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): November 9, 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 November 9, 2023, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter ended September 30, 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 November 9, 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.

By: /s/ Bradley Saenger

Bradley Saenger
Chief Financial Officer

Date: November 9, 2023

Exhibit 99.01

Tonix Pharmaceuticals Reports Third Quarter 2023 Financial Results and Operational Highlights

Topline Results from Phase 3 Potentially NDA-Enabling Study of TNX-102 SL in Fibromyalgia Expected Late December 2023: Centrally-Acting Non-Opioid Analgesic

Topline Results from Phase 2 Proof-of-Concept Study of TNX-1900 in Chronic Migraine Expected Early December 2023: Intranasal Potentiated Oxytocin

Meaningful Progress Made in Obtaining External Support for Clinical Trials from U.S. Government Agencies and Other Institutions

Revenue from Marketed Acute Migraine Products: Zembrace® SymTouch® (sumatriptan injection) and Tosymra® (sumatriptan nasal spray) Included in Third Quarter Financial Statements

CHATHAM, N.J., November 9, 2023 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a biopharmaceutical company with marketed products and a pipeline of development candidates, today announced financial results for the third quarter ended September 30, 2023, and provided an overview of recent operational highlights.

“Tonix expects topline results from its Phase 3 fibromyalgia study and Phase 2 chronic migraine study before year end,” said Seth Lederman, M.D., Chief Executive Officer of Tonix. “The Phase 3 RESILIENT trial in fibromyalgia, if successful, is expected to be the final efficacy trial required for submitting a New Drug Application (NDA) for approval by the U.S. Food and Drug Administration (FDA) for TNX-102 SL (cyclobenzaprine HCl sublingual tablets). In the Phase 2 proof-of-concept PREVENTION study in chronic migraine of TNX-1900 (intranasal potentiated oxytocin), all patients have completed their final visit and topline results are expected in early December 2023.”

Dr. Lederman continued, “We are continuing to shift the expense of clinical trials from our operating budget to U.S. government agencies and other institutions through partnerships. The U.S. Department of Defense (DoD) is supporting the upcoming Phase 2 study of TNX-102 SL in acute stress disorder, being conducted and sponsored by University of North Carolina (UNC). The U.S. National Institutes of Health (NIH) and National Institute of Allergy and Infectious Diseases (NIAID), through its Project NextGen, will conduct the Phase 1 study of our vaccine candidate TNX-1800 (modified recombinant horsepox virus, live vaccine). The National Institute of Drug Abuse (NIDA) is supporting our Phase 2 study of TNX-1300 (recombinant double mutant cocaine esterase) for cocaine intoxication. Massachusetts General Hospital (MGH) is conducting Phase 2 studies of TNX-1900 in binge eating disorder and pediatric obesity, and the University of Washington is conducting a Phase 2 study of TNX-1900 in social anxiety disorder. Finally, we continue to collaborate with MGH on several preclinical non-human primate studies for TNX-1500 (anti-CD40L Fc-modified humanized monoclonal antibody), currently in a Phase 1 study being conducted by Tonix. These outside collaborations leverage our internal resources and allow us to progress our clinical programs in a capital efficient manner.”

Partnerships with External Funding – Recent Highlights

- NIH/NIAID selected Tonix’s vaccine candidate, TNX-1800, as part of Project NextGen; a Phase 1 study is expected to start in the second half of 2024. NIH/NIAID will cover the full cost of the clinical trial, while Tonix will supply the vaccine candidate.
- NIDA is supporting a Phase 2 study on TNX-1300 for cocaine Intoxication; expected to start enrolling patients in the fourth quarter of 2023.
- DoD is supporting a Phase 2 investigator-initiated study of TNX-102 SL for acute stress disorder at UNC for motor vehicle accident victims; expected to start enrolling patients in 2024.
- MGH/Harvard Medical School is conducting Phase 2 investigator-initiated studies of TNX-1900 in binge eating disorder and adolescent obesity.
- The University of Washington is conducting a Phase 2 investigator-initiated study of TNX-1900 in social anxiety disorder.

