



#### December 2018

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The preliminary prospectus, dated December 3, 2018, is available on the SEC Web site at www.sec.gov/Archives/edgar/data/.

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### **Tonix Development Highlights**

Tonmya®1 - lead program; FDA Breakthrough Therapy for Posttraumatic Stress Disorder (PTSD) - Bedtime treatment in Phase 3 Development

- · Results from 2 efficacy studies improve the new Phase 3 study design
- New Phase 3 P302/RECOVERY study design features accepted by the FDA<sup>2</sup>
- P302/RECOVERY study with Week 4 primary endpoint to initiate in 1Q2019

TNX-102 SL - FDA Fast Track development program for agitation in Alzheimer's disease (AAD)

IND<sup>3</sup> ready to support Phase 2 potential pivotal efficacy study

Pipeline

TNX-6014 - Pre-IND candidate for daytime treatment for PTSD

Nonclinical development ongoing

TNX-8015 - Smallpox-preventing vaccine candidate

- Efficacy demonstrated in mouse model
- cGMP process development underway

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

3 FDA Breakthrough Therapy Type B Clinical Guidance Meeting Minutes (November 26, 2018)

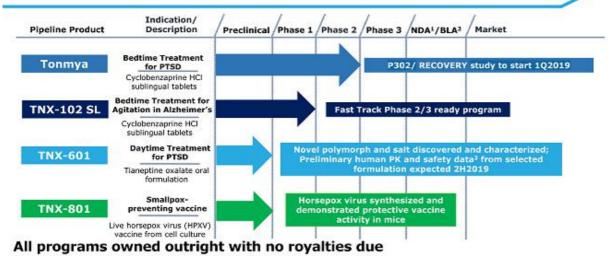
3 IND: Investigational New Drug Application

4 Flaneptine oxalate

5 Synthesized live horsepox virus



### **Candidates in Development**





#### **Management Team**



### **Prevalence of PTSD Among Civilians and Veterans**

7



4.7% General population<sup>1</sup>



19-31%

Vietnam veterans<sup>2</sup>





11 million American adults affected4,5



Women more likely to develop than men1



Susceptibility may run in families1

<sup>1</sup>Goldstein et al., 2016; <sup>2</sup>Norris, PTSD Res Quar. 2013; <sup>3</sup>Analysis of VA Health Care Utilization among Operation Enduring Freedom, Operation Iraqi Freedom, and Operation New Dawn Veterans, from 1st Qtr FY 2002 through 2nd Qtr FY 2015, Washington, DC; Among 1.9M separated OEF/OIF/OND veterans, 1.2M have obtained VA healthcare; 685k evaluated by VA with possible mental disorder, and 379k diagnosed with PTSD; <sup>4</sup> Goldstein et al., 2016; <sup>5</sup> Veterans: VA/DDD Clinical Practice Guidelines for the Managements of PTSD and Acute Stress Disorder, 2017, page 15



# TNX-102 SL Intellectual Property – U.S. Protection until 2034

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#### Composition of matter (eutectic): Protection expected to 2034

- United States Patent and Trademark Office (USPTO) issued U.S. Patent No. 9,636,408 in May 201 7U.S. Patent No. 9,956,188 in May 2018 and U.S. Patent No. 10,117,936 in November 2018
- · Japanese Patent Office (JPO) issued Japanese Patent No. 6310542 in March 2018
- · New Zealand Intellectual Property Office (NZIPO) issued New Zealand Patent No. 631152 in May 2017
- · 37 patent applications pending (2 allowed (US and South Africa))

#### Pharmacokinetics (PK): Protection expected to 2033

- JPO issued Japanese Patent No. 6259452 in December 2017
- · NZIPO issued New Zealand Patent No. 631144 in March 2017
- Taiwanese Intellectual Property Office issued Taiwanese Patent No. I590820 in July 2017
- · 21 patent applications pending (1 allowed (Australia))

#### Method of use for active ingredient cyclobenzaprine: Protection expected to 2030

- · USPTO issued U.S. Patent 9,918,948 in March 2018
- European Patent Office Issued European Patent No. 2 501 234B1 in September 2017 (validated in 38 countries). Opposition filed in June 2018
- · 2 patent applications pending



# Tonmya®¹ - Breakthrough Therapy for Treatment of PTSD Targets Sleep Disturbance

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Tonmya - first investigational new drug to show treatment effect in military-related PTSD in two large, 12-week, multi-center studies

Retrospective analyses showed Tonmya reduced PTSD severity in participants who experienced index traumas during military service in 2001 or later

 The severity of PTSD symptoms were measured by the CAPS-5<sup>2</sup> assessment scale, the endpoint required by FDA for marketing approval

Breakthrough Therapy Designation from FDA in December 2016 Collaboration with Army: Tonix-USAMMDA CRADA signed 2015

<sup>1</sup>Tonmya has been conditionally accepted by the U.S. FDA as the proposed trade name for TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for the treatment of PTSD. TNX-102 SL is an investigational new drug and has not been approved for any indication. 

