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 15, 2021

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, Suite 101, 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 Global 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 March 15, 2021, Tonix Pharmaceuticals Holding Corp. (the "Company") announced its operating results for the quarter and year ended December 31, 2020. 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 7.01 Regulation FD Disclosure.

On March 15, 2021, the Company issued a press release announcing that it achieved 50% enrollment in the Phase 3 RALLY study of its TNX-102 SL product candidate for the management of fibromyalgia. A copy of the press release is furnished as Exhibit 99.02 hereto and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.02 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 15, 2021, the Company announced that 50% of the planned total number of participants were randomized in the Phase 3 RALLY study (TNX-CY-F306) of its TNX-102 SL product candidate for the management of fibromyalgia. An interim analysis of the first 50% of randomized participants in the RALLY study will be conducted shortly after the 14-week treatment period has been completed by these participants. Pending approval of the interim statistical analysis plan by the U.S. Food and Drug Administration (the "FDA"), results from the interim analysis are expected in the third quarter of 2021. The Company believes that it is on track to release topline data from the RALLY study in the fourth quarter of 2021. If topline results are positive, the Company expects to be in a position to submit a New Drug Application for TNX-102 SL for fibromyalgia to the FDA in 2022.

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 results of the Phase 3 RELIEF study, 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 March 15, 2021
99.02	Press release of the Company, dated March 15, 2021

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 15, 2021

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

Exhibit 99.01

Tonix Pharmaceuticals Reports Fourth Quarter and Full Year 2020 Financial Results and Operational Highlights

Announced Positive Phase 3 RELIEF Study Results for TNX-102 SL 5.6 mg in Fibromyalgia

Interim Analysis Results from Second Confirmatory Phase 3 Study, RALLY, Expected in Third Quarter 2021: Interim Cohort Enrolled

Efficacy Data from Animal Studies of COVID-19 Vaccine Candidate, TNX-1800, Expected in First Quarter 2021

Phase 1 Safety Study in Humans of TNX-1800 Expected to Start in Second Half 2021

At December 31, 2020, Cash and Cash Equivalents Totaled $77.1 Million;
Approximately $110 Million in Gross Proceeds Raised Subsequent to Year-End

CHATHAM, NJ, March 15, 2021 (GLOBE NEWSWIRE) – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced financial results for the fourth quarter and full year ended December 31, 2020, and provided an overview of recent operational highlights.

"We continue to make progress across our development programs and are steadily advancing our diverse pipeline of CNS and immunology product candidates," said Seth Lederman, M.D., President and Chief Executive Officer. "In 2021, we expect to deliver on several important milestones. Following on the success of our first pivotal Phase 3 fibromyalgia study, RELIEF, we look forward to reporting interim and topline data from a second potentially pivotal Phase 3 fibromyalgia study, RALLY, this year. We recently reported that we achieved enrollment of the first 50 percent of participants in RALLY, which we expect will be the interim analysis cohort. We also expect to report preclinical efficacy data from our COVID-19 vaccine candidate this quarter and start a Phase 1 study in humans in the second half of this year. Finally, we expect to initiate new clinical trials this year for several other programs including a Phase 2 cocaine intoxication trial, Phase 2 migraine trial, and a proof-of-concept study for the skin test for COVID-19 exposure to measure T cell immunity."

Recent Highlights

*Research and Development**

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

- TNX-102 SL is a non-opioid, centrally-acting analgesic, taken once daily at bedtime, being developed for the management of fibromyalgia. In December 2020, Tonix announced TNX-102 SL met its pre-specified primary endpoint in the Phase 3 RELIEF study (p=0.01), significantly reducing daily pain compared to placebo in participants with fibromyalgia. Activity was also shown in key secondary endpoints of improving sleep, reducing fatigue, and improving overall fibromyalgia symptoms and function. The drug was generally well tolerated with no new safety signals observed. RELIEF was a 14-week randomized, double-blind, placebo-controlled trial of TNX-102 SL 5.6 mg that included 503 participants with fibromyalgia.

- Tonix recently announced that 50 percent of the planned total number of participants have been randomized in the second potentially pivotal Phase 3 trial of TNX-102 SL for fibromyalgia, the RALLY study. Approximately 670 participants are targeted for enrollment for the full study. The Company expects the results of an interim analysis in the third quarter of 2021, followed by topline results in the fourth quarter of 2021. Following a second positive Phase 3 study, Tonix expects to submit a New Drug Application for TNX-102 SL for fibromyalgia to the U.S. Food and Drug Administration (FDA) in 2022.

