

**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 16, 2016

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.)

509 Madison Avenue, Suite 306, New York, New York 10022
(Address of principal executive offices) (Zip Code)

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

Copy of correspondence to:

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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))
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Item 5.05 Amendments to the Registrant’s Code of Ethics, or Waiver of a Provision of the Code of Ethics.

On February 9, 2016, the Board of Directors of Tonix Pharmaceuticals Holding Corp. (the “Company”) adopted and approved an amended and restated Code of Business Conduct and Ethics for Employees, Executive Officers and Directors (the “Code of Ethics”) as part of its regular review of the corporate governance policies of the Company.

The amendments are intended to update the Code to better conform to current best practices and include expanded guidelines. The conflicts of interests section in the Code of Ethics was expanded to (i) provide additional guidance on the types of situations that may create conflicts of interests, (ii) provide more detail on the Company’s processes for reviewing and handling situations that may create conflicts of interest and (iii) clarify the duty to report conflicts of interest or potential conflicts of interest. In addition, the insider trading section in the Code of Ethics was revised to clarify on the types of situations that could result in insider trading. In addition, the revised Code of Ethics provides more detailed guidance with respect to confidentiality, corporate opportunities, public disclosures, discrimination and harassment, political contributions and activities and compliance, reporting and enforcement of the Code of Ethics.

The foregoing description is a summary and is qualified in its entirety by reference to the full text of the revised Code of Ethics, which is filed as Exhibit 14.01 to this Current Report on Form 8-K. A copy of the revised Code of Ethics is publicly available on the Company’s website “www.tonixpharma.com” under the Governance Documents section of the Investors page.

Item 7.01 Regulation FD Disclosure.

The Company intends to utilize an updated investor presentation to conduct meetings with investors, stockholders and analysts and at investor conferences, and which the Company intends to place on its website, which may contain non-public information. A copy of the presentation is filed as Exhibit 99.01.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01, is furnished pursuant to, and shall not be deemed to be “filed” for the purposes of, Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information contained in Item 7.01 of this Current Report shall not be incorporated by reference into any registration statement or any other document filed pursuant to the Securities Act of 1933, as amended, except as otherwise expressly stated in such filing. By filing this Current Report on Form 8-K and furnishing the information contained in this Item 7.01, including Exhibit 99.01, the Company makes no admission as to the materiality of any such information that it is furnishing.

Item 8.01 Other Events.

On February 16, 2016, the Company issued a press release announcing the top line data results from its Phase 2 proof-of-concept clinical study of TNX-201 (dexisometheptene mucate) in episodic tension-type headache.

A copy of the press release that discusses this matter is filed as Exhibit 99.02 to, and incorporated by reference in, this report. The information in this Current Report is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

14.01 Code of Business Conduct and Ethics for Employees, Executive Officers and Directors, adopted February 9, 2016

99.01 Corporate Presentation by the Company for February 2016*

99.02 Press Release, dated February 16, 2016, issued by Tonix Pharmaceuticals Holding Corp.*

* Furnished herewith.

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 16, 2016

By: /s/ JESSICA MORRIS
Jessica Morris
Acting Chief Financial Officer

TONIX PHARMACEUTICALS HOLDING CORP.

Code of Business Conduct and Ethics for Employees, Executive Officers and Directors

Effective as of February 9, 2016

Introduction

Tonix Pharmaceuticals Holding Corp. (the “**Company**”) strives to apply high ethical, moral and legal principles in every aspect of its business conduct. This Code of Business Conduct and Ethics is a guide for all Company personnel consisting of employees and directors.

This Code applies to all Company personnel, and is addressed to each employee and director individually. It sets forth broad ethical principles that the Company has established for the conduct of its business, and outlines certain key legal requirements of which all Company personnel must be aware and with which all Company personnel must comply. This Code is not intended to cover every issue that may arise, and in the course of performing their duties and responsibilities for the Company, all personnel should act with these principles in mind and should use good judgment and common sense at all times.

This Code is designed to deter wrongdoing and promote the following:

- Honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest;
- Avoidance of conflicts of interest, including disclosure to an appropriate Company representative of any material transaction or relationship that reasonably could be expected to give rise to such a conflict;
- Full, fair, accurate, timely, and understandable disclosure in reports and documents that the Company files with the Securities and Exchange Commission (“**SEC**”) and in other public communications made by the Company;
- Compliance with applicable governmental laws, rules and regulations;
- protection of Company assets, including corporate opportunities and confidential information;
- Prompt internal reporting of violations of this Code to an appropriate person; and
- Accountability for adherence to this Code.

Each director, officer and employee must act with integrity and observe the highest ethical standards of business conduct in his or her dealings with the Company's customers, suppliers, partners, service providers, competitors, employees and anyone else with whom he or she has contact in the course of performing his or her job.

Company personnel who violate the standards contained in this Code will be subject to disciplinary action, possibly including termination of employment.

