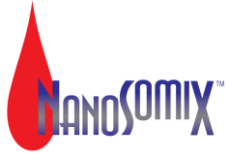




**Helping to accelerate AD therapy  
development with a  
Proprietary Blood Test for  
**Alzheimer's Disease (AD)****

**Dr. Dennis Van Epps, VP, Scientific Affairs**

[www.nanosomix.com](http://www.nanosomix.com)



# NanoSomiX, Inc. (NSX)

## Mission:

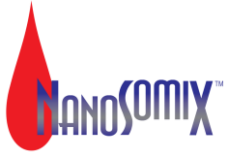
- Commercialize a blood test for identification and monitoring of AD and other neurologic disorders

## Technology:

- Enrich and analyze brain derived biomarkers contained in Neural Derived Exosomes (NDE's)

## Goal:

- Provide investigators and therapy developers with a simple blood test to assess and monitor AD and other neurodegenerative diseases to speed development of effective therapies



# Business Overview

## Company Formation:

- Founded in 2014 based on work by Dr. Ed Goetzl

## Business Model:

- Service Lab

## Intellectual Property:

- 4 patents pending

## Funding:

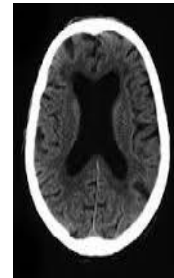
- Angel Funding to date
- Series A planned for late 2017/early 2018

# Current Neurodegenerative Disease Diagnostics

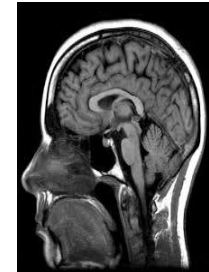


**Biopsy: Not Possible**

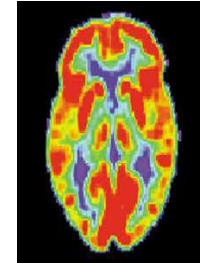
**Cerebrospinal fluid:**  
*Too Invasive! (\$2K+)*



CT



MRI



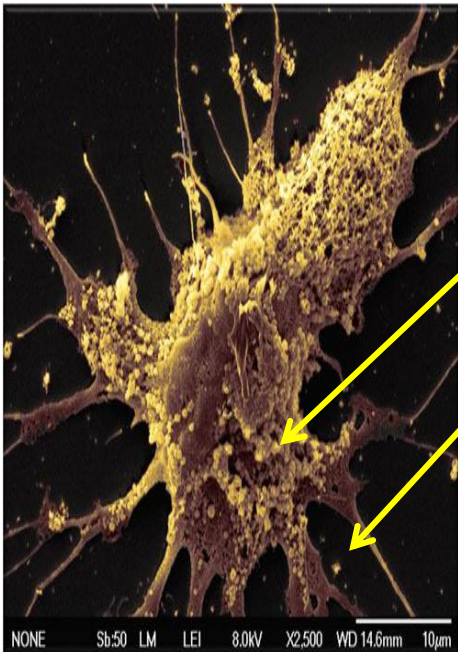
PET



**Image analysis:**  
*Too Expensive!*  
*(\$5K+)*

***Current diagnostic techniques aren't practical for routine testing***

NanoSomiX' technology selectively enriches blood NDE's using proprietary L1-Cam immunoaffinity technology and measures inclusive pathogenic AD proteins and biomarkers  
**"Window to the Brain"**



