TONIX PHARMACEUTICALS

Fact Sheet

Background

Tonix is a clinical-stage biopharmaceutical company focused on discovering and developing pharmaceutical products to treat serious neuropsychiatric conditions and biological products to improve biodefense through potential medical counter-measures. Tonix's lead product candidate, Tonmya®*, or TNX-102 SL, is in Phase 3 development as a bedtime treatment for PTSD. Tonix is also developing TNX-102 SL as a bedtime treatment for agitation in Alzheimer's disease (AAD) under a separate IND (Investigational New Drug) application which has been cleared for a Phase 2, potential pivotal, efficacy study. TNX-601 (tianeptine oxalate) is in the pre-IND application stage, also for the treatment of PTSD but designed for daytime dosing. Tonix's lead biologic candidate, TNX-801, is a potential smallpox-preventing vaccine based on a live synthetic version of horsepox virus, currently in the pre-IND application stage.

*Tonmya has been conditionally accepted by the U.S. Food and Drug Administration (FDA) as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication.

Financial Snapshot (as of June 1, 2018)

- Ticker: Nasdaq: TNXP
- Stock Price: $3.35
- Shares Outstanding (May 10, 2018): 8.5M
- Market Cap.: $28.5M
- Cash* (March 31, 2018): $19.3M
- Average Volume (Past 3 months): 70,127
- 52-week Range: $2.70 - $4.99

* Cash and cash equivalents

Lead Phase 3 Program: Tonmya for PTSD

- Tonmya is a Breakthrough Therapy targeting a serious, chronic psychiatric disorder
- Active ingredient cyclobenzaprine has well-established safety profile with no discernible abuse or dependency potential
- Therapeutic dose identified in Phase 2 AtEase study
- Phase 3 protocol and product registration plan accepted by U.S. FDA[1]
- Submission of single-study new drug application (NDA) could be possible if topline data are statistically persuasive[2]

[1] August 2016 End-of-Phase 2 meeting minutes
[2] March 2017 Initial Cross-Disciplinary Breakthrough meeting

Phase 2 AtEase Study Results

- General study characteristics:
  - First large multi-center trial demonstrating efficacy of an investigational new drug in military-related PTSD
  - Randomized, double-blind, placebo-controlled, 12-week trial in military-related PTSD
  - 2:1:2 randomized ratio to Tonmya 2.8 mg, Tonmya 5.6 mg, or placebo sublingual tablets at bedtime daily
  - Efficacy analysis from 231 participants across 24 U.S. clinical sites
- Primary efficacy endpoint:
  Mean change from baseline in total Clinician Administered PTSD Scale (CAPS-5) score at week 12 compared between Tonmya 2.8 mg and placebo (p=0.211)
- Secondary efficacy endpoint:
  - Mean change from baseline in total CAPS-5 score at week 12 compared between Tonmya 5.6 mg and placebo

Category	Endpoint	p value - 5.6 mg[1]
PTSD Symptoms	CAPS-5 (MMRM w/ MI)[2]	0.031
Global improvement	CGI-I	0.041
Arousal and Reactivity	CAPS-5 cluster	0.048
Sleep Quality	CAPS-5 sleep	0.010

p<0.05 indicates statistical significance
[1] TNX-102 SL was found to be effective at the 5.6 mg dose.
[2] Mixed-effect model repeated measures with multiple imputation

- Tonmya was well-tolerated and there were no serious adverse events (AEs) related to treatment. The most common AEs were local site-administration reactions, including mild and transient tongue numbness.

Breakthrough Therapy Designation

- Breakthrough Therapy designation granted to Tonmya by the U.S. FDA for the treatment of PTSD in December 2016
- Eligible for priority review of NDA within 6 months instead of 10 months and rolling submission of completed portions of the NDA
- Organizational commitment by FDA senior managers to ensure efficient execution of the drug development program
- Breakthrough Therapy designation is granted to drugs that are intended to treat serious conditions and that have clinical evidence showing substantial improvement over existing therapies

Phase 3 HONOR Study: Enrolling

- General study characteristics:
  - Adaptive-design study in military-related PTSD
  - Randomized, double-blind, fixed dose (5.6 mg) versus placebo over 12 weeks of treatment
  - Entrance criteria CAPS-5 ≥ 33
  - Interim Analysis (IA) at approximately 50% of randomized participants
  - Potential to enroll 550 participants at approximately 40 U.S. sites
  - Add on 12-week and/or 40-week open-label extension studies
- Primary efficacy endpoint:
  - Mean change from baseline in total CAPS-5 score at week 12 compared between Tonmya 5.6 mg and placebo

Milestones

- ✓ 1Q'17 — FDA concurrence with Phase 3 HONOR study design and NDA registration plan
- ✓ 1Q'17 — Initial Cross-disciplinary Breakthrough Meeting discussed possible single-study NDA approval
- ✓ 1Q'17 — Commenced enrollment of Phase 3 HONOR study
- ✓ 2Q'18 — Randomization of 50% of HONOR study participants
- ○ 3Q'18 — Anticipated interim analysis of Phase 3 HONOR study at ~50% of randomized participants
- ○ 1Q'19 — Anticipated topline results of Phase 3 HONOR study in ~550 randomized participants (if needed)