Marketed Products – Recent Highlights

- In September 2023, Tonix announced that it is committed to meeting potential increased demand for Tosymra® (sumatriptan nasal spray) 10 mg after GlaxoSmithKline’s planned discontinuation of Imitrex® (sumatriptan) nasal spray 5 mg and 20 mg products after January 2024. Tonix is preparing for potential increased demand for Tosymra to help avoid possible drug shortages for patients who suffer from migraines. Tosymra nasal spray is approved on the basis of bioequivalence to Imitrex injection 4 mg.
- Tonix completed the acquisition of Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra from Upsher-Smith Laboratories, LLC in June 2023. Both products are indicated for the treatment of acute migraine with or without aura in adults.

Key Product Candidates* -- Recent Highlights

Central Nervous System (CNS) Pipeline

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

- The Company announced in August 2023 that it completed enrollment of its potentially confirmatory Phase 3 RESILIENT trial of TNX-102 SL 5.6 mg in FM. 457 participants were randomized in the trial, which, if successful, is expected to serve as the final, well-controlled efficacy trial required for submission of NDA for approval by the FDA. RESILIENT is a registration-quality, double-blind, placebo-controlled study. Topline results from the RESILIENT trial are expected in late December of 2023.

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

- In September 2023, the Company announced that the UNC Institute for Trauma Recovery has been awarded a $3 million grant from the DoD to investigate the potential of Tonix's TNX-102 SL to reduce the frequency and severity of adverse effects of acute trauma, which include ASR and ASD, and development of PTSD. 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 MVC 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 or placebo.

- Initiation of patient enrollment in the proposed investigator-sponsored OASIS study is anticipated in the beginning of 2024, subject to clearance by the FDA of an investigator-initiated Investigational New Drug (IND) application.

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

- In September 2023, the Company announced 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 0.5 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. The meeting is expected to take place in the first quarter of 2024.

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

- In October 2023, the Company announced it completed the clinical phase of the PREVENTION study, a Phase 2 proof-of-concept study of TNX-1900 for the prevention of migraine headaches in chronic migraineurs, as the last of 88 enrolled patients completed their final study visit. PREVENTION is a registration-quality, double-blind, placebo-controlled study.

- Topline results from the PREVENTION Phase 2 trial are expected in early December 2023.

- In September 2023, the Company announced that David C. Yeomans, Ph.D. presented data relevant to the proposed mechanism of TNX-1900 in treating chronic migraine in a poster and an oral presentation at the 2023 International Headache Congress (IHC) in Seoul, South Korea. The poster and oral presentation titled, "*Human trigeminal ganglia possess oxytocin receptors on CGRP positive neurons: expression increased by inflammation*," include research sponsored by and licensed to Tonix. The presentations show that oxytocin receptors are co-expressed with calcitonin gene-related peptide (CGRP) on human trigeminal ganglia neurons, which is similar to Professor Yeomans' previous findings in animal trigeminal ganglia. The inflammatory cytokine IL-6 upregulated expression of oxytocin receptors on human trigeminal neurons, consistent with the previously observed impact of inflammation on the potency of oxytocin on its receptor. In animals, oxytocin has been shown to functionally inhibit the excitability of trigeminal neurons, which is consistent with oxytocin inhibiting the release of CGRP at trigeminal nerve terminals.[1]

- Tonix announced in July 2023 that the first participant was enrolled in the investigator-initiated Phase 2 STROBE Study of TNX-1900 for the treatment of binge-eating disorder at MGH. Tonix is supporting the STROBE study through a clinical trial agreement with MGH.

- Tonix announced in July 2023 that the first participant was enrolled in a Phase 2 investigator-initiated, proof-of-concept study of TNX-1900 for enhancing social safety learning in SADSAD. Tonix entered into an agreement with the University of Washington to examine the potential role of TNX-1900 in enhancing vicarious extinction learning in SAD, compared to healthy controls.