Johan Skog,

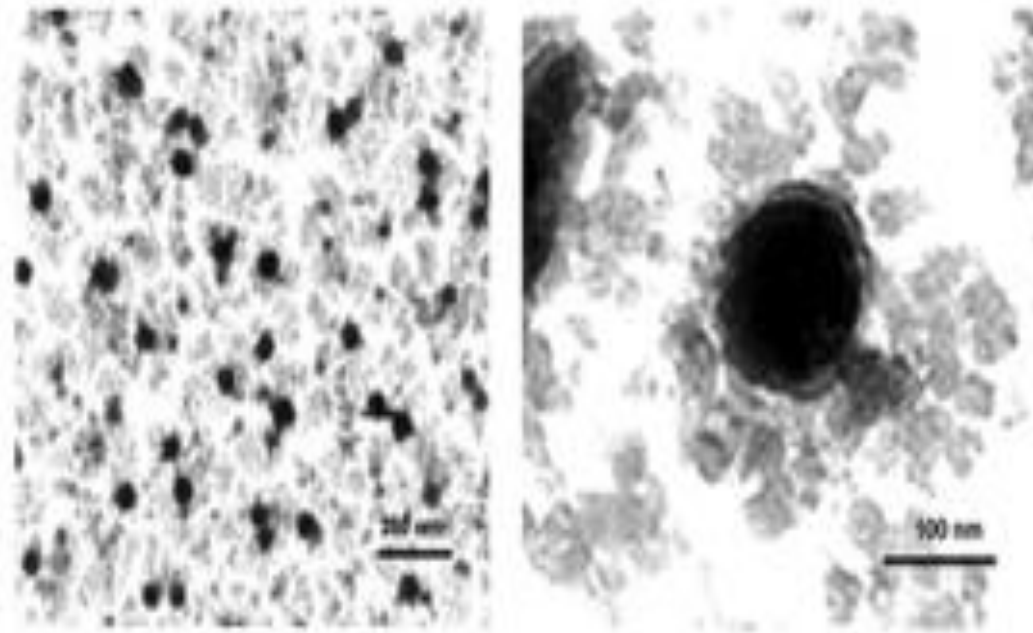
<http://www.genengnews.com/>

**Exosomes:**  
Micro vesicles containing numerous biomarkers

### WHY VALUABLE?

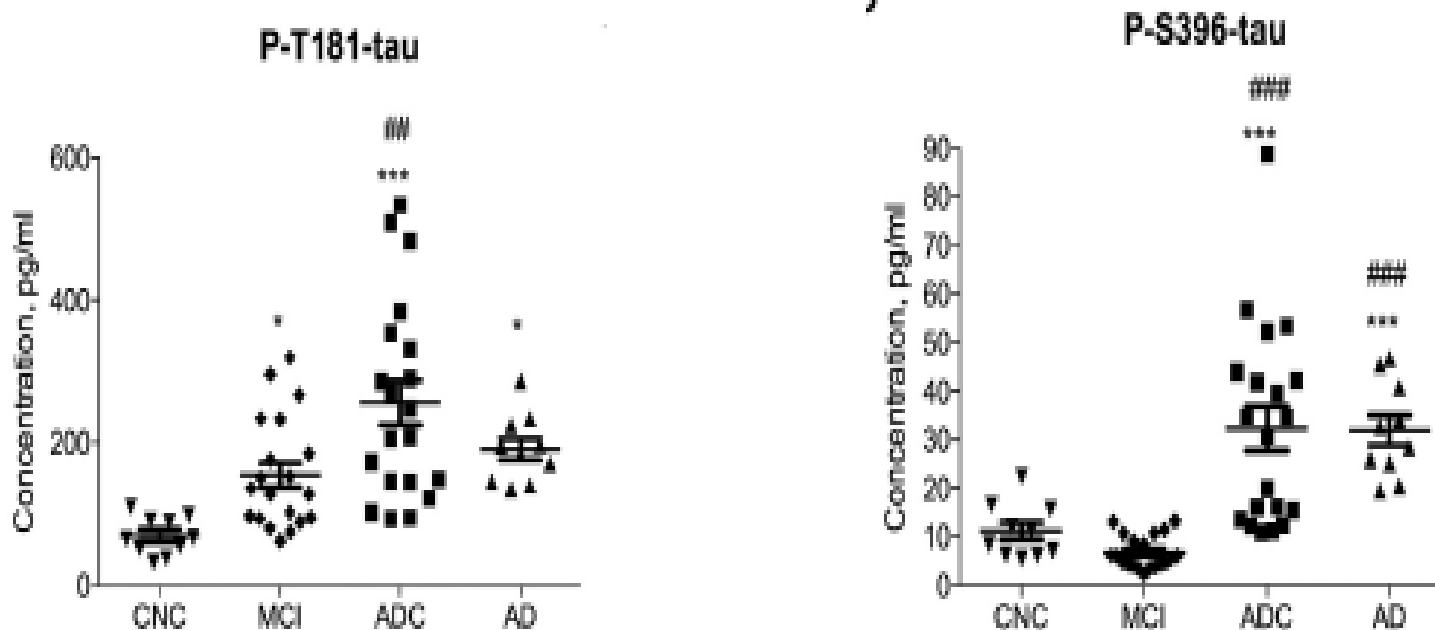
- Neural Derived Exosomes (NDE's) cross blood brain barrier into blood
- Contents protected from degradation in blood by membrane

## AD and MCI Patient NDEs Following Enrichment



- NDEs average  $\sim 7$  to  $10 \times 10^{11}$  particles per ml in patients
- AD & MCI NDEs average  $89.75 \pm 2.15$  &  $94.5 \pm 4.48$  nm in size

