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): January 12, 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

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))

ITEM 7.01 Regulation FD Disclosure.

Tonix Pharmaceuticals Holding Corp. (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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.01 Corporate Presentation by the Company for January 2015*

_____

* 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: January 12, 2015

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

Exhibit 99.01

NASDAQ: TNXP

January 2015

Safe harbor statement

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 ability to continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payer reimbursement; limited sales and marketing 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 amended Annual Report on Form 10-K for the year ended December 31, 2013, as filed with the Securities and Exchange Commission (the "SEC") on March 28, 2014 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

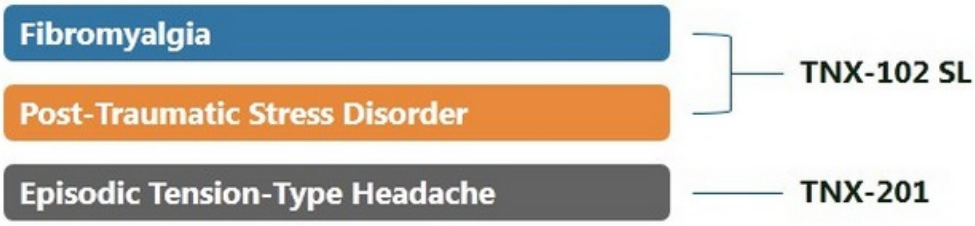
TONIX PHARMACEUTICALS

New approaches to treating CNS disorders

First-in-class medicines for common disorders of the central nervous system (CNS)

- Innovative treatment paradigms
- Late stage candidates
- Large unmet medical needs

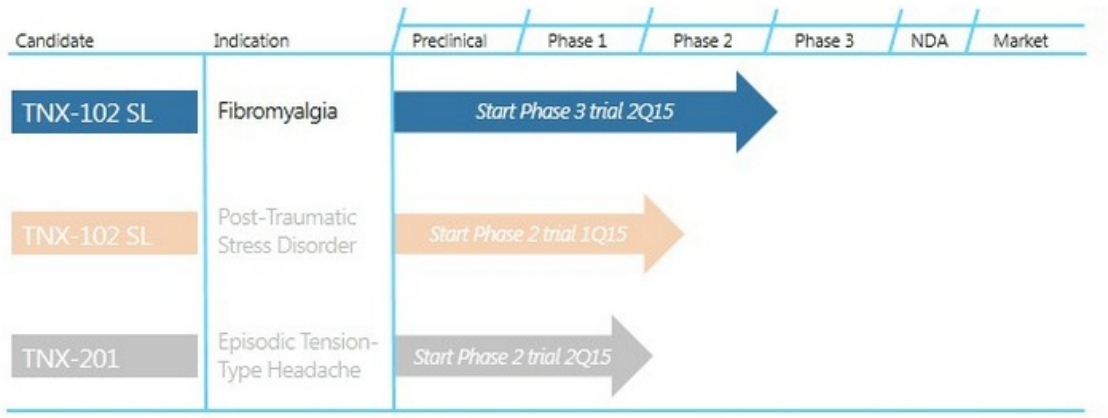
Entering 2015 with three clinical development programs



TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg and TNX-201 ((R)-isometheptene mucate) are Investigational New Drugs and are not approved for any indication.

TONIX PHARMACEUTICALS

Pipeline led by TNX-102 SL for fibromyalgia



TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg and TNX-201 ((R)-isometheptene mucate) are Investigational New Drugs and are not approved for any indication.

TONIX PHARMACEUTICALS

Fibromyalgia market opportunity

*Estimated to affect 5 - 15 million U.S. adults**

Three FDA approved prescription medications:

Class	Product	Company	Approval Year in FM
Membrane Stabilizer	Lyrica®	Pfizer	2007
SNRI	Cymbalta®	Eli Lilly	2008
	Savella®	Forest	2009

Tonix is pursuing a different approach:

Sleep Quality	TNX-102 SL	Tonix

** Lawrence et al, Arthritis Rheum 2008;58:26-35; Vincent et al, Arthritis Care Res 2013;65:786-792.*
*** Estimates based on information from publicly-available sources*

SNRI = Serotonin Norepinephrine Reuptake Inhibitor

TONIX PHARMACEUTICALS

Sleep quality is a new target for fibromyalgia therapy

Restorative sleep improves pain and other fibromyalgia symptoms

- >90% of fibromyalgia patients complain of poor sleep quality*
- Sleep quality improvement is not a feature of approved medications

Phase 2a study with low-dose cyclobenzaprine (CBP) capsule showed proof-of-concept**

TNX-102 SL is a sublingual tablet formulation of CBP

- Pharmacokinetic profile well-suited to bedtime administration
- Tolerability profile well-suited to chronic use

Phase 2b BESTFIT results support Phase 3 program in fibromyalgia

- Contribute to evidence of efficacy to support the planned NDA
- Phase 3 confirmatory trial to begin in 2Q 2015

** Swick, Ther Adv Musculoskel Dis 2011;3:167-178.*
*** Moldofsky et al., J Rheum 2011;38:2653-63.*
TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

BESTFIT Phase 2b trial in fibromyalgia

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 were randomized 1:1 at 17 U.S. sites
One sublingual tablet of TNX-102 SL 2.8 mg or placebo daily at bedtime for twelve weeks

Primary efficacy endpoint

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

First Patient – First Dose
September 2013

→

Last Patient – Last Dose
August 2014

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

TONIX PHARMACEUTICALS

TNX-102 SL improved pain in fibromyalgia in the BESTFIT study

Outcome Measure at Week 12	Intent-to-Treat Population†	*p* value	Method
Daily Pain Diary, NRS	Mean Change**	0.086 0.172	MMRM JTC-MI
Daily Pain Diary, NRS	Proportion Achieving 30% Improvement*	0.033	LR
Clinic NRS 7-day pain recall	Mean Change	0.029	MMRM
FIQ-R Pain Item	Mean Change	0.004	MMRM

NRS = Numeric Rating Scale for pain; **FIQ-R** = Fibromyalgia Impact Questionnaire-Revised
MMRM = Mixed-Effect Model Repeated Measure; **JTC-MI** = Jump to Control-Multiple Imputation (FDA-preferred analysis); **LR** = Logistic Regression

** Declared primary endpoint; was primary endpoint for FDA approvals of Lyrica and Cymbalta
* Declared secondary endpoint; will be the primary endpoint in the upcoming Phase 3 study
† N=205 (TNX-102 SL N=103, placebo N=102)

***p* < 0.05 → achieved statistical significance**

Source: Phase 2b BESTFIT preliminary top line results
TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

TNX-102 SL improved sleep quality in fibromyalgia in the BESTFIT study

Outcome Measure at Week 12	Intent-to-Treat Population	*p* value	Method
Daily Sleep Quality Diary, NRS	Mean Change*	<0.001	MMRM
PROMIS Sleep Disturbance	T-score Change*	0.005 0.004	MMRM JTC-MI
FIQ-R Sleep Quality Item	Mean Change	<0.001	MMRM

PROMIS = Patient-Reported Outcome Measures in Sleep

* Declared secondary endpoint

***p* < 0.05 → achieved statistical significance**

Source: Phase 2b BESTFIT preliminary top line results
TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

TNX-102 SL broadly improved fibromyalgia symptoms in the BESTFIT study

Outcome Measure at Week 12	Intent-to-Treat Population	*p* value	Method
Patient Global Impression of Change	Responder Analysis*	0.025	LR
FIQ-R Total Score	Mean Change*	0.014 0.015	MMRM JTC-MI
FIQ-R Symptom Domain	Mean Change	0.004	MMRM
FIQ-R Function Domain	Mean Change	0.060	MMRM
FIQ-R Anxiety Item	Mean Change	0.015	MMRM
FIQ-R Sensitivity Item	Mean Change	0.017	MMRM
FIQ-R Stiffness Item	Mean Change	0.039	MMRM

* Declared secondary endpoint

***p* < 0.05 → achieved statistical significance**

Source: Phase 2b BESTFIT preliminary top line results
TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

TNX-102 SL was well-tolerated in the BESTFIT Study

No serious adverse events (SAE) reported

Systemic adverse events reported by at least 3.0% of the total study population	**TNX-102 SL** *(N=103)*	**Placebo** *(N=101)*	**Total** *(N=204)*
Somnolence	1.9	6.9	4.4
Dry Mouth	3.9	4.0	3.9
Back Pain	4.9	3.0	3.9

Most frequent local adverse events were administration site reactions

Previously reported in TNX-102 SL Phase 1 studies; no detectable bias on efficacy results
Transient tongue numbness (42% TNX-102 SL vs. 1% 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 preliminary top line results
TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

Registration program for TNX-102 SL in fibromyalgia

Phase 2b BESTFIT study confirmed activity and tolerability

Statistically-significant improvements across key fibromyalgia symptoms were observed
Systemic tolerability similar to placebo
2.8 mg daily dose confirmed for future development

Phase 3 program to commence in 2Q 2015

Randomized, double-blind, parallel-group, placebo-controlled
N=500; 30-35 U.S. sites; 1:1 randomization
12-week study similar to the BESTFIT design
One sublingual tablet of TNX-102 SL 2.8 mg or placebo daily at bedtime

30% responder analysis at 12 weeks* – primary efficacy endpoint based on FDA written acceptance

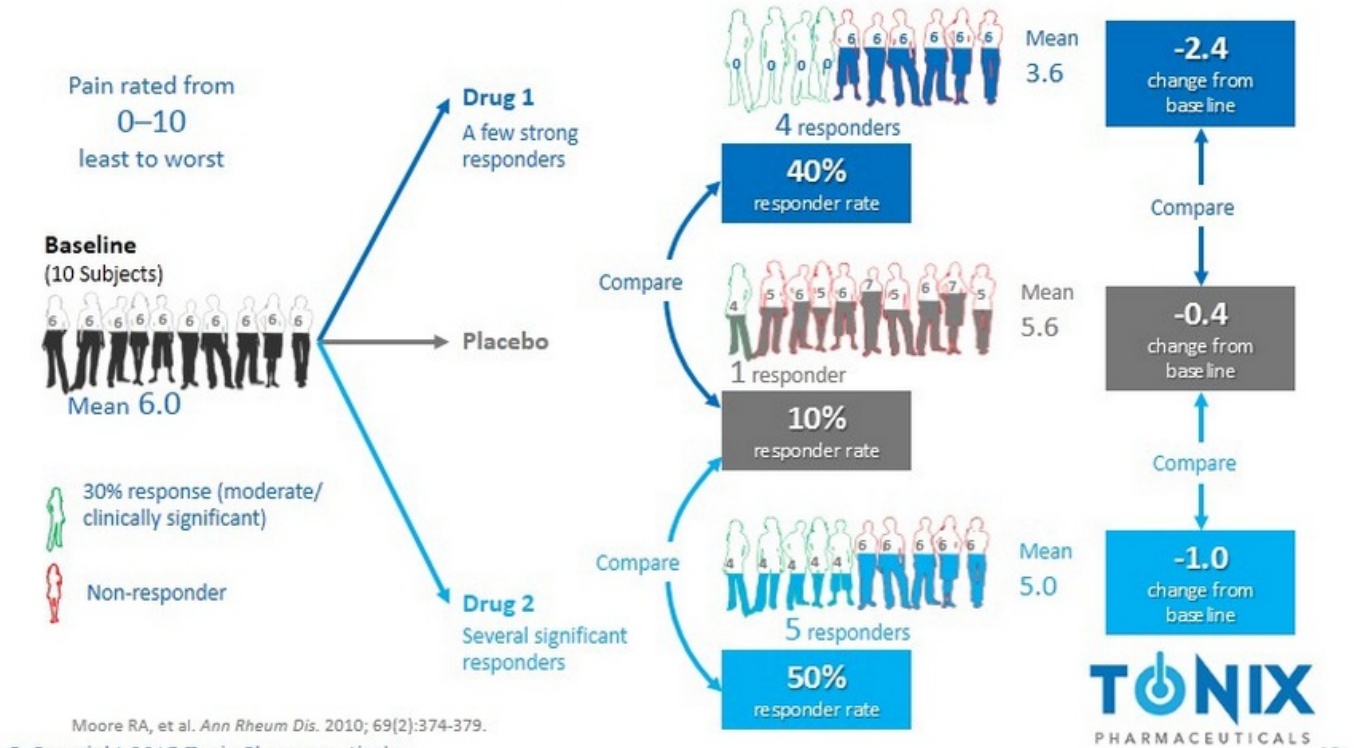
**TNX-102 SL demonstrated p=0.03 in BESTFIT 30% responder analysis (pre-specified secondary endpoint)*

