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 7, 2022

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 7, 2022, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter ended September 30, 2022. 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 7, 2022
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: November 7, 2022

By: /s/ Bradley Saenger

Bradley Saenger
Chief Financial Officer

Exhibit 99.01

Tonix Pharmaceuticals Reports Third Quarter 2022 Financial Results and Operational Highlights

Five Potentially Pivotal Phase 2 or 3 Studies for CNS Programs Expected to be in the Clinic by First Quarter 2023

Data from Planned Interim Analyses of TNX-102 SL in Phase 3 Fibromyalgia Study and Phase 2 Long COVID Study Expected Second Quarter 2023

Advanced Development Center in Dartmouth, Mass. and Infectious Disease Research and Development Facility in Frederick, Md. Operational

Cash and Cash Equivalents Totaled Approximately $140 Million at September 30, 2022

CHATHAM, N.J., November 7, 2022 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced financial results for the third quarter ended September 30, 2022, and provided an overview of recent operational highlights.

"Tonix continues to make meaningful progress in the development of multiple programs within its robust pipeline, having already commenced a confirmatory Phase 3 study for fibromyalgia in the second quarter of this year and a potentially pivotal Phase 2 study for Long COVID in the third quarter of this year," said Seth Lederman, M.D., Chief Executive Officer of Tonix. "We look forward to the interim data from both of these TNX-102 SL studies in the second quarter of 2023. Additionally, we look forward to advancing our other central nervous system or CNS product candidates including TNX-102 SL for PTSD, TNX-1900 for chronic migraine, TNX-1300 for cocaine intoxication, and TNX-601 ER for depression, all of which we expect to be in the clinic by first quarter 2023. Finally, we continue to make strides in immunology with TNX-1500 for preventing organ transplant rejection expected to enter into a Phase 1 study in the first half of 2023, as well as in infectious diseases with TNX-801, a vaccine to prevent smallpox and monkeypox, expected to enter into a Phase 1 study also in the first half of next year."

Recent Highlights—Key Product Candidates*

Central Nervous System (CNS) Pipeline

TNX-102 SL (cyclobenzaprine HCl sublingual tablet): small molecule for the management of fibromyalgia (FM)

- Enrollment continues in the RESILIENT study, a double-blind, randomized, placebo-controlled, potentially pivotal confirmatory Phase 3 study of TNX-102 SL for the management of fibromyalgia. Results from a planned interim analysis are expected in the second quarter of 2023.

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

- Enrollment continues in the PREVAIL study, a potentially pivotal Phase 2 study of TNX-102 SL for Long COVID. Results from a planned interim analysis are currently anticipated in the second quarter of 2023.

- Tonix presented data from a previously announced retrospective observational database study in patients with Long COVID at the International Association for the Study of Pain (IASP) 2022 World Congress on Pain. The poster presentation titled, "Retrospective Observational Database Study of Patients with Long COVID with Multi-site Pain, Fatigue, and Insomnia: A Real-World Analysis of Symptomatology and Opioid Use," included data showing that approximately 40% of patients had fibromyalgia-like multi-site pain, the rate of opioid use in Long COVID patients with multi-site pain was 34%, which increased to approximately 50% when sleep disturbance was also present. These findings support the feasibility of the currently enrolling Phase 2 study for patients with Long COVID whose symptoms overlap with fibromyalgia.

TNX-102 SL for the treatment of Posttraumatic Stress Disorder (PTSD)

- Tonix expects to begin enrolling a Phase 2 study of TNX-102 SL in police in Kenya in the fourth quarter of 2022.

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

- Tonix expects to initiate a new, potentially pivotal, Phase 2 clinical study of TNX-1300 for the treatment of cocaine intoxication in the first quarter of 2023, pending agreement with the U.S. Food and Drug Administration (FDA).

- In August 2022, Tonix received a Cooperative Agreement grant from the National Institute on Drug Abuse (NIDA), part of the National Institutes of Health (NIH), to support development of TNX-1300.

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

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

- The Company expects to begin enrollment in a Phase 2 study of TNX-1900 for the prevention of migraine headache in chronic migraineurs in the fourth quarter of 2022.

