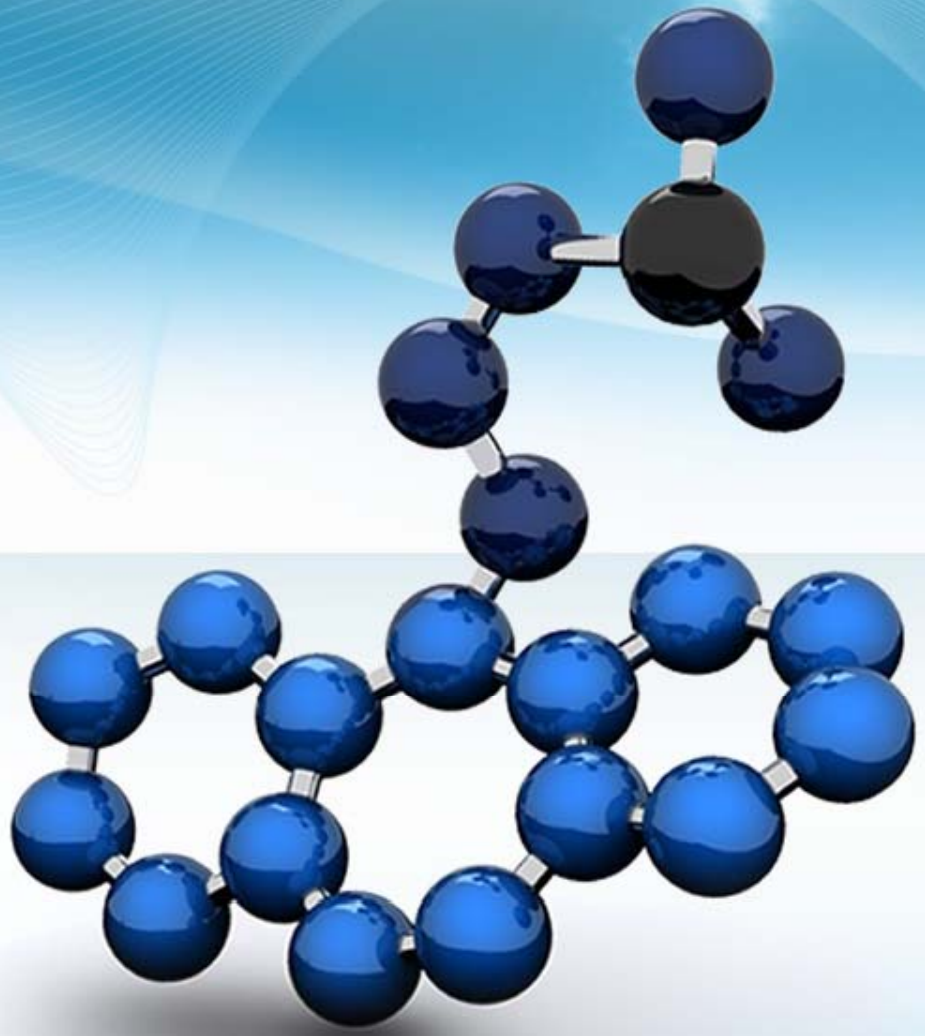
TONIX PHARMACEUTICALS



Corporate Presentation

November 2011

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TONIX Pharmaceuticals Summary

- **Specialty pharmaceutical company developing innovative products for high-value CNS indications**
- **Lead programs target fibromyalgia syndrome (FM) and post traumatic stress disorder (PTSD)**
  - Reformulated cyclobenzaprine
  - Capital-efficient, low-risk development pathway
  - High ROI commercial strategy
  - Expect to follow successes of Lyrica® and Cymbalta® in FM
- **Fibromyalgia Phase 2(a) demonstrated statistically significant improvements in core symptoms**
- **Pipeline of additional CNS product candidates**

Experienced Leadership

Management Team

Seth Lederman, MD
Founder, CEO, Chairman
Co-founder, Vela, Targent, Validus, Fontus

