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, 2020**

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.)

509 Madison Avenue, Suite 1608, New York, New York 10022
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(212) 980-9155**

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))

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. ☐

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 Global Market

Item 2.02 Results of Operations and Financial Condition

On November 9, 2020, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter ended September 30, 2020. A copy of the press release that discusses this matter 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 dated November 9, 2020, issued by the Company

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 9, 2020

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

Exhibit 99.01

Tonix Pharmaceuticals Reports Third Quarter 2020 Financial Results and Operational Highlights

Data from Animal Studies of COVID-19 Vaccine Candidate, TNX-1800, Expected in Fourth Quarter 2020

Phase 1 Safety Study in Humans of TNX-1800 Expected to be Initiated in 2021

CHATHAM, NJ, November 9, 2020 (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, 2020, and provided an overview of recent operational highlights.

"This is an exciting time for Tonix as we advance TNX-1800, our COVID-19 vaccine candidate, and expect to report our first data from animal studies before year end," said Seth Lederman, M.D., President and Chief Executive Officer. "In 2021, we anticipate initiation of a Phase 1 study in humans. TNX-1800 is a live replicating vaccine based on our proprietary horsepox vector system and is designed to elicit a strong and durable T cell response in addition to antibody response to SARS-CoV-2 (CoV-2), the virus that causes COVID-19."

Recent Highlights

Research and Development

TNX-1800 (live attenuated vaccine based on Tonix's horsepox virus vector): COVID-19 vaccine candidate designed as a single-administration vaccine to elicit T cell immunity

- Data from small animal and non-human primate studies of TNX-1800 in COVID-19 models to measure safety and the immune response to the CoV-2 Spike protein are expected in the fourth quarter of 2020.
- Data from small animal and non-human primate studies of TNX-1800 to measure efficacy in CoV-2 challenge studies are expected in the first quarter of 2021.

COV-LOGIC, observational study: COVID-19 research collaboration with Southern Research

- In September, Tonix announced that the first healthy volunteer was enrolled in the observational COV-LOGIC study, a multi-cohort sample collection study of T cell and antibody immune responses to CoV-2 in volunteers who have recovered or remain asymptomatic after exposure to COVID-19. The research is part of an ongoing and broader collaboration between Tonix and Southern Research to develop and conduct animal testing of Tonix's COVID-19 vaccine candidate TNX-1800.
- Data are expected in the first half of 2021.

PRECISION, observational study: COVID-19 research collaboration with Columbia University

- In October, Tonix announced enrollment of the first participant in the observational PRECISION study, designed to examine the immune responses to COVID-19 in healthy volunteers who have recovered from COVID-19 or were asymptomatic. The research is part of an ongoing collaboration between Columbia University and Tonix that focuses on T cell and antibody responses to CoV-2. The research is designed to provide detailed immune responses to COVID-19 and to provide a foundation upon which to target vaccines and therapeutics to appropriate individuals using precision medicine.

- Data are expected in 2021.

TNX-2300 (live attenuated vaccine based on bovine parainfluenza virus): COVID-19 vaccine candidate in partnership with Kansas State University – platform designed to elicit T cell immunity by co-stimulation with CD40-ligand

- In July, Tonix entered into a research and exclusive license option agreement with Kansas State University to develop a vaccine candidate for the prevention of COVID-19 that utilizes a novel live virus vaccine vector platform and the CD40-ligand, also known as CD154 or 5c8 antigen, to stimulate T cell immunity.

- Data from small animals to measure efficacy in challenge studies using CoV-2 are expected in the second quarter of 2021.

TNX-102 SL (cyclobenzaprine HCl sublingual tablets): small molecule product candidate for management of fibromyalgia

- In September, following results from a pre-planned interim analysis, Tonix announced plans to complete the Phase 3 RELIEF study with the 503 enrolled participants and to report topline results in the fourth quarter of 2020. The independent data monitoring committee (IDMC) made the non-binding recommendation that the trial continue to completion with the addition of 210 participants to the original sample size of 470 participants, which is the maximum number of participants that could be added under the interim statistical analysis plan.

