UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of report (date of earliest event reported): November 10, 2015

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

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

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

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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))

Item 8.01 Other Events.

On November 10, 2015, Tonix Pharmaceuticals Holding Corp. (the "Company") announced additional results from its BESTFIT study, a randomized, double-blind, placebo-controlled Phase 2b clinical trial of Tonmya™ (cyclobenzaprine HCl sublingual tablets, 2.8 mg) in fibromyalgia, presented in three posters entitled:

- "Bedtime, Rapidly Absorbed Sublingual Cyclobenzaprine (TNX-102 SL) for the Treatment of Fibromyalgia: Results of a Phase 2b Randomized, Double-Blind, Placebo-Controlled Study";
- "Relationship of Sleep Quality and Fibromyalgia Outcomes in a Phase 2b, Randomized, Double-Blind, Placebo-Controlled Study of Bedtime, Rapidly Absorbed, Sublingual Cyclobenzaprine (TNX-102 SL)"; and
- "Responder Compared to Mean Change Analyses in a Fibromyalgia Phase 2b Clinical Study of Bedtime Rapidly Absorbed Sublingual Cyclobenzaprine (TNX-102 SL)" (collectively, the "Posters").

The Posters were presented at the 2015 American College of Rheumatology / Association of Rheumatology Health Professionals Annual Meeting in San Francisco, CA.

The foregoing description of the Posters is qualified in its entirety by reference to the Posters, copies of which are filed as Exhibits 99.01, 99.02 and 99.03 to, and are incorporated by reference in, this report.

On November 10, 2015, the Company issued a press release announcing the presentation of the Posters. A copy of the press release that discusses this matter is filed as Exhibit 99.04 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.

99.01	Bedtime, Rapidly Absorbed Sublingual Cyclobenzaprine (TNX-102 SL) for the Treatment of Fibromyalgia: Results of a Phase 2b Randomized, Double-Blind, Placebo-Controlled Study Poster
99.02	Relationship of Sleep Quality and Fibromyalgia Outcomes in a Phase 2b, Randomized, Double-Blind, Placebo-Controlled Study of Bedtime, Rapidly Absorbed, Sublingual Cyclobenzaprine (TNX-102 SL) Poster
99.03	Responder Compared to Mean Change Analyses in a Fibromyalgia Phase 2b Clinical Study of Bedtime Rapidly Absorbed Sublingual Cyclobenzaprine (TNX-102 SL) Poster
99.04	Press Release, dated November 10, 2015, issued by Tonix Pharmaceuticals Holding Corp.

SIGNATURE

Pursuant to the requirement of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: November 10, 2015

By: */s/ LELAND GERSHELL*
Leland Gershell
Chief Financial Officer

Bedtime, Rapidly Absorbed Sublingual Cyclobenzaprine (TNX-102 SL) for the Treatment of Fibromyalgia: Results of a Phase 2b Randomized, Double-Blind, Placebo-Controlled Study

Seth Lederman[1], R Michael Gendreau[2], Daniel J. Clauw[3], Lesley M. Arnold[4], Judith Gendreau[5], Bruce Daugherty[5], and Amy Forst[5]

[1]Tonix Pharmaceuticals, Inc., [2]Gendreau Consulting LLC, [3]University of Michigan, [4]University of Cincinnati, [5]Tonix Pharmaceuticals

Background

- Fibromyalgia is characterized by chronic widespread pain and sleep disturbance
- Treatments that improve sleep quality in fibromyalgia patients may improve fibromyalgia by a mechanism distinct from centrally acting analgesics
- TNX-102 SL* is a proprietary eutectic sublingual (SL) tablet formulation of low-dose cyclobenzaprine HCl (2.8 mg) designed for rapid absorption and long-term bedtime use
- This double-blind, randomized, placebo-controlled multicenter study (BESTFIT) evaluated the safety and efficacy of TNX-102 SL in fibromyalgia

Methods

BESTFIT Study Characteristics and Endpoint Measures

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

- 12-week, randomized, double-blind, placebo-controlled study in patients diagnosed with fibromyalgia by 2010 ACR criteria
- 1:1 randomization of 205 participants in 17 centers in the United States
  - Placebo (n=102)
  - TNX-102 SL 2.8 mg (n=103)

Entry Criteria

- The patients had a diagnosis of primary fibromyalgia as defined by the 2010 ACR Preliminary Diagnostic Criteria for fibromyalgia, including all of the following:
  a) Widespread Pain Index (WPI) ≥7 and Symptom Severity (SS) scale score ≥5; or WPI 3-6 and SS scale score ≥9; and
  b) Symptoms present at a similar level for at least 3 months; and
  c) Patients did not have a disorder that would have otherwise explained their pain