1. Conflicts of Interest

A “conflict of interest” exists when an individual’s private interest (or the interest of a member of his or her family) interferes with or appears to interfere with the interests of the Company. A conflict of interest can arise when the individual (or a member of his or her family) acts or has interests that may make it difficult for him or her to objectively and effectively perform his or her work for the Company. Conflicts of interest also can arise when the individual, or a member of his or her family, receives improper personal benefits because of his or her position in the Company.

Unless approved by the Board, neither you nor any member of your immediate family can acquire a financial interest in, or accept employment with, an entity doing business with the Company if the interest or employment could conflict with your duties to the Company and the performance of such duties. For example, it is usually a conflict of interest for Company personnel to work simultaneously for a competitor, customer or supplier. Also, you cannot work for a competitor as an employee, consultant or board member.

Loans by the Company to, or guarantees by the Company of obligations of, employees or their family members are of special concern and could constitute improper personal benefits to the recipients of such loans or guarantees, depending on the facts and circumstances. Loans by the Company to, or guarantees by the Company of obligations of, any director or executive officer or their family members are expressly prohibited.

In addition, you and your immediate family members cannot accept material gifts or favors that could create the appearance that your business judgment could be affected by the receipt of such gifts or favors. You and members of your immediate family, however, can accept gifts of nominal value from existing sources, prospective sources or persons, firms or companies with whom the Company does or might do business.

The purpose of business entertainment and gifts in a commercial setting is to create good will and sound working relationships, not to gain unfair advantage with customers. You cannot offer gifts or favors to any employee, or a member of the employee’s immediate family, of a competitor, supplier or customer if the gifts or favors might place the recipient under any obligation to you or to the Company.

Conflicts of interest are prohibited as a matter of Company policy. You are required to bring any conflict of interest or potential conflict of interest to the attention of your immediate supervisor, the Company’s chief financial officer or other appropriate person as described in Section 14. Conflicts of interest may not always be apparent, so if you have a question regarding whether a particular situation is a conflict of interest, you should consult with your immediate supervisor or contact the Company’s chief financial officer. Executive officers or members of the Board should consult with a member of the Audit Committee of the Board, which consists entirely of outside, independent directors.

2. Corporate Opportunities

All directors, officers and employees owe a duty to the Company to advance its interests when the opportunity arises. Directors, officers and employees are prohibited from taking for themselves personally (or for the benefit of friends or family members) opportunities that are discovered through the use of Company assets, property, information or position. Directors, officers and employees may not use Company assets, property, information or position for personal gain (including gain of friends or family members). In addition, no director, officer or employee may compete with the Company.

3. Confidentiality

Company personnel must maintain the confidentiality of all confidential and nonpublic information received from the company or its customers and suppliers, except when disclosure is authorized by an executive officer of the Company or compelled by disclosure laws or valid legal process. Confidential information includes all information that, if disclosed, might be of use to competitors, or harmful to the Company or its customers or suppliers. It also includes information that customers and suppliers have entrusted to the Company. For example, confidential information includes financial documents, pricing or vendor information, corporate development materials, the cost of goods, personnel files, manuals and procedures, computer software, design documents, videos and internal reports or memoranda. Information that the Company has made public, such as press releases, advertisements or documents filed with governmental regulatory authorities, is not confidential information. The obligation to preserve confidential information extends beyond the term of employment with, or service to, the Company. Furthermore, in addition to your ethical obligation to preserve the confidential nature of such sensitive information, you must abide by the terms of your proprietary information and assignment of inventions agreement with the Company.

4. Fair Dealing

The Company seeks to outperform its competition fairly and honestly through superior performance and not through unethical or illegal business practices. Company personnel must deal fairly with the Company's customers, suppliers, partners, service providers, competitors, employees and anyone else with whom he or she has contact in the course of performing his or her job. Company personnel cannot steal proprietary information, possess trade secret information obtained without the owner's consent, or induce such disclosures by past or present employees of other companies. You may not take unfair advantage of anyone through manipulation, concealment, abuse of confidential information, misrepresentation of material facts or any other intentional unfair practice. The knowing or deliberate falsification of any documents or data in connection with service to the Company will be the basis for immediate discharge and may subject the violator to civil and/or criminal penalties.

5. Protection and Proper Use of Company Assets

Company personnel must endeavor to protect the Company's assets and property and ensure their efficient use. Theft, carelessness, and waste have a direct adverse impact on the Company's profitability and are prohibited. All payments with Company funds require approval by an authorized officer who has knowledge of the purpose of the payment, adequate substantiation of the identity of the payee and written contracts establishing the payment obligation. Company personnel must report any suspected incident of fraud or theft immediately for investigation. Moreover, Company personnel must use all assets and property of the Company only for legitimate business purposes.

