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): April 1, 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 April 1, 2024, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter and year ended December 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 April 1, 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: April 1, 2024

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

Exhibit 99.01

Tonix Pharmaceuticals Reports Fourth Quarter and Full Year 2023 Financial Results and Operational Highlights

Positive results from confirmatory Phase 3 RESILIENT study reported in December 2023 position Tonmya™ for fibromyalgia for NDA submission second half of 2024; pre-NDA meeting with FDA scheduled for second quarter 2024

Commercial planning underway, including go-to-market, supply chain and manufacturing strategies, for U.S. launch of Tonmya, a potential new first-line, centrally-acting, non-opioid analgesic for the management of fibromyalgia

CHATHAM, N.J., April 1, 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 fourth quarter and full year ended December 31, 2023, and provided an overview of recent operational highlights.

"Our near-term focus is seeking U.S. marketing approval for Tonmya (cyclobenzaprine HCl sublingual tablets) for the treatment of fibromyalgia from the U.S. Food and Drug Administration (FDA)," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Our pre-NDA meeting with the FDA is scheduled to take place this quarter and we plan to submit our New Drug Application (NDA) for Tonmya™ in the second half of 2024. We believe the positive Phase 3 RESILIENT results reported in December of 2023 together with the positive results from the first Phase 3 RELIEF study should satisfy the requirements for approval and, if so, would provide the opportunity for Tonix to launch the first FDA-approved drug for fibromyalgia in more than a decade. We believe the activity of Tonmya on improving pain, sleep quality, fatigue and brain fog in the RESILIENT study are indicative of the broad-spectrum of activity in fibromyalgia."

Dr. Lederman added, "While Tonix is focusing its resources on progressing Tonmya toward NDA submission and potential FDA approval, we are seeking partnerships and collaborations on our pipeline programs from government agencies, non-profit organizations and other biotechnology or pharmaceuticals companies. Tonix has already shifted portions of our research and development (R&D) expenses to U.S. government agencies and other institutions through partnerships involving grants and in-kind contributions. These outside collaborations leverage our internal resources, and we believe they provide a capital efficient strategy for progress."

Selected Product Candidates* -- Recent Highlights

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).

- The Company announced in December 2023 that the Phase 3 RESILIENT study, a registration-quality, double-blind, placebo-controlled study evaluating TNX-102 SL met its pre-specified primary endpoint in the second of two positive Phase 3 clinical trials, significantly reducing daily pain compared to placebo (p=0.00005) in participants with fibromyalgia. Statistically significant and clinically meaningful results were also seen in all key secondary endpoints related to improving sleep quality, reducing fatigue, and improving patient global ratings and overall fibromyalgia symptoms and function. Additionally, as it relates to improving daily pain, treatment with TNX-102 SL showed a robust and clinically meaningful analgesic Cohen's *d* effect size of 0.38, with rapid onset of action, separating from placebo for every week of the study. TNX-102 SL was well tolerated with an adverse event profile comparable to prior studies and no new safety signals observed. Tonix plans to submit an NDA to the FDA in the second half of 2024 for TNX-102 SL for the management of fibromyalgia.
- In January 2024, Tonix presented additional safety and tolerability data from the Phase 3 RESILIENT study that showed TNX-102 SL treatment was not associated with increases in systolic or diastolic blood pressure or body weight, nor were there any reported sexual side effects.
- In January 2024, Tonix announced that the FDA has conditionally accepted the trade name, Tonmya, for the Company's drug product candidate TNX-102 SL for the management of fibromyalgia.
- In February 2024, Tonix announced positive 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 February 2024, Tonix selected Rho, Inc., a global contract research organization, to support Tonix's preparation and planned submission of its NDA to the FDA for the approval of Tonmya for the management of fibromyalgia.
- In March 2024, Tonix announced the selection of two 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 *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 UNC Institute for Trauma Recovery and supported by a $3 million grant from the U.S. Department of Defense (DoD), 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 (MVC). 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 expects 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.

