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): February 2, 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 7.01 Regulation FD Disclosure.

On February 2, 2023, Tonix Pharmaceuticals Holding Corp. (the "Company") announced that it entered into an agreement pursuant to which it acquired all of the assets of Healion Bio, Inc. ("Healion"), including its portfolio of next-generation antiviral technology assets. 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 February 2, 2023, the Company announced that it entered into an agreement pursuant to which it acquired all of the assets of Healion, including its portfolio of next-generation antiviral technology assets. Healion's drug portfolio includes a class of broad-spectrum small molecule oral antiviral drug candidates with a novel host-directed mechanism of action, including TNX-3900, formerly known as HB-121. Host-directed antivirals modulate human cells and tissues and are different from direct-acting antivirals which inhibit virus proteins and processes. TNX-3900 are cathepsin protease inhibitors, some of which have strong activity *in vitro* against SARS-CoV-2, and are a class of molecules with potential broad spectrum anti-viral activity, either as monotherapies or in combination with other antivirals. Broad-spectrum antiviral agents have the potential to reduce viral load and allow the adaptive immune system to alert other arms of the immune system to mount a protective response.

The Company believes that its facilities and drug development experience have the potential to advance the TNX-3900 class of drugs into clinical trials.

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.
99.01	Press release of the Company, dated February 2, 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.

Date: February 2, 2023

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

Exhibit 99.01

Tonix Pharmaceuticals Announces Acquisition of Preclinical Infectious Disease Portfolio from Healion Bio, Inc.

The Acquired Portfolio of Infectious Disease Assets Includes a Class of Potential Broad Spectrum Oral Antiviral Agents, TNX-3900 with a Host-Directed Mechanism

Tonix Plans to Develop the TNX-3900 Series of Molecules as Oral Antivirals Either as Monotherapy or in Combination with Other Antivirals

The TNX-3900 Class of Antivirals Has a Novel Mechanism of Action Based on Inhibition of Certain Cathepsin Proteases which are Required for Cell Infection by Many Viruses like SARS-CoV-2

Sina Bavari, Ph.D., Tonix EVP of Infectious Disease R&D and Director of the Frederick, MD Research and Development Center (RDC) was a Scientific Founder of Healion Bio, Inc.

CHATHAM, N.J., February 2, 2023 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced an agreement whereby Tonix has acquired all of the assets of Healion Bio, Inc. (Healion) including its entire portfolio of next-generation antiviral technology assets. Healion's drug portfolio includes a class of broad-spectrum small molecule oral antiviral drug candidates with a novel host-directed mechanism of action. Host-directed antivirals modulate human cells and tissues and are different from direct-acting antivirals which inhibit virus proteins and processes. Tonix's TNX-3900, formerly known as HB-121, are cathepsin protease inhibitors, some of which have strong activity *in vitro* against SARS-CoV-2.

"We are excited to develop Healion's drug programs that include TNX-3900, which is a class of drugs with potential broad spectrum anti-viral activity, either as monotherapies or in combination with other antivirals", said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Broad-spectrum antiviral agents have the potential to reduce viral load and allow the adaptive immune system to alert the other arms of the immune system to mount a protective response. Examples of other classes of host-directed antivirals that have been approved by the U.S. Food and Drug Administration (FDA) include alpha interferon like Pegasys® (peginterferon alfa-2a) for viral hepatitis, the CCR5 antagonist Selzentry® (maraviroc) for HIV, and the anti-IL-6 receptor antagonist monoclonal antibody Actemra® (tocilizumab) for COVID-19."

Sina Bavari, Ph.D., Executive Vice President for Infectious Disease Research at Tonix said, "I am pleased to be reunited with the infectious disease assets of Healion, since I was the scientific founder of Healion after I retired from my position as Chief of R&D at the United States Army Medical Research Institute of Infectious Disease (USAMRIID). While Healion made some progress developing these advanced technologies, Tonix's state-of-the art facilities and depth of drug development expertise have the potential to advance the TNX-3900 class of drugs into clinical trials. On behalf of the talented scientific team that I direct at our 48,000 square-foot cutting-edge infectious disease research facility in Frederick, Md., I am pleased to add this technology to the therapeutic development programs underway."

About TNX-3900

TNX-3900 is the term for a series of molecules that inhibit essential cathepsins which are required by viruses such as coronaviruses and filoviruses to infect cells. Because of the unique antiviral mechanism of these compounds, the Company believes they can potentiate the activity of other antivirals with differing mechanisms. The Company believes this makes cathepsin inhibitors suitable for combination therapy.

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. 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 second 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 first quarter of 2023. 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 second quarter of 2023. Tonix's infectious disease pipeline includes a vaccine in development to prevent smallpox and monkeypox, TNX-801, a next-generation vaccine to prevent COVID-19, TNX-1850, a platform to make fully human monoclonal antibodies to treat COVID-19, TNX-3600, and humanized anti-SARS-CoV-2 monoclonal antibodies, TNX-3800, recently licensed from Curia. 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 second half of 2023.

** 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 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, 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.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 904-8182

Olipriya Das, Ph.D. (media)
Russo Partners
Olipriya.Das@russopartnersllc.com
(646) 942-5588

Peter Vozzo (investors)
ICR Westwicke
peter.vozzo@westwicke.com
(443) 213-0505