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

TONIX PHARMACEUTICALS

Study measuring pain reduction for two hypothetical drugs

30% improvement is considered moderate or clinically significant response



Moore RA, et al. *Ann Rheum Dis.* 2010; 69(2):374-379.

TONIX PHARMACEUTICALS

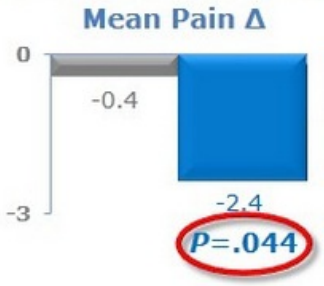
Illustration of mean pain vs. responder analyses with hypothetical drugs 1 and 2

30% Responder Rate (RR) indicates how many patients have ≥30% (clinically meaningful) improvement in pain score

Drug 1

A few strong responders

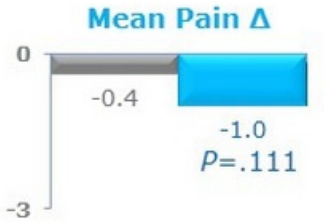
- Mean pain Δ is significant
- 30% RR is not



Drug 2

Several significant responders

- 30% RR is significant
- Mean pain Δ is not

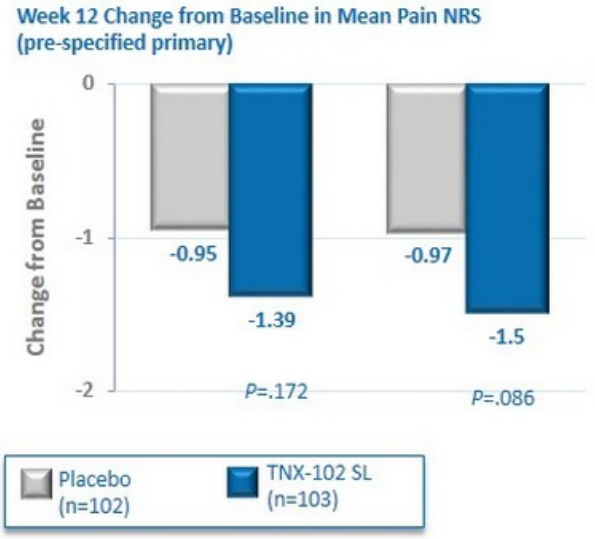


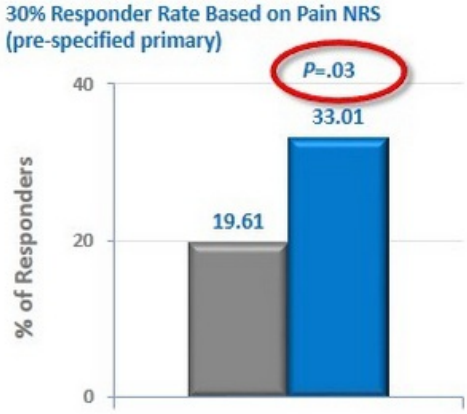
Farrar JT, et al. *Pain*. 2001; 94(2):149-158.

Both change in mean pain and 30% responder analysis are FDA-acceptable primary endpoints for FM trials.

TONIX PHARMACEUTICALS

TNX-102 SL had a significant effect on 30% response rate but not mean pain in BESTFIT





JTC-I = Jump-to-Control, Multiple Imputation; MMRM = Mixed-Effects Model Repeated Measures; NRS = Numeric Rating Scale

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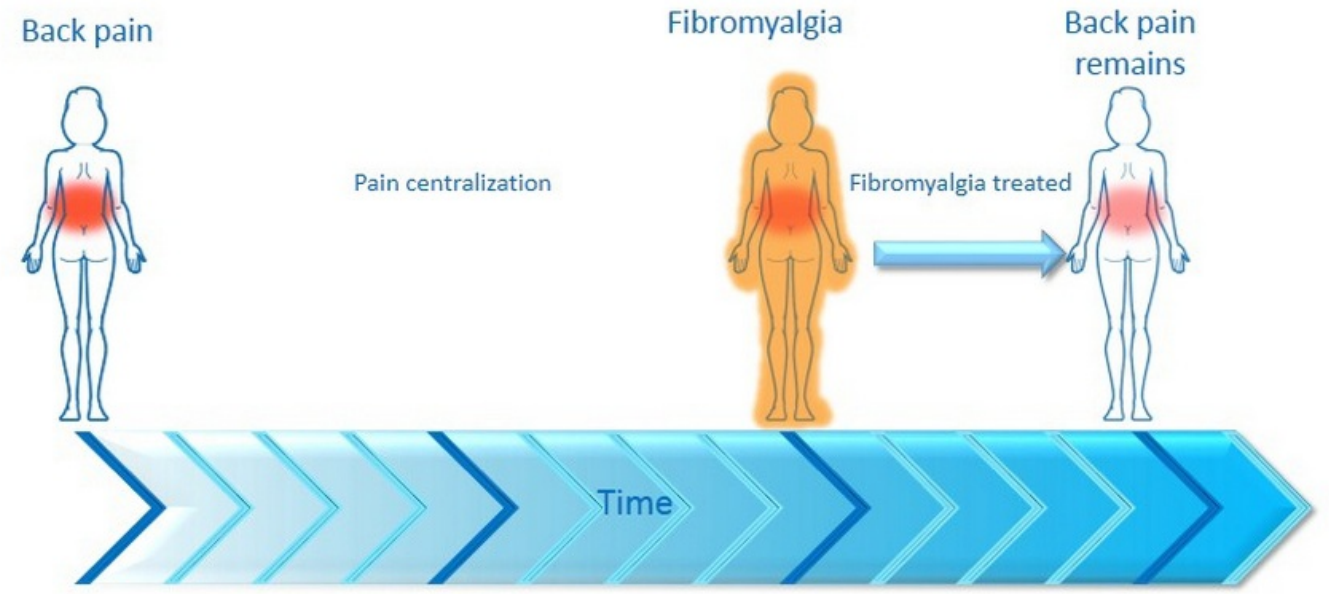
Chronic pain conditions lead to the development of central pain conditions

Reversal of the central pain syndrome may reveal the original cause



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Central sensitization contributes to hyperalgesia and allodynia

- Nociception and touch pathways are normally separate
- Central sensitization amplifies response to pain and reduces inhibition of pain

Woolf CJ. *Pain*. 2011; 152(3 Suppl):S2-15.

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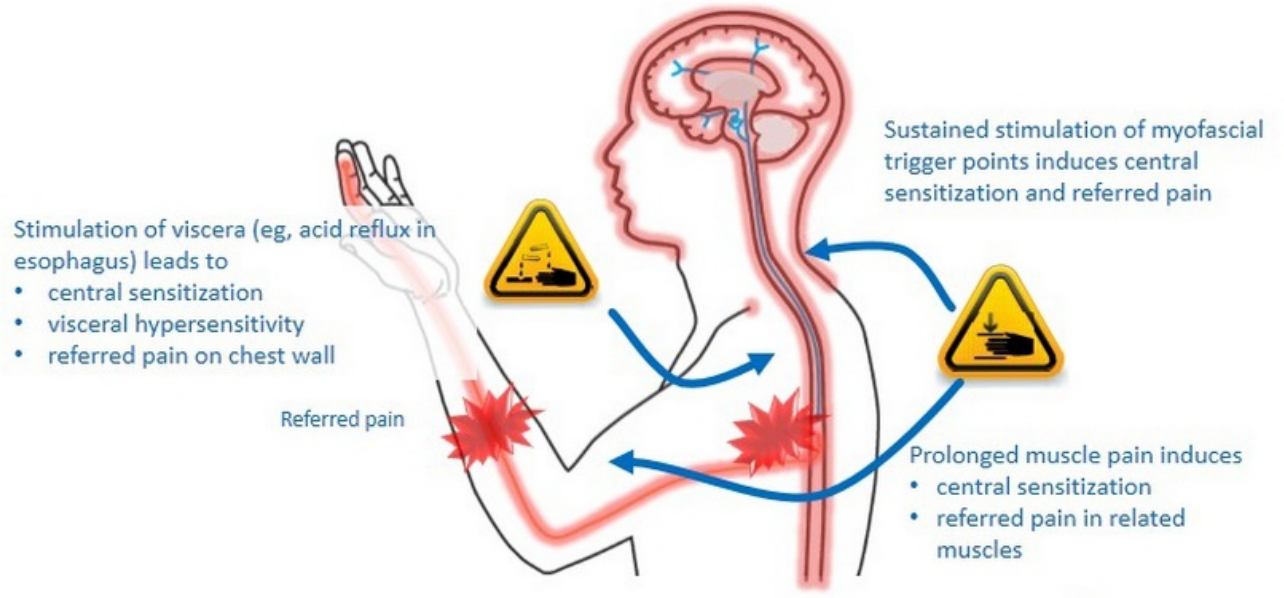
Conditioning of the peripheral and visceral nerves can lead to central sensitization and dermatome hypersensitivity



Woolf CJ. *Pain*. 2011; 152(3 Suppl):S2-15.