Primary Efficacy Endpoint

- Mean change from baseline in the weekly average daily diary pain score during week 12
- (0-10) Numerical Rating Scale (NRS) to assess prior 24-hour average pain intensity

Key Secondary Efficacy Endpoints

- Patient Global Impression of Change (PGIC)
- Fibromyalgia Impact Questionnaire-Revised (FIQ-R)
- Daily Sleep Diary (0-10 NRS averaged weekly)
- Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance Instrument

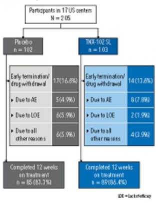
Safety Evaluation

- Adverse Events (AEs)
- Administration site reactions/local oral adverse events

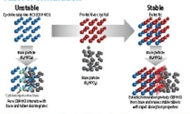
Baseline Characteristics

Characteristic	Placebo N=101	TNX-102 SL N=103
Age	49.7 (11.7)	50.7 (9.9)
Males (%)	3 (3%)	7 (6.8%)
Caucasian (%)	88 (87%)	91 (88%)
Weight, kg (SD)	80.9 (17.2)	80.6 (16.7)
BMI (SD)	30.0 (5.5)	30.0 (5.7)
WPI, mean (SD)	12.9 (3.43)	12.9 (3.54)
SS, mean (SD)	8.8 (1.80)	8.9 (1.82)
Tender Point Count, mean (SD)	14.2 (2.90)	14.7 (2.56)

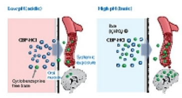
Patient Disposition



Proprietary Cyclobenzaprine Hydrochloride Eutectic Mixture Stabilizes Tablet Formulation

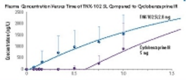


Base Increases Systemic Absorption of Cyclobenzaprine Free Base During Buccal Administration



Cyclobenzaprine is Detected in Plasma Within 20 Minutes Following Sublingual Administration of TNX-102 in Phase 1 Comparative Pharmacokinetic Study

Plasma Concentration Versus Time of TNX-102 SL Compared to Cyclobenzaprine IR

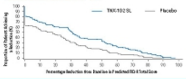


Pharmacokinetics of Cyclobenzaprine Formulations and Active Metabolite

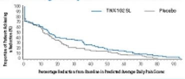
Parameter	TNX-102 2.8 mg SL	Oral IR CBP	Comparison
Dose	2.8 mg sublingual tablet	5 mg oral tablet	44% lower dose for SL
Absorption Lag time (t_{lag})	[illegible]	[illegible]	[illegible]
Relative Bioavailability	[illegible]	-	[illegible]
T_{max}	[illegible]	[illegible]	Similar
C_{max}	[illegible]	[illegible]	[illegible]
AUC	[illegible]	[illegible]	[illegible]
Active Metabolite	nCBP	nCBP	
C_{max}	[illegible]	[illegible]	[illegible]
AUC	[illegible]	[illegible]	[illegible]

TNX-102 SL Continuous Responder Analysis

Continuous Responder Analysis on FIQ-R Total Score at Week 12

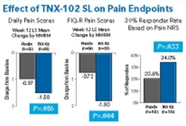


Continuous Responder Analysis on IVRS NRS Average Daily Pain Scores at Week 12



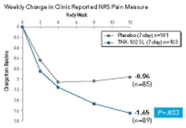
TNX-102 SL Provides Relief from Pain

Effect of TNX-102 SL on Pain Endpoints



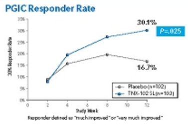
MMRM=Mixed model for repeated measures

Time Course of Pain Reduction



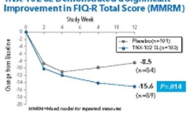
TNX-102 SL Improves Fibromyalgia Global and Functional Measures

PGIC Responder Rate



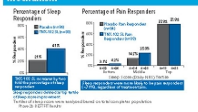
Responder defined as "much improved" or "very much improved"

TNX-102 SL Demonstrated a Significant Improvement in FIQ-R Total Score (MMRM)



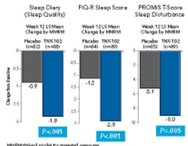
MMRM=Mixed model for repeated measures

TNX-102 SL Effect on Sleep Responders Supports Hypothesis of Restorative Sleep Mechanism



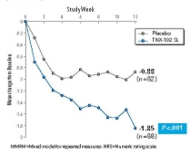
TNX-102 SL Improves Sleep Quality

All Sleep Secondary Endpoints Improved on TNX-102 SL



MMRM=Mixed model for repeated measures

Change from Baseline in NRS Weekly Average of Daily Sleep Quality Scores (MMRM)