The obligation of Company personnel to protect the Company's assets extends to the Company's intellectual property. Intellectual property includes trade secrets, patents, patent applications, trademarks, and copyrights, as well as business, marketing and service plans, clinical studies, regulatory dossiers, formulations, designs, databases, records, salary information and any non-public financial data and reports. Unauthorized use or distribution of this information violates Company policy and may subject the violator to civil and/or criminal penalties.

6. Compliance with Laws, Rules and Regulations

Employees, officers and directors should comply, both in letter and spirit, with all applicable laws, rules and regulations in the cities, states and countries in which the Company operates. Although not all employees, officers and directors are expected to know the details of all applicable laws, rules and regulations, it is important to know enough to determine when to seek advice from appropriate personnel. Company personnel should contact the Company's chief financial officer with any questions as to the applicability of any law, rule or regulation or the appropriate manner of compliance therewith. The chief financial officer will be responsible for conferring with legal counsel and resolving the issue.

7. Insider Trading

No director, officer or employee may purchase or sell any Company securities while in possession of material non-public information regarding the Company, nor may any director, officer or employee purchase or sell another company's securities while in possession of material non-public information regarding that company. It is against Company policies and illegal for any director, officer or employee to use material non-public information regarding the Company or any other company to:

- obtain profit for himself or herself; or
- directly or indirectly "tip" others who might make an investment decision on the basis of that information.

Company personnel who have access to confidential information cannot use or share such information for stock trading purposes or for any other purpose except the proper conduct of the Company's business. All Company personnel are subject to the Company's Policy on Insider Trading and Confidentiality in effect from time to time. Insider trading is a crime and can lead to criminal and civil fines, penalties and charges against the Company and the violator.

If you have any questions regarding non-public information and the use of such information or the Company's Policy on Insider Trading and Confidentiality, you should contact the Company's chief financial officer.

8. Disclosure

The Company's periodic reports and other documents filed with the SEC, including all financial statements and other financial information, must comply with applicable federal securities laws and SEC rules. Each director, officer and employee who contributes in any way to the preparation or verification of the Company's financial statements and other financial information must ensure that the Company's books, records and accounts are accurately maintained. Each director, officer and employee must cooperate fully with the Company's accounting and internal audit departments, as well as the Company's independent public accountants and counsel.

Each director, officer and employee who is involved in the Company's disclosure process must:

- be familiar with and comply with the Company's disclosure controls and procedures and its internal control over financial reporting; and

take all necessary steps to ensure that all filings with the SEC and all other public communications about the financial and business condition of the Company provide full, fair, accurate, timely and understandable disclosure.

9. Discrimination and Harassment

The Company requires strict adherence to its policies and applicable laws regarding equal employment opportunities and discrimination in the workplace. The Company will not tolerate illegal discrimination or harassment. Relationship with colleagues and business relationships with competitors, suppliers and customers always must be conducted free of any discrimination, including based on race, color, creed, religion, age, sex, sexual preference, national origin, marital status, veteran status, handicap or disability.

10. Health and Safety

The Company strives to provide all Company personnel with a safe and healthful work environment. You share responsibility for maintaining a safe and healthy workplace by following safety and health rules and practices and reporting accidents, injuries and unsafe equipment, practices or condition.

The Company will not tolerate violence or threatening behavior in the workplace. In addition, Company personnel are required to report to work in condition to perform their duties, free from the influence of illegal drugs or alcohol. The Company will not tolerate the use of illegal drugs in the workplace.

11. Record-Keeping

The Company requires honest and accurate recording and reporting of information in order to make responsible business decisions. You must document and record accurately all of your business expenses. If you are unsure whether a particular expense is legitimate, you should ask the Company's chief financial officer. Executive officers or members of the Board should confer with a member of the Audit Committee. Rules and guidelines regarding business expenses are available from the Company's account department.

All of the Company's books, records, accounts and financial statements must be maintained in reasonable detail, must appropriately reflect the Company's transactions and must conform both to applicable legal requirements and to the Company's system of internal controls. Unrecorded or "off the books" funds or assets cannot be maintained unless permitted by applicable laws or regulations. Furthermore, all Company personnel are subject to the Company's Document Retention Policy. Any questions concerning the Company's Document Retention Policy should be directed to the Company's chief compliance officer.

Company personnel must avoid exaggeration, derogatory remarks, guesswork or inappropriate characterizations of people and companies in business records and communications. This prohibition applies equally to e-mail, internal memos and formal reports.

12. Payments to Government Personnel or Candidates for Office

The Foreign Corrupt Practices Act prohibits giving anything of value, directly or indirectly, to officials of foreign governments or foreign political parties or candidates to obtain or retain business. Making payments to government officials of any country is illegal.

Kickbacks, bribes, rebates or other illegal consideration are prohibited, and must never be given or accepted by any Company personnel. All Company personnel dealing with government agencies must be aware of, and comply with, any agency rules limiting or prohibiting gifts or other favors.

The Company cannot contribute, directly or indirectly, to any political campaign or party. Company personnel cannot use expense accounts to pay for any personal political contributions or seek any other form of reimbursement from the Company for such contributions. Of course, you are free to engage in political activity with your own resources on your own time.