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Review of fibromyalgia endpoints reflects dissatisfaction with current treatments

- Fibromyalgia is one of 16 conditions chosen by FDA's Patient-Focused Drug Development program
  - Solicit patient input to determine meaningful clinical endpoints

http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm347317.htm

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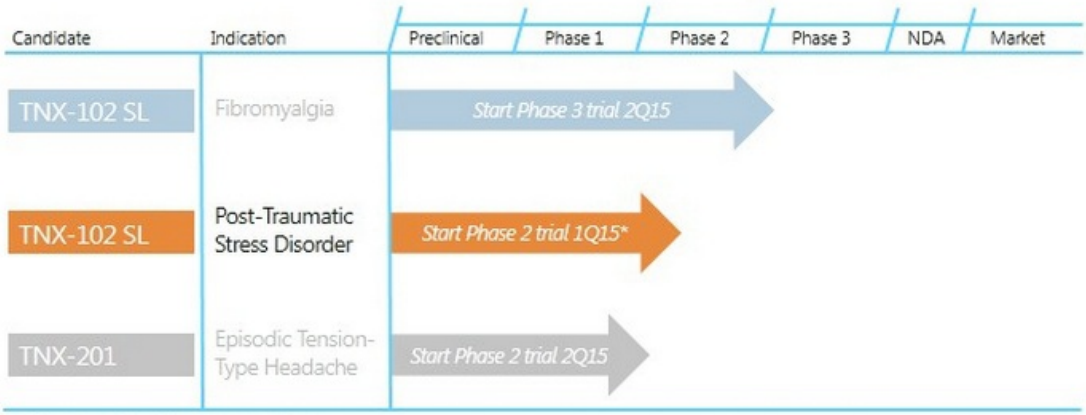
Phase 2 trial of TNX-102 SL for PTSD is recruiting



** Recruitment begin in December 2014.*

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TONIX PHARMACEUTICALS

PTSD: A Significant and Growing Public Health Problem

Post-traumatic stress disorder is a chronic, debilitating condition

- High incidence among soldiers and veterans, but experiencing any trauma can lead to PTSD
- Associated with suicide and unpredictable, violent behaviors
- Patients desperate despite two FDA approved drugs; no new treatment in >10 years

Among 8.5 million U.S. patients, approximately half are receiving medical treatment*

FDA approved prescription medications:

Class	Product	Company	Approval Year in PTSD
SSRI	Paxil®	Glaxo	2001
	Zoloft®	Pfizer	1999

Tonix is pursuing a different approach:

Sleep Quality	TNX-102 SL	Tonix	2019E

** Kessler et al, Arch Gen Psych 2005;62:617-627; Wang et al, Arch Gen Psych 2005;62:629-640.*
SSRI = Selective Serotonin Reuptake Inhibitor

TONIX PHARMACEUTICALS

Rationale for Developing TNX-102 SL for PTSD

Overlap between PTSD and fibromyalgia

- ~50% of fibromyalgia or PTSD patients meet criteria for the other disorder
- Patients experience disturbed sleep
- Widespread pain is considered "co-morbid" with PTSD
- Opioid, benzodiazepine, other sedative-hypnotic drug misuse common

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

TONIX PHARMACEUTICALS

Sleep Quality is a New Target for PTSD Therapy

Poor sleep quality after trauma is linked to onset of PTSD

PTSD patients complain of poor sleep quality as a core symptom

- Distressing dreams (nightmares) are part of "re-experiencing"
- Restless sleep is part of "hyper-arousal"
- Correlated with depression, substance abuse and suicide

Military-related PTSD is an unmet need

- Evidence suggests that SSRIs may be ineffective in military-related PTSD

Response of PTSD in men to SSRIs has not been adequately studied

TNX-102 SL targets mechanisms associated with treating disturbed sleep in PTSD

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

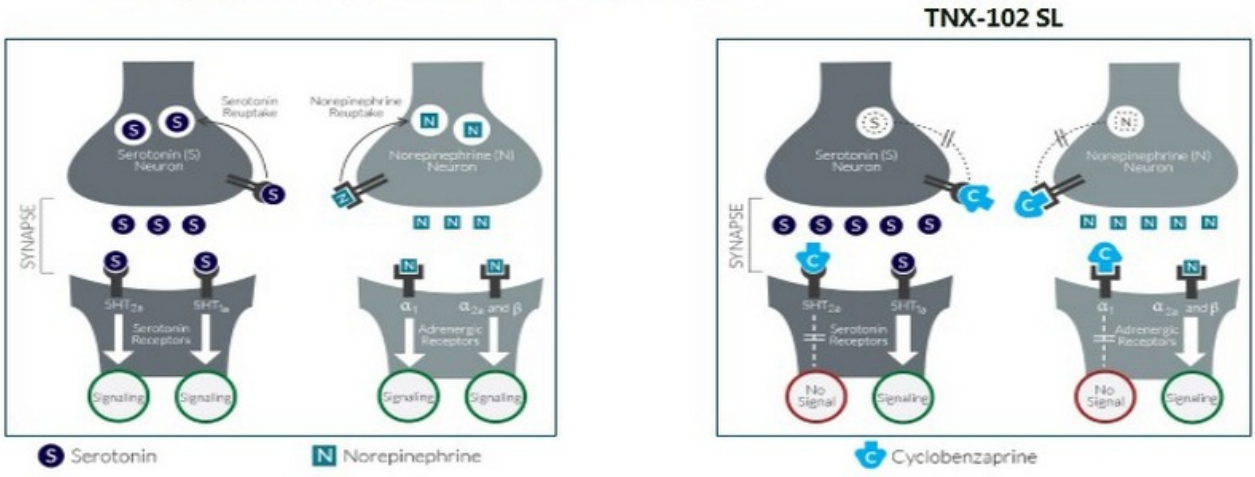
TONIX PHARMACEUTICALS

TNX-102 SL acts on neurotransmitter systems intrinsic to sleep physiology

Serotonin and Norepinephrine Antagonist and Reuptake Inhibitor (SNARI)

Blocks serotonin and norepinephrine reuptake

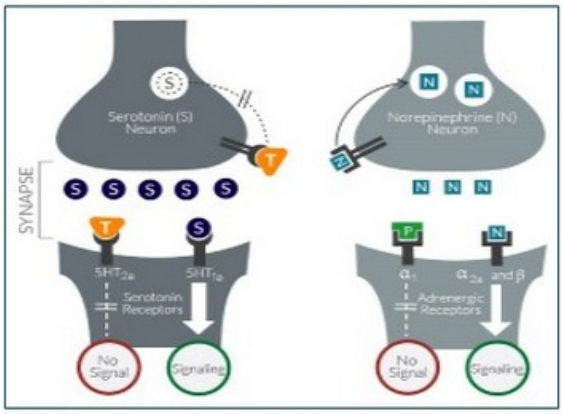
Selectively blocks serotonin 2A and α-1 adrenergic receptors



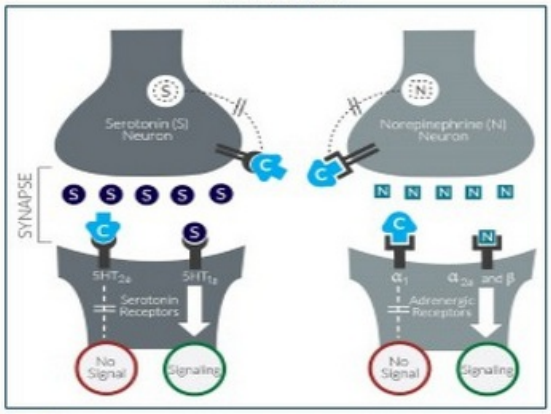
TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg is an Investigational New Drug and is not approved for any indication.

Mechanistic relationship of TNX-102 SL with trazodone and prazosin

Trazodone blocks serotonin reuptake and 2A receptors
Prazosin blocks α-1 adrenergic receptors



TNX-102 SL



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PTSD program with TNX-102 SL

Fibromyalgia program informs development of TNX-102 SL in PTSD

Safety data from fibromyalgia studies are potentially supportive for PTSD program

Efficacy data support potential for activity in PTSD

Improvements in several outcomes analyses of BESTFIT that relate to PTSD core symptoms: sleep; FIQ-R sensitivity; and FIQ-R anxiety

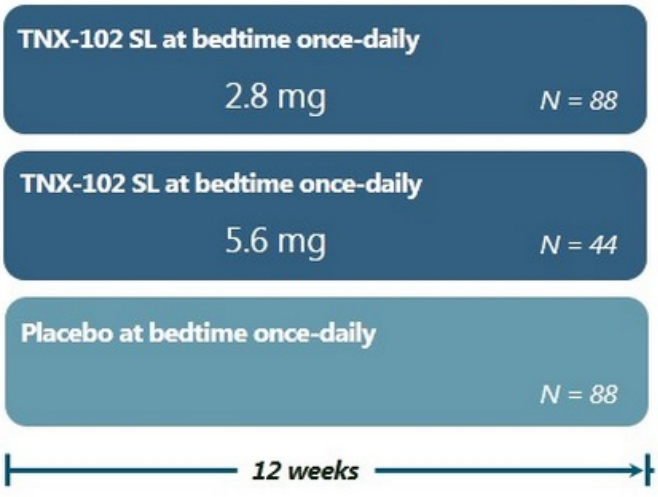
2.8 mg dose supported by BESTFIT study results

Phase 2 study of TNX-102 SL in military-related PTSD ("AtEase") is recruiting

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

TONIX PHARMACEUTICALS

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



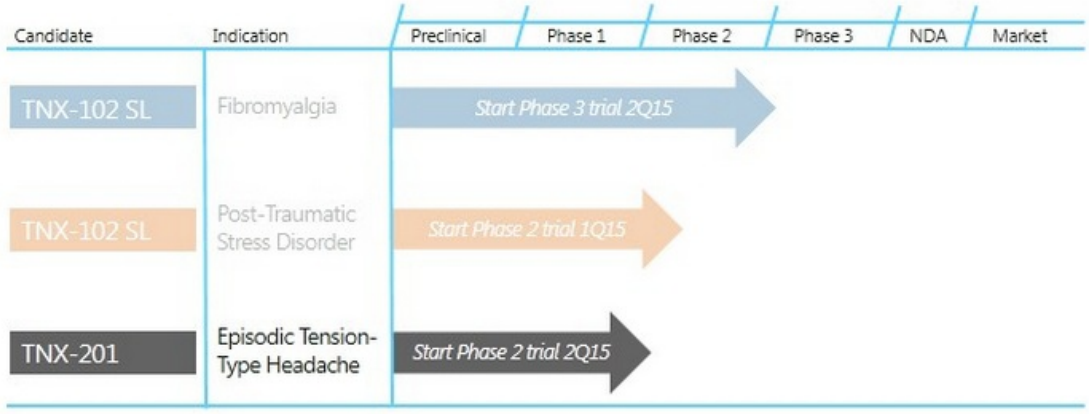
Randomized, double-blind, placebo-controlled trial in military-related PTSD

N=220; 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

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

TNX-201 in development for episodic tension-type headache



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TONIX PHARMACEUTICALS

Episodic tension-type headache (ETTH)

75 million adults in the U.S. experience frequent episodic tension-type headaches*

- Constant band of pressure on the back/sides of head; "squeezed in a vice" feeling
- "Frequent" = one to 15 headaches per month over a three-month period
- Approximately 60% receive treatment**

All of the FDA approved prescription medications contain barbiturates

- Over-the-counter medications are inadequate for many
- No new medications introduced for >40 years

Class	Product	Company	Regulatory Status	Approval Year in ETTH
Barbiturate	Fiorinal®	Actavis	Approved NDA	1976
	Fioricet®	Actavis	Approved NDA	1992
Barbiturate + Opiate	Fiorinal with Codeine®	Actavis	Approved NDA	1990

** Schwartz et al, JAMA 1998;279:381-383; Chowdhury, Ann Ind Acad Neurol 2012;15:83-88; company analysis of public literature.*
*** Scher et al, Cephalalgia 2010;30:321-328; company analysis of public literature.*

TONIX PHARMACEUTICALS

TNX-201 in clinical development for ETTH

TNX-201 is (R)-isometheptene mucate

- Tonix is developing TNX-201 for ETTH
- Phase 2 study to begin in 2Q 2015

Racemic isometheptene mucate is a mixture of (R) and (S) isomers

- Had been widely prescribed for many decades in the U.S. as:
  - a single-agent medicine (pre-1962)
  - a component of combination drug products
    - Midrin® – NDA withdrawn
    - Prodrin® – marketed under "unapproved drug category"

No product containing isometheptene mucate is currently FDA-approved for any indication

TNX-201 ((R)-isometheptene mucate) is an Investigational New Drug and is not approved for any indication.