MMRM=Mixed model for repeated measures; NRS=Numeric rating scale

TNX-102 SL Adverse Events

Adverse Events Reported in More than 2 Subjects in Either Group

System Organ Class	Adverse Event Term	Placebo (n=101)	TNX-102 SL (n=103)
	At least 1 TEAE	59 (58.4%)	82 (79.6%)
Gastrointestinal disorders	Hypoaesthesia oral	2 (2.0%)	45 (43.7%)
	Dry Mouth	4 (4.0%)	4 (3.9%)
	Nausea	2 (2.0%)	5 (4.9%)
	Constipation	1 (1.0%)	4 (3.9%)
	Glossitis	1 (1.0%)	3 (2.9%)
	Vomiting	0	4 (3.9%)
	Diarrhoea	0	3 (2.9%)
	Paraesthesia oral	0	3 (2.9%)
Infections and infestations	Sinusitis	3 (3.0%)	4 (3.9%)
	Nasopharyngitis	2 (2.0%)	3 (2.9%)
	Upper respiratory tract infection	2 (2.0%)	3 (2.9%)
	Urinary tract infection	1 (1.0%)	4 (3.9%)
	Bronchitis	1 (1.0%)	3 (2.9%)
	Gastroenteritis viral	0	3 (2.9%)
Nervous system disorders	Somnolence	7 (6.9%)	2 (1.9%)
	Dizziness	3 (3.0%)	3 (2.9%)
Musculoskeletal and connective tissue disorders	Back pain	3 (3.0%)	5 (4.9%)
General disorders and administration site conditions	Product taste abnormal	0	8 (7.8%)
Psychiatric disorders	Abnormal dreams	2 (2.0%)	3 (2.9%)
	Anxiety	4 (4.0%)	1 (1.0%)
	Insomnia	3 (3.0%)	1 (1.0%)
Respiratory, thoracic and mediastinal disorders	Cough	3 (3.0%)	0

- Local administration site oral hypoaesthesia (transient tongue or sublingual numbness) was reported in 45 out of 103 treated patients
- Only 3 patients withdrew from participation in the study due to local adverse events

Conclusions

- TNX-102 SL provides multisymptom relief
- TNX-102 SL significantly improved global and functional measures such as PGIC and FIQ-R total score
- Systemic adverse events for TNX-102 SL were similar to placebo in the BESTFIT study
- Local site administration reactions of oral hypoaesthesia and abnormal product taste were the only commonly reported adverse events with an incidence of >5% and at least twice the rate of placebo
- TNX-102 SL has simple, once-daily dosing at bedtime with no need to titrate or adjust the dose
- TNX-102 SL increased sleep quality as evidenced by an increase in sleep responders
- Correlation of pain response with sleep response, regardless of treatment arm, suggests that improving sleep improves pain outcomes
- TNX-102 SL may be improving pain outcomes by improving restorative sleep

References

1. Data on file, Tonix Pharmaceuticals.

*TNX-102 SL is an Investigational New Drug and has not been approved for any indication.

51037

Relationship of Sleep Quality and Fibromyalgia Outcomes in a Phase 2b, Randomized, Double-Blind, Placebo-Controlled Study of Bedtime, Rapidly Absorbed, Sublingual Cyclobenzaprine (TNX-102 SL)

Harvey Moldofsky[1], R Michael Gendreau[2], Daniel J. Clauw[3], Judith Gendreau[4], Benjamin Vaughn[5], Bruce Daugherty[4], Amy Forst[4], Gregory Sullivan[4], and Seth Lederman[6]

[1]Centre for Sleep/Chronobiology, [2]Gendreau Consulting LLC, [3]University of Michigan, [4]Tonix Pharmaceuticals, [5]Rho, [6]Tonix Pharmaceuticals, Inc.

Background

- Fibromyalgia is characterized by chronic widespread pain and sleep disturbance
- Non-restorative sleep is believed to play an important role in the pathophysiology of fibromyalgia
- Treatments that improve sleep quality in fibromyalgia patients may improve fibromyalgia by a mechanism distinct from centrally acting analgesics
- TNX-102 SL* is a proprietary orally disintegrating sublingual (SL) tablet formulation of low-dose cyclobenzaprine HCl (2.8 mg) designed for rapid absorption and long-term bedtime use
- This double-blind, randomized, placebo-controlled multicenter study (BESTFIT) evaluated the safety and efficacy of TNX-102 SL in fibromyalgia

Methods

BESTFIT Study Characteristics and Endpoint Measures

BESTFIT = Bedtime Sublingual TNX-102 SL in Fibromyalgia Intervention Therapy

- 12-week, randomized, double-blind, placebo-controlled study in patients diagnosed with fibromyalgia by 2010 ACR criteria
- 1:1 randomization of 265 participants in 17 centers in the United States
  - Placebo (n=102)
  - TNX-102 SL 2.8 mg (n=103)