13. Waivers of the Code of Business Conduct and Ethics

Any waiver of this Code for executive officers or directors requires the approval of the Board and must be disclosed promptly as required by applicable law, rules or regulations, including the SEC and the NASDAQ Stock Market.

14. Compliance, Reporting and Enforcement

If you are concerned about a possible ethical or illegal situation or any violation of this Code or are not sure whether specific conduct meets applicable Company standards, you should discuss the situation with your immediate supervisor or contact the Company's chief financial officer. Executive officers or members of the Company's board of directors should discuss the situation with a member of the Audit Committee.

Company personnel must report violations of laws, rules, and regulations of this Code to immediate supervisors, the Company's chief financial officer, or the chairperson of the Audit Committee. Executive officers or members of the Board must report such matters to a member of the Audit Committee.

After receiving a report of an alleged prohibited action, the Audit Committee or the chief financial officer must promptly take all appropriate actions necessary to investigate. All directors, officers and employees are expected to cooperate in any internal investigation of misconduct.

The Company prohibits retaliation for reports of ethical misconduct made by Company personnel in good faith. If a situation requires that the identity of the person reporting any such misconduct not be disclosed, the Company will protect his or his anonymity, to the extent legally possible.

For further information and guidance regarding the reporting of potential violations of this Code, you should review the Audit Committee's Whistleblower Procedures.

15. Amendments

This Code may only be amended by the Board. The Company must report promptly any amendments pertaining to executive officers or senior financial officers as required by applicable laws, rules or regulations.

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NASDAQ: TNXP

Investor Presentation

February 2016

Version: P0006-02-16-16

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Cautionary note on forward-looking statements

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Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are "forward-looking statements" as defined by 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" 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, substantial competition; our possible 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 risks related to failure to obtain U.S Food and Drug Administration clearances or approvals and noncompliance with its regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by the Company on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2014 and Quarterly Report on Form 10-Q for the period ended September 30, 2015, as filed with the Securities and Exchange Commission (the "SEC") on February 27, 2015 and November 6, 2015, respectively, and future periodic reports filed with the SEC on or after the date hereof. All of the Company's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.



Developing innovative medicines for large and growing markets

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- **Targeting a common pain condition and a serious psychiatric disorder**
 - One clinical-stage proprietary candidate targeting two indications
 - Differentiated products with potential for sustainable competitive advantages
- **2016 to reveal results from two clinical trials**
 - Fibromyalgia – Phase 3 to report in 3Q
 - Post-traumatic stress disorder – Phase 2 to report in 2Q
- **All intellectual property owned by Tonix – from internal R&D**

Pipeline led by TNX-102 SL for fibromyalgia

Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Market	Near-term Catalyst	
TNX-102 SL (Tonmya™)	Fibromyalgia								Top line data 3Q 2016
TNX-102 SL	Post-Traumatic Stress Disorder								Top line data 2Q 2016

* Tonmya™ has been conditionally accepted by the FDA as the proposed tradename of TNX-102 SL for fibromyalgia.

*NDA = New Drug Application; FDA = U.S. Food and Drug Administration.
 TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.*

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Fibromyalgia is a chronic, debilitating disorder that imposes a significant societal and economic burden

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- **Fibromyalgia is considered neurobiological disorder characterized by¹:**
 - Chronic widespread pain
 - Nonrestorative sleep
 - Fatigue
 - Diminished cognition
- **Believed to result from amplified sensory and pain signaling in central nervous system¹**
- **Causes significant impairment in all areas of life²**
 - Lower levels of health-related quality of life – reduced daily functioning
 - Interference with work (loss of productivity, disability)
- **Inflicts substantial strain on the healthcare system**
 - Average patient has 20 physician office visits per year³
 - Annual direct medical costs are twice those for non-fibromyalgia individuals⁴

¹Phillips K & Clauw DJ, *Best Pract Res Clin Rheumatol* 2011;25:141.

²Schaefer et al., *Pain Pract*, 2015, May 16.

³Robinson et al, *Pain Medicine* 2013;14:1400.

⁴White et al, *J Occupational Environ Med* 2008;50:13.

Fibromyalgia is a prevalent disorder but remains underdiagnosed

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Estimated that >22 million prescriptions are issued for the treatment of fibromyalgia (on- and off-label usage) each year^{2,4}

- **1.1% diagnosis rate = 2.7 million U.S. adults¹**
 - Suggests under-diagnosis
- **Approximately 2.3 million U.S. adults receive treatment²**
- **Approved drugs achieved 2014 U.S. sales of \$1.2 billion³**
 - Represent about 5.6 million prescriptions⁴

¹Lawrence et al, *Arthritis Rheum* 2008;58:26; Vincent et al, *Arthritis Care Res* 2013;65:786; Jones et al, *Arthritis Rheum* 2015;67:568.

