN*. 2023. DOI: 10.1097/j.pain.0000000000003129.

[3] Lassiter G., et al. *Am J Transplantation*. 2023. https://doi.org/10.1016/j.ajt.2023.03.022

[4] Miura S., et al. *Am J Transplantation*. 2023. https://doi.org/10.1016/j.ajt.2023.03.025

[5] Massachusetts General Hospital press release. March 21, 2024. "World's First Genetically Edited Pig Kidney Transplant into Living Recipient Performed at Massachusetts General Hospital." www.massgeneral.org/news/press-release/worlds-first-genetically-edited-pig-kidney-transplant-into-living-recipient (accessed March 29, 2024)

[6] Anand, R.P., et al *Nature*. 622, 393–401 (2023). https://doi.org/10.1038/s41586-023-06594-4

[7] Stoico, N. *Boston Globe*. May 11, 2023. "Mass Man who received first kidney transplant from genetically engineered pig has died, family says".

Recent Highlights – Financial

As of March 31, 2024, Tonix had $7.0 million of cash and cash equivalents, compared to $24.9 million as of December 31, 2023. Net cash used in operations was approximately $17.6 million for first quarter 2024, compared to net cash used in operations of $32.9 million for the same period in 2023.

On April 1, 2024, the Company closed a financing with existing healthcare-focused institutional investors for upfront gross proceeds of approximately $4.4 million through a registered direct offering.

First Quarter 2024 Financial Results

Net product revenue for the first quarter 2024 was approximately $2.5 million. Net product revenue consisted of combined net sales of Zembrace® SymTouch® and Tosymra®, which were acquired from Upsher-Smith Laboratories, LLC on June 30, 2023. Cost of Sales for the first quarter 2024 was approximately $1.7 million.

Research and development expenses for the first quarter 2024 were $12.9 million, compared to $26.5 million for the same period in 2023. This decrease is predominantly due to decreased clinical, non-clinical and manufacturing expenses.

General and administrative expenses for the first quarter 2024 were $9.3 million, compared to $7.4 million for the same period in 2023. The increase was primarily due to sales and marketing and the transition services expenses associated with the Company's recently acquired marketed products offset by a decrease in financial reporting expenses.

Net loss was $(14.9) million, or $(0.18) per share, basic and diluted, for the first quarter 2024, compared to net loss of $(33.0) million, or $(3.21) per share, basic and diluted, for the same period in 2023. The basic and diluted weighted average common shares outstanding for the first quarter 2024 was 80,879,108 compared to 10,268,500 shares for the same period in 2023.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a fully-integrated biopharmaceutical company focused on developing, licensing and commercializing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's development portfolio is focused on central nervous system (CNS) disorders. Tonix's priority is to submit a New Drug Application (NDA) to the FDA in the second half of 2024 for Tonmya[1], a product candidate for which two statistically significant Phase 3 studies have been completed for the management of fibromyalgia. TNX-102 SL is also being developed to treat acute stress reaction as well as fibromyalgia-type Long COVID. Tonix's CNS portfolio includes TNX-1300 (cocaine esterase), a biologic designed to treat cocaine intoxication that has Breakthrough Therapy designation. Tonix's immunology development portfolio consists of 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. Tonix also has product candidates in development in the areas of rare disease and infectious disease. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg for the treatment of acute migraine with or without aura in adults.

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*Tonix's product development candidates are investigational new drugs or biologics and have not been approved for any indication.

[1]Tonmya™ is conditionally accepted by the U.S. Food and Drug Administration (FDA) as the tradename for TNX-102 SL for the management of fibromyalgia. Tonmya 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 the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; risks related to the failure to successfully market any of our products; 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, 2023, as filed with the Securities and Exchange Commission (the "SEC") on April 1, 2024, 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,	
	2024	**2023**
REVENUES:		
Product revenue, net	$ 2,482	$ —
COSTS AND EXPENSES:		
Cost of sales	1,660	—
Research and development	12,863	26,511
General and administrative	9,310	7,391
Total Operating Expenses	23,833	33,902
Operating loss	(21,351)	(33,902)
Gain on change in fair value of warrant liabilities	7,005	—
Other (expense) income, net	(593)	897
Net loss available to common stockholders	$ (14,939)	$ (33,005)
Net loss to common stockholders per common share, basic and diluted	$ (0.18)	$ (3.21)
Weighted average common shares outstanding, basic and diluted	80,879,108	10,268,500

See the accompanying notes to the condensed consolidated financial statements

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

	March 31, 2024	**December 31, 2023[1]**
Assets		
Cash and cash equivalents	$ 7,049	$ 24,948
Inventory	12,351	13,639
Prepaid expenses and other	10,698	9,181
Total current assets	30,098	47,768
Other non-current assets	105,245	106,689
Total assets	$ 135,343	$ 154,457
Liabilities and stockholders' equity		
Total liabilities	$ 27,200	$ 48,932
Stockholders' equity	108,143	105,525
Total liabilities and stockholders' equity	$ 135,343	$ 154,457

1 The condensed consolidated balance sheet for the year ended December 31, 2023 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.

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