Entry Criteria

- The patients had a diagnosis of primary fibromyalgia as defined by the 2010 ACR Preliminary Diagnostic Criteria for fibromyalgia, meeting all of the following criteria:
  a) Widespread pain index (WPI) ≥7 and Symptom Severity (SS) scale score ≥5, or WPI 3-6 and SS scale score ≥9
  b) Symptoms present at a similar level for at least 3 months
  c) Patient did not have a disorder that would have otherwise explained their pain

Primary efficacy endpoint

- Mean change from baseline in the weekly average of pain scores collected nightly on a telephonic diary system after 12 weeks
- 0-10 Numerical Rating Scale (NRS) to assess prior 24-hour average pain intensity.

Key secondary efficacy endpoints

- Patient Global Impression of Change (PGIC)
- Fibromyalgia Impact Questionnaire Revised (FIQ-R)
- Daily Sleep Diary (0-10 NRS averaged weekly)
- Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance Instrument

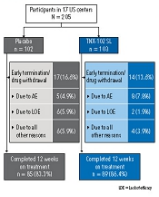
Safety Evaluation

- Adverse Events (AEs)
- Administration site reactions/local oral adverse events

Baseline Characteristics

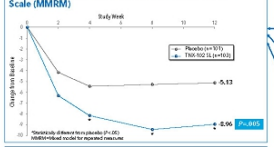
Characteristic	Placebo N=101	TNX-102 SL N=102
Age	49.7 (11.7)	50.7 (9.9)
Males (%)	2 (2%)	7 (6.8%)
Caucasian (%)	88 (87%)	91 (88%)
Weight, kg (SD)	80.9 (17.2)	80.6 (16.7)
BMI (SD)	30.0 (5.5)	30.0 (5.7)
WPI, mean (SD)	12.9 (3.42)	12.9 (3.56)
SS, mean (SD)	8.6 (1.80)	8.9 (1.82)
Tender Point Count, mean (SD)	14.2 (2.90)	14.7 (2.56)

Patient Disposition

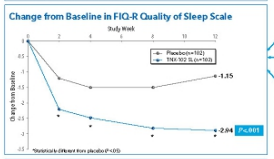


Sleep Outcomes

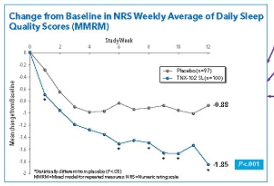
Change from Baseline in PROMIS Sleep Disturbance Scale (MMRM)



Change from Baseline in FIQ-R Quality of Sleep Scale



Change from Baseline in NRS Weekly Average of Daily Sleep Quality Scores (MMRM)

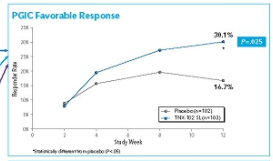


Correlations between sleep and other fibromyalgia endpoints at Week 12

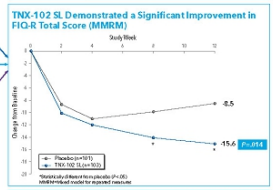
R=0.6 P≤.001
R=0.5 P≤.001
R=0.3 P≤.001
R=0.6 P<.001
R=0.7 P<.001
R=0.5 P<.001
R=0.5 P≤.001
R=0.6 P≤.001
R=0.6 P≤.001

Fibromyalgia and Pain Outcomes

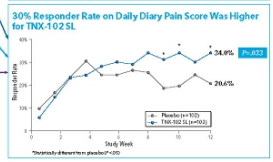
PGIC Favorable Response



TNX-102 SL Demonstrated a Significant Improvement in FIQ-R Total Score (MMRM)



30% Responder Rate on Daily Diary Pain Score Was Higher for TNX-102 SL



Prior Sleep Quality Affects Pain

- For up to 5 previous days in advance, the average measure of sleep quality is increasingly predictive of the current day's pain
- Pain and fatigue responders to TNX-102 SL show greater advanced improvement in sleep quality than with placebo. (Lead-lag statistical analyses: $P<.001$)