Phase 1 study of TNX-201 completed

Phase 1 study in healthy volunteers

Single ascending dose study (N=45) – three cohorts of 15 subjects
Randomized to TNX-201, racemic isometheptene mucate, or placebo (3:1:1 ratio, resp.)

	TNX-201 35 mg *(N=9)*	**TNX-201 70 mg** *(N=9)*	**TNX-201 140 mg** *(N=9)*	**Rac. Isometh. 70 mg** *(N=9)*	**Placebo** *(N=9)*
Subjects reporting ≥1 adverse event, %	22	11	0	11	33

Adverse events reported by TNX-201 subjects all rated as "mild" and most are not study drug-related
No subject discontinued due to treatment-emergent adverse events
Dose-related increase in TNX-201 plasma levels (Cmax, AUC)
No evidence of isomer interconversion

Results support the advancement of TNX-201 into Phase 2 development

TNX-201 ((R)-isometheptene mucate) is an Investigational New Drug and is not approved for any indication.

Phase 2 trial of TNX-201 in ETTH to begin in 2Q15

Randomized, double-blind, placebo-controlled trial in episodic tension-type headache

N=150; approximately 10 U.S. clinical sites

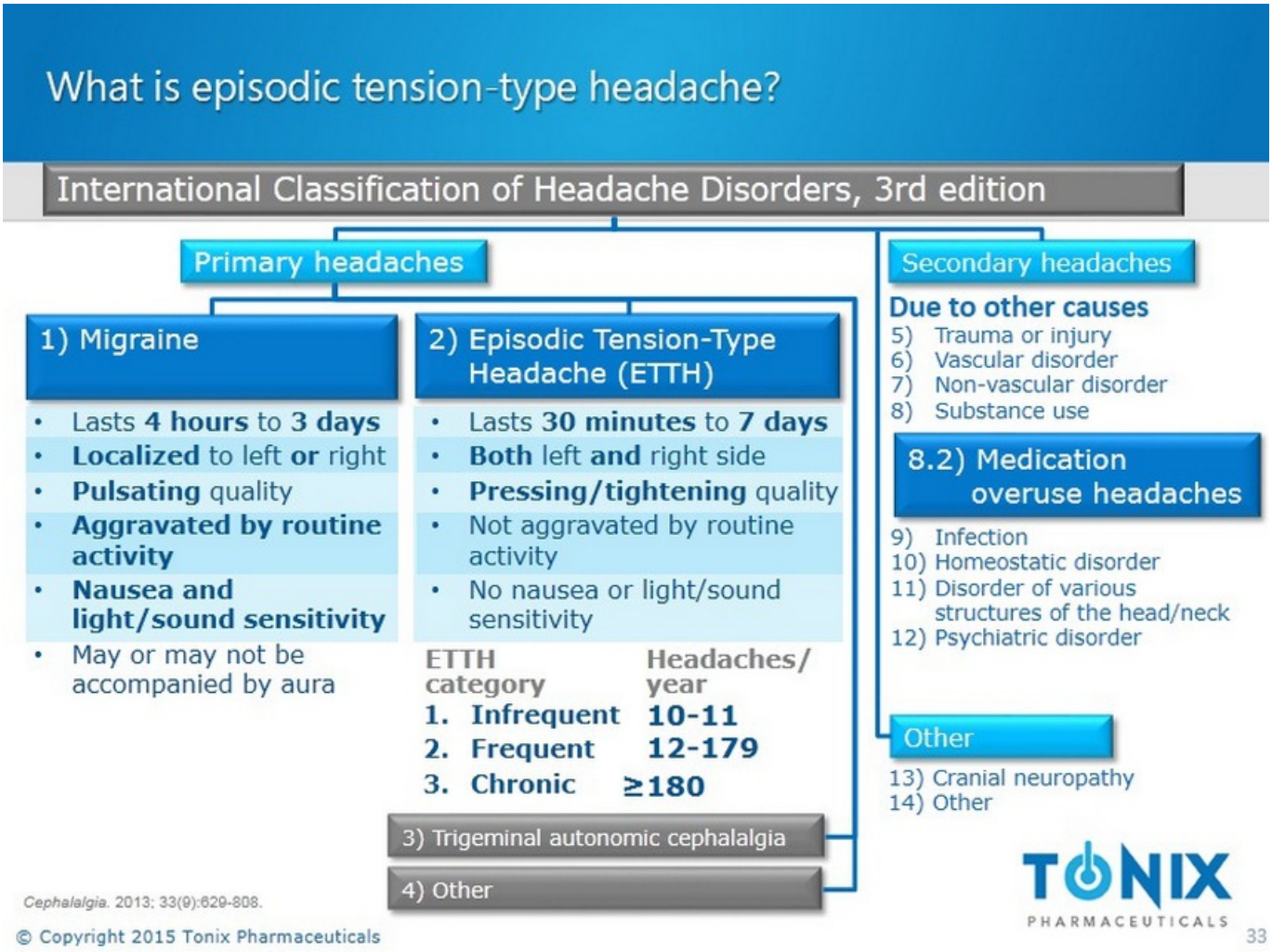
Primary efficacy endpoint:

Number of subjects who report "pain free" at two hours following one dose of study medication (upon first ETTH episode experienced)

TNX-201 ((R)-isometheptene mucate) is an Investigational New Drug and is not approved for any indication.

TONIX PHARMACEUTICALS

What is episodic tension-type headache?



Cephalalgia. 2013; 33(9):629-808.

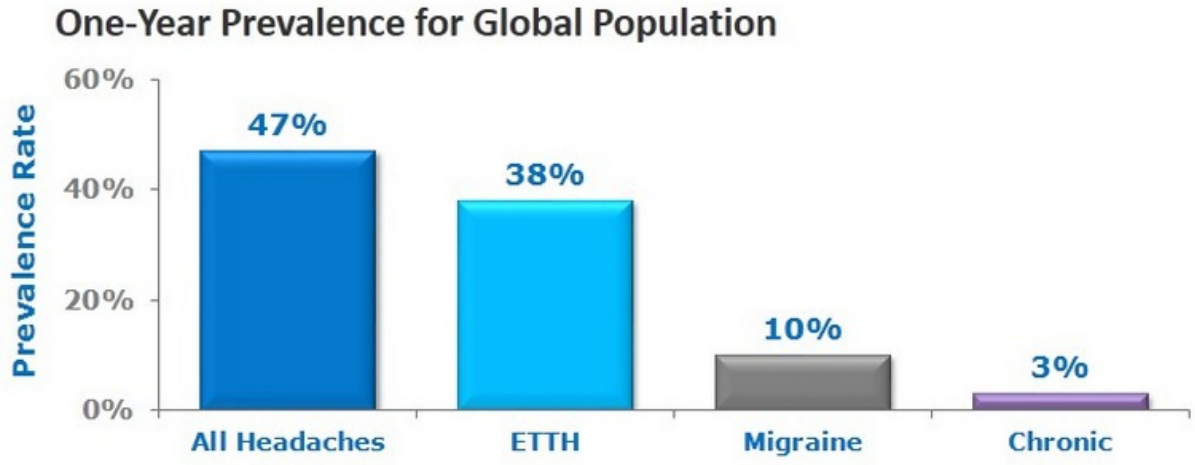
TONIX PHARMACEUTICALS

ETTH is the most common type of headache

Global prevalence of ETTH

A review of 107 publications on the epidemiology of headache

- Regional differences exist (higher in Europe, lower in Asia)



Stovner L, et al. *Cephalalgia*. 2007; 27(3):193-210.

TONIX PHARMACEUTICALS

ETTH is the most type of headache

US Prevalence of ETTH

Episodic tension-type headaches account for approximately:

- 63% of all headaches
- 80% of all non-migraine headaches
  - "Non-migraine" consists primarily of ETTH; >70% female

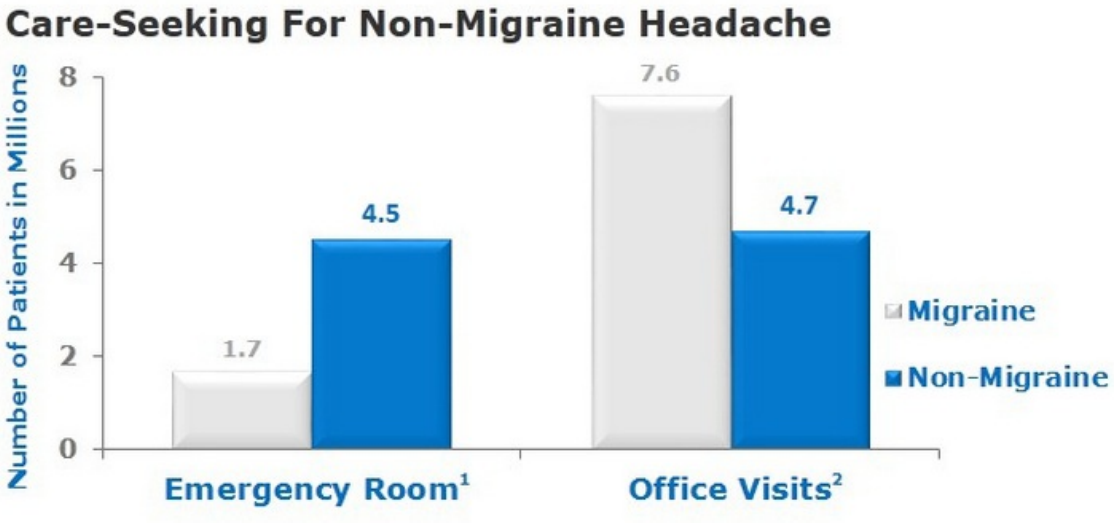
One-Year Prevalence for U.S. Adult Population (18-65)

1) Schwartz et al., JAMA, 1998; 279:381-383
2) Stovner L, et al. *Cephalalgia*. 2007; 27(3):193-210