TNX-1800 (live attenuated vaccine based on Tonix's horsepox virus vector, TNX-801): COVID-19 vaccine candidate designed as a single-administration vaccine to elicit T cell immunity

- In November 2020, the Company announced results following vaccination of non-human primates with TNX-1800 in COVID-19 models to measure safety and the immune response to the SARS-CoV-2 Spike protein. Data demonstrated that TNX-1800 at a low dose induces a strong immune response to SARS-CoV-2 in non-human primates, with all eight animals manifesting "takes", a skin reaction which is a validated biomarker of functional T cell immunity.

- Efficacy results from a study of TNX-1800 in which non-human primates were vaccinated with TNX-1800 and challenged with live SARS-CoV-2 are expected in the first quarter of 2021.

- A Phase 1 safety study using TNX-1800 in humans is anticipated to start in the second half of 2021, pending Investigational New Drug (IND) clearance from the FDA.

TNX-2100 (diagnostic skin test): SARS-CoV-2 epitope peptide mixtures for intradermal administration to measure the delayed-type hypersensitivity (DTH) reaction to SARS-CoV-2

- Based on guidance from the FDA the Company plans to file an IND in the second quarter of 2021 and initiate clinical trials in the second half of 2021. The Company has already manufactured peptides under cGMP. TNX-2100 is designed to measure functional, or meaningful, *in vivo* T cell immunity to SARS-CoV-2. T cell immunity to SARS-CoV-2 persists longer than antibody immunity, is sometimes present in the absence of a measurable antibody response and is believed to provide an important element of protection against serious COVID-19 illness after infection with SARS-CoV-2. TNX-2100 is a test comprising three different mixtures of synthetic peptides (TNX-2110, -2120 and -2130), which are designed to represent different protein components of the SARS-CoV-2 virus.

- Tonix's proposed skin test has the potential to serve as: 1) a biomarker for cellular immunity and protective immunity; 2) a method to stratify participants in COVID-19 vaccine trials by immune status; 3) an endpoint in COVID-19 vaccine trials, and 4) a biomarker of durability of vaccine protection.

TNX-1900 (intranasal potentiated oxytocin): small peptide product candidate for migraine, craniofacial pain, insulin resistance and related disorders

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- Tonix intends to submit an IND application to the FDA in the second 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 third quarter of 2021. A Phase 2 trial under an investigator-initiated IND was completed in the U.S. using TNX-1900 prior to Tonix's acquisition of the program.

- In June 2020, Tonix acquired the assets of Trigemina, Inc., including the rights to develop TNX-1900 for migraine and craniofacial pain. In December 2020, Tonix acquired an exclusive license to the University of Geneva's technology for using oxytocin to treat insulin resistance and related syndromes, including obesity. This license allows Tonix to expand its intranasal potentiated oxytocin development program into cardiometabolic syndromes, which include insulin resistance, impaired glucose tolerance, and obesity.

TNX-2900 (novel formulation of intranasal potentiated oxytocin): small peptide product candidate for the treatment of Prader-Willi syndrome

- In February 2021, Tonix announced an agreement whereby the Company has licensed technology using oxytocin-based therapeutics for the treatment of Prader-Willi syndrome from Inserm, the French National Institute of Health and Medical Research. The co-exclusive license allows Tonix to expand its intranasal potentiated oxytocin development program to a new indication.

- Prader-Willi syndrome is an orphan disease that occurs in approximately one in 15,000 births, and is recognized as the most common genetic cause of life-threatening childhood obesity, affecting males and females with equal frequency and all races and ethnicities. There is currently no approved treatment for either the suckling (breastfeeding) deficit in infants or the obesity and hyperphagia in older children associated with Prader-Willi syndrome. Tonix plans to submit applications to the FDA for Orphan Drug and Fast Track designations for TNX-2900.

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

- Tonix expects to initiate a Phase 2 open-label safety study in an emergency room setting to study TNX-1300 in the second quarter of 2021. Results of a positive Phase 2 study of volunteer cocaine users in a controlled laboratory setting were reported prior to Tonix licensing the technology. Cocaine esterase is the most potent known catalyst for cocaine degradation.

TNX-1500 (monoclonal antibody anti-CD154): third generation monoclonal antibody as a potential first line monotherapy for preventing or treating organ transplant rejection and treating autoimmune disorders

- In January 2021, Tonix announced a second research collaboration the Massachusetts General Hospital (MGH) in Boston to develop TNX-1500, a humanized monoclonal antibody (mAb) that targets the CD40-ligand for the prevention of organ transplant rejection. The new collaboration will focus on kidney transplantation, while an earlier collaboration with MGH is focused on heart transplantation. The Company expects to have TNX-1500 GMP material available in the third quarter of 2021.