\*Clinician Administered PTSD Scale for DSM-5



#### Unmet Need for Effective and Safe Therapies for Treatment of Military PTSD

#### PTSD is signature wound of last 25 years of war

- · Affects servicemember health and performance, force readiness, retention
- · Believed to be the underlying cause of suicide in many cases

### No FDA-approved products for PTSD since Pfizer's Zoloft® (sertraline) and GSK's Paxil® (paroxetine) circa 2000

- · Neither has shown efficacy in military-related PTSD
- · Male PTSD patients often unresponsive or intolerant of current treatments
- Side effects relating to sexual dysfunction, sleep and weight gain are commonly reported

### U.S. Department of Defense (DoD) is working to understand and treat PTSD

- · Increased scrutiny of PTSD-related discharges for behavioral problems
- · Wider recognition that PTSD is a service-related disability



#### **Potential Therapeutic Advantages of Tonmya**

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#### Tonmya is believed to treat PTSD by improving sleep quality

- · The brain naturally processes memories during sleep
- PTSD sufferers' emotionally charged memories disturb sleep and disrupt the natural processing of memories during sleep
- Tonmya is believed to normalize memory processing and facilitate extinction consolidation (breaking the link between "triggers" and PTSD symptoms)

#### Tonmya is NEITHER a benzodiazepine nor a narcotic

 The active ingredient of Tonmya, cyclobenzaprine, does <u>NOT</u> interact with the same receptors as traditional hypnotic sleep drugs associated with retrograde amnesia; is <u>NOT</u> an opiate

#### Tonmya is non-addictive

- Cyclobenzaprine is the active ingredient of an orally ingested immediate release tablet (Flexeril®), approved 40 years ago
- Flexeril's current labeling indicates no abuse and dependence concern at higher doses than Tonmya (15-30 mg/day v. 5.6 mg/day); NDA can be filed without drug abuse and dependency assessment studies

#### Once-daily sublingual dose taken at bedtime enhances patient adherence



#### Tonmya for the Treatment of PTSD

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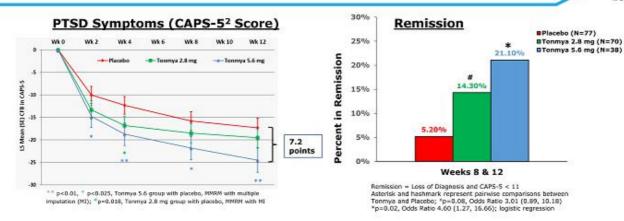
# One Phase 2 study completed and one Phase 3 study stopped early due to inadequate separation from placebo

- Both studies were accepted by the FDA as potential pivotal efficacy studies in military-related PTSD if successful
- · No serious or unexpected adverse events related to Tonmya were reported
- · Phase 2 study (P201) formed the basis of FDA Breakthrough Therapy designation
- Phase 3 study (P301) provided evidence of effectiveness as early as 4 weeks after treatment but diminished over time due to high placebo response in subpopulation >9 years since trauma
- Results from both studies can be used as supportive efficacy and safety data for Tonmya NDA submission

#### Retrospective analyses of P301 showed treatment effect

Formed the basis of the FDA accepted P302/RECOVERY study design<sup>2</sup>

<sup>1</sup> NDA = New Drug Application; <sup>2</sup>FDA Breakthrough Therapy Type B Clinical Guidance Meeting Minutes, November 26, 2018



Phase 2 P201/AtEase study: Retrospective analysis of Tonmya 5.6 mg on CAPS-5 ≥33 (high-moderate) subgroup. Primary analysis of P201/AtEase was on Tonmya 2.8 mg in participants with entry CAPS-5 ≥29, moderate PTSD severity.