²Robinson RL et al, *Pain Med* 2012;13:1366.

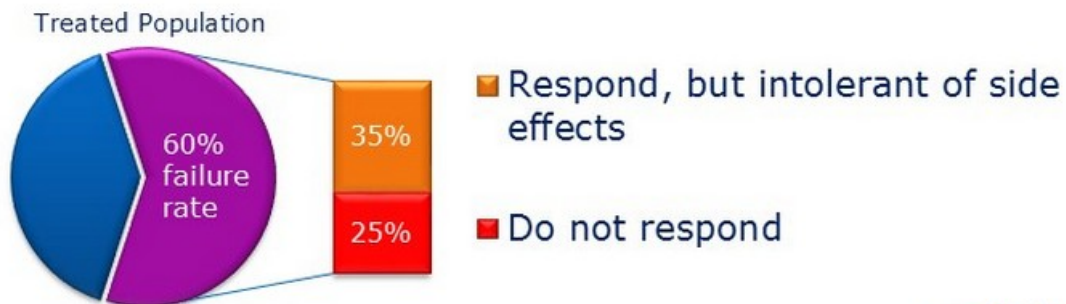
³Product sales derived from IMS MIDAS; IMS NDTI used to factor usage for fibromyalgia; data accessed April 2015.

⁴Independent study conducted by IMS Consulting Group, April 2015 using IMS MIDAS (ex-manufacturing price), factored for fibromyalgia based on IMS National Disease and Therapeutic Index (NDTI).

Fewer than half of those treated receive sustained benefit from the three FDA-approved drugs

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- The treatment objective is to restore functionality and quality of life by broadly improving symptoms while avoiding significant side effects
- The majority fail therapy due to **lack of a response** or **poor tolerability**¹



¹Market research by Frost & Sullivan, commissioned by Tonix (2011).

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Large need for new fibromyalgia therapies that provide broad symptom improvement with better tolerability

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- **Currently-approved medications may have side effects that limit long-term use¹**
 - Many patients skip doses or discontinue altogether within months of treatment initiation
- **Medication-related side effects may be similar to fibromyalgia symptoms**
- **High rates of discontinuation, switching and augmentation**
 - Attempt to treat multiple symptoms and/or avoid intolerable side effects
 - Average of 2-3 medications used simultaneously²
 - The typical patient has tried six different medications³
- **Substantial off-label use of narcotic painkillers and prescription sleep aids³**

¹Nuesch et al, *Ann Rheum Dis* 2013;72:955-62.

²Robinson RL et al, *Pain Medicine* 2012;13:1366.

³"Patient Trends: Fibromyalgia", *Decision Resources*, 2011.

Tonix is developing TNX-102 SL for fibromyalgia

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- **Advanced sublingual tablet containing low-dose cyclobenzaprine (CBP)**
 - Designed for daily bedtime administration with no titration
 - Efficient transmucosal absorption
 - Avoidance of first-pass metabolism reduces formation of long-lived metabolite
- **TNX-102 SL's pharmacologic action is believed to improve sleep quality**
 - Non-restorative sleep is a common clinical and diagnostic feature of fibromyalgia¹
 - Evolving understanding of the role of sleep in pain control and fibromyalgia development²
 - TNX-102 SL targets receptors believed to play key roles in sleep physiology
- **Phase 2b "BESTFIT" study was successfully completed in 3Q14**
- **Top line data from ongoing Phase 3 "AFFIRM" study expected to report in 3Q16**

¹Swick TJ, *Ther Adv Musculoskel Dis* 2011;3:167-178.

²Choy EHS, *Nat Rev Rheumatol* adv online pub 28 April 2015.

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

Phase 2b “BESTFIT” study of TNX-102 SL in fibromyalgia

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- **BESTFIT = Bedtime Sublingual TNX-102 SL as Fibromyalgia Intervention Therapy**

- Randomized, double-blind, placebo-controlled trial
- 2010 American College of Rheumatology diagnostic criteria for fibromyalgia
- 205 participants randomized 1:1 at 17 U.S. sites
- Sublingual tablet of TNX-102 SL 2.8 mg or placebo daily at bedtime for 12 weeks
- Evaluated measures of pain, sleep quality, and other assessments of fibromyalgia

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

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BESTFIT results on key clinical endpoints

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Category	Endpoint – week 12 ¹	p value
Pain Relief	30% responder analysis ²	0.033
Sleep Quality	PROMIS Sleep Disturbance	0.005
Overall response to therapy	PGIC	0.025
Assessment of disease impact	FIQ-R Total score	0.014

p < 0.05 → statistically significant

BESTFIT pre-specified primary endpoint:
change in week 12 mean pain score
(p=0.172)

- PROMIS = Patient-Reported Outcomes Measurement Information System
- PGIC = Patient Global Impression of Change
- FIQ-R = Fibromyalgia Impact Questionnaire - Revised

¹Intent-to-treat analysis, N=205 (TNX-102 SL N=103, placebo N=102).