TNX-102 SL Adverse Events

Adverse Events Reported in More than 2 Subjects in Either Group

System Organ Class	Adverse Event Term	Placebo (n=101)	TNX-102 SL (n=102)
	At least 1 TEAE	59 (58.4%)	82 (79.6%)
Gastrointestinal disorders	Hypoaesthesia oral	2 (2.0%)	45 (43.7%)
	Dry mouth	4 (4.0%)	4 (3.9%)
	Nausea	2 (2.0%)	5 (4.9%)
	Constipation	1 (1.0%)	4 (3.9%)
	Diarrhea	1 (1.0%)	3 (2.9%)
	Vomiting	0	4 (3.9%)
	Diarrhea	0	3 (2.9%)
	Paraesthesia oral	0	3 (2.9%)
Infections and infestations	Sinusitis	3 (3.0%)	4 (3.9%)
	Nasopharyngitis	2 (2.0%)	3 (2.9%)
	Upper respiratory tract infection	2 (2.0%)	3 (2.9%)
	Urinary tract infection	1 (1.0%)	4 (3.9%)
	Bronchitis	1 (1.0%)	3 (2.9%)
	Gastroenteritis viral	0	3 (2.9%)
Nervous system disorders	Somnolence	7 (6.9%)	2 (1.9%)
	Dizziness	3 (3.0%)	3 (2.9%)
Musculoskeletal and connective tissue disorders	Back pain	3 (3.0%)	5 (4.9%)
General disorders and administration site conditions	Product taste abnormal	0	8 (7.8%)
	Abnormal dreams	2 (2.0%)	3 (2.9%)
Psychiatric disorders	Anxiety	4 (4.0%)	1 (1.0%)
	Insomnia	3 (3.0%)	1 (1.0%)
Respiratory, thoracic and mediastinal disorders	Cough	3 (3.0%)	0

- Local administration site oral hypoaesthesia (transient tongue or sublingual numbness) was reported in 45 out of 103 treated patients
- Only 3 patients withdrew from participation in the study due to local adverse events

Conclusions

- Improvements in measures of sleep quality with bedtime administration of TNX-102 SL correlate with reductions in fibromyalgia pain symptoms
- Local site administration reactions of oral hypoaesthesia and abnormal product taste we re the only commonly reported adverse events with an incidence of >5% and at least twice the rate of placebo
- Sleep quality improvements during preceding nights positively influences subsequent fibromyalgia pain. Increasing duration (up to 5 prior days) of sleep improvements increasingly predicts current pain reduction
- Sleep quality improvements with TNX-102 SL were associated with higher responder rates based on daytime pain and global fibromyalgia measures

References

1. Data on file, Tonix Pharmaceuticals.

*TNX-102 SL is an Investigational New Drug and has not been approved for any indication.

American College of Rheumatology Annual Meeting: November 6-11, 2015, San Francisco, CA

51091

Responder Compared to Mean Change Analyses in a Fibromyalgia Phase 2b Clinical Study of Bedtime Rapidly Absorbed Sublingual Cyclobenzaprine (TNX-102 SL)

R Michael Gendreau[1], Daniel J. Clauw[2], Judith Gendreau[3], Bruce Daugherty[3], and Seth Lederman[4]

[1]Gendreau Consulting LLC, [2]University of Michigan, [3]Tonix Pharmaceuticals, [4]Tonix Pharmaceuticals, Inc.

Background

- Fibromyalgia is characterized by symptoms that include widespread pain and sleep disruption
- Clinical studies that rely on patient self-reported outcome measures such as pain scales may be analyzed by responder analysis (comparisons of proportions of treated patients achieving a predefined clinically meaningful improvement threshold) and by group mean changes
- In a phase 2b trial of TNX-102 SL,* a proprietary eutectic sublingual (SL) tablet formulation of low-dose cyclobenzaprine HCl (2.8 mg) in fibromyalgia patients (BESTFIT), we compared responder analyses to group mean change analyses for the evaluation of changes in pain and fibromyalgia symptoms

Methods

BESTFIT Study Characteristics and Endpoint Measures

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

- 12-week, randomized, double-blind, placebo-controlled study in patients diagnosed with fibromyalgia by 2010 ACR criteria
- 1:1 randomization of 205 participants in 17 centers in the United States
  - Placebo (n=102)
  - TNX-102 SL 2.8 mg (n=103)

Entry Criteria

- The patients had a diagnosis of primary fibromyalgia as defined by the 2010 ACR Preliminary Diagnostic Criteria for fibromyalgia as all of the following:
  - a) Widespread pain index (WPI) ≥7 and Symptom Severity (SS) scale score ≥5; or WPI 3-6 and SS scale score ≥9; and
  - b) Symptoms present at a similar level for at least 3 months; and
  - c) Patients did not have a disorder that would have otherwise explained their pain

Primary Efficacy Endpoint

- Mean change from baseline in the weekly average daily diary pain score during week 12
- Pain was measured on a 0-10 Numerical Rating Scale (NRS) that was completed every evening using a telephonic system
- Topline results from BESTFIT are presented elsewhere