Clinician administered PTSD Scale for DSM-5



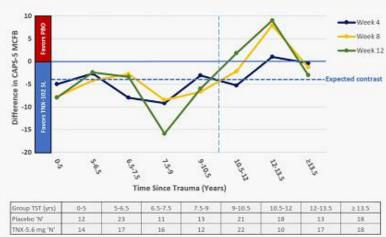
# Retrospective Comparison of Time Since Trauma in P201/AtEase versus P301/HONOR (Tonmya 5.6 mg Groups)



#### P301 study was initiated approximately two years later than Phase 2 P201

 The median time since trauma in Phase 3 was 9.5 years compared to the median time since trauma in Phase 2 of 6.0 years for TNX-102 SL 5.6 mg treated groups

# CAPS-5 Mean Change from Baseline Difference from Placebo of Tonmya 5.6 mg in TST Subgroupings<sup>1</sup>



MCFB=mean change from baseline; 'N'=number of participants in group; PBO=placebo; TST=time since trauma
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- The mITT sample was divided into groups based on TST (1.5-2 years each as well as 0-5 years and ≥13.5 years groups)
- 0-5 years and ≥13.5 years groups)
  Graph shows the CAPS-5 differences in MCFB between TNX 5.6 mg and PBO for Weeks 4, 8, and 12 post-baseline timepoints
  Expected contrast" horizontal dashed line
- "Expected contrast" horizontal dashed line indicates observed effect from Phase 2 P201 study
- For TST <10.5 years groups, TNX 5.6 mg showed good separation from PBO (left side of vertical dashed 10.5 year line)
- For TST >10.5 years groups, separation of TNX 5.6 mg from PBO was either small or worked in the favor of PBO (right side of vertical dashed 10.5 year line)

<sup>1</sup>Time Since Trauma in PTSD: Phase 3 Multi-Center, Double-Blind, Placebo-Controlled Trial of TNX-102 SL, a Sublingual Formulation of Cyclobenzaprine, in Military-Related PTSD (Study TNX-CY-930) Presented at CNS Summit in Boca Raton, FL November 1-4, 2018; Poster 8A, Friday Nov. 2, 5:00-7:00 PM EDT, Reception and Poster Session, and abstract published in Innovations in Clinical Neuroscience, November-December 2018;15(11-12,suppl):S10.https://content.equisolve.net/tonixpharma/media/1d0c4055b2863fc74e1ef45f9ddaf42b.pdf

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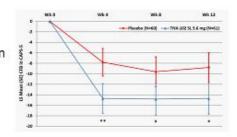
#### Phase 3 P301/HONOR Study

#### Modified intent to treat (mITT) population

# 

\*p=0.019, TNX-102 St. 5.6 mg group v. placebo, using mixed model repeated measures (NNRM) with multiple imputation (MI)

#### Time Since Trauma ≤9 yrs



\*\*p=0.004, \*p=0.039, \*p=0.069, TNX-102 SL 5.6 mg group v. placebo,



#### Sustained Remission in Phase 2 and Phase 3 Studies: Retrospective Analyses of P201 Entry CAPS-5 ≥33 and P301 ≤9 Years Since Trauma Subgroups

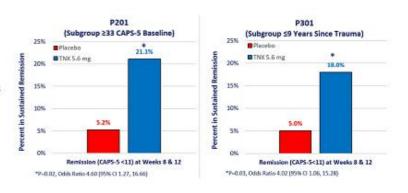
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#### Remission is a clinical state that is essentially asymptomatic

#### In order to confirm remission:

 Determined rates of participants who met remission status at both Week 8 and Week 12

Rate of remission in ≤9 years since trauma group in P301 is similar to baseline CAPS-5 ≥ 33 group in P201<sup>1</sup>



'Majority of P201 participants were ≤ 9 years since trauma and ~80% of P201 participants and all of P301 participants were ≥ 33 CAPS-5 at baseline



# Adverse Events (AEs) in P201/AtEase and P301/HONOR Studies

		P201		P	301
Category of Adverse Reaction Preferred Term	Placebo (N=94)	TNX 2.8 mg (N=93)	TNX 5.6 mg (N=50)	Placebo (N=134)	TNX 5.6 mg (N=134)
Systemic Adverse Events**		N 1, - 1, -	A CONTRACTOR OF A		
Somnolence	6.4%	11.8%	16.0%	9.0%	15.7%
Dry mouth	10.6%	4.3%	16.0%		20000000
Headache	4.3%	5.4%	12.0%		
Insomnia	8.5%	7.5%	6.0%		
Sedation	1.1%	2.2%	12.0%		
Local Administration Site Reaction	ns*"				
Hypoaesthesia oral	2.1%	38.7%	36.0%	1.5%	37.3%
Paraesthesia oral	3.2%	16.1%	4.0%	0.7%	9.7%
Glossodynia	1.1%	3.2%	6.0%		100000
Product Taste Abnormal				3.0%	11.9%