Benjamin Selzer
Chief Operating Officer
Aton, Reliant, investment banking (Lehman Brothers & Banc of America Securities)

Rhonda Rosen, CPA
Chief Financial Officer
CFO, Validus, Fontus , two divisions of CIGNA , PricewaterhouseCoopers

Accomplished Independent Board

Board of Directors

Seth Lederman, MD
Founder, CEO, Chairman

Stuart Davidson
Former CEO of Alkermes & Combion

Patrick Grace
WR Grace, Chemed, Grace Institute

Donald W. Landry, MD, PhD
Columbia Chair of Medicine

Ernest Mario, PhD
Former CEO of Glaxo, Alza & Reliant

Charles Mather
Janney Securities, Cowen, Smith Barney

John Rhodes
Former Partner at Booz Allen Hamilton

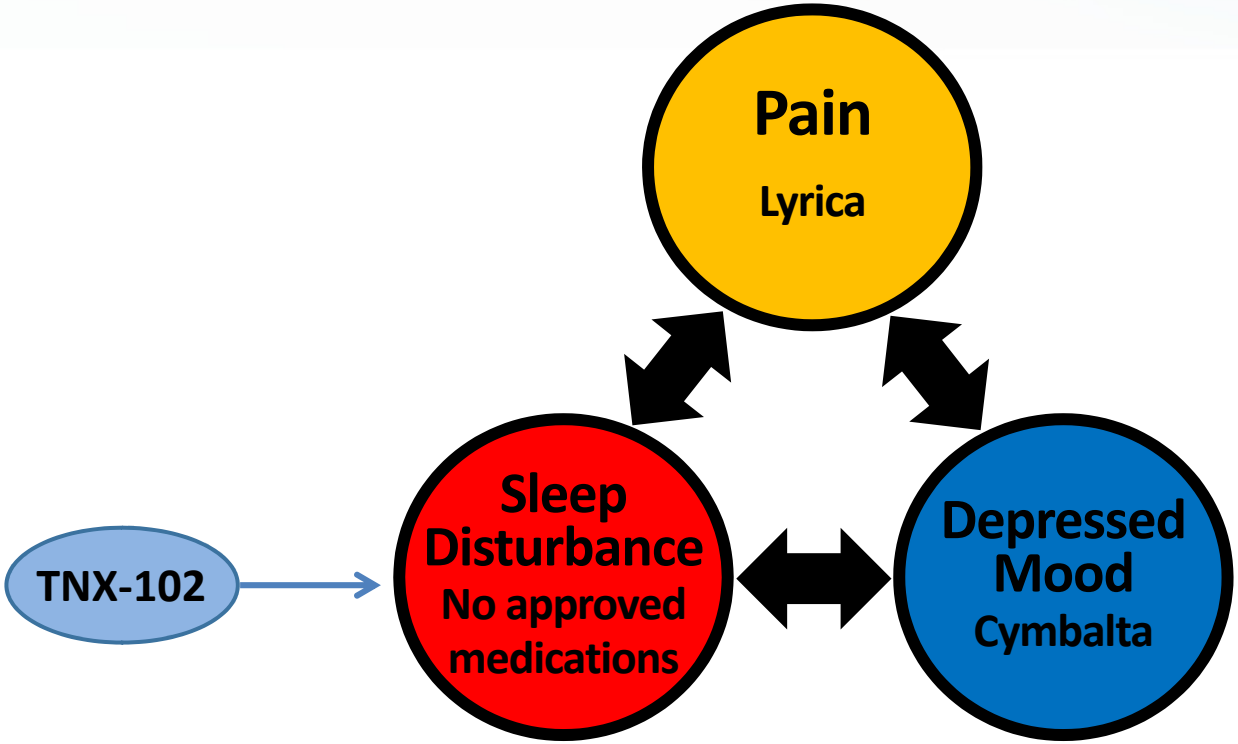
Fibromyalgia Market Opportunity

- **Approximately 5 million U.S. fibromyalgia (FM) patients***
- **U.S. FM drug market estimated at $1.2 billion****
  - 2007-2010 CAGR of 18.4%**
- **Until 2007, there were no FDA approved FM drugs**
  - Lyrica® (Pfizer) was approved for FM in 2007 and is replacing off-label generic analgesics
  - Cymbalta® (Lilly) was approved for FM in 2008 and is replacing off-label generic anti-depressants
- **TNX-102 is expected to be FDA approved as a first-in-class drug for FM and to replace off-label generic muscle relaxants**