TONIX PHARMACEUTICALS

Non-migraine headaches lead to 9.2 million emergency room or office visits

Patients with non-migraine headache (primarily ETTH) seek medical attention

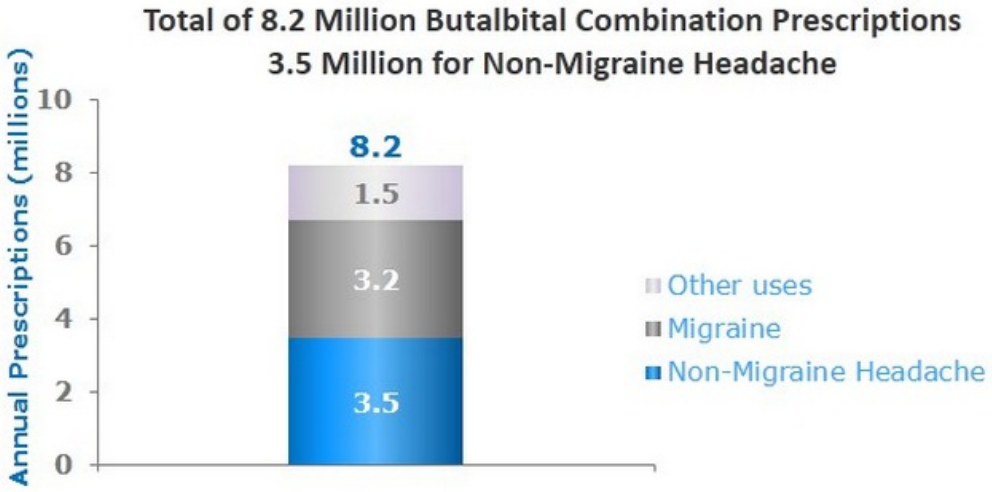


1) Heath Care Utilization Project data, 2011
2) IMS National Disease and Therapeutic Index™ 2013

TONIX PHARMACEUTICALS

Butalbital combinations are the only prescription medications approved for ETTH

Butalbital combinations are used extensively to treat headaches

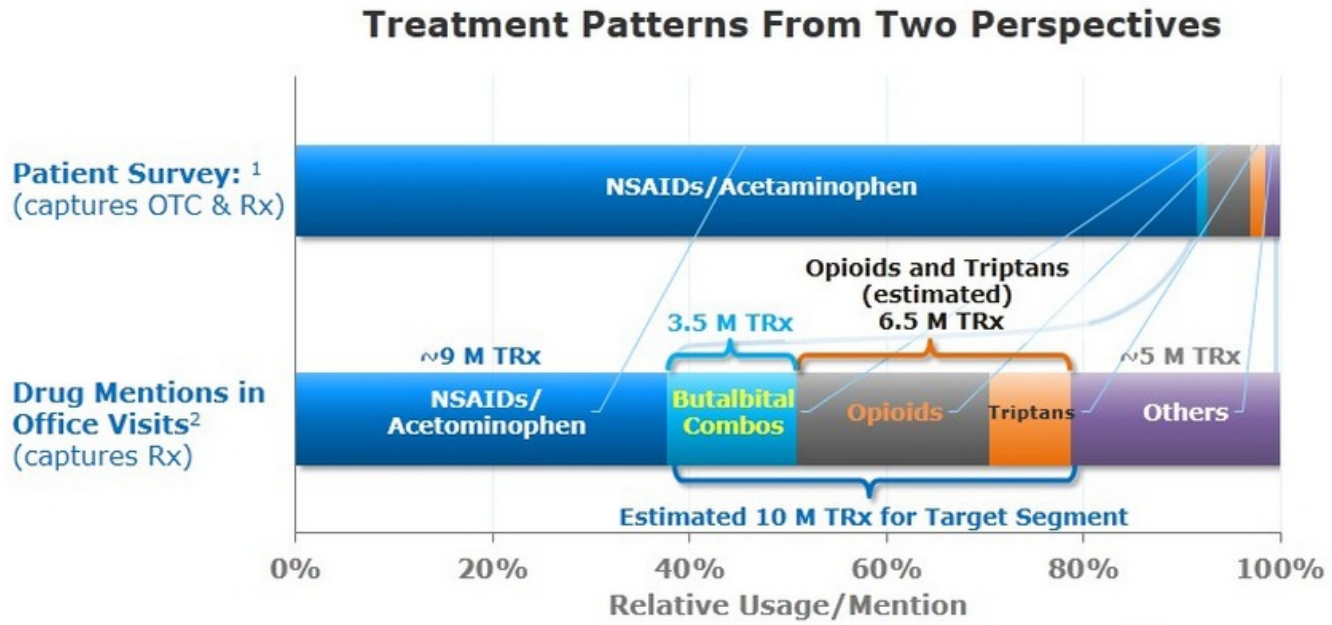


Source: IMS Health, IMS National Prescription Audit™, 08/2013 – 07/2014 and IMS National Disease and Therapeutic Index™ , Q3 2008 – Q3 2014

TONIX PHARMACEUTICALS

Current treatment pattern for non-migraine

OTC products dominate but prescription market is still sizable (~10 M TRx)



1) Scher AI, et al. *Cephalalgia*. 2010; 30(3):321-328.
2) Based on independent study conducted by Trinity Partners using IMS National Prescription Audit (8/2013 – 7/142014) and IMS National Disease and Therapeutic Index™ Q3 2008 – Q3 2014

TONIX PHARMACEUTICALS

Annual cost of health care for migraine and headache in the U.S. exceeds $4B

Costs for different treatment settings in 2010 dollars[1]

- Prescription costs are not included in these amounts

Better pharmacological treatment **reduced overall annual healthcare costs** by almost **$19K/patient** in an HMO setting[2]

1) Insinga RP, et al. *Cephalalgia*. 2011; 31(15):1570-1575.
2) Maizels M, et al. *Headache*. 2003; 43(6):621-627.

TONIX PHARMACEUTICALS

Public health attention to headache has increased in the past decade

- **2004**
  Lifting the Burden initiated
  The global campaign against headache involving WHO and 3 international headache NGOs
- **2007**
  Eurolight Project initiated
  European Union–level health agency initiative on treatment of headache disorders to systematically fill gaps in knowledge
- **2010**
  Updated guidelines for clinical trials for ETTH
- **2012**
  Migraine ranked 7th leading cause of disability by WHO's Global Burden of Disease 2010
- **2013**
  3rd edition of the International Classification of Headache Disorders
- **2014**
  Principal results of Eurolight project published
  Significant global impact of headache on family and work life, and need for additional research in ETTH and medication-overuse headache

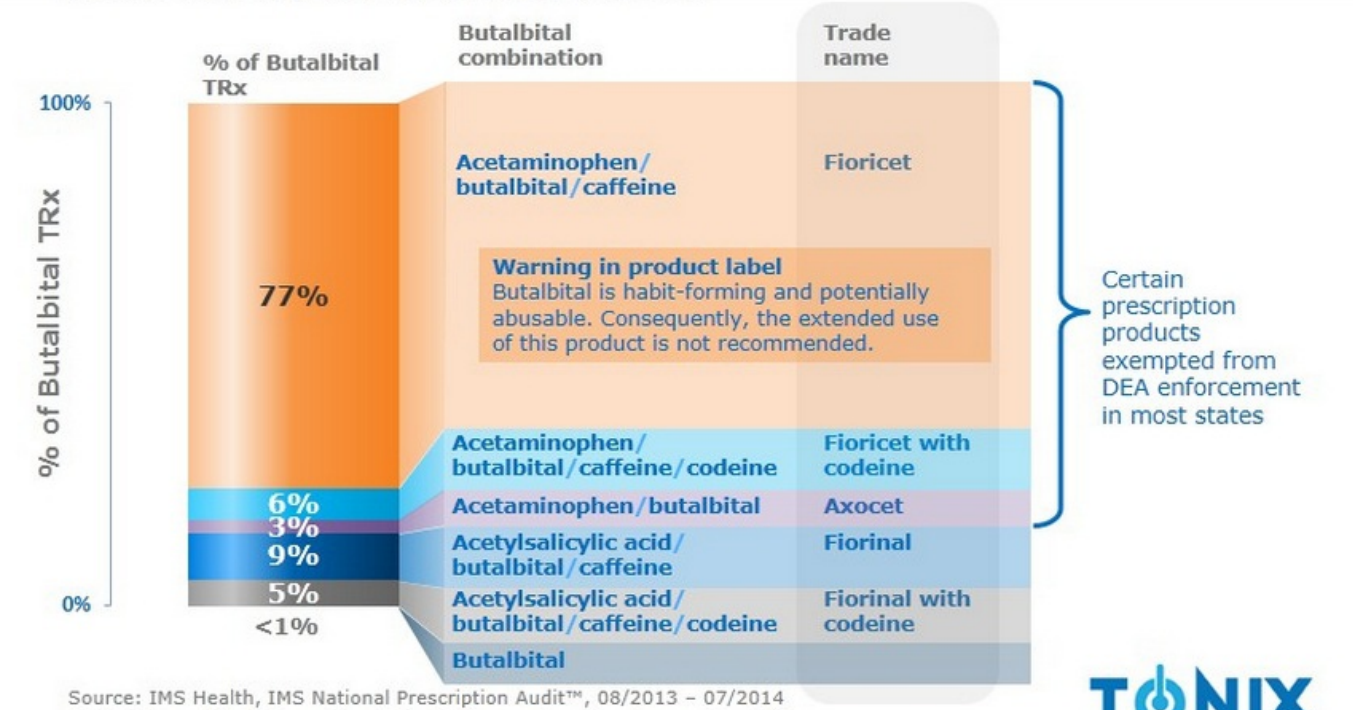
NGO = Non-governmental organization

1) Bendtsen L, et al. *Cephalalgia*. 2010; 30(1):1-16.
2) Steiner TJ. *Lancet Neurol*. 2004; 3(4):204-205.
3) Vos T, et al. *Lancet*. 2012; 380(9859):2163-2196.
4) *Cephalalgia*. 2013; 33(9):629-808.