<sup>\*</sup>only adverse events (AEs) are listed that are at a rate of  $\geq$  5% in any TNX-treated group \*no values in a row for either study means the AE in the active group(s) in that study was at a rate of <5%

#### No serious or unexpected AEs in P201 or P301 related to Tonmya

- Systemic AEs comparable between studies and also consistent with those described in approved cyclobenzaprine product labeling
- · Similar severity and incidence of oral hypoesthesia (oral numbness)



# Response to Tonmya for Female Participants in P301/HONOR Study<sup>1</sup>

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Females made up only 11% of the P301/HONOR study mITT population

Difference in mean change from baseline in CAPS-5 in females between placebo (N=17) and Tonmya 5.6 mg (N=10) was:

- At 4 weeks -11.5 points
- · At 12 weeks -9.1 points

Indicates substantial separation from placebo in the small number of female participants

Predicts therapeutic response to Tonmya 5.6 mg likely in mixed civilian and military PTSD population to be studied in upcoming P302/RECOVERY trial

Civilian PTSD population tends to be about 2/3 female

Time Since Trauma in PTSD: Phase 3 Multi-Center, Double-Blind, Placebo-Controlled Trial of TNX-102 St., a Sublingual Formulation of Cyclobenzaprine, in Military-Related PTSD (Study TNX-CY-P301) Presented at CNS Summit in Boca Raton, FL November 1-4, 2018; Poster 8A, Friday Nov. 2, 5:00-7:00 PM EDT, Reception and Poster Session, and abstract published in Innovations in Clinical Neuroscience, November-December 2018;15(11-12,suppl):S10.https://content.equisolve.net/tonixpharma/media/1d0c4055b2863fc74e1ef45f9ddaf42b.pdf



# Response to Tonmya for Non-Combat Traumas in P301/HONOR Study in ≤9 Years Time Since Trauma Subgroup¹

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Non-combat traumas studied are similar to traumas experienced in civilian populations with PTSD

To determine the therapeutic effects of Tonmya 5.6 mg in a mixed civilian and military population, difference in MCFB in CAPS-5 was assessed in non-combat traumas in ≤9 years TST subgroup (placebo N=14, Tonmya 5.6 mg N=10):

- At 4 weeks -4.8 points
- At 12 weeks -4.4 points

Non-combat traumas treated with Tonmya 5.6 mg showed clinically meaningful separation from placebo at Weeks 4 and 12, suggesting a mixed civilian and military sample within 9 years of index trauma may show a therapeutic response to Tonmya

<sup>1</sup>Time Since Trauma in PTSD: Phase 3 Multi-Center, Double-Blind, Placebo-Controlled Trial of TNX-102 SL, a Sublingual Formulation of Cyclobenzaprine, in Military-Related PTSD (Study TNX-CY-P301) Presented at CNS Summit in Boca Raton, FL November 1-4, 2018; Poster 8A, Friday Nov. 2, 5:00-7:00 PM EDT, Reception and Poster Session, and abstract published in Innovations in Clinical Neuroscience, November-December 2018;15(11-12,suppl):S10.https://content.equisolve.net/tonixpharma/media/1d0c4055b2863fc74e1ef45f9ddaf42b.pdf

CAPS-5=Clinician-Administered PTSD Scale for DSM-5; MCBF=mean change from baseline; mITT=modified Intent-to-Treat sample; TST=time since trauma

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#### Summary of Clinical Experience with Tonmya/ TNX-102 SL in PTSD

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Median time since trauma (TST) in TNX-102 SL 5.6 mg group in the P301/HONOR study (9.5 years) was longer than P201/AtEase study (6 years)

- · Both studied military-related PTSD
- · Time has passed since the surge in Iraq

In retrospective analysis, the ≤ 9 year subgroup of P301 study had similar results as the P201 study (primary and secondary)

- TST is important in placebo-controlled clinical study
- Potential enrichment in ≤ 9 years TST subgroup for treatment responders

The ≤ 9 year subgroup of P301 may be enriched for "Remitting Phase" of PTSD1-4

· Expect remitting phase of PTSD is more amenable to drug studies

Results from retrospective analyses lead to improved Phase 3 study design

\*Kessler et al. Arch Gen Psychiatry 1995;52:1048-1060. \*Armenta et al. BMC Psychiatry 2018;18:48. \*Galatzer-Levy et al. PLOS DME 2013;8:e70084. \*Perkonigg et al. Am J Psychiatry 2005;162:1320-1327.