- Tonix announced that U.S. Patent 11,389,473 issued in July 2022. The patent, entitled "Magnesium-Containing Oxytocin Formulations and Methods of Use" claims methods and compositions for treating pain, including migraine headaches, using intranasal magnesium-containing oxytocin formulations. This patent, excluding possible patent term extensions, is expected to provide Tonix with U.S. market exclusivity until January 2036.

TNX-601 ER (tianeptine hemioxalate extended-release tablets): a once-daily small molecule for the treatment of major depressive disorder (MDD), PTSD, and neurocognitive dysfunction associated with corticosteroid use.

- In October 2022, Tonix announced that the FDA has cleared the Investigational New Drug (IND) application to support a Phase 2 study of TNX-601 ER for the treatment of MDD, which the Company expects to initiate in the first quarter of 2023.

- TNX-601 ER is being developed as a monotherapy and first-line treatment for MDD. No tianeptine-containing product has been approved by the FDA.

Rare Disease Pipeline

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

- In July 2022, Tonix delivered a presentation titled, "TNX-2900 (Intranasal Oxytocin + Magnesium) in Development for the Treatment of Hyperphagia in Adolescents and Young Adults with Prader-Willi Syndrome" at the World Orphan Drug Congress USA.

- TNX-2900 has been granted Orphan Drug designation from the FDA for the treatment of PWS.

Immunology Pipeline

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

- Tonix announced data from three oral presentations at the 29th International Congress of The Transplantation Society (TTS 2022) by faculty at the Center for Transplantation Sciences, Massachusetts General Hospital for TNX-1500 targeting CD40-ligand (CD40L), which is also known as CD154.

- The presentations titled, "Long-Term Rejection Free Renal Allograft Survival with Fc-Modified Anti-CD154 Antibody Monotherapy in Nonhuman Primates," and "Monotherapy with TNX-1500, a Fc-Modified Anti-CD154mAb, Prolongs Cardiac Allograft Survival in Cynomolgus Monkeys," include data demonstrating that TNX-1500 treatment showed activity in preventing organ rejection and was well tolerated in non-human primates. These presentations suggested that blockade of CD40L with TNX-1500 monotherapy consistently and safely prevented pathologic alloimmunity in non-human primate cardiac and kidney allograft models without clinical thrombosis

- The presentation titled, "Long-term (>1 year) Rejection-Free Survival of Kidney Xenografts with Triple Xenoantigen Knockout and Multiple Human Transgenes in NonHuman Primates," includes data demonstrating that TNX-1500 treatment showed activity in preventing xenograft kidney rejection and was well tolerated in non-human primates. These presentations suggested that blockade of CD40L with TNX-1500 monotherapy consistently and safely prevented pathologic xenoimmunity in non-human primate kidney xenograft models without clinical thrombosis.

- A Phase 1 study of TNX-1500 is expected to start in the first half of 2023.

Infectious Disease Pipeline

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

- As previously mentioned, Tonix announced a collaboration with the Kenya Medical Research Institute (KEMRI) to plan, seek regulatory approval for and conduct a Phase 1 clinical study in Kenya to develop TNX-801 as a vaccine to protect against monkeypox and smallpox. The study is expected to start in the first half of 2023.

- Tonix presented data from a research collaboration with The University of Alberta in a poster presentation at the 4th Symposium of the Canadian Society for Virology on June 5, 2022. The poster titled, "Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox," describes data from animals vaccinated with TNX-801 to protect against monkeypox. The poster presentation reports that all animals (n=8) vaccinated with TNX-801 were fully protected with sterilizing immunity from a challenge with intra-tracheal monkeypox. The vaccinations with TNX-801 were well tolerated. Synthetic horsepox virus is the basis for the Company's TNX-801 vaccine in development to protect against monkeypox and smallpox and for the Company's Recombinant Pox Virus (RPV) platform to protect against other pathogens, including SARS-CoV-2.

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

Recent Highlights--Financial

As of September 30, 2022, Tonix had $140.0 million of cash and cash equivalents, compared to $178.7 million as of December 31, 2021.