Responder Analysis vs Mean Change from Baseline

- Responders for comparison to group mean changes are defined as follows:
  - Pain: ≥30% improvement from baseline
  - Patient Global Impression of Change (PGIC): score of 1 or 2 on the 1-7 score
  - Fibromyalgia Impact Questionnaire-Revised (FIQ-R) total score, pain item and domain scores: ≥30% improvement from baseline

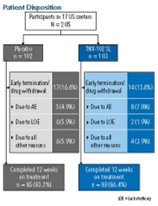
Safety Evaluation

- Adverse Events (AEs)
- Administration site reactions/local oral adverse events

Baseline Characteristics

Characteristic	Placebo N=101	TNX-102 SL N=103
Age	49.7 (11.7)	50.7 (9.9)
Males (%)	3 (3%)	7 (6.8%)
Caucasian (%)	88 (87%)	91 (88%)
Weight, kg (SD)	80.9 (17.2)	80.6 (16.7)
BMI (SD)	30.0 (5.5)	30.0 (5.7)
WPI, mean (SD)	12.9 (3.43)	12.9 (3.54)
SS, mean (SD)	8.8 (1.80)	8.9 (1.82)
Tender Point Count, mean (SD)	14.2 (2.90)	14.7 (2.56)

Patient Disposition



Efficacy Measurements

Numerical Rating Scale (NRS) of average pain intensity

- Patients assessed using a daily telephone diary (interactive voice response system [IVRS])

On a scale of 0 to 10, with 0 being no pain at all and 10 being the worst pain imaginable, how would you rate your average pain over the past 24 hours?

Please rate your average pain	No pain 0	1	2	3	4	5	6	7	8	9	Worst possible pain 10

Patient Global Impression of Change (PGIC)

- Patients assessed at weeks 2, 4, 8 and 12

Overall, since the start of the study, my fibromyalgia is:

	Very much improved	Much improved	Minimally improved	No change	Minimally worse	Much worse	Very much worse
Score	1	2	3	4	5	6	7

Fibromyalgia Impact Questionnaire-Revised (FIQ-R)

- Assess the impact of fibromyalgia on a patient's well-being
- 7-day recall
- Patients assessed at weeks 2, 4, 8 and 12

Functional Domain

Brush/comb hair
Walk continuously for 20 minutes
Prepare homemade meal
Vacuum, scrub, sweep floors
Lift/carry bag full of groceries
Climb 1 flight of stairs
Change bed sheets
Sit in chair for 45 minutes
Shop for groceries

No difficulty — Very difficult: NA 0 … 10

Overall Impact Domain

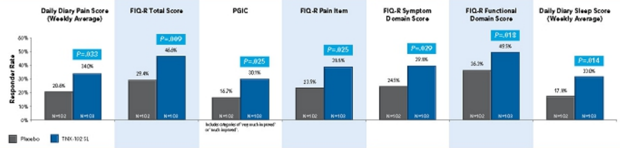
Fibromyalgia prevented goal accomplishment
Completely overwhelmed by fibromyalgia symptoms

Never — Always: 0 … 10

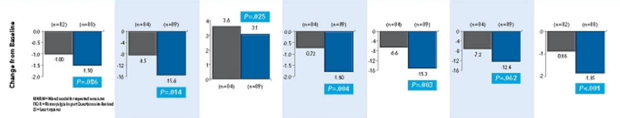
Symptoms Domain

Item	0	10
Level of pain	No pain	Unbearable pain
Level of energy	Lots of energy	No energy
Level of stiffness	No stiffness	Severe stiffness
Quality of sleep	Awoke rested	Awoke very tired
Level of depression	No depression	Very depressed
Level of memory problems	Good memory	Very poor memory
Level of anxiety	Not anxious	Very anxious
Level of tenderness to touch	No tenderness	Very tender
Level of balance problems	No imbalance	Severe imbalance
Level of sensitivity to loud noises, bright lights, odors, and cold	No sensitivity	Extreme sensitivity

Responder Analysis (≥30% Improvement from Baseline)



Mean Change from Baseline at Week 12 (MMRM)