# Tonmya/TNX-102 SL - New Phase 3 Study (P302/RECOVERY) Features

In two prior clinical trials, Tonmya 5.6 mg consistently reduced military-related PTSD severity for participants with ≤9 years since trauma

These data provide the rationale to study Tonmya's effect in participants with ≤9 years since trauma in P302/RECOVERY study

#### Additional design features include:

- · Civilian and military-related PTSD will be studied (shortening recruitment time)
- Primary endpoint: CAPS-5 at Week 4 (minimizing drop-out)
- 12-week treatment period (providing CAPS-5 at Week 12 a key secondary endpoint)

Targeting study initiation: 1Q 2019



#### New Phase 3 P302/RECOVERY Study – Expected to Start 1Q 2019

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#### General study characteristics:

- Randomized, double-blind, placebo-controlled study with baseline CAPS-5¹ ≥ 33 in approximately 25 U.S. sites
- Enrollment restricted to study participants with PTSD who experienced an index trauma ≤ 9 years from the date of screening
- · Both civilian and military-related PTSD to be included

Tonmya once-daily at bedtime
5.6 mg (2 x 2.8 mg tablets) N= 125

Placebo once-daily at bedtime
N= 125

#### Primary endpoint CAPS-51:

Mean change from baseline at Week 4 (Tonmya 5.6 mg vs. placebo)

#### Key Secondary endpoints include:

CAPS-5 mean change from baseline at Week 12 (Tonmya 5.6 mg vs. placebo)

Potential pivotal efficacy study to support NDA approval

<sup>1</sup>CAPS-5 = Clinician-Administered PTSD Scale for DSM-5



#### **Late-Stage PTSD Drug Candidates**

#### **Tonmya**

 Breakthrough Therapy in Phase 3; development program focused on military-related and civilian PTSD; showed activity in treatment of military-related PTSD in large multi-center trials

#### MDMA-assisted psychotherapy

 Breakthrough therapy that is Phase 3-ready; showed activity in a Phase 2 study of PTSD

#### Other drugs currently (or recently) in Phase 2 development

- Rexulti® (brexpiprazole) Otsuka/Lundbeck; atypical antipsychotic; positive clinical results from Phase 2 study reported in November 2018 for brexpiprazole, when used in combination with an approved PTSD medication, sertraline, but not as monotherapy
- BNC-201 Bionomics; nicotinic receptor modulator (program stopped after Phase 2)





# TNX-102 SL – Bedtime Treatment for Multiple Potential Indications

#### Management of Fibromyalgia (FM) - chronic pain condition

- TNX-102 SL studied at low dose (2.8 mg) half the dose being developed for PTSD – did not separate from placebo on primary endpoint, average pain improvement (responder analysis)
- Retrospective analysis showed average pain improvement (secondary endpoint) after 12 weeks of treatment showed statistical significance (P< 0.05, MMRM)
- Low dose TNX-102 SL (2.8 mg) showed an improvement in sleep quality in Phase 2 and Phase 3 FM trials
- Efficacy of TNX-102 SL 5.6 mg in FM can be studied in a potential pivotal study to support product registration

#### Agitation in Alzheimer's Disease

- · Fast Track designation granted July 2018
- Phase 2/ potential pivotal efficacy study protocol received FDA comments in October 2018



# TNX-102 SL for Agitation in Alzheimer's – Regulatory Status and Registration Strategy

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### FDA confirmed no additional study is needed prior to IND submission

 Pre-IND meeting established open dialogue with the FDA on pivotal clinical study design and efficacy endpoints to support product registration

### Proposed Phase 2 IND study can potentially serve as a pivotal efficacy study to support NDA approval

· FDA comments on final protocol received October 2018

### Registration Strategy of TNX-102 SL for agitation in Alzheimer's disease

 Efficacy Supplement (sNDA<sup>1</sup>) may be leveraged from the PTSD/FM development program and supported by Initial NDA approval for PTSD/FM