# NDE P-T181 and P-S396 Tau Following MCI Conversion to AD



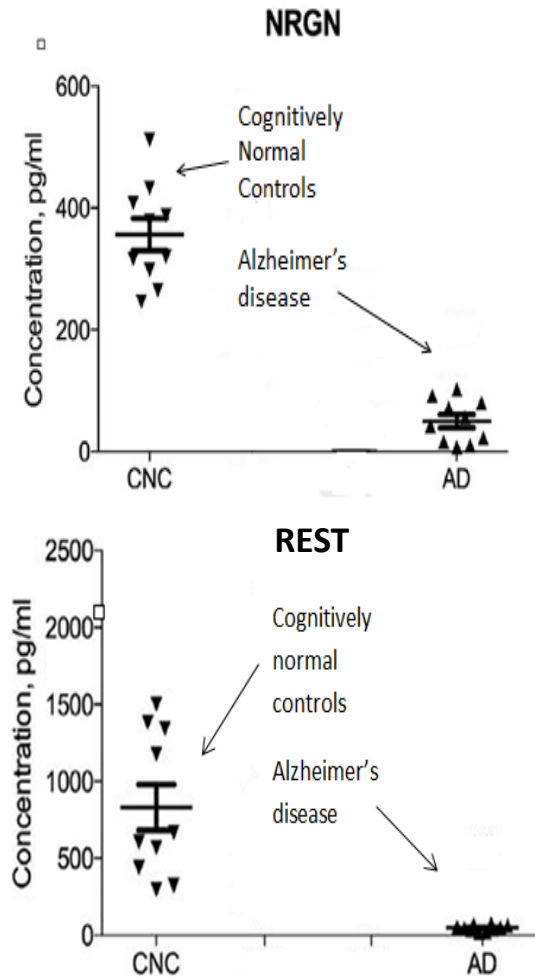
CNC= Controls (MMSE 27-30; CSF A $\beta$ 1 >190mg/ml)  
MCI= Minimal Cognitive Impairment (MMSE >24, intact ADL)  
ADC= MCI transitioned to AD over 36 months  
AD= Alzheimer's Disease (MMSE<20, A $\beta$ 1 <190mg/ml)

- Elevated NDE P-T181-tau & P-S396-tau correlate with advancing disease\*
- Elevated blood NDE pTau levels observed up to 10 yrs prior to clinical AD\*\*

\*Winston, et.al. Alzheimer's & Dementia, 2016

\*\*Fiandaca et. al. Alzheimer's & Dementia 2014

# Blood NDE Assay Applicable to Multiple Biomarkers



## PLATFORM POTENTIAL:

Additional NDE markers further differentiate AD from Control:

- ↓ Synaptic proteins
- ↑ Cathepsin D
- ↓ Insulin resistance
- ↓ GAP43 (growth assoc. protein 43)
- ↑ Ubiquitin
- ↑ LAMP1 (lysosome Assoc. membrane protein 1)

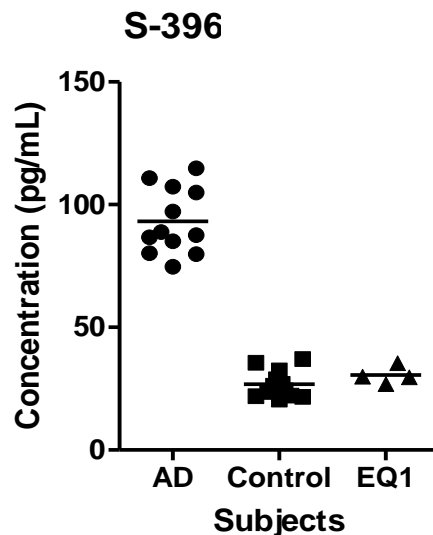
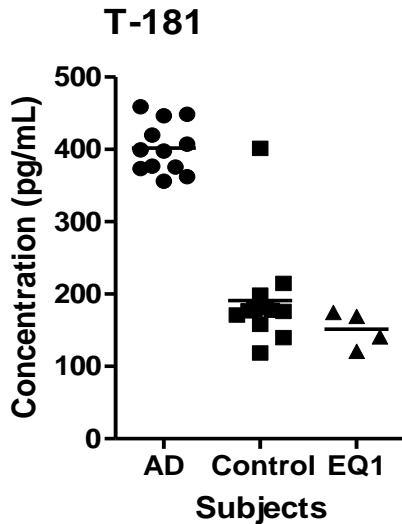
Winston, et.al., Alzheimer's & Dementia, 2016  
 Goetzl et al. FASEB, 2016  
 Goetzl et.al. Acad. Neurology, 2015  
 Kapogiannis et al, FASEB 2015

NRGN= Neurogranin (post synaptic nerve transmission)

REST= Repressor Element Silencing Transcription Factor (neuron Survival)



# Example of NSX Testing of AD & Control Plasma



## Potential Clinical Application:

- Testing with well defined AD & Control plasma at NSX parallels published data
- NSX NDE assay measures 4 key pathologic biomarkers in plasma: P-T181-tau, T-S396-tau, A $\beta$ 1-42, & Tau

AD :

- MMSE  $\leq$  28 (range 22-28), abnormal CSF A $\beta$ 1-42 levels
- Ages 67-82; half male-half female

Controls:

- Age and gender matched
- MMSE normal 3 to 5 years prior

EQ1:

- Normal plasma process control



## NSX Direct™ Product Status

- Finalizing RUO certification in CLIA Lab
- Current tests: NDE content of  $A\beta$ 1-42, Tau, p-tau T181 and p-tau S396
- Expansion of RUO NDE biomarkers in progress
- Working with several companies to test potential disease and treatment applications

### Going Forward:

- Expand control and AD patient database to establish biomarker range and applicability
- Seeking partners to explore multiple neurologic disease applications
- Transition to LDT to support identification and monitoring of AD and other neurologic disorders



# Thank You

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