TONIX PHARMACEUTICALS

All of the FDA-approved medications for ETT contain butalbital

Butalbital is a DEA schedule III substance due to its abuse potential and its extended use is not recommended



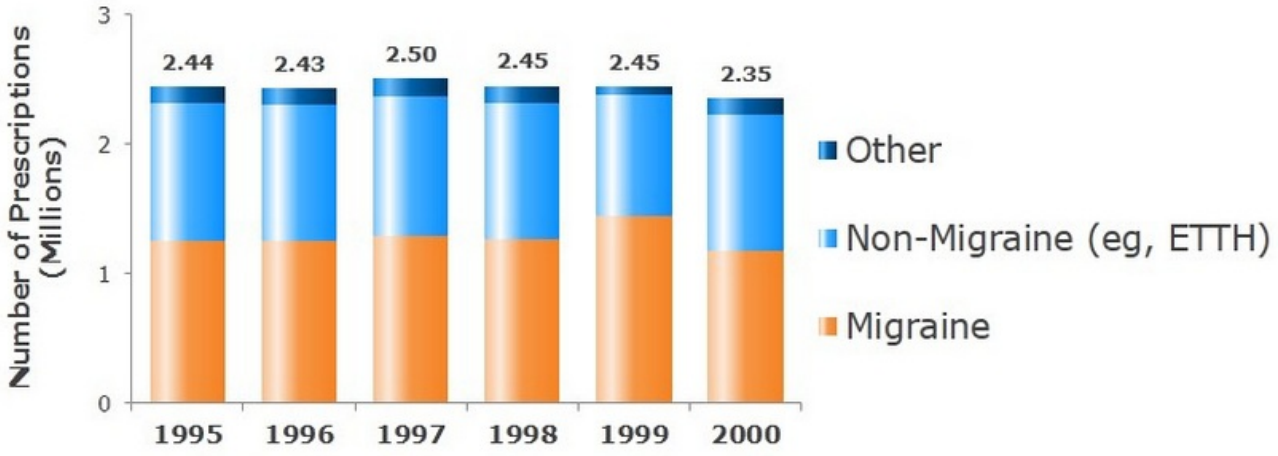
Source: IMS Health, IMS National Prescription Audit™, 08/2013 – 07/2014
Fioricet Prescribing Information. Actavis Pharma, Inc: Parsippany, NJ; 2014.
DEA = Drug Enforcement Agency

TONIX PHARMACEUTICALS

Racemic isometheptene combination (RIC) prescriptions had been commonly written

Number of RIC prescriptions peaked at 2.5 million

Usage of RIC Prescriptions for All Diagnoses

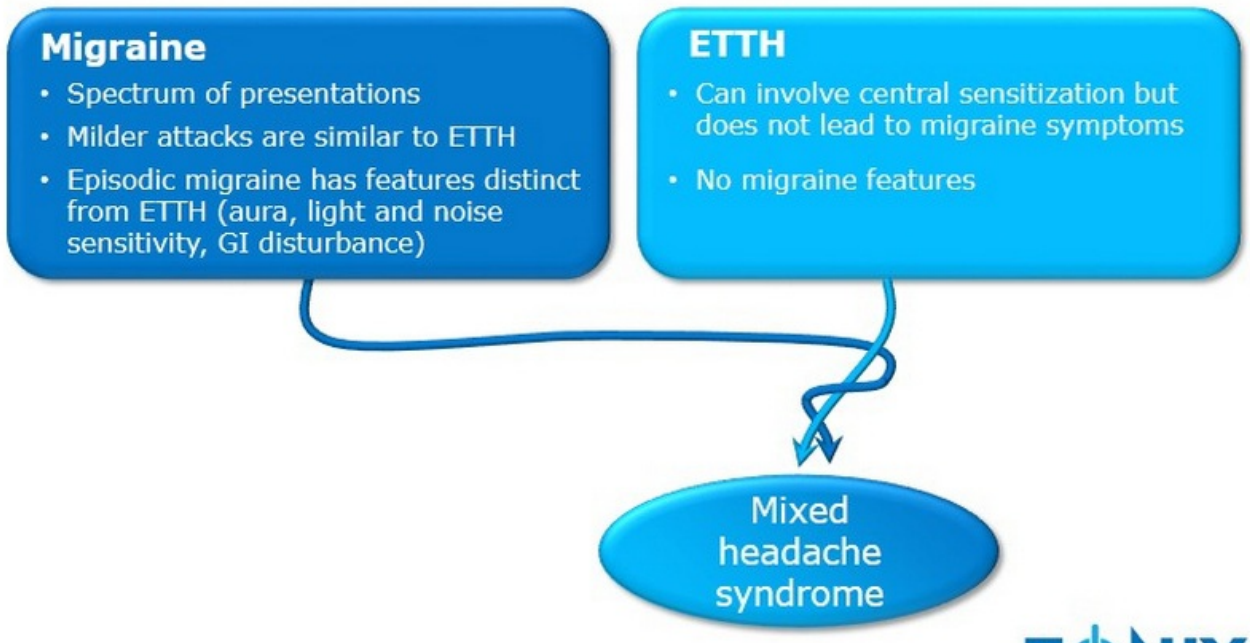


Source: IMS Health, National Prescription Audit, 01/1995 – 12/2000- extracted 8/2014
IMS Health, IMS National Disease and Therapeutic Index™, 01/1995 – 12/2000, extracted 8/2014

TONIX PHARMACEUTICALS

Migraine and ETTH can exist together in mixed headache syndrome

Distinct from each other in pathophysiology and clinical presentation

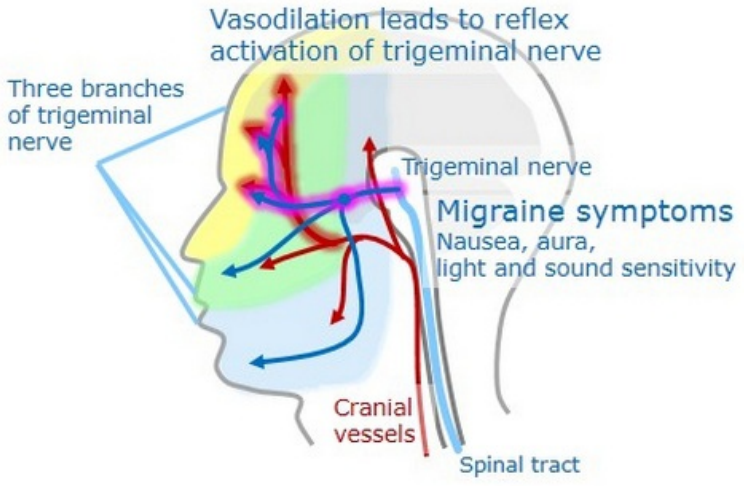


Blumenfeld A, et al. *Curr Pain Headache Rep.* 2010; 14(6):465-469.

TONIX PHARMACEUTICALS

Pathophysiology of migraine and ETTH

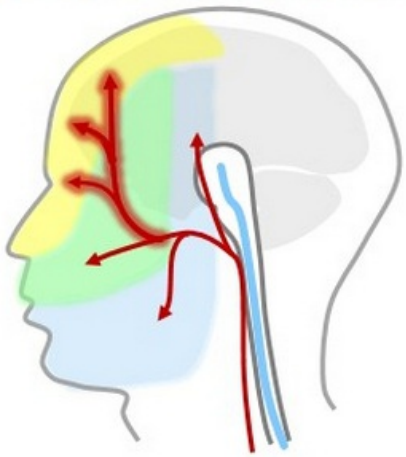
Migraine



Solomon GD. *Semin Pediatr Neurol.* 1995; 2(2):165-177.

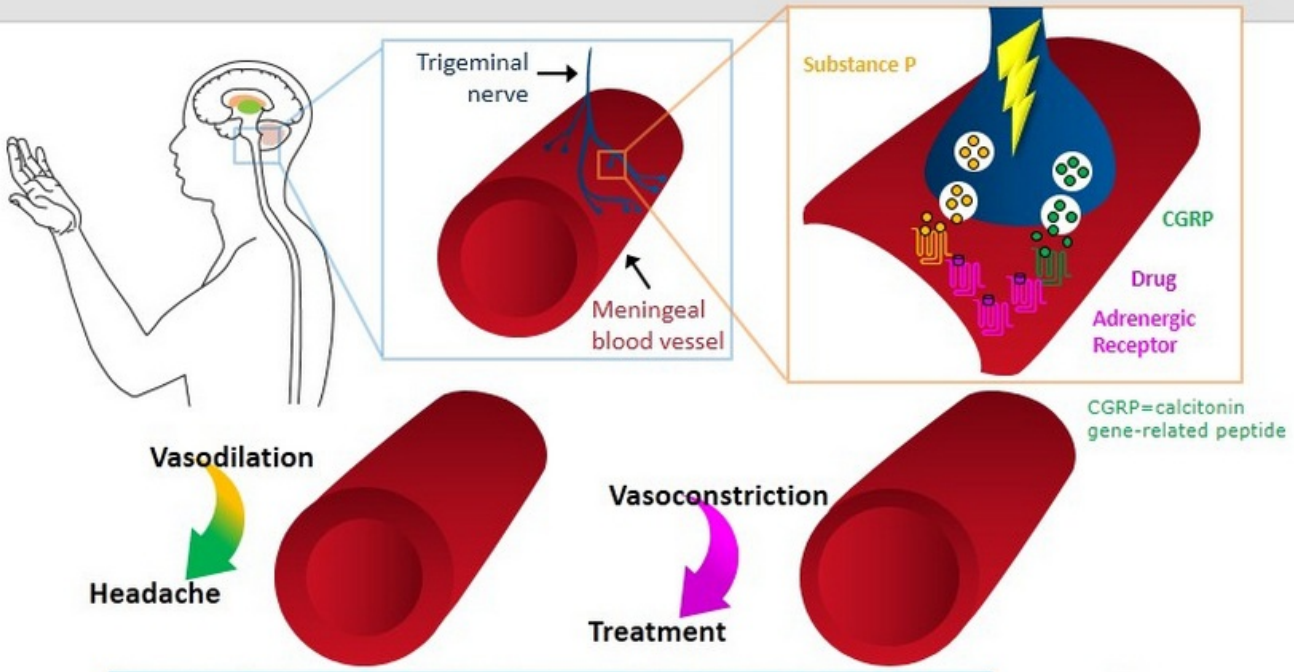
ETTH

- May be a mild form of migraine or have distinct etiology
- Believed to involve vasodilation



TONIX PHARMACEUTICALS

The vascular theory of headache pathogenesis and treatment



Sympathomimetic control of vasoconstriction has historically been the focus of a considerable amount of drug development

Solomon GD. *Semin Pediatr Neurol.* 1995; 2(2):165-177.

TONIX PHARMACEUTICALS

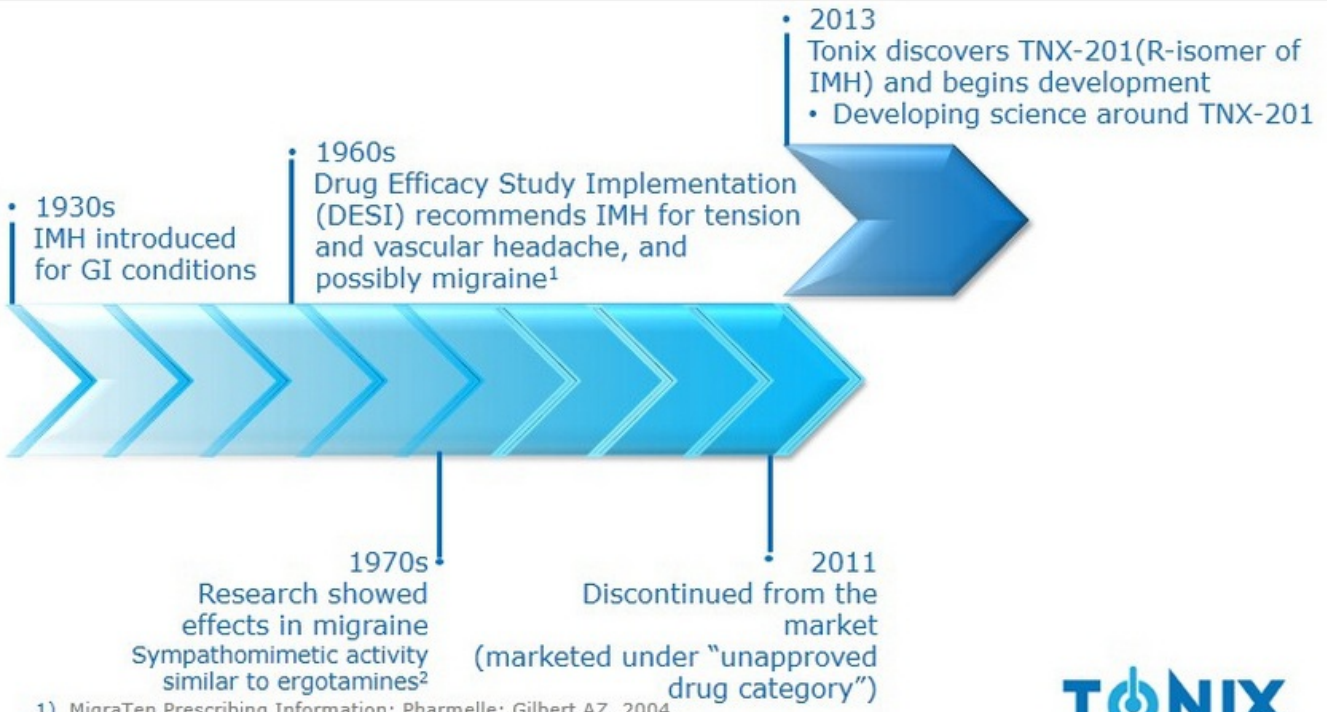
Targets in the treatment of headache and pain