** National Institutes of Health, U.S. Department of Health and Human Services*
*** Source: Frost & Sullivan Fibromyalgia Market Study, December 2010*

Fibromyalgia: Vicious Cycle

- **Medications that target pain or depressed mood are approved for the maintenance of FM**
- **TNX-102 will be a first-in-class medication targeting disturbed or non-restorative sleep (NRS) in FM**



Comparison of Fibromyalgia Drugs

- **Physicians often switch drugs when patients are dissatisfied**
- **TNX-102 is a first-in-class bedtime treatment and is not expected to compete with approved treatments**

Pipeline Treatments

TNX-102

- Nonrestorative Sleep category
- 1 dose
- Not restricted by DEA
- Should be available at all pharmacies

Rekinla® (JZP-6)*

- Nonrefreshing Sleep category
- 2 doses (bedtime & 4 hours later)
- Amnesia liability
- Strongest DEA schedule limits pharmacy and patient accessibility

Approved Treatments

LYRICA® PREGABALIN

- Analgesic category
- DEA scheduled
- Taken 2 times a day
- Interferes with sleep

Cymbalta® duloxetine HCl

- Antidepressant category
- Suicidality warning
- Taken 1-2 times a day
- Interferes with sleep

Savella® milnacipran HCl

- Antidepressant category
- Suicidality warning
- Taken 1-2 times a day
- Interferes with sleep

** Jazz recently announced they are discontinuing the development of Rekinla*

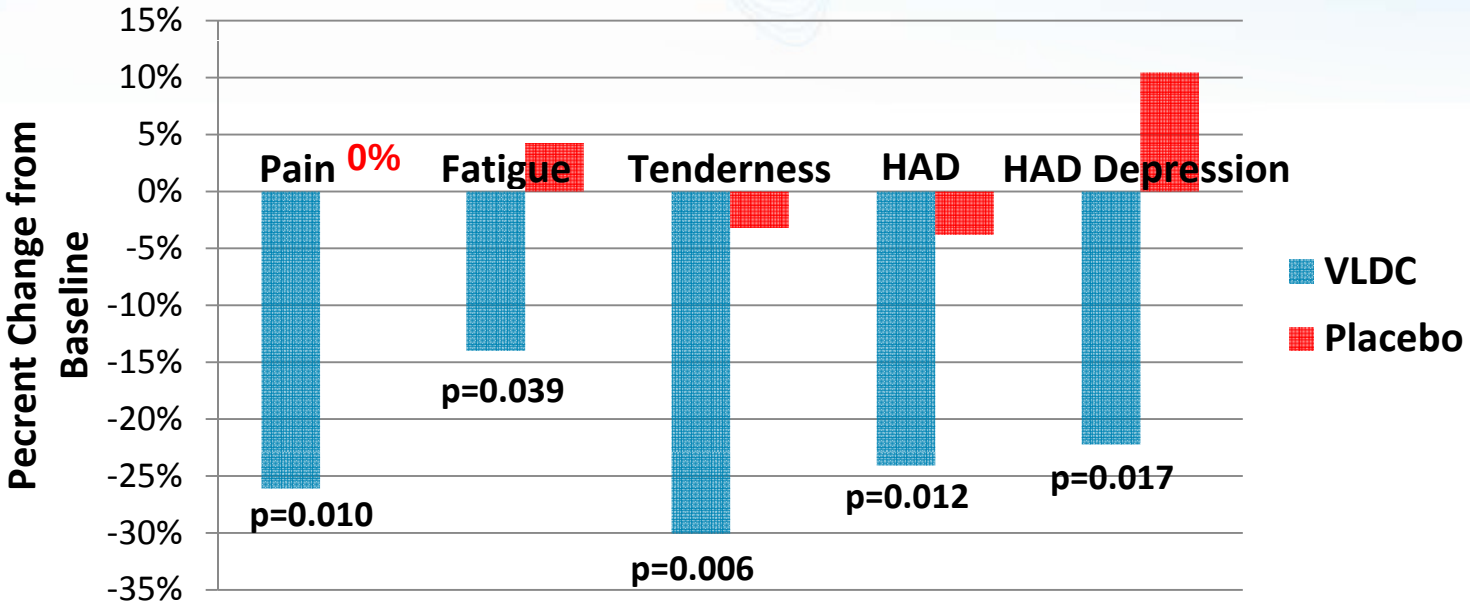
Cyclobenzaprine Has an Impressive Safety Record and is Widely Used