- Tonix announced in July 2023 that the first participant was enrolled in the Phase 2 POWER study of TNX-1900 for the treatment of pediatric obesity with MGH. MGH is the sponsor of the NIH-funded trial, being conducted under an investigator-initiated IND.

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 the fourth quarter of 2023. In 2022, Tonix was awarded a Cooperative Agreement grant from NIDA, part of the 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)

- In October 2023, Herbert Harris, M.D., Ph.D., Executive Vice President, Translational Medicine of Tonix Pharmaceuticals, provided an overview of Tonix's TNX-2900 program at the Foundation for Prader-Willi Research (FPWR) Family Conference in Denver, CO. The presentation highlights preclinical 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 adolescents with PWS. In preclinical studies, Mg^{2+} increases the potency of oxytocin, which is a peptide hormone that reduces appetite and signals fullness, potentially improving receptor binding and resulting in improved therapeutic action.

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.

- In October 2023, the Company announced data from two oral presentations which were delivered recently at the American College of Surgeons (ACS) Clinical Congress 2023, and The International Pancreas and Islet Transplant Association (IPITA), the International Xenotransplantation Association (IXA), and the Cell Transplant and Regenerative Medicine Society (CTRMS) Joint Congress by faculty at the Center for Transplantation Sciences, MGH. 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 xeno 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*[2] 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 August 2023, Tonix announced the initiation of a 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.

- 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. Two peer reviewed publications described the work at the MGH on allogeneic transplants in animals were published.[3,4]

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

- In November 2023, Tonix announced that NIAID, a part of the NIH, will conduct a Phase 1 clinical trial with TNX-1800 as part of Project NextGen. The Phase 1 trial of TNX-1800 is expected to start in the second half of 2024. 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 RPV platform.

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

- 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.

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

[1]Tzabazis A, et al. *Cephalalgia*. 2016. 36(10):943-50·

[2]Anand R.P., et al. *Nature.* 2023. 622, 393–401.

[3]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

[4]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

Recent Highlights—Financial

As of September 30, 2023, Tonix had approximately $6.9 million of cash and cash equivalents, compared to $120.2 million as of December 31, 2022. Additionally, Tonix had inventory totaling approximately $13.3 million as of September 30, 2023. In August 2023, Tonix received net proceeds of approximately $6.3 million through a public offering of common stock, after deducting underwriting discount and other offering expenses. Cash used in operations was approximately $79.7 million for the nine months ended September 30, 2023, compared to $75.8 million for the same period in 2022. Cash used by investing activities for the nine months ended September 30, 2023 was approximately $28.6 million.

On September 28, 2023, the Company sold 4,050,000 shares of common stock, pre-funded warrants to purchase up to 4,950,000 shares of common stock, and accompanying common A warrants to purchase 9,000,000 shares of common stock and common B warrants to purchase up to 9,000,000 shares of common stock in a public offering for net proceeds of approximately $4.0 million, after deducting underwriting discount and other offering expenses. This public offering closed on October 3, 2023.

Third Quarter 2023 Financial Results

Net product revenue for the third quarter 2023 was approximately $4.0 million. As a reminder, Tonix completed the acquisition of two currently marketed products from Upsher-Smith Laboratories, LLC on June 30, 2023.

During the three months ended September 30, 2023, Tonix received $0.4 million from NIDA for the TNX-1300 study to treat cocaine intoxication.

R&D expenses for the third quarter 2023 were approximately $21.1 million, compared to $22.2 million for the same period in 2022. This decrease is predominantly due to decreased non-clinical and manufacturing expenses, offset by an increase in clinical, employee-related and professional expenses.