· In September 2023, the Company reported topline results from its Phase 2 PREVAIL proof-of-concept study of TNX-102 SL for fibromyalgia-type Long COVID. TNX-102 SL showed a robust Cohen's *d* effect size of 0.50 in improving fatigue relative to placebo; and it showed consistent activity across secondary measures of sleep quality, cognitive function, disability and Patient Global Impression of Change, but did not meet the primary endpoint of multi-site pain reduction at Week 14. TNX-102 SL was generally well tolerated and no new safety signals were observed. The Company intends to request an End-of-Phase 2 meeting with the FDA to discuss a potential Phase 3 program based on a proposed primary outcome measure using the PROMIS Fatigue scale.

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 bone health in autism, social anxiety disorder (SAD), adolescent obesity and binge eating disorder

· In November 2023, Tonix announced that the first participant was enrolled in an investigator-initiated Phase 2 study of TNX-1900 for improving bone health in children with autism spectrum disorder, named the BOX study, at Massachusetts General Hospital (MGH). The aim of this DoD funded study is to investigate the efficacy and safety of TNX-1900 as a novel therapeutic agent to increase bone density and improve bone structure and strength in children with autism spectrum disorder. Tonix is providing active drug and placebo for the BOX study as part of a drug donation agreement with MGH. MGH is the sponsor of the trial, which is being conducted under an investigator-initiated IND application.

· TNX-1900 is also being studied in three other ongoing investigator-initiated Phase 2 studies as follows:
  - o MGH Phase 2 study for binge-eating disorder (BED)
  - o University of Washington Phase 2 study for social anxiety disorder (SAD)
  - o MGH Phase 2 study for adolescent obesity

<u>*Rare Disease Pipeline*</u>

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

· In December 2023, Tonix announced that the FDA has cleared the IND application to support clinical development of TNX-2900 to treat PWS in children and adolescents. The Phase 2 study approved under the IND 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.

· In March 2024, Tonix announced that it received Rare Pediatric Disease designation from the FDA for TNX-2900 for the treatment of PWS.

<u>*Immunology Pipeline*</u>

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 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 at the Massachusetts General Hospital (MGH) on allogeneic transplants in animals were published.[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 approximately 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 October 2023, the Company announced data from two oral presentations delivered at medical meetings in 2023. The oral presentations titled, "*Pilot Evaluation of a Clinical Xeno Heart Transplant Regimen in a Preclinical Model*" and "*Extended Survival of 9- and 10-Gene Edited Pig Heart Xenografts with Ischemia Minimization and CD154 Costimulation Blockade-Based Immunosuppression*" by Dr. Ikechukwu Ileka *et al.* include data demonstrating the use of TNX-1500 as maintenance therapy after xenogeneic heart transplant in non-human primates. In both studies, genetically engineered (GE) pigs in baboon transplants were treated with cold-perfused ischemia minimization and a novel costimulation-based immunosuppressive regimen that includes TNX-1500.

· In October 2023, Tonix announced that a study published in the Journal *Nature*[5] by faculty at the Center for Transplantation Sciences, MGH, in collaboration with biotechnology company, eGenesis, utilized TNX-1500 as part of the immune modulating regimen to prevent organ transplant rejection. The *Nature* article titled, "*Design and testing of a humanized porcine donor for xenotransplantation*" includes data that provide additional support for TNX-1500's activity in preventing pig xenograft organ rejection and for its safety and tolerability in non-human primates.

- 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. Topline results are expected in the third quarter of 2024. 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 patent in collaboration with eGenesis, which produced the pig donors.[6] Some of the pre-clinical work that supported this transplant was performed in collaboration with Tonix and used TNX-1500.[5]

Infectious Disease Pipeline

TNX-1800 (modified recombinant horsepox virus, live vaccine): potential vaccine to protect against COVID-19 designed to express the SARS-CoV-2 spike protein

- Results from a study with our TNX-1800 vaccine that showed animals were protected from challenge with SARS-CoV-2 were published as an article in the peer reviewed journal, *Viruses* in 2023.[7]

- In November 2023, Tonix announced that NIH and National Institute of Allergy and Infectious Diseases (NIAID) will conduct a Phase 1 clinical trial with TNX-1800 as part of Project NextGen. NIAID will cover the full cost of the clinical trial, including operations and related analyses. Tonix will be responsible for providing clinical trial materials, and upon completion will have the right to rely on the findings in regulatory filings with the FDA to support the approval of its COVID-19 vaccine and other vaccines based on the recombinant pox vaccine (RPV) platform.