- **Merck developed and launched Flexeril® in 1977**
- **Over one billion tablets prescribed in 2010**
- **Extensive safety & efficacy studies conducted by Merck in 1990s**
- **FDA approved controlled release products in 2007 (15 mg and 30 mg)**
- **No DEA scheduling, no recognized addictive potential**
- **Off-label Cyclobenzaprine is the third most widely prescribed medication for FM***

** Source: Frost & Sullivan Fibromyalgia Market Study, December 2010*

VLDC FM Pilot Study Results: Symptom Measures*

- **Study published in Journal of Rheumatology Dec. 2011**
- **Lead investigator Harvey Moldofsky thought leader in FM**



Change from Baseline (week 8): tenderness measured by dolorimetry; HAD is the Hospital Anxiety and Depression Scale; HAD Depression is the HAD depression subscale

** Moldofsky et al., J. Rheum. December 2011: http://jrheum.org/content/early/2011/08/30/jrheum.110194.full.pdf+html*

TNX-102: VLDC New Formulation

- **Designed for the treatment of fibromyalgia**
  - Muscle relaxant products aim for stable high blood levels over 24 hours
  - Aiming for faster and more reliable absorption for FM
  - Designed for high blood levels during the night and lower levels the next day to reduce next day somnolence
- **Differentiated from, but not competitive with other FM therapies**
  - First-in-class sleep quality treatment for fibromyalgia
  - Bedtime versus daytime (Cymbalta, Lyrica, Savella)
  - Physicians switch patients between different classes when they are dissatisfied

TNX-102: Development Plan

- **PK trial to begin 4Q 2011 and clinical phase will be completed by year-end**
  - 30 subjects; three week study
  - To be conducted by PharmaNet Canada, a division of inVentive Health
  - TNX-102 vs. generic 5 mg tablet
  - TNX-102 fed/fasted
  - Expect differentiation in time-concentration curve relative to generic
- **Following PK trial, plan is to begin first pivotal trial**
  - 2 arm, 12 week study with approximately 150 patients per arm
  - Study design and endpoints to mirror those used by Lyrica and Cymbalta
    - Pain and a composite endpoint of other FM symptoms
  - Results expected mid-2013

TNX-102: Compelling Risk / Reward Profile

- **Low risk – safety, efficacy and demand established**

Risk Factor	Commentary
FDA Risk - Safety	• Cyclobenzaprine is one of the more widely prescribed pharmaceuticals; 1 billion tablets per year in the U.S. • FDA approved and prescribed since the 1970's • Widely studied in modern safety trials • 505(b)(2) registration; TONIX to benefit from existing safety data
FDA Risk - Efficacy	• Off-label Cyclobenzaprine is third most-widely-prescribed drug for FM • Phase 2a study demonstrated strong efficacy with very low dose cyclobenzaprine
Commercial Risk	• Off-label cyclobenzaprine already has market acceptance by physicians and patients despite never having been marketed for FM • TNX-102 would be approved as a first-in-class treatment for FM and is expected to replace off-label use of muscle relaxants • Widely used off label for FM; 48.3 million tablets in 2010 (Frost & Sullivan)
Reimbursement Risk	• TNX-102 is expected to be approved as a first-in-class treatment for FM • Currently no generic FM products
Generic Competition	• New, differentiated formulation relative to generic cyclobenzaprine • Lyrica and Cymbalta took market share from cheaper off-label generics once they obtained FDA approval for FM