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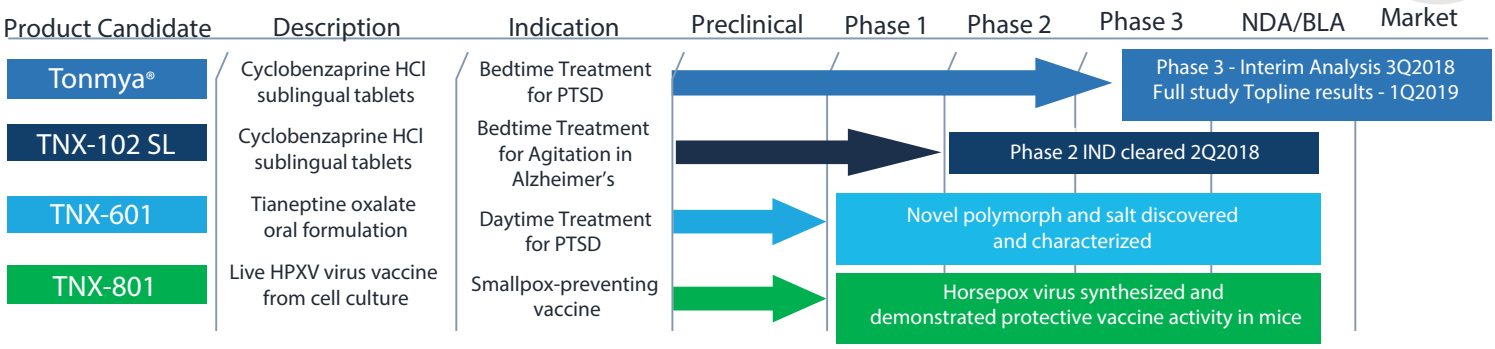
Products in Development



Proprietary Patented Formulation*: Tonmya or TNX-102 SL

- Advanced sublingual tablet containing low-dose cyclobenzaprine (CBP) and mannitol eutectic designed for bedtime delivery
- Faster absorption in the body by bypassing digestive system and avoiding first-pass liver metabolism
- Lowers exposure to long-lived active major metabolite, norcyclobenzaprine, which has a long half-life and is less selective for target receptors
- Designed to align CBP exposure with sleep

*U.S. Patent No. 9,636,408 issued May 2017 by U.S. Patent and Trademark Office

Mechanism of Action: TNX-102 SL

- The active ingredient, TNX-102, is a tricyclic molecule that targets 3 receptors in the brain that are believed to be associated with enhancing sleep quality
- Sleep disturbance is a core PTSD symptom (component of intrusion and hyperarousal symptom clusters)

Market Opportunity

- PTSD is a prevalent problem for civilians and the military
  - 20% of women and 8% of men in the U.S. who experience significant trauma develop PTSD[1]
  - 8.6M Americans affected (3.5% of pop.)[2]
  - 1.8M Americans diagnosed[3]
  - ~638K affected veterans in the VA* health system[4]
  - 20% of veterans from recent conflicts will have potential or provisional PTSD[5]
- FDA-approved drugs have either failed to show efficacy[5] or were insufficiently studied in male and military-related PTSD[6]
- Important tolerability issues with SSRIs** in this population (sexual dysfunction, insomnia, weight gain)
- Off-label use of anxiolytics, sedative-hypnotics, and antipsychotics is common[3]

[1] Kessler RC et al., Arch Gen Psychiatry 1995;52:1048
[2] Kessler et al., Arch Gen Psychiatry. 2005;62: 617; Prevalence rate of 3.5% applied to U.S. Census estimate of 247 million U.S. adult (>18) population in 2015 (www.census.gov/quickfacts/table/PST045215/00)
[3] Bernardy et al., J. Clin Psychiatry, 2012
[4] Bowe and Rosenheck, 2015 (638,451 veterans diagnosed with PTSD in the VA in fiscal year 2012 across all medical centers)
[5] Bowe et al., J. Dual Diagnosis 2015;11:22
[6] Friedman MJ et al., J. Clin Psychiatry 2007;68:711-20
* Veterans Affairs
**Selective serotonin reuptake inhibitors

Financials (in thousands)

Category	Mar31 2018	Dec 31 2017	Sept 30 2017
Cash, cash equivalents & marketable securities	19,253	25,496	29,310
Working capital	18,318	24,317	28,369
Total assets	20,980	26,754	30,535
Accumulated deficit	(169,298)	(162,363)	(156,870
Total stockholders' equity	18,611	24,616	28,680

Intellectual Property

Wholly-owned by Tonix with no obligations to others

TNX-102 SL

Composition-of-matter (eutectic) includes:
- Eutectic Proprietary Protectic™ Formulation Patent No. 9,636,408 issued May 2017
- Protection expected to 2034

Pharmacokinetics (PK)
- Japanese Patent No. 6,259,452 issued December 2017
- Protection expected to 2033

Method-of-use
- European Patent No. 2,501,234 issued September 2017 for cyclyobenzaprine method of use
- U.S. Patent No. 9,918,948 issued March 2018 for cyclobenzaprine method of use
- Protection in both locations expected to 2030

Additional claims and jurisdictions pending for all of the above

TNX- 601

Composition-of-matter
- Patent application filed on novel salt

5-year Hatch-Waxman exclusivity

TNX-801

Composition-of-matter
- Patent application filed on novel virus

12 years exclusivity under the Patient Protection and Affordable Care Act

Contact

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