SG&A expenses for the third quarter 2023 were $8.7 million, compared to $7.4 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 $28.0 million, or $1.83 per share, basic and diluted, for the third quarter 2023, compared to net loss available to common stockholders of $29.0 million, or $4.24 per share, basic and diluted, for the same period in 2022. The basic and diluted weighted average common shares outstanding for the third quarter 2023 was 15,327,558 compared to 6,843,099 shares for the same period in 2022.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a biopharmaceutical company focused on commercializing, developing, discovering and licensing therapeutics to treat and prevent human disease and alleviate suffering. Tonix Medicines, our commercial subsidiary, markets Zembrace® SymTouch® (sumatriptan injection) 3 mg and Tosymra® (sumatriptan nasal spray) 10 mg under a transition services agreement with Upsher-Smith Laboratories, LLC from whom the products were acquired on June 30, 2023. Zembrace SymTouch and Tosymra are each indicated for the treatment of acute migraine with or without aura in adults. Tonix's development portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS development portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead development CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia, having completed enrollment of a potentially confirmatory Phase 3 study in the third quarter of 2023, with topline data expected in late December 2023. TNX-102 SL is also being developed to treat fibromyalgia-type Long COVID, a chronic post-acute COVID-19 condition, and topline results were reported in the

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third quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), is in development as a preventive treatment in chronic migraine, and enrollment has completed in a Phase 2 proof-of-concept study with topline data expected in early December 2023. TNX-1900 is also being studied in binge eating disorder, pediatric obesity and social anxiety disorder by academic collaborators under investigator-initiated INDs. 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 fourth quarter of 2023. Tonix's rare disease development 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 development 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 was initiated in the third quarter of 2023. Tonix's infectious disease pipeline includes TNX-801, a vaccine in development to prevent smallpox and mpox. TNX-801 also serves as the live virus vaccine platform or recombinant pox vaccine platform for other infectious diseases, including TNX-1800, in development as a vaccine to protect against COVID-19. During the fourth quarter of 2023, TNX-1800 was selected by the U.S. National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID) Project NextGen for inclusion in Phase 1 clinical trials. The infectious disease development portfolio also includes TNX-3900 and TNX-4000, which are classes of broad-spectrum small molecule oral antivirals.

*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. Intravail is a registered trademark of Aegis Therapeutics, LLC, a wholly owned subsidiary of Neurelis, Inc. 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 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
REVENUE:				
Product revenue, net	$ 3,989	$ —	$ 3,989	$ —
COSTS AND EXPENSES:				
Cost of revenue	$ 2,374	$ —	$ 2,374	$ —
Research and development	21,050	22,201	69,537	57,202
Selling, general and administrative	8,712	7,390	23,129	22,161

	32,136	29,591	95,040	79,363
Operating loss	(28,147)	(29,591)	(91,051)	(79,363)
Interest income, net	172	610	1,715	825
Net loss	(27,975)	(28,981)	(89,336)	(78,538)
Preferred stock deemed dividend	—	—	—	4,255
Net loss available to common stockholders	$ (27,975)	$ (28,981)	$ (89,336)	$ (82,793)
Net loss per common share, basic and diluted	$ (1.83)	$ (4.24)	$ (7.40)	$ (18.58)
Weighted average common shares outstanding, basic and diluted	15,327,558	6,843,099	12,079,583	4,455,943

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)

	September 30, 2023	December 31, 2022[1]
Assets		
Cash and cash equivalents	$ 6,914	$ 120,229
Inventory	13,317	—
Receivables, net	1,562	—
Prepaid expenses and other	9,544	10,548
Total current assets	31,337	130,777
Other non-current assets	107,945	94,913
Total assets	$ 139,282	$ 225,690
Liabilities and stockholders' equity		
Total liabilities	$ 18,449	$ 18,508
Stockholders' equity	120,833	207,182
Total liabilities and stockholders' equity	$ 139,282	$ 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
- 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

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- 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 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 adverse effects of prescription drugs to the FDA. Visit www.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.