- Tonix is enrolling in a second potentially pivotal Phase 3 trial of TNX-102 SL for fibromyalgia, the RALLY study, and expects results in the second half of 2021.

TNX-1900 (novel formulation of intranasal oxytocin): small peptide product candidate for migraine and craniofacial pain

- In July, preclinical results of TNX-1900 (oxytocin formulation for intranasal delivery) were presented in a poster at the American Academy of Neurology's first-ever Sports Concussion Conference. The title of the poster was "Intranasal (IN) Oxytocin Relieves Pain and Depressive Behavior in a Rodent Model of Mild Traumatic Brain Injury (TBI)." The research was sponsored by Trigemina, Inc. In June, Tonix acquired the assets of Trigemina including certain rights to the data described on the poster.

- Tonix intends to submit an Investigational New Drug (IND) application for this program to the U.S. Food and Drug Administration (FDA) in the first quarter of 2021 and is targeting to start a Phase 2 study of TNX-1900 for the prophylactic treatment of chronic migraine in the U.S. in the second quarter of 2021. A Phase 2 trial under an investigator-initiated IND has been completed in the U.S. using TNX-1900.

TNX-1300 (cocaine esterase): biologic product candidate for cocaine intoxication

- Tonix expects to initiate a Phase 2 open-label safety study in an emergency room setting to study TNX-1300 in the first quarter of 2021. Results of a positive Phase 2 study of volunteer cocaine users in a controlled setting were reported prior to Tonix licensing the technology.

Advanced Development Center for process and analytical development

- In September 2020, Tonix completed the purchase of an approximately 40,000 square foot facility in Massachusetts to enable accelerated development and manufacturing of vaccines, including vaccines for COVID-19. Tonix expects the facility to be operational within 24 months with single-use bioreactors and purification suites with equipment for Good Manufacturing Practice (GMP) production of vaccines for clinical trials, including when fully operational the capability of producing sterile vaccines in glass vials

New Corporate Headquarters

- In the third quarter, Tonix relocated its corporate headquarters to Chatham, N.J. Within the U.S., Tonix also maintains offices in New York, Massachusetts and California.

Financial

Third Quarter 2020 Financial Results

As of September 30, 2020, Tonix had $55.7 million of cash and cash equivalents, compared to $11.2 million as of December 31, 2019. Cash used in operations was approximately $15.3 million for the three months ended September 30, 2020, compared to $6.6 million for the three months ended September 30, 2019.

Research and development expenses for the third quarter of 2020 were $8.8 million, compared to $5.1 million for the same period in 2019. This increase is predominantly due to the timing of development milestones related to the Phase 3 RELIEF and RALLY studies in fibromyalgia in 2020, as well as increased activities for the development of potential vaccine candidates, TNX-1800 and TNX-801.

General and administrative expenses for the third quarter of 2020 were $3.2 million, compared to $2.8 million for the same period in 2019. The increase is primarily due to an increase in financial reporting expenses and non-cash compensation expense.

Net loss was $12.0 million, or $0.09 per share, for the third quarter of 2020, compared to net loss of $7.8 million, or $5.69 per share, for the third quarter of 2019. The weighted average common shares outstanding, basic and diluted, for the third quarter of 2020 was 127,199,834, compared to 1,377,857 shares for the third quarter of 2019.