²FDA-accepted primary endpoint in current Phase 3 AFFIRM study.

Source: Phase 2b BESTFIT study data.

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

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TNX-102 SL safety and tolerability profile in the BESTFIT study

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- **No serious adverse events (SAE) reported with TNX-102 SL**
- **Systemic adverse events reported by at least 3% of the total BESTFIT population**

	TNX 102 SL (N=103)	Placebo (N=101)
Somnolence	1.9	6.9
Dry Mouth	3.9	4.0
Back Pain	4.9	3.0

- **Most frequent local adverse events were administration site reactions**
 - Previously reported in Phase 1 studies; no detectable bias on efficacy results
 - Transient tongue numbness (44% TNX=102 SL vs. 2% placebo)
 - Abnormal taste (8% TNX-102 SL vs. 0% placebo)
- **Trial completion rates of 86% with TNX-102 SL vs. 83% with placebo**

Source: Phase 2b BESTFIT study data.

TNX-102 SL (cydobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

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TNX-102 SL in Phase 3 clinical development for fibromyalgia

- Phase 3 AFFIRM Study is underway

TNX-102 SL once-daily at bedtime
2.8 mg N = 250

Placebo once-daily at bedtime
N = 250

- Randomized, double-blind, placebo-controlled study in fibromyalgia
- N=500; approximately 35 U.S. clinical sites
- Primary efficacy endpoint:**
 - Difference in 30% pain responder analysis at Week 12 between TNX-102 SL and placebo



Top line data expected 3Q 2016

- Second Phase 3 Study ("REAFFIRM") expected to begin in 2Q 2016
 - Expected to be similar to AFFIRM in design and size

Source: Phase 2b BESTFIT study data.
TNX-102 SL (cydobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

TNX-102 SL in Phase 2 development for post-traumatic stress disorder (PTSD)

Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	NDA	Market	Near-term Catalyst
TNX-102 SL (Tonmya™*)	Fibromyalgia							Top line data 3Q 2016
TNX-102 SL	Post-Traumatic Stress Disorder							Top line data 2Q 2016

* Tonmya™ has been conditionally accepted by the FDA as the proposed tradename of TNX-102 SL for fibromyalgia.

NDA = New Drug Application; FDA = U.S. Food and Drug Administration.

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.



PTSD is a chronic stress disorder triggered by a traumatic event

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- **PTSD is characterized by:**
 - re-experiencing the triggering event
 - negative alterations in mood/cognition
 - situation/stimulus avoidance
 - hypervigilance (anxiety, difficulty sleeping)
- **Considered a stress response, but prolonged and does not resolve with time**
 - 20% of women and 8% of men who experience significant trauma develop PTSD¹
- **Associated with significant life disruption**
 - Social isolation, inability to maintain employment, loss of independent living
 - Unpredictable acts of violence, suicidal thoughts

¹ Kessler et al, *Arch Gen Psychiatry* 1995;52:1048.

PTSD is a prevalent problem for both civilians and the military

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- **~70% are considered to have moderate to severe symptoms**
- **Of those diagnosed, ~50% utilize professional healthcare (psycho/pharmacotherapy)²**
- **Higher prevalence in military population**
 - 20% of veterans from recent conflicts will have potential/provisional PTSD³
 - ~638,000 veterans with PTSD in the VA health system (2012)⁴
 - Majority are male
 - Alcohol and substance abuse are common

¹Kessler RC et al, *Arch Gen Psychiatry* 2013;62:617; U.S. Census Bureau, 2013 Projection.

²Wang et al, *Arch Gen Psychiatry* 2005;62:629.

³Report on VA Facility Specific Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND) Veterans Diagnosed with Potential or Provisional PTSD.

⁴Bowe et al, *J Dual Diagnosis* 2015;11:22.

Significant gap in current therapeutic landscape for PTSD

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- **Medicines approved for PTSD often provide inadequate and/or inconsistent benefit**
 - Limited to two SSRI antidepressants, both of which carry suicidality warnings
 - U.S. Institute of Medicine (IOM) concluded that evidence of treatment effect is low¹
 - Lack of efficacy evidence in those with a history of combat-related trauma²
- **Sleep dysfunction in PTSD is resistant to currently-approved options**
 - 95%+ report insomnia, 83% report recurrent dreams of the trauma³
 - Correlated with disease severity, depression, substance abuse and suicide⁴
 - Drugs approved for insomnia have been shown to not improve PTSD sleep dysfunction
- **Off-label use of anxiolytics, sedative-hypnotics, and antipsychotics is common⁵**
 - Limited evidence of effectiveness; may be harmful
 - May interfere with other treatments such as cognitive behavioral therapy (CBT)

SSRI = selective serotonin reuptake inhibitor.

¹ Marshall et al, *Am J Psychiatry* 2001;158:1982.

² Jonathan Davidson, *personal communications*, 2014.