- We believe the TNX-1800 vaccine development plan addresses several priority vaccine attributes advanced by the White House Office of Science and Technology Policy's Pandemic Preparedness Plan,[8] the National Biodefense Science Board[9] and BARDA.[10] Tonix believes its RPV platform can address a wide variety of disease targets of public health interest.

TNX-801 (recombinant horsepox virus, live vaccine): potential vaccine to protect against mpox disease and smallpox.

- Results from a study with our TNX-801 vaccine that showed animals were protected from mpox were reported at a meeting in the first quarter of 2020 and published as an article in the peer reviewed journal, *Viruses* in 2023.[11]

- On December 14, 2023, Dr. Lederman participated in a panel discussion on Vaccine Research & Development at the National Academies of Sciences, Engineering, and Medicine (NAS) Committee on the Current State of Research, Development, and Stockpiling of Smallpox Medical Countermeasures public meeting. Discussions explored lessons learned from the recent COVID-19 pandemic and mpox multi-country outbreak to inform an evaluation of the current state of research, development, and stockpiling of smallpox readiness and response measures. The Consensus Study Report was issued on March 28, 2024.[12] Some of the conclusions included recommendations for single dose vaccines, safer vaccines, vaccine platforms and attention to supply chain and manufacturing. Tonix believes TNX-801 has the potential to address some of the recommendations from the NAS Committee since it provides single dose protection to animals, and has the potential for favorable dose, manufacturing and cold chain requirements.

- In August 2023, Tonix received the official written response from a Type B pre-IND meeting with the FDA to develop TNX-801 as a potential vaccine to protect against mpox disease (formerly known as monkeypox) and smallpox. Tonix believes the FDA feedback provides a path to agreement on the design of a Phase 1/2 study and the overall clinical development plan. The Phase 1/2 clinical trial will assess the safety, tolerability, and immunogenicity of TNX-801, following the submission and clearance of an IND.

- Concerns about current state of new smallpox and mpox vaccines in development have been raised by the U.S. Bipartisan Commission on Biodefense[13] and by an outbreak of mpox in the Democratic Republic of the Congo.[14]

- Results from a study with our TNX-801 vaccine that showed decreased virulence relative to traditional live vaccinia vaccine strains were posted on the website BioRxiv in 2023.[15]

Broad-spectrum anti-viral programs

Tonix is developing potential broad-spectrum antiviral drugs in three programs: CD45-targeted therapeutics (TNX-4200), cathepsin inhibitors (TNX-3900) and viral glycan-targeted engineered biologics (TNX-4000). In 2020, the DoD announced that they are seeking broad spectrum antiviral drugs since it would be hard to predict which or how many viruses may be deployed on the battlefield.[16] Tonix hopes that one or more of our programs may help the DoD address that goal.

Marketed Products – Recent Highlights

- Tonix completed the acquisition of Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra (sumatriptan nasal spray) 10 mg from Upsher-Smith Laboratories, LLC on June 30, 2023. Both products are indicated for the treatment of acute migraine with or without aura in adults.

- Combined net product revenue of $7.8 million reported for the period July 1, 2023 – December 31, 2023 for Zembrace Symtouch and Tosymra.

- 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

- Tonix's Advanced Development Center (ADC) located in the New Bedford business park in Dartmouth, Massachusetts, is an approximately 45,000 square foot BSL-2 facility and is intended to accelerate development and clinical scale manufacturing of live-virus vaccines and biologics to support clinical trials. Tonix has engaged CBRE, an international real estate brokerage firm, to find a strategic partner for, or buyer of, ADC.

- Tonix's Research and Development Center (RDC) in Frederick, Maryland, consisting of one building totaling approximately 48,000 square feet, conducts research on central nervous system, immunology, and infectious disease candidates. The RDC facility is mostly biosafety level 2 (BSL-2), with some components designated BSL-3.

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

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

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

[6] 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)

[7] Awasthi M, et al. 2023. *Vaccines* (Basel) 11(11):1682. https://doi:10.3390/vaccines11111682

[8] Office of Science and Technology Policy (OSTP). American Pandemic Preparedness: Transforming Our Capabilities. September 2021

[9] National Biodefense Science Board (NBSB). Prioritization of Product Attribute Categories to Maximize Access for Next Generation COVID-19 Vaccines and Therapeutics. August 2023

[10] BARDA Strategic Plan 2022-2026.