- Sodium channel,[1] $Na(V)_{1.7/1.8}$
- Nerve growth factor[2]
- Calcium channel alpha-2-delta ("gabapentinoids")[3]
- Serotonin receptors, $5\text{-}HT_{1B/D/F}$[4] ("triptans")
- Prostanoid receptors (EP_2/EP_4) [4]
- Calcitonin gene-related peptide (CGRP) receptor[4]
- NO receptor[4]
- Cannabinoid receptors ("cannabinoids")[5]
- Opioid receptors (naltrexone, low dose)[6]
- NMDA receptor (ketamine)[7]

1) Dib-Hajj SD, et al. *Pain Med.* 2009; 10(7):1260-1269.
2) Ossipov MH. *Curr Pain Headache Rep.* 2011; 15(3):185-192.
3) Hauser W, Pain.2009;145(1-2):69-81.
4) Nagy AJ, et al. *Neurol Sci.* 2013; 34 Suppl 1:S101-108.
5) Lynch ME, et al. Br J Clin Pharmacol.2011;72(5):735-744.
6) Younger J, et al. Arthritis Rheum. 2013;65(2):529-538.
7) Staahl C, et al. Br J Clin Pharmacol 2009;68:322–41.

TONIX PHARMACEUTICALS

Racemic isometheptene (IMH) has a long track record of use



1) MigraTen Prescribing Information; Pharmelle; Gilbert AZ, 2004.
2) Diamond S, et al. *Headache.* 1975; 15(3):211-213.

TONIX PHARMACEUTICALS

Racemic IMH is a sympathomimetic amine

Sympathomimetic activity presumed to account for activity in headache

- Sympathomimetic action leads to vasoconstriction in cranial vessels
  - Common therapeutic strategy for vascular headaches
- New proprietary data points to a different mechanism

Willems EW, et al. *Naunyn Schmiedebergs Arch Pharmacol.* 2001; 364(1):27-32.

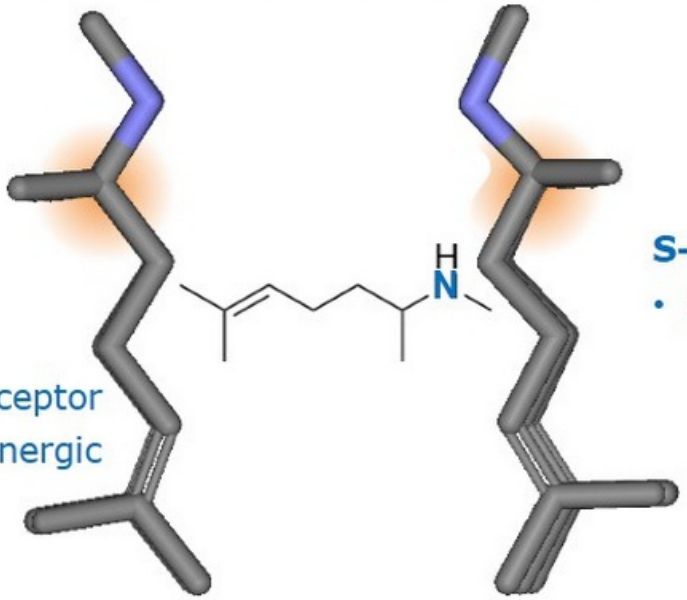
TONIX PHARMACEUTICALS

IMH isomers have different pharmacological activities

- Previously marketed isometheptene drugs were a mixture of two chemically distinct, mirror-image isomers

R-isomer

- Analgesic
- Binds to imidazoline-1 receptor
- Inactive on adrenergic receptors



S-isomer

- Sympathomimetic

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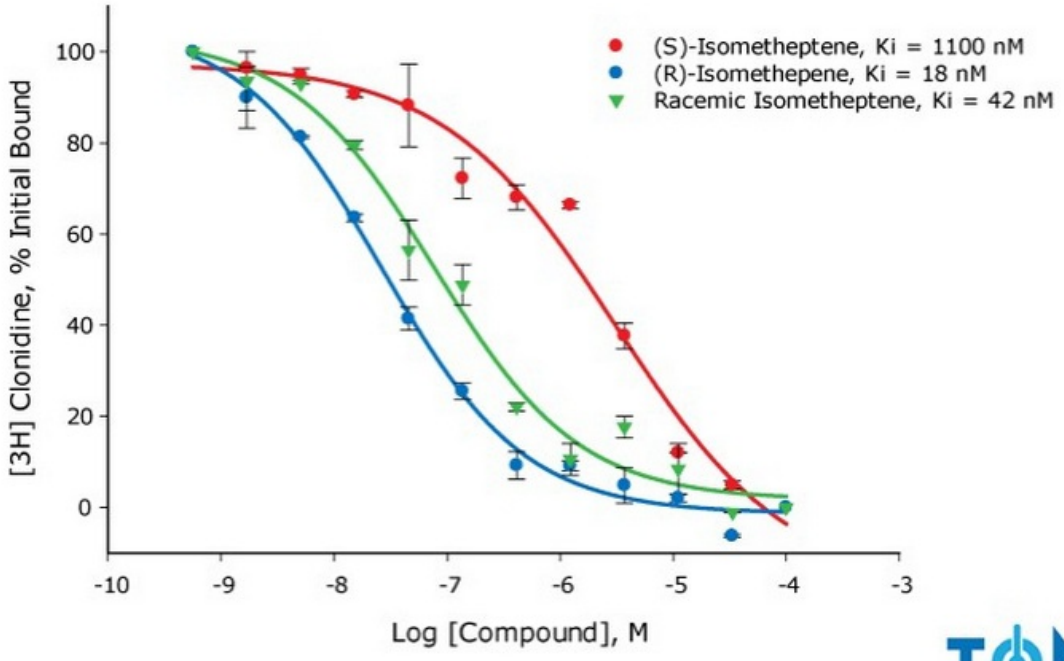
R-IMH binds to the imidazoline-1 receptor

Binding of isometheptene isomers and racemic mixture to I_1-R

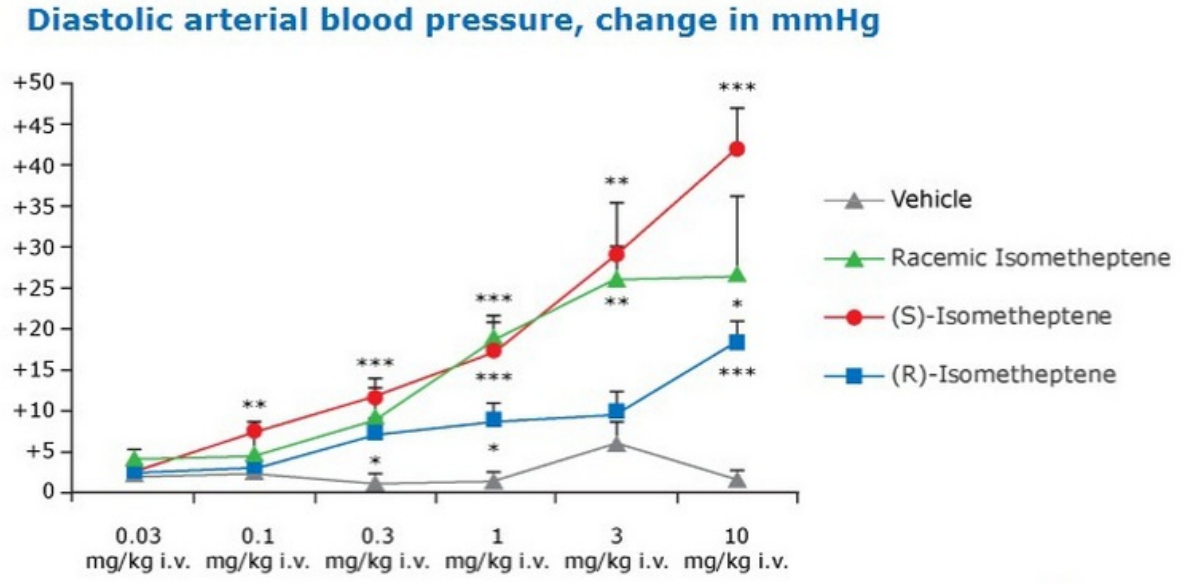


Data on file. Tonix Pharmaceuticals, 2015.

TONIX PHARMACEUTICALS

R-IMH has reduced effects on blood pressure compared to S-IMH and racemic IMH

Comparison of the effects of isometheptene mucate (IMH), (R)-IMH, and (S)-IMH on blood pressure following IV administration in anesthetized rats at doses ranging from 0.03 to 10 mg/kg



Data on file. Tonix Pharmaceuticals, 2015.

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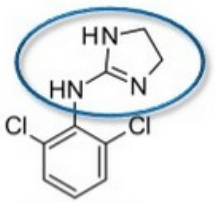
Discovery of the imidazoline receptor

- Clonidine has been in clinical use for 40 years[1]
  - High blood pressure, migraine, pain, psychiatric disorders
  - Use in pain limited by side effects
  - Primary activity—α_2 adrenergic agonist
- Imidazoline receptor hypothesized in '80s when α_2 activity could not fully explain pharmacologic action[2]

Imidazoline



Clonidine

1) Neil MJ. *Curr Clin Pharmacol.* 2011; 6(4):280-287.
2) Bousquet P, et al. *J Pharmacol Exp Ther.* 1984; 230(1):232-236.

TONIX PHARMACEUTICALS

The imidazoline-1 receptor is a novel target for the treatment of pain

Imidazoline I_1 Receptor (I_1-R)

Characteristics[1]

- Transmembrane receptor
- Distinct from α_2AR and MAO receptor subtypes
- No sequence similarity to GPCRs or ATP-sensitive K^+ channels
- Shares similarities to ryanodine and cytokine receptors

Mouse Studies[2]

- I_1-R null mice show **no difference** in systolic blood pressure or heart rate compared to wild type
- I_1-R null mice show a **reduction in pain threshold** compared to wild type in both the hot plate and tail flick tests

Hot Plate Test

1) Piletz JE et al. DNA and Cell Biology. 2000; 19(6):319-329.
2) Zhang L et al. CNS Neurosci Ther. 2013; 19(12):978-981.