³ Green B. *Post-traumatic stress disorder: Symptom profiles in men and women. Curr Med Res Opin* 2003;19:200-4.

⁴ Germain et al, *J Anxiety Disord* 2005;19:233; Krakow et al, *J Nerv Ment Dis* 2002;190:442.

⁵ Bernardy et al., *J Clin Psychiatry*, 2012, 73:297-303.

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TNX-102 SL's potential as a treatment for PTSD is supported by clinical evidence and pharmacology

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- **TNX-102 SL is active on receptor sites believed to have treatment potential for sleep problems in PTSD**
 - Targeted receptors include 5-HT_{2a}, alpha-1 adrenergic, and histamine-1 receptors
- **Efficacy of “tricyclic” drug class in PTSD is supported by clinical data¹**
 - Oral tricyclics have side effects that limited their use
- **Improvements observed in BESTFIT study relate to PTSD core symptoms²**

Outcome Measure at Week 12 in BESTFIT	<i>p</i> value
PROMIS Sleep Disturbance	0.005
FIQ-R Anxiety Item	0.015
FIQ-R Sensitivity Item	0.017

$p < 0.05 \rightarrow$
statistically significant

¹ Davidson J, *J Psychopharm* 2015;29;264.

² Phase 2b BESTFIT study data.

TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

Phase 2 "AtEase" trial of TNX-102 SL in PTSD is fully enrolled

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TNX-102 SL at bedtime once-daily

2.8 mg

N = 88

TNX-102 SL at bedtime once-daily

5.6 mg

N = 44

Placebo at bedtime once-daily

N = 88

- Randomized, double-blind, placebo-controlled trial in military-related PTSD
- N=240+; approximately 25 U.S. clinical sites
- **Primary efficacy endpoint:**
 - Difference in Clinician-Administered PTSD Scale (CAPS) score between TNX-102 SL 2.8 mg and placebo at 12 weeks

12 weeks →open-label extension

Top line data
expected 2Q 2016

¹TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

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TNX-102 SL

Fibromyalgia, PTSD

- **Composition-of-matter (eutectic)**
 - Patents filed
 - Protection expected to 2034
- **Pharmacokinetics (PK)**
 - Patents filed
 - Protection expected to 2033
- **Method-of-use**
 - Fibromyalgia: patents issued, 2020 expiry
 - PTSD: patents filed

¹TNX-102 SL (cyclobenzaprine HCl sublingual tablets, 2.8 mg) is an Investigational New Drug and is not approved for any indication.

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NASDAQ: TNPX

Cash, cash equivalents, and marketable securities reported at September 30, 2015 \$ 55.0 million

Cash used in operations in 2015 through September 30 \$ 30.6 million

Shares outstanding (February 13, 2016) 18.8 million

Management team

Seth Lederman, MD
President & CEO



Bruce Daugherty, PhD, MBA
Chief Scientific Officer



Gregory Sullivan, MD
Chief Medical Officer



COLUMBIA UNIVERSITY
Department of Psychiatry

New York State
Psychiatric Institute

Jessica Edgar Morris
Acting CFO, Chief Administrative Officer

Deutsche Bank



Ronald Notvest, PhD
SVP, Commercial Planning & Development



Board of directors

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Seth Lederman, MD

Chairman

Ernest Mario, PhD

ALZA, Glaxo, Reliant Pharma

Stuart Davidson

Labrador Ventures, Alkermes, Combion

Charles Mather

BTIG, Janney, Jefferies, Cowen, Smith Barney

Patrick Grace

Apollo Philanthropy, WR Grace, Chemed

John Rhodes

NYSERDA, NRDC, Booz Allen Hamilton

Donald Landry, MD, PhD

Chair of Medicine, Columbia University

Samuel Saks, MD

Jazz Pharma, ALZA, Johnson & Johnson

Milestones – recent and upcoming

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TNX-102 SL – Fibromyalgia

- May 2015** **Began Phase 3 AFFIRM study**
- November 2015** **Presented additional data from Phase 2b BESTFIT study at ACR Meeting**
- 3Q 2016** **Report top-line results from AFFIRM study**

TNX-102 SL – Post-Traumatic Stress Disorder

- December 2015** **Entered into CRADA with USAMMDA**
- December 2015** **Reported completion of enrollment in Phase 2 AtEase study**
- 2Q 2016** **Report top-line results from AtEase study**



NASDAQ: TNXP

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Tonix Pharmaceuticals Reports Top Line Results from Phase 2 Proof-of-Concept Clinical Study of TNX-201 in Episodic Tension-Type Headache

New York, NY – February 16, 2016 – [Tonix Pharmaceuticals Holding Corp.](#) (NASDAQ: TNXP) (Tonix), which is developing next-generation medicines for fibromyalgia and post-traumatic stress disorder (PTSD), today announced topline results of the Phase 2 proof-of-concept (POC) clinical study of TNX-201 (dexisometheptene mucate) in episodic tension-type headache (ETTH).