TNX-102: Compelling Risk / Reward Profile

- **Short-term Monetization Focus**
  - The first of two pivotal clinical trials to commence Q3 2012
  - Initial, “interim”, data should be available by Q1 2013, with final study report available Q2-Q3 2013
  - Somewhere between those two milestones, TONIX plans seek a major pharmaceutical partner or to monetize the company

TNX-105: VLDC for PTSD

- **3.5% of U.S. adult population will have suffered from PTSD in past 12 months***
  - Any trauma can lead to PTSD
- **Unsatisfied market**
  - Only Zoloft® and Paxil® have FDA approval
- **Widespread painkiller abuse and addiction**
- **Leveraging formulation and clinical work from TNX-102 to advance TNX-105**

** National Institutes of Mental Health & National Institutes of Health*

FM & PTSD - Related Conditions

- **PTSD, like FM is characterized by groups of symptoms**
  - Some patients with FM meet PTSD criteria
  - Some patients with PTSD meet FM criteria
  - Some are believed to suffer from both conditions simultaneously
- **Overlap of PTSD and FM symptoms suggests VLDC may treat PTSD**
  - PTSD is thought to be exacerbated by non-restorative sleep
- **PTSD has both combat and civilian forms**
  - Zoloft and Paxil are approved for PTSD but market is unsatisfied
  - Brand prescriptions are now filled by generic sertraline and paroxetine
  - DOD has a strong interest in promoting research on therapeutics

TONIX Pharmaceuticals Pipeline

- **TONIX has a comprehensive pipeline of CNS products**

Product	Indication	Status
TNX-102	Fibromyalgia	• Very low dose cyclobenzaprine in novel formulation • Phase 2a successfully completed • PK trial in new formulation expected completion YE 2011 • First of two pivotal trials expected to begin Q3 2012
TNX-105	Post-Traumatic Stress Disorder	• Low dose cyclobenzaprine in novel formulation • Will leverage data from TNX-102 PK trial • Pivotal trials anticipated to start 2012 • Applying for Department of Defense funding
TNX-201	Headache	• NDA to be filed for existing DESI product • Potentially shortened process for FDA approval • DESI to NDA switch products enjoy mandated exclusivity
TNX-301	Alcoholism	• US patent allowed • Potential for government funding

Exclusivity & Patents

- **TNX-102**
  - Issued Methods of Use patents for use of VLDC in treatment of fibromyalgia with expiration mid-2020
  - Two issued formulation patents with expiration in mid-2021
  - Further patents on pharmacokinetics expected to be filed in near term
- **TNX-105**
  - Filed Methods of Use patent for use of VLDC in treatment of PTDS
  - Two issued formulation patents with expiration in mid-2021
- **Active patenting strategy to extend exclusivity**
  - Plan to file patents around TONIX products' unique PK profiles, which are difficult to circumvent
- **Hatch-Waxman exclusivity 3 years post launch for new indications**

Upcoming Milestones

- **Short and intermediate term value inflection milestones**

Timing	Milestones Related to TNX-102
December 2011	• Pharmacokinetic (PK) trial
Jan-Feb 2012	• PK data analysis and new patent filings
Q1 2012	• Announcement of pharmacokinetic trial completion
Q3 2012	• Commencement of initial pivotal trial
Q1 2013	• Interim look at initial pivotal trial data
Q2-Q3 2013	• Completion of initial pivotal trial • Partnering or monetization event

Why Invest in TONIX?

- **Capital efficient drug development strategy focused on high-value, first-in-class products**
- **FM and PTSD are significant unmet needs with large market opportunities**
- **TNX-102 is expected to be a first-in-class treatment for FM and differentiated from generic cyclobenzaprine**
- **Low risk, low-cost development pathway**
- **Short-term monetization**
- **Experienced management and Board**