<sup>1</sup>Supplemental New Drug Application



#### Pre-IND Candidate

Targeting a **Condition** with

Significant

#### Targeted as a 1st line monotherapy for PTSD: oral formulation for daytime dosing

- Leverages expertise in PTSD (clinical and regulatory experience, market analysis,
- ✓ Mechanism of Action (MOA) is different from TNX-102 SL
- · Tianeptine sodium (amorphous) has been approved in EU, Russia, Asia and Latin America for depression since 1987 with established post-marketing experience
- Identified new oxalate salt polymorph with improved pharmaceutical properties ideal for
- Preliminary human pharmacokinetic and safety data (non-IND study) from selected formulation expected in second half 2019

#### Filed patent application on novel salt polymorph

· Issued patent on steroid-induced cognitive impairment and memory loss issues

#### Clinical evidence for PTSD

Several studies have shown tianeptine to be active in the treatment of PTSD<sup>14</sup>

- **Unmet Need**
- Frančíškovič T, et al. Psychiatr Danub. 2011 Sep;23(3):257-63. PMID: 21963693
   Rumyantsova GM and, Stepanov AL. Neurosci Behav Physiol. 2008 Jan;38(1):55-61. PMID: 18097761
   Rudskandrovskiř Sd, et al. Zd. Neurof Psikhizer Im S S forsakova. 2005;105(11):24-9. PMID: 16329631 [Russian]
   Onder E, et al. Eur Psychiatry. 2006 (3):174-9. PMID: 15964747



#### TNX-801 (Synthesized Live Horsepox Virus): A Smallpox-Preventing Vaccine Candidate

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#### Pre-IND Stage

#### Potential improvement over current biodefense tools against smallpox

- ✓ Leverages Tonix's government affairs effort
- ✓ Collaboration with Professor David Evans and Dr. Ryan Noyce at University of Alberta
- ✓ Demonstrated protective vaccine activity in mice
- ✓ Patent application on novel vaccine submitted

#### Regulatory strategy

- We intend to meet with FDA to discuss the most efficient and appropriate investigational plan to support the licensure, either:
  - ✓ Application of the "Animal Rule", or
  - ✓ Conducting an active comparator study using ACAM2000
- · Good Manufacturing Practice (GMP) viral production process in development

#### Targeting a Potential Public Health Issue

#### Material threat medical countermeasure under 21st Century Cures Act

- Qualifies for Priority Review Voucher (PRV) upon licensure\*
  - ✓ PRVs have no expiration date, are transferrable and have sold for ~\$125 M

\*BLA/NDA priority 6-month review is expected.



# Milestones – Recently Completed and Upcoming

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ď	July 2018	Completed P301/HONOR study interim analysis - result did not support study continuation but strengthened new Phase 3 study
<b>S</b>	August 2018	Presentation of P301/HONOR study results at Military Health System Scientific Symposium
¥	October 2018	Met with FDA and received preliminary agreement on the design of new Phase 3 study of Tonmya for PTSD (P302/RECOVERY study)
4	November 2018	Received FDA minutes confirming agreement on the design of P302/RECOVERY study
	First Quarter 2019	P302/RECOVERY study to be initiated
	Second Half 2019	Preliminary human pharmacokinetic and safety data (non-IND study) from selected TNX-601 (tianeptine oxalate) formulation expected
0	First Half 2020	Topline data from P302/RECOVERY study expected

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## **Capitalization Table**

As of 11/30/2018	# of Shares	% of Fully Diluted
Common Shares Outstanding	1,529,427	88.4%
Stock Options & Warrants	201,513	11.6%
Fully Diluted Shares Outstanding	1,730,940	100%

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### Phase 3 development of Breakthrough Therapy treatment for PTSD, including military-related PTSD

- · Major unmet need; ~11 million Americans affected
- · Benefited from FDA 505(b)(2) NDA approval requirement

#### New indication in development for agitation in Alzheimer's Disease

- · Unmet medical need, no approved drug available
- · Fast Track Phase 2/3 ready program

#### Complimentary day-time PTSD treatment in development

 Leverages development expertise in PTSD, i.e., regulatory, trial recruitment and execution

#### Innovative vaccine in development to prevent Smallpox

- · Opportunity to supply stockpiling requirement; short development path
- · Studies in mice suggest improved safety profile





### Thank you!