TNX-102 SL Adverse Events

Adverse Events Reported in More than 2 Subjects in Either Group

System Organ Class	Adverse Event Term	Placebo (n=101)	TNX-102 SL (n=103)
	At least 1 TEAE	59 (58.4%)	82 (79.6%)
Gastrointestinal disorders	Hypoaesthesia oral	2 (2.0%)	45 (43.7%)
	Dry Mouth	4 (4.0%)	4 (3.9%)
	Nausea	2 (2.0%)	5 (4.9%)
	Constipation	1 (1.0%)	4 (3.9%)
	Glossitis	1 (1.0%)	3 (2.9%)
	Vomiting	0	4 (3.9%)
	Diarrhoea	0	3 (2.9%)
	Paraesthesia oral	0	3 (2.9%)
Infections and infestations	Sinusitis	3 (3.0%)	4 (3.9%)
	Nasopharyngitis	2 (2.0%)	3 (2.9%)
	Upper respiratory tract infection	2 (2.0%)	3 (2.9%)
	Urinary tract infection	1 (1.0%)	4 (3.9%)
	Bronchitis	1 (1.0%)	3 (2.9%)
	Gastroenteritis viral	0	3 (2.9%)
Nervous system disorders	Somnolence	7 (6.9%)	2 (1.9%)
	Dizziness	3 (3.0%)	3 (2.9%)
Musculoskeletal and connective tissue disorders	Back pain	3 (3.0%)	5 (4.9%)
General disorders and administration site conditions	Product taste abnormal	0	8 (7.8%)
Psychiatric disorders	Abnormal dreams	2 (2.0%)	3 (2.9%)
	Anxiety	4 (4.0%)	1 (1.0%)
	Insomnia	3 (3.0%)	1 (1.0%)
Respiratory, thoracic and mediastinal disorders	Cough	3 (3.0%)	0

- Local administration site oral hypoaesthesia (transient tongue or sublingual numbness) was reported in 45 out of 103 treated patients
- Only 3 patients withdrew from participation in the study due to local adverse events

Conclusions

- Results from this Phase 2b trial support the finding that responder analyses for pain studies and other indications relying on patient-reported outcomes may reveal significant and meaningful effects that are missed by group mean changes[1]
- Local site administration reactions of oral hypoaesthesia and abnormal product taste were the only commonly reported adverse events with an incidence of >5% and at least twice the rate of placebo
- Although the primary endpoint for BESTFIT was based on analysis of improvements in pain, the mechanism of action of this intervention is believed to be targeting of nonrestorative sleep. Consistent with this mechanism, observed improvements in sleep quality preceded improvement in pain
- An ongoing confirmatory Phase 3 study will utilize a responder analysis of pain as the primary endpoint. Key secondary endpoints will also be analyzed as responder analyses, which seems to be a more appropriate approach to the evaluation of TNX-102 SL in fibromyalgia

References

1. Witter J, Simon LS, Dionne R. Are means meaningless? The application of individual responder analysis to analgesic drug development. APS Bulletin. 2003; 13:4-7.
2. Data on file, Tonix Pharmaceuticals.

*TNX-102 SL is an Investigational New Drug and has not been approved for any indication.

American College of Rheumatology Annual Meeting, November 6-11, 2015, San Francisco, CA

Exhibit 99.04

Tonix Pharmaceuticals Presents Additional Data on Tonmya™ Demonstrating Improvements in Sleep, Pain, and Other Outcomes in Fibromyalgia at 2015 ACR/ARHP Annual Meeting

Phase 2b BESTFIT clinical study results reveal correlations between sleep quality and key clinical measures

New York, NY – November 10, 2015 – Tonix Pharmaceuticals Holding Corp. (NASDAQ: TNXP) ("Tonix"), which is developing next-generation medicines for fibromyalgia, post-traumatic stress disorder (PTSD), and episodic tension-type headache, today presents additional results from its completed 12-week, 205-patient Phase 2b BESTFIT clinical study of Tonmya (TNX-102 SL; cyclobenzaprine HCl sublingual tablets, 2.8 mg) for the treatment of fibromyalgia. Tonmya is designed for chronic daily use at bedtime to treat fibromyalgia.

Tonmya is currently being evaluated in the 500-patient Phase 3 AFFIRM study in fibromyalgia. As accepted by the U.S. Food and Drug Administration, the primary outcome measure for this Phase 3 study is a pain responder analysis, defined as the proportion of patients who report at least a 30% reduction in pain from baseline at the end of the 12-week treatment period. Tonix expects to report top-line data from the AFFIRM trial in the third quarter of 2016.

"Our new analyses of the BESTFIT data show that those patients who reported the greatest improvement in sleep quality were the most likely to experience pain relief," said Seth Lederman, M.D., Tonix's chairman and CEO. "We also observed that the group treated with Tonmya was approximately twice as likely as placebo-treated patients to be in the top third of reported sleep quality improvement. Among all patients in BESTFIT who ranked highest in reported sleep quality improvement, twice as many Tonmya-treated patients experienced at least a 30% improvement in their pain as compared to those treated with placebo."

Of the 174 patients who completed the BESTFIT study, 172 were evaluable for the analyses described in this paragraph. Of these 172, 88 patients were treated with Tonmya ("Tonmya group"), and 84 were treated with placebo ("placebo group"). According to a tertile analysis of reported sleep quality improvement, the 54 of these 172 patients who reported the greatest improvement in sleep quality, or top sleep tertile, were examined in further detail. Of those in the Tonmya group, 36, or 41%, were in the top sleep tertile compared to 18 of the 84 patients, or 21%, in the placebo group. Of the 42 patients in the top sleep tertile who experienced at least a 30% improvement in their pain from baseline, 28, or 67%, had received Tonmya, compared to 14, or 33%, who had received placebo.

