

**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): March 9, 2022

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

**Nevada
(State or Other Jurisdiction
of Incorporation)**

**001-36019
(Commission
File Number)**

**26-1434750
(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 7.01 Regulation FD Disclosure.

On March 9, 2022, Tonix Pharmaceuticals Holding Corp. (the "Company") issued a press release announcing the appointment of Jeffrey Rosenfeld, Ph.D., as its Executive Director, Genomics and Bioinformatics. A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On March 9, 2022, the Company issued a press release announcing the appointment of Jeffrey Rosenfeld, Ph.D., as its Executive Director, Genomics and Bioinformatics.

Forward-Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's filings with

the SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d)	Exhibit No.	Description.
	<u>99.01</u>	<u>Press release of the Company, dated March 9, 2022</u>
	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: March 9, 2022

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

Tonix Pharmaceuticals Announces Appointment of Jeffrey Rosenfeld, Ph.D., as Executive Director, Genomics and Bioinformatics

CHATHAM, N.J., March 9, 2022 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced the appointment of Jeffrey Rosenfeld, Ph.D., as its new Executive Director, Genomics and Bioinformatics. In this role, Dr. Rosenfeld will direct Tonix's pharmacogenomics efforts including applying artificial intelligence, genome-wide association studies and mathematical modeling techniques to the analysis of patient outcomes in Tonix's clinical trials.

"Dr. Rosenfeld brings substantial genomics expertise to Tonix that will support our efforts in pharmacogenomics and companion diagnostics," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "As we continue to advance our pipeline and programs, Dr. Rosenfeld's abilities and his passion for genomics will support the future success of our drug development efforts."

"I am excited to join Tonix to lead the Company's efforts to integrate genomics with clinical trials," said Dr. Rosenfeld. "I look forward to working closely with the team to fully realize the potential of the Company's deep portfolio of product candidates."

Dr. Rosenfeld has a record of achievement in genomics and bioinformatics. Over his 15-year career in genomics, he has contributed to a wide range of biological and genetic projects, including genetic association studies of schizophrenia and clinical cancer genome sequencing. Most recently, he led an effort to investigate markers for autism in paternal sperm. For the past seven years, Dr. Rosenfeld has been an Assistant Professor of Pathology and Laboratory Medicine and the Manager of the Biomedical Informatics Shared Resource at the Rutgers Cancer Institute of New Jersey. In 2013, he founded Genome Liberty which developed tools for direct-to-consumer pharmacogenomics testing. Dr. Rosenfeld earned his B.S. in Biology and M.S. in Biotechnology from the University of Pennsylvania and a Ph.D. in Biology from New York University. He completed doctoral research at the Cold Spring Harbor Laboratory.

About Tonix Pharmaceuticals Holding Corp.

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics and diagnostics to treat and prevent human disease and alleviate suffering. Tonix's portfolio is composed of immunology, central nervous system (CNS) and infectious disease product candidates. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including Tonix's lead immunology candidate TNX-1500¹, which is a humanized monoclonal antibody targeting CD40 ligand being developed for the prevention of allograft rejection and the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to start in the second half of 2022. The Company's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL², (cyclobenzaprine HCl sublingual tablets), is a small molecule drug in mid-Phase 3 development for the management of fibromyalgia, with a new Phase 3 study expected to start in the first half of 2022. TNX-102 SL is also being developed to treat Long COVID, a chronic post-COVID-19 condition. Tonix expects to initiate a Phase 2 study in Long COVID in the first half of 2022. TNX-1300³ is a biologic designed to treat cocaine intoxication that is expected to start a Phase 2 trial in the first half of 2022. Tonix's infectious disease pipeline includes a vaccine in development to prevent smallpox, next-generation vaccines to prevent COVID-19 and an antiviral to treat COVID-19. Tonix's lead vaccine program is TNX-801 (live horsepox virus for percutaneous administration) for preventing smallpox and monkeypox⁴. Horsepox is also the basis for Tonix's recombinant pox vaccine (RPV) platform. Tonix's lead vaccine candidates designed for COVID-19, TNX-1840 and TNX-1850⁵, are live virus vaccines in development based on the RPV platform. Finally, TNX-3500⁶ (sangivamycin, i.v. solution) is a small molecule antiviral drug to treat acute COVID-19 and is in the pre-IND stage of development.

¹TNX-1500 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.

²TNX-102 SL is an investigational new drug and has not been approved for any indication.

³TNX-1300 is an investigational new biologic and has not been approved for any indication.

⁴TNX-801 is an investigational new biologic at the pre-IND stage of development and has not been approved for any indication.

⁵TNX-1840 and TNX-1850 are investigational new biologics at the pre-IND stage of development and have not been approved for any indication. TNX-1840 and TNX-1850 are designed to express the spike protein of SARS-CoV-2 from omicron and BA.2 variants, respectively, based on the experience from TNX-1800, which expresses the spike protein from the ancestral Wuhan strain.

⁶TNX-3500 is an investigational new drug at the pre-IND stage of development and has not been approved for any indication.

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

Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; 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, 2020, as filed with the Securities and Exchange Commission (the "SEC") on March 15, 2021, 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.

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