[11] Noyce RS, et al. *Viruses*. 2023 26;15(2):356. doi: 10.3390/v15020356

[12] U.S. National Academy of Sciences. March 28, 2024. "Consensus Study Report: Future State of Smallpox Medical Countermeasures." https://nap.nationalacademies.org/catalog/27652/future-state-of-smallpox-medical-countermeasures

[13] Bipartisan Commission on Biodefense. (2024). *Box the Pox: Reducing the Risk of Smallpox and Other Orthopoxviruses.* Bipartisan Commission on Biodefense: Washington, DC. https://biodefensecommission.org/reports/box-the-pox-reducing-the-risk-of-smallpox-and-other-orthopoxviruses/

[14] Emanuel, G. *NPR*. March 27, 2024. "Why the mpox outbreak in the Democratic Republic of Congo is worrying disease docs." URL: www.npr.org/sections/goatsandsoda/2024/03/27/1239276957/mpox-outbreak-democratic-republic-of-congo-deadlier-strain

[15] Trefry, SV et al., BioRxiv 2023.10.25.564033; doi: https://doi.org/10.1101/2023.10.25.564033

[16] U.S. Department of Defense. Chemical and Biological Defense Program. 2022. "Approach for Research, Development, and Acquisition of Medical Countermeasure and Test Products." U.S. Department of Defense. https://media.defense.gov/2023/Jan/10/2003142624/-1/-1/0/APPROACH-RDA-MCM-TEST-PRODUCTS.PDF (accessed March 5, 2024)

Recent Highlights—Financial

As of December 31, 2023, Tonix had approximately $24.9 million of cash and cash equivalents, compared to $120.2 million as of December 31, 2022. Additionally, Tonix had inventory totaling approximately $13.6 million as of December 31, 2023. Net cash used in operations was approximately $102.0 million for the full year ended December 31, 2023, compared to $98.1 million for the same period in 2022. Net cash used by investing activities for the full year ended December 31, 2023 was approximately $29.1 million compared to $48.1 million for the same period in 2022.

In August 2022, the Company announced that it received a Cooperative Agreement grant from the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health, to support the development of its TNX-1300 product candidate for the treatment of cocaine intoxication. During the year ended December 31, 2023, Tonix received $2.7 million in funding as a reduction of related research and development expenses. Included in prepaid expense and other is an additional $0.2 million that was not received until January 2024.

On December 8, 2023, the Company executed a Loan and Guaranty Agreement (the "Loan Agreement") to issue a 36-month term loan (the "Term Loan") in the principal amount of $11.0 million with a maturity date of December 8, 2026 (the "Maturity Date"). The Term Loan was funded with an original issue discount of 9% of the principal amount of the Term Loan, or $1.0 million, which is being amortized over the term of the debt as an adjustment to the effective interest rate on the outstanding borrowings.

On December 20, 2023, the Company announced it had signed securities purchase agreements with existing healthcare-focused institutional investors for upfront gross proceeds of approximately $30 million through a registered direct offering.

On March 28, 2024, the Company announced it had signed securities purchase agreements with existing healthcare-focused institutional investors for upfront gross proceeds of approximately $4.4 million through a registered direct offering.

As of April 1, 2024, there were 84,490,862 shares of Tonix Pharmaceuticals common stock outstanding.

Fourth Quarter 2023 Financial Results

Net product revenue for the fourth quarter 2023 was approximately $3.8 million. Cost of Sales for the fourth quarter 2023 was approximately $2.4 million. Tonix completed the acquisition of two currently marketed products from Upsher-Smith Laboratories, LLC on June 30, 2023.

R&D expenses for the fourth quarter 2023 were approximately $17.1 million, compared to $24.7 million for the same period in 2022. This decrease is predominantly due to decreased non-clinical and manufacturing expenses.

SG&A expenses for the fourth quarter 2023 were $11.6 million, compared to $8.1 million for the same period in 2022. 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 compensation-related expenses.

Net loss available to common stockholders was $27.3 million, or $0.86 per share, basic and diluted, for the fourth quarter 2023, compared to net loss available to common stockholders of $34.1 million, or $3.42 per share, basic and diluted, for the same period in 2022. The basic and diluted weighted average common shares outstanding for the fourth quarter 2023 was 31,756,759 compared to 9,952,780 shares for the same period in 2022.