In other analyses, the relationships between reported sleep quality and several standard measures of fibromyalgia were evaluated. According to each of the three different assessments of sleep quality used in BESTFIT, improvement in patient-reported sleep quality was found to significantly correlate with improvement in pain as well as broader measures of fibromyalgia symptoms and impact.

These findings from BESTFIT may support the hypothesis that improving sleep quality facilitates pain improvement over time, and is consistent with the growing recognition of a reciprocal relationship between sleep and chronic, widespread pain. Nonrestorative sleep has been linked to altered processes in the brain that are thought to be responsible for certain fibromyalgia symptoms.

These results are included within a larger body of data being presented today at the 2015 American College of Rheumatology / Association of Rheumatology Health Professionals Annual Meeting in San Francisco, CA, in three posters entitled:

- "Relationship of Sleep Quality and Fibromyalgia Outcomes in a Phase 2b Randomized, Double-Blind, Placebo-Controlled Study of Bedtime, Rapidly Absorbed, Sublingual Cyclobenzaprine (TNX-102 SL)." (abstract no. 2307);
- "Responder Compared to Mean Change Analyses in a Fibromyalgia Phase 2b Clinical Study of Bedtime Rapidly Absorbed Sublingual Cyclobenzaprine (TNX-102 SL)." (abstract no. 2308); and
- "Bedtime, Rapidly Absorbed Sublingual Cyclobenzaprine (TNX-102 SL) for the Treatment of Fibromyalgia: Results of a Phase 2b Randomized, Double-Blind, Placebo-Controlled Study." (abstract no. 2309).

The posters are available on Tonix's website at www.tonixpharma.com.

About the BESTFIT Study

The Phase 2b BESTFIT study was designed to evaluate the efficacy of Tonmya taken daily at bedtime in improving pain, sleep quality, and other clinical measures of fibromyalgia, as well as safety and tolerability. In BESTFIT, 205 patients were randomized to Tonmya (n=103) or placebo (n=102) for 12 weeks. The study was conducted at 17 sites in the U.S. Top-line results from BESTFIT were first reported in September 2014. In the BESTFIT study, in which a 30% pain responder analysis was a pre-specified secondary outcome measure, Tonmya resulted in a response rate at week 12 that was statistically-significantly higher than placebo (p=0.033). In addition, Tonmya resulted in statistically-significant improvements at week 12 in the pre-specified secondary analyses of the Patient Global Impression of Change, or PGIC (p=0.025) and the Fibromyalgia Impact Questionnaire-Revised, or FIQ-R (p=0.014). The study showed statistically-significant improvements with Tonmya on measures of sleep quality at week 12, including the Patient-Reported Outcomes Measurement Information System, or PROMIS, instrument for Sleep Disturbance (p=0.005). Tonmya was well tolerated in the BESTFIT study. All of the reported systemic adverse events occurred in less than five percent of treated participants, and no serious adverse events were reported. The most common adverse events were local and related to sublingual administration. Mild and transient tongue or mouth numbness occurred in 44% of participants on Tonmya vs. 2% on placebo, and bitter taste in 8% on Tonmya compared to none on placebo. Among subjects randomized to the active and control arms, 86% and 83%, respectively, completed the 12-week dosing period.

About Fibromyalgia

Fibromyalgia is a chronic neurobiological disorder that is thought to result from amplified sensory and pain signaling. Fibromyalgia afflicts five to 15 million Americans, and physicians and patients report widespread dissatisfaction with currently marketed products. Common symptoms of fibromyalgia include chronic widespread pain, non-restorative 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. To learn more, please visit www.affirmstudy.com.

About Tonix Pharmaceuticals Holding Corp.

Tonix is dedicated to the invention and development of novel pharmaceutical products that it believes will have broad societal impact, since they address medical conditions that are not well served by currently available therapies and that represent large potential commercial opportunities. Tonix's lead product candidate Tonmya is currently being evaluated in the Phase 3 AFFIRM study in fibromyalgia. TNX-102 SL, the same proprietary product candidate as Tonmya, is currently being evaluated in the Phase 2 AtEase study in post-traumatic stress disorder. A Phase 2 proof-of-concept study of TNX-201 in episodic tension-type headache is ongoing. This press release and further information about Tonix can be found at www.tonixpharma.com.

Tonmya, TNX-102 SL and TNX-201 are Investigational New Drugs and have not been approved for any indications.

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" 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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