As of November 6, 2020, the Company has an aggregate of 156,585,050 shares of common stock outstanding.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing small molecules and biologics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is primarily composed of central nervous system (CNS) and immunology product candidates. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer and autoimmune diseases. The CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead vaccine candidate, TNX-1800*, is a live replicating vaccine based on the horsepox viral vector platform to protect against COVID-19, primarily by eliciting a T cell response. Tonix expects data from animal studies of TNX-1800 in the fourth quarter of this year. TNX-801*, live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox. Tonix is also developing TNX-2300* and TNX-2600*, live replicating vaccine candidates for the prevention of COVID-19, but using bovine parainfluenza as the vector. Tonix's lead CNS candidate, TNX-102 SL**, is in Phase 3 development for the management of fibromyalgia. The Company expects topline data in the Phase 3 RELIEF study in the fourth quarter of 2020. Tonix is also currently enrolling participants in the Phase 3 RALLY study for the management of fibromyalgia using TNX-102 SL, and the results are expected in second half of 2021. TNX-102 SL is also in development for agitation in Alzheimer's disease and alcohol use disorder (AUD). Both programs are Phase 2 ready, and the AAD program has FDA Fast Track designation. Tonix's programs for treating addiction conditions also include TNX-1300* (T172R/G173Q double-mutant cocaine esterase 200 mg, i.v. solution), which is in Phase 2 development for the treatment of life-threatening cocaine intoxication and has FDA Breakthrough Therapy designation. TNX-601 CR** (tianeptine oxalate controlled-release tablets) is another CNS program, currently in Phase 1 development as a daytime treatment for depression while TNX-1900**, intranasal oxytocin, is in development as a non-addictive treatment for migraine and cranio-facial pain. Tonix's preclinical pipeline includes TNX-1600** (triple reuptake inhibitor), a new molecular entity being developed as a treatment for PTSD; TNX-1500* (anti-CD154), a monoclonal antibody being developed to prevent and treat organ transplant rejection and autoimmune conditions; and TNX-1700* (rTFF2), a biologic being developed to treat gastric and pancreatic cancers.

*TNX-1800, TNX-801, TNX-2300, TNX-2600, TNX-1300, TNX-1500 and TNX-1700 are investigational new biologics and have not been approved for any indication.

**TNX-102 SL, TNX-601 CR, TNX-1600 and TNX-1900 are investigational new drugs and have not been approved for any indication.

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

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as “anticipate,” “believe,” “forecast,” “estimate,” “expect,” and “intend,” among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to 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, 2019, as filed with the Securities and Exchange Commission (the “SEC”) on March 24, 2020, 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 Reports Third Quarter 2020 Financial Results

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,	
	2020	**2019**	**2020**	**2019**
Costs and expenses				
Research and development	$ 8,813	$ 5,052	$ 24,060	$ 12,502
General and administrative	3,186	2,839	9,428	7,592
Total costs and expenses	11,999	7,891	33,488	20,094
Operating loss	(11,999)	(7,891)	(33,488)	(20,094)
Interest income, net	9	53	46	183
Net loss	$ (11,990)	$ (7,838)	$ (33,442)	$ (19,911)
Warrant deemed dividend	—	—	(451)	—
Preferred stock deemed dividend	—	—	(1,260)	—
Net loss available to common stockholders	$ (11,990)	$ (7,838)	$ (35,153)	$ (19,911)
Net loss per common share, basic and diluted	$ (0.09)	$ (5.69)	$ (0.49)	$ (23.93)
Weighted average common shares outstanding, basic and diluted	127,199,834	1,377,857	71,329,221	832,050

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(Unaudited)

	September 30, 2020	December 31, 2019[(1)]
Assets		
Cash and cash equivalents	$ 55,658	$ 11,249
Prepaid expenses and other	6,360	2,699
Total current assets	62,018	13,948
Other non-current assets	5,599	610
Total assets	$ 67,617	$ 14,558
Liabilities and stockholders' equity		
Total liabilities	$ 5,049	$ 5,141
Stockholders' equity	62,568	9,417
Total liabilities and stockholders' equity	$ 67,617	$ 14,558

(1) The condensed consolidated balance sheet for the year ended December 31, 2019 has been derived from the audited financial statements but does 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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