In October 2022, Tonix issued 1,400,000 shares of Series A convertible redeemable preferred stock and 100,000 shares of Series B convertible redeemable preferred stock to certain institutional investors in a private placement for gross proceeds of $15.0 million. The Company expects to use the proceeds to redeem the preferred stock.

Cash used in operations was approximately $23.5 million for the three months ended September 30, 2022, compared to $12.9 million for the same period in 2021. The increase in cash outlays was primarily due to an increase in research and development activities. Capital expenditures were approximately $8.8 million for the three months ending September 30, 2022 compared to $7.8 million for the same period in 2021. The increase was primarily due to the continued buildout of the ADC in North Dartmouth, Mass.

Third Quarter 2022 Financial Results

Research and development (R&D) expenses for the three months ended September 30, 2022 were $22.2 million, compared to $13.1 million for the same period in 2021. The increase is predominately due to increased clinical, manufacturing, non-clinical, employee-related and laboratory expenses. The Company continues to expect R&D expenses to increase throughout the remainder of 2022 as it moves its clinical development programs forward and invests in its development pipeline.

General and administrative (G&A) expenses for the three months ended September 30, 2022 were $7.4 million, compared to $5.5 million for the same period in 2021. The increase is primarily due to increased employee-related and financial reporting expenses.

Net loss available to common stockholders was $29.0 million, or $0.69 per share, basic and diluted, for the three months ended September 30, 2022, compared to net loss of $18.5 million, or $1.60 per share, basic and diluted, for the same period in 2021. The basic and diluted weighted average common shares outstanding for the three months ended September 30, 2022 was 41,944,289 compared to 11,581,367 shares for the same period in 2021.

Tonix Pharmaceuticals Holding Corp.*

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study launched in the second quarter of 2022 and interim data expected in the second quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute-COVID-19 condition. Tonix initiated a Phase 2 study in Long COVID in the third quarter of 2022 and expects interim data in the second quarter of 2023. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the first quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the fourth quarter of 2022. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily formulation of tianeptine being developed as a potential treatment for major depressive disorder (MDD) with a Phase 2 study expected to be initiated in the first quarter of 2023. Tonix's rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the first half of 2023. Tonix's infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. TNX-801, Tonix's vaccine in development to prevent smallpox and monkeypox, also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases. A Phase 1 study of TNX-801 is expected to be initiated in Kenya in the first half of 2023. Tonix's lead vaccine candidate for COVID-19 is TNX-1850, a live virus vaccines based on Tonix's recombinant pox live virus vector vaccine platform.

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

This press release and further information about Tonix can be found atwww.tonixpharma.com.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission (the "SEC") on March 14, 2022, 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,	
	2022	**2021**	**2022**	**2021**
COSTS AND EXPENSES:				
Research and development	$ 22,201	$ 13,082	$ 57,202	$ 46,542
General and administrative	7,390	5,453	22,161	16,291
	29,591	18,535	79,363	62,833
Operating loss	(29,591)	(18,535)	(79,363)	(62,833)
Interest income, net	610	7	825	99
Net loss	(28,981)	(18,528)	(78,538)	(62,734)
Preferred stock deemed dividend	—	—	4,255	—
Net loss available to common stockholders	$ (28,981)	$ (18,528)	$ (82,793)	$ (62,734)
Net loss per common share, basic and diluted	$ (0.69)	$ (1.60)	$ (3.06)	$ (6.02)
Weighted average common shares outstanding, basic and diluted	41,944,289	11,581,367	27,066,489	10,429,028

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

	September 30, 2022	December 31, 2021[1]
Assets		
Cash and cash equivalents	$ 139,978	$ 178,660
Prepaid expenses and other	11,161	10,389
Total current assets	151,139	189,049
Other non-current assets	91,507	51 ,851
Total assets	$ 242,646	$ 240,900
Liabilities and stockholders' equity		
Total liabilities	$ 13,722	$ 22,183
Stockholders' equity	228,924	218,717
Total liabilities and stockholders' equity	$ 242,646	$ 240,900

[1]The condensed consolidated balance sheet for the year ended December 31, 2021 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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