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

Financial

As of December 31, 2020, Tonix had $77.1 million of cash and cash equivalents, compared to $11.2 million as of December 31, 2019. Cash used in operations was approximately $48.6 million for the full year ended December 31, 2020, compared to $26.7 million for full year ended December 31, 2019. The increase in cash used in operations resulted principally from an increase in research and development and general and administrative activities as defined below.

For the year ended December 31, 2020, net proceeds from financing activities were $123.1 million, predominantly from the sale of common stock and exercise of warrants. In January 2021, the Company sold 50,000,000 shares of common stock at $0.80 per share, priced at-the-market, for gross proceeds of approximately $40 million, and net proceeds of approximately $36.9 million, after deducting the underwriting discount and other offering expenses. In February 2021, the Company sold 58,333,334 shares of common stock at $1.20 per share in a registered direct public offering, priced at-the-market, for gross proceeds of approximately $70 million, and net proceeds of approximately $65.0 million, after deducting the underwriting discount and other offering expenses.

Fourth Quarter 2020 Financial Results

Research and development expenses for the fourth quarter of 2020 were $12.1 million, compared to $5.7 million for the same period in 2019. This increase is predominantly due to two Phase 3 studies ongoing during this time for TNX-102 SL for fibromyalgia as well as the development of potential COVID-19 vaccine candidate, TNX-1800, which was not in development in 2019.

General and administrative expenses for the fourth quarter of 2020 were $4.9 million, compared to $3.0 million for the same period in 2019. The increase is primarily due to an increase in financial reporting expenses, patent prosecution and maintenance costs and an increase in headcount.

Net loss available to common stockholders was $17.0 million, or $0.10 per share, basic and diluted, for the fourth quarter of 2020, compared to net loss of $11.2 million, or $2.86 per share, basic and diluted, for the fourth quarter of 2019. The basic and diluted weighted average common shares outstanding for the fourth quarter of 2020 was 163,873,489, compared to 3,912,800 shares for the fourth of 2019.

Full Year 2020 Financial Results

Research and development expenses for full year 2020 were $36.2 million, compared to $18.2 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, increased activities for the development of potential vaccine candidates, TNX-1800 and TNX-801 as well as the Trigemina asset acquisition.

General and administrative expenses for full year 2020 were $14.4 million, compared to $10.6 million for the same period in 2019. The increase is primarily due to an increase in legal fees, patent prosecution and maintenance costs, financial reporting expenses and increased employee headcount.

Net loss available to common stockholders was $52.2 million, or $0.55 per share, basic and diluted, for full year 2020, compared to net loss available to common stockholders of $31.1 million, or $19.33 per share, basic and diluted, for full year 2019. The basic and diluted weighted average common shares outstanding for full year 2020 was 94,591,715, compared to 1,608,568 shares for full year 2019.

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 CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL[1], is in mid-Phase 3 development for the management of fibromyalgia, and positive data on the RELIEF Phase 3 trial were recently reported. The Company expects interim data from a second Phase 3 study, RALLY,

in the third quarter of 2021[2] and topline data in the fourth quarter of 2021. The immunology portfolio includes vaccines to prevent infectious diseases and biologics to address immunosuppression, cancer, and autoimmune diseases. 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 efficacy data from animal studies of TNX-1800 in the first quarter of 2021. TNX-801[3], live horsepox virus vaccine for percutaneous administration, is in development to protect against smallpox and monkeypox.

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

[2]Pending submission and agreement from FDA on statistical analysis plan.

[3]TNX-1800 and TNX-801 are investigational new 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 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 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 Fourth Quarter 2020 Financial Results

TONIX PHARMACEUTICALS HOLDING CORP.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(Unaudited)

	Full Year Ended December 31,		Three Months Ended December 31,	
	2020	2019	2020	2019
Costs and expenses				
Research and development	$ 36,157	$ 18,192	$ 12,097	$ 5,690
General and administrative	14,354	10,636	4,926	3,044
Total costs and expenses	50,511	28,828	17,023	8,734
Operating loss	(50,511)	(28,828)	(17,023)	(8,734)
Interest income, net	48	210	2	27
Net loss	$ (50,463)	$ (28,618)	$ (17,021)	$ (8,707)
Warrant deemed dividend	(451)	—	—	—
Preferred stock deemed dividend	(1,260)	(2,474)	—	(2,474)
Net loss available to common stockholders	$ (52,174)	$ (31,092)	$ (17,021)	$ (11,181)
Net loss per common share, basic and diluted	$ (0.55)	$ (19.33)	$ (0.10)	$ (2.86)
Weighted average common shares outstanding, basic and diluted	94,591,715	1,608,568	163,873,489	3,912,800