TONIX PHARMACEUTICALS

The imidazoline-1 receptor is a novel target for the treatment of pain

Imidazoline I_1 Receptor (I_1-R)

Drugs with I_1-R Affinity[1]

Drug	I_1 agonist	α_1/α_2 agonist
Clonidine	✓	✓
Rilmenidine	✓	✓
Moxonidine	✓	✓
Dexmedetomidine	✓	✓
Isometheptene	✓	✗

Isometheptene is a non-imidazoline, selective imidazoline-1 receptor (NISIR) agonist

1) Khan ZP et al. *Anaesthesia*. 1999;54:146-165.

TONIX PHARMACEUTICALS

Initial physician response to TNX-201

- Based on the established use of racemic isometheptene, the single isomer, TNX-201, should have a superior safety profile* with similar efficacy compared to NSAIDs and Fioricet
- The likelihood of a non-habit forming nature and a low rebound risk, judging from the racemate, differentiate TNX-201 from other tension-type headache therapies
- Familiarity and experience with racemic isometheptene translates to physician comfort using TNX-201

* Preliminary Phase 1 results showed that TNX-201 is well tolerated at all doses studied. The adverse event profile is similar to placebo.

Data on file. Tonix Pharmaceuticals, 2015.

TONIX PHARMACEUTICALS

Future opportunities for TNX-201

- There are currently a limited number of MOAs used in treating headache pain
- The MOA of TNX-201 on headache pain is novel, with the imidazole I_1 receptor representing a strong candidate

TONIX PHARMACEUTICALS

Intellectual property

All IP wholly-owned by Tonix without obligations to others

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, 3Q 2020 expiry
PTSD: patents filed

TNX-201
Headache

Composition-of-matter (isomer)
Patents filed
Protection expected to 2033

TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg and TNX-201 ((R)-isometheptene mucate) are Investigational New Drugs and are not approved for any indication.

TONIX PHARMACEUTICALS

Financial summary

NASDAQ: TNXP	
Cash reported at September 30, 2014	$ 46.2 million
Net cash used in operations in 3Q14	$ 4.9 million
Shares outstanding†	10.8 million

† *As of January 9, 2015*

TONIX PHARMACEUTICALS

Management team

Seth Lederman, MD
Chief Executive Officer

TARGENT · Fusilev (levoleucovorin) for injection · vela PHARM

Leland Gershell, MD, PhD
Chief Financial Officer

COWEN AND COMPANY · ATON PHARMA · Zolinza [vorinostat] capsules

Bruce Daugherty, PhD
Chief Scientific Officer

MERCK · Roche

Don Kellerman, PharmD
SVP, Clinical Development
& Regulatory Affairs

MAP PHARMACEUTICALS, INC. · GlaxoWellcome · INSPIRE PHARMACEUTICALS, INC. · SEPRACOR

Milestones – recent and upcoming

TNX-102 SL – Fibromyalgia

- ☑ September 2014 – Reported top line results from Phase 2b BESTFIT study
- ☑ January 2015 – Reported on FDA acceptance of 30% responder analysis as primary endpoint
- ☐ 2Q 2015 – Begin Phase 3 program

TNX-102 SL – Post-Traumatic Stress Disorder

- ☑ June 2014 – Received IND clearance in PTSD
- ☑ December 2014 – Began recruiting Phase 2 AtEase study in military-related PTSD

TNX-201 – Episodic Tension-Type Headache

- ☑ October 2014 – Received IND clearance in ETTH
- ☑ December 2014 – Completed clinical pharmacology study
- ☐ 2Q 2015 – Begin Phase 2 study in ETTH

TNX-102 SL (cyclobenzaprine HCl sublingual tablet) 2.8 mg and TNX-201 ((R)-isometheptene mucate) are Investigational New Drugs and are not approved for any indication.

TONIX PHARMACEUTICALS

NASDAQ: TNXP

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www.tonixpharma.com

BACKUP SLIDES

Headache costs U.S. employers approximately $20B annually

Costs due to missed work time and reduced performance while at work

- Headache is the most common pain condition causing lost productive time, costing employers $19.6B annually(2002 US $)[1]

19.55

Lost productivity* in days/year[2]

$3309

Annual loss to employers per patient* (2000 US $)[2]

- ETTH contributes the majority of the disability burden (>58%)[3]

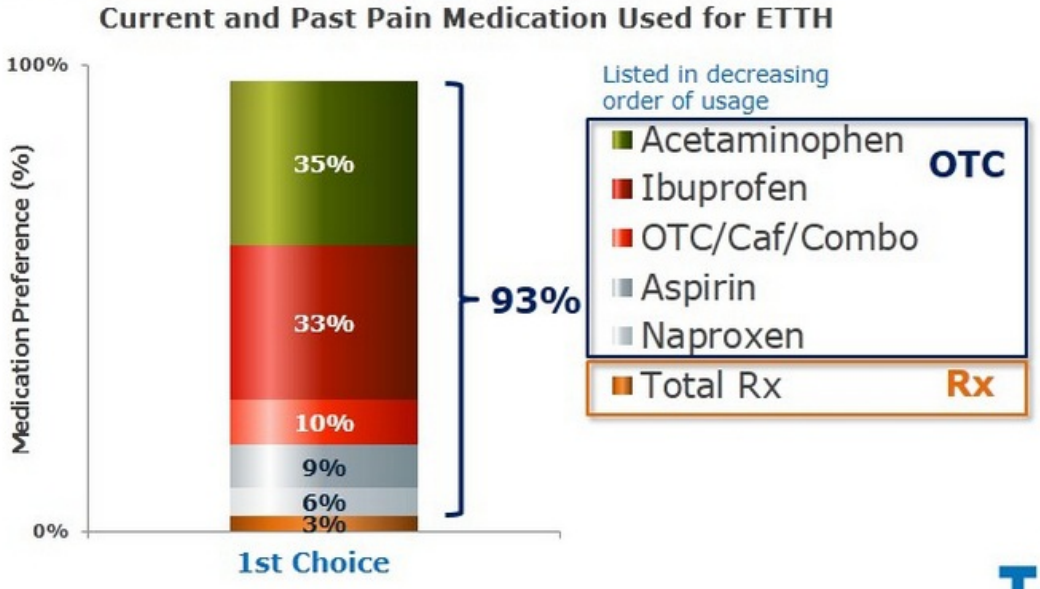
*Due to migraine only

1) Stewart WF, et al. *JAMA*. 2003; 290(18):2443-2454.
2) Gerth WC, et al. *Pharmacoeconomics*. 2001; 19(2):197-206.
3) Stovner L, et al. *Cephalalgia*. 2007; 27(3):193-210.

TONIX PHARMACEUTICALS

Medications used for treatment of ETTH

A vast majority of people with episodic headache are treated with analgesics



Scher AI, et al. *Cephalalgia*. 2010; 30(3):321-328.

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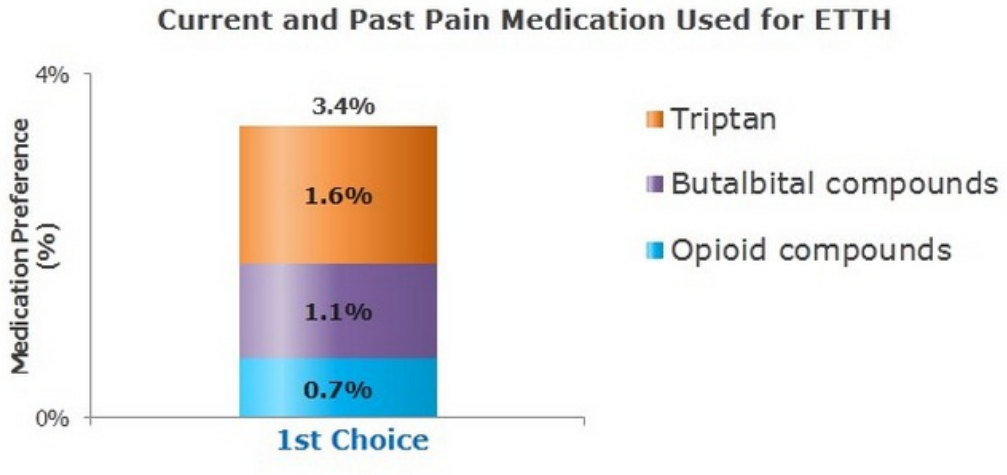
Rx medications used for treatment of ETTH

Existing prescription therapies have low market penetration



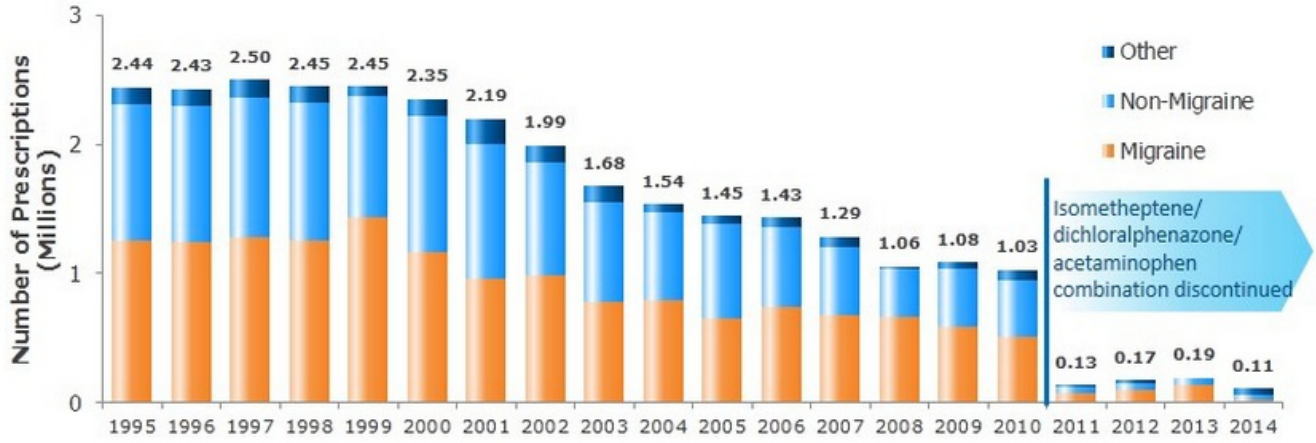
Scher AI, et al. *Cephalalgia*. 2010; 30(3):321-328.

TONIX PHARMACEUTICALS

Isometheptene prescriptions previously were commonly written

Number of Isometheptene prescriptions peaked at 2.5 million

Usage of Isometheptene Combinations for all Diagnoses



Source: IMS Health, National Prescription Audit, 01/1995 – 7/2014- extracted 8/2014
IMS Health, IMS National Disease and Therapeutic Index™, 01/1995 – 12/2000, extracted 8/2014

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