Based on preliminary analysis of the results from this exploratory study, Tonix has determined that the study did not achieve its primary efficacy endpoint of participants achieving headache pain-free status at two hours after dosing. The study also did not achieve two other primary endpoints, which were the proportion of participants with at least a 70% reduction in pain from baseline on the Visual Analog Scale (VAS) at two hours after dosing, and an increase of the mean change from baseline to two hours post-dose in the VAS score. The goal of this POC trial was to evaluate the potential clinical benefit of using TNX-201 to treat tension-type headache. A single 140 mg dose of TNX-201 was compared to placebo for the treatment of a single tension-type headache. A single 140 mg dose of TNX-201 proved to be safe and extremely well tolerated by all participants with ETTH. No serious adverse events were reported throughout the duration of the study. There were no treatment emergent adverse event categories reported by more than one participant (1.4%) in either treatment group during the double-blinded treatment period.

“We were interested in exploring the potential clinical benefit of TNX-201 as a new class of analgesic that might offer a non-addictive headache treatment option. Racemic isometheptene mucate previously had been used as a treatment for both tension-type headaches and migraine,” said Seth Lederman, M.D., Tonix’s president and CEO. “Given the current treatment landscape, we determined tension-type headache to be the most probable and feasible path to commercialization for TNX-201. We executed a well-designed and efficient POC study to determine whether our hypothesis had merit. Among other things, the data showed that TNX-201 did not demonstrate efficacy in patients with ETTH whether or not they had a history of migraine headaches. Although TNX-201 has proved to be safe and very well tolerated in the study, our review of the results supports discontinuing all work on this program.”

“These results are disappointing, but we designed the study to challenge our hypothesis rapidly and with minimal capital investment. We are satisfied that we achieved a definitive outcome,” continued Dr. Lederman. He concluded, “We are excited to continue the rigorous execution of our registration-quality Phase 2 study of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) in post-traumatic stress disorder, as well as our flagship development program, a Phase 3 trial in fibromyalgia of Tonmya Ô (TNX-102 SL, cyclobenzaprine HCl sublingual tablets, 2.8 mg). We look forward to reporting data from these studies, planned for the second and third quarters this year, respectively.”

The POC study of TNX-201 was a randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of a single 140 mg dose of TNX-201 versus placebo in 147 patients treating a single tension-type headache. The TNX-201 (n = 75) and placebo groups (n = 72) were similar in participant demographics. The patient self-reported outcome measures were collected on an electronic diary that was programmed to capture qualifying headache information. The primary efficacy endpoint of headache pain-free at two hours post-dose was assessed on a four-point Numeric Rating Scale (NRS), a Visual Analog Scale (VAS), and a binary questionnaire for self-report of pain. In addition to the primary efficacy endpoint of pain-free at two hours post-dose, this study assessed efficacy according to a variety of measures, including the proportion of participants reported to be pain-free at several other post-dose time intervals, the proportion of participants who utilized rescue medication during the 24-hour post-dose period, and the change from baseline pain severity at several time intervals.

The United States Food and Drug Administration (FDA) has conditionally accepted “Tonmya” as the proposed trade name of TNX-102 SL for fibromyalgia. TNX-201, Tonmya and TNX-102 SL are Investigational New Drugs and have not been approved by FDA for any indication.

About TNX-201

The active ingredient in TNX-201 is dexisomethptene mucate, the (R) isomer of isomethptene mucate. The dose of 140 mg TNX-201 is calculated as the free base, which is equivalent to approximately 244 mg of dexisomethptene mucate salt. Racemic isomethptene mucate, a mixture of both the (R) and (S) isomers, had been widely used as a single-agent prescription medicine and as a component of combination drug products (e.g. Midrin[®]) for many decades in the U.S. for various indications including tension-type headache. Isomethptene mucate was introduced as a pharmaceutical prior to 1962, and no products containing isomethptene mucate currently are approved by the FDA for any indication. Studies in several animal models have shown that TNX-201 significantly increases the pain threshold of acute pain response, and potently and selectively binds to receptors in the central nervous system known as imidazoline type-1 (I1) receptors, where it acts as a receptor agonist.

About Tonix Pharmaceuticals Holding Corp.

Tonix is developing next-generation medicines for common disorders of the central nervous system, including fibromyalgia and post-traumatic stress disorder. These disorders are characterized by chronic disability, inadequate treatment options, high utilization of healthcare services, and significant economic burden. This press release and further information about Tonix can be found at www.tonixpharma.com.

Safe Harbor / 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, substantial competition; our possible 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 risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. 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, 2014 and Quarterly Report on Form 10-Q for the period ended September 30, 2015, as filed with the Securities and Exchange Commission (the “SEC”) on February 27, 2015 and November 6, 2015, respectively, and future periodic reports filed with the SEC on or after the date hereof. 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 hereof.

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Source: Tonix Pharmaceuticals Holding Corp.

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