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

	December 31, 2020[1]	December 31, 2019[1]
Assets		
Cash and cash equivalents	$ 77,068	$ 11,249
Prepaid expenses and other	10,921	2,699
Total current assets	87,989	13,948
Other non-current assets	10,194	610
Total assets	$ 98,183	$ 14,558
Liabilities and stockholders' equity		
Total liabilities	$ 10,535	$ 5,141
Stockholders' equity	87,648	9,417
Total liabilities and stockholders' equity	$ 98,183	$ 14,558

[1] The condensed consolidated balance sheets for the years ended December 31, 2020 and December 31, 2019 have 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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Exhibit 99.02

Tonix Pharmaceuticals Achieves 50 Percent Enrollment in RALLY, the Second Phase 3 Study of TNX-102 SL for Management of Fibromyalgia

Enrollment Continues in Phase 3 RALLY Study, with Interim Analysis of the First 50 Percent of Participants Expected Third Quarter 2021

Topline Results of Approximately 670 Participants in RALLY Expected Fourth Quarter 2021

Positive Topline Results from RELIEF, the First Phase 3 Study of TNX-102 SL for Management of Fibromyalgia, Previously Announced December 2020

CHATHAM, N.J., March 15, 2021 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that 50 percent of the planned total number of participants have been randomized in the Phase 3 RALLY study (TNX-CY-F306) for the management of fibromyalgia. RALLY is the Company's second of two potential pivotal Phase 3 studies of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) 5.6 mg, a non-opioid, centrally acting analgesic, taken daily at bedtime. The RALLY study utilizes the same protocol design as the Company's first positive Phase 3 study, RELIEF, but with an additional 200 patients.

"We believe that achieving this milestone keeps us on plan for the anticipated release of interim results from RALLY in the third quarter and topline data in the fourth quarter of this year," said Tonix's President and Chief Executive Officer, Seth Lederman, M.D. "If the topline results are positive, we expect to be in a position to submit a New Drug Application (NDA) for TNX-102 SL for fibromyalgia to the U.S. Food and Drug Administration (FDA) in 2022."

In December 2020, the Company reported positive topline results from the RELIEF study, its first Phase 3 study for TNX-102 SL 5.6 mg in fibromyalgia. In the RELIEF study, the 5.6 mg dose achieved statistically significant pain reduction over placebo at Week 14 (primary endpoint, p=0.01). In addition, TNX-102 SL was generally well tolerated with an adverse event profile comparable to prior studies, and no new safety signals observed.

An interim analysis of the first 50 percent of randomized participants in the RALLY study will be conducted shortly after the 14-week treatment period has been completed by these participants. Pending approval of the interim statistical analysis plan by the FDA, results from the interim analysis are expected in the third quarter of 2021. The interim analysis will be conducted by an Independent Data Monitoring Committee (IDMC) which will review the unblinded data and make one of four recommendations: (1) stop the study for success; (2) continue to enroll the full study as planned; (3) continue to enroll with a specified increase in the total number of participants in the full study; or (4) stop the study for futility.

About the Phase 3 RALLY Study

The RALLY study is a double-blind, randomized, placebo-controlled trial designed to evaluate the efficacy and safety of TNX-102 SL (cyclobenzaprine HCl sublingual tablets). The two-arm trial is expected to enroll approximately 670 patients across approximately 40 U.S. sites. For the first two weeks of treatment, there is a run-in period in which participants start on TNX-102 SL 2.8 mg (1 tablet) or placebo. After the first two weeks, all participants have the dose increased to TNX-102 SL 5.6 mg (2 x 2.8 mg tablets) or two placebo tablets for 12 weeks. The primary endpoint is daily diary pain severity score change (TNX-102 SL 5.6 mg vs. placebo) from baseline (using the weekly averages of the daily numerical rating scale scores), analyzed by mixed model repeated measures with multiple imputation.

About Fibromyalgia

Fibromyalgia is a chronic pain disorder that is thought to result from amplified sensory and pain signaling. Fibromyalgia afflicts an estimated 6-12 million adults in the U.S, and physicians and patients report widespread dissatisfaction with currently marketed products. Common symptoms of fibromyalgia include chronic widespread pain, nonrestorative sleep, fatigue, and morning stiffness. Other associated symptoms include cognitive dysfunction and mood disturbances, including anxiety and depression. Individuals suffering from fibromyalgia struggle with their daily activities, have impaired quality of life, and frequently are disabled.

Tonix Pharmaceuticals Holding Corp.

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

[2]Pending submission and agreement from FDA on statistical analysis plan.

[3]TNX-1800 and TNX-801 are investigational new 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 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 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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