Full Year 2023 Financial Results

Net product revenue for the full year 2023 was approximately $7.8 million. Cost of sales for the full year 2023 was approximately $4.7 million.

R&D expenses for the full year 2023 were approximately $86.7 million, compared to $81.9 million for the same period in 2022. This increase is predominantly due to decreased non-clinical and regulatory expenses, offset by an increase in clinical, manufacturing, employee-related and professional expenses.

SG&A expenses for the full year 2023 were $34.8 million, compared to $30.2 million for the same period in 2022. The increase was primarily due to sales and marketing associated with the Company's recently acquired marketed products.

Net loss available to common stockholders was $116.7 million, or $6.85 per share, basic and diluted, for the full year 2023, compared to net loss available to common stockholders of $116.9 million, or $20.01 per share, basic and diluted, for the same period in 2022. The basic and diluted weighted average common shares outstanding for the full year 2023 was 17,039,309 compared to 5,841,447 shares for the same period in 2022.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a 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, a product candidate for which two positive 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.

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

Zembrace SymTouch and Tosymra are registered trademarks of Tonix Medicines. All other marks are property of their respective owners.

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 as filed with the Securities and Exchange Commission (the "SEC") 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)

	Year Ended December 31,		Three Months Ended December 31,	
	2023	2022	2023	2022
REVENUE:				
Product revenue, net	$ 7,768	$ —	$ 3,779	$ —
COSTS AND EXPENSES:				
Cost of revenue	$ 4,741	$ —	$ 2,367	$ —
Research and development	86,655	81,876	17,120	24,674
Selling, general and administrative	34,752	30,215	11,621	8,054
	126,148	112,091	31,108	32,728
Operating loss	(118,380)	(112,091)	(27,329)	(32,728)
Other income, net	1,722	1,873	7	1,048
Net loss	(116,658)	(110,218)	(27,322)	(31,680)
Preferred stock deemed dividend	—	6,659	—	2,404
Net loss available to common stockholders	$ (116,658)	$ (116,877)	$ (27,322)	$ (34,084)
Net loss per common share, basic and diluted	$ (6.85)	$ (20.01)	$ (0.86)	$ (3.42)
Weighted average common shares outstanding, basic and diluted	17,039,309	5,841,447	31,756,759	9,952,780

See the accompanying notes to the condensed consolidated financial statements

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

	December 31, 2023	December 31, 2022[1]
Assets		
Cash and cash equivalents	$ 24,948	$ 120,229
Inventory	13,639	-
Prepaid expenses and other	9,181	10,548
Total current assets	47,768	130,777
Other non-current assets	106,689	94,913
Total assets	$ 154,457	$ 225,690
Liabilities and stockholders' equity		
Total liabilities	$ 48,932	$ 18,508
Stockholders' equity	105,525	207,182
Total liabilities and stockholders' equity	$ 154,457	$ 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.

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Zembrace® SymTouch® (sumatriptan Injection): IMPORTANT SAFETY INFORMATION

Zembrace SymTouch (Zembrace) can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop use and get emergency help if you have any signs of a heart attack:

- discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

Zembrace is not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam shows no problem.

Do not use Zembrace if you have:

- history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- hemiplegic or basilar migraines. If you are not sure if you have these, ask your provider.
- had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation
- severe liver problems
- taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, dihydroergotamine.
- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure.
- an allergy to sumatriptan or any of the components of Zembrace

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

Zembrace can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

Zembrace may cause serious side effects including:

- changes in color or sensation in your fingers and toes
- sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever

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- cramping and pain in your legs or hips; feeling of heaviness or tightness in your leg muscles; burning or aching pain in your feet or toes while resting; numbness, tingling, or weakness in your legs; cold feeling or color changes in one or both legs or feet
- increased blood pressure including a sudden severe increase even if you have no history of high blood pressure
- medication overuse headaches from using migraine medicine for 10 or more days each month. If your headaches get worse, call your provider.
- serotonin syndrome, a rare but serious problem that can happen in people using Zembrace, especially when used with anti-depressant medicines called SSRIs or SNRIs. Call your provider right away if you have: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.
- hives (itchy bumps); swelling of your tongue, mouth, or throat
- seizures even in people who have never had seizures before

The most common side effects of Zembrace include: pain and redness at injection site; tingling or numbness in your fingers or toes; dizziness; warm, hot, burning feeling to your face (flushing); discomfort or stiffness in your neck; feeling weak, drowsy, or tired.

Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of Zembrace. For more information, ask your provider.

This is the most important information to know about Zembrace but is not comprehensive. For more information, talk to your provider and read thePatient Information and Instructions for Use. You can also visitwww.upsher-smith.com or call 1-888-650-3789.

You are encouraged to report adverse effects of prescription drugs to the FDA. Visitwww.fda.gov/medwatch, or call 1-800-FDA-1088.

INDICATION AND USAGE

Zembrace is a prescription medicine used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine.

Zembrace is not used to prevent migraines. It is not known if it is safe and effective in children under 18 years of age.

Tosymra® (sumatriptan nasal spray): IMPORTANT SAFETY INFORMATION

Tosymra can cause serious side effects, including heart attack and other heart problems, which may lead to death. Stop Tosymra and get emergency medical help if you have any signs of heart attack:

- discomfort in the center of your chest that lasts for more than a few minutes or goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort

- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

Tosymra is not for people with risk factors for heart disease (high blood pressure or cholesterol, smoking, overweight, diabetes, family history of heart disease) unless a heart exam is done and shows no problem.

Do not use Tosymra if you have:

- history of heart problems
- narrowing of blood vessels to your legs, arms, stomach, or kidney (peripheral vascular disease)
- uncontrolled high blood pressure
- severe liver problems
- hemiplegic or basilar migraines. If you are not sure if you have these, ask your healthcare provider.
- had a stroke, transient ischemic attacks (TIAs), or problems with blood circulation
- taken any of the following medicines in the last 24 hours: almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, ergotamines, or dihydroergotamine. Ask your provider if you are not sure if your medicine is listed above.
- are taking certain antidepressants, known as monoamine oxidase (MAO)-A inhibitors or it has been 2 weeks or less since you stopped taking a MAO-A inhibitor. Ask your provider for a list of these medicines if you are not sure.
- an allergy to sumatriptan or any ingredient in Tosymra

Tell your provider about all of your medical conditions and medicines you take, including vitamins and supplements.

Tosymra can cause dizziness, weakness, or drowsiness. If so, do not drive a car, use machinery, or do anything where you need to be alert.

Tosymra may cause serious side effects including:

- changes in color or sensation in your fingers and toes
- sudden or severe stomach pain, stomach pain after meals, weight loss, nausea or vomiting, constipation or diarrhea, bloody diarrhea, fever
- cramping and pain in your legs or hips, feeling of heaviness or tightness in your leg muscles, burning or aching pain in your feet or toes while resting, numbness, tingling, or weakness in your legs, cold feeling or color changes in one or both legs or feet
- increased blood pressure including a sudden severe increase even if you have no history of high blood pressure
- medication overuse headaches from using migraine medicine for 10 or more days each month.**If your headaches get worse, call your provider**.
- serotonin syndrome, a rare but serious problem that can happen in people using Tosymra, especially when used with anti-depressant medicines called SSRIs or SNRIs. **Call your provider right away if you have** mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; or trouble walking.

- hives (itchy bumps); swelling of your tongue, mouth, or throat
- seizures even in people who have never had seizures before

The most common side effects of Tosymra include: tingling, dizziness, feeling warm or hot, burning feeling, feeling of heaviness, feeling of pressure, flushing, feeling of tightness, numbness, application site (nasal) reactions, abnormal taste, and throat irritation.

Tell your provider if you have any side effect that bothers you or does not go away. These are not all the possible side effects of Tosymra. For more information, ask your provider.

This is the most important information to know about Tosymra but is not comprehensive. For more information, talk to your provider and read the Patient Information and Instructions for Use. You can also visit www.upsher-smith.com or call 1-888-650-3789.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

INDICATION AND USAGE
Tosymra is a prescription medicine used to treat acute migraine headaches with or without aura in adults.

Tosymra is not used to treat other types of headaches such as hemiplegic or basilar migraines or cluster headaches.

Tosymra is not used to prevent migraines. It is not known if Tosymra is safe and effective in children under 18 years of age.