# Neurotez Inc.: Innovative solutions for brain disorders A vibrant company with unparalleled talent and capabilities to transform Alzheimer's disease.



## **Memtin**<sup>TM</sup>

Our patented hormone replacement therapy for slowing cognitive decline in Alzheimer's disease and other dementias

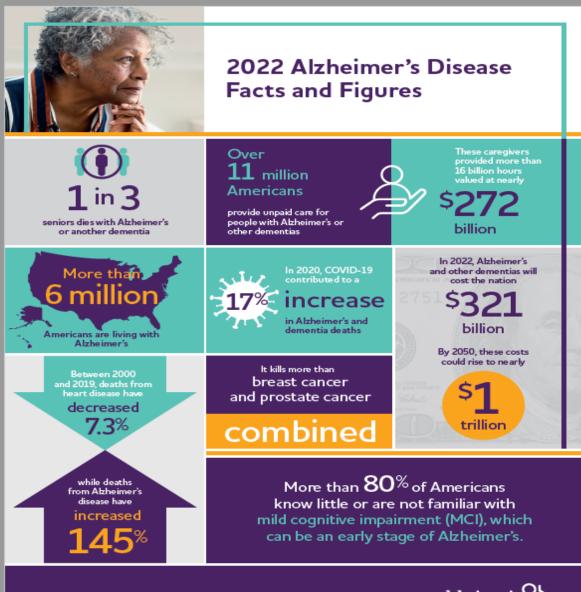
"Our flagship and a personal commitment"

Nikolaos Tezapsidis, President & CEO









# A Devastating Unmet Medical Need



## **A Very Promising Solution**

# MEMTIN™ (Leptin) for Cognitive Decline

- Ten years of in vitro and in vivo preclinical studies (Neurotez)
- Retrospective (including Neurotez's) and prospective human studies and a few anecdotal interventional human studies

#### Support a role of Leptin in:

- Neuroprotection,
- Cognitive enhancement,
- Decreasing levels of phospho-tau/tau,
- Decreasing beta amyloid (Aβ) and is associated with lower risk for dementia in elderly

#### **Leptin as Replacement Therapy**

- A relatively de-risked multi-functional preventative and therapeutic approach for cognitive decline due to Alzheimer's and optimally for early stage (prodromal AD) hypoleptinimics.
- Several novel use patents in prominent markets and Biologics Act protection
- Derisked 505(b)(2) path to Phase 2
- Targeted phenotypic and genotypic selection of patients



## **Novel, Differentiating**

#### **MEMTIN**<sup>TM</sup>

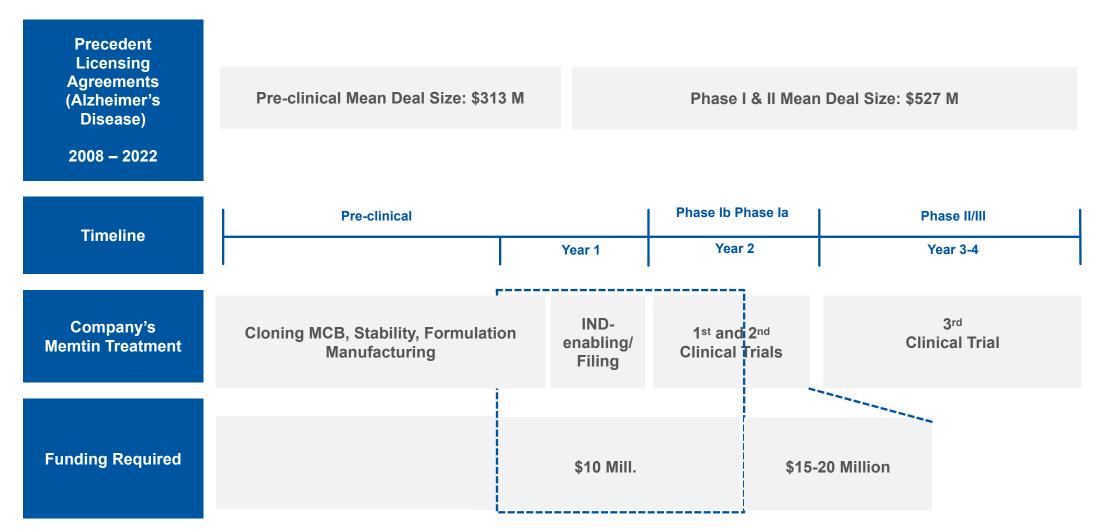
- Alzheimer's disease as diabetes of the brain or Type III diabetes
- A natural protein with procognitive properties at Low levels in Alzheimer's (AD) with known Safety Profile (Effectively Phase II ready)
- Ameliorates both Abeta and tau pathologies, upstream molecular target related to metabolism
- Clinical Strategy involving enrichment of patients, targeting patient group most likely to respond

#### **PREVIOUS FAILURES**

- Antibodies directed against Abeta or tau are difficult to penetrate into the brain and are toxic at the high doses needed for efficacy
- Heterogeneity in patient groups and targeting late stage AD patients
- Wrong targets (Abeta and/or tau may be biomarkers, not culprits



## Drug Development Path for Memtin™ (Leptin): Key Milestones





## **Experienced Management Team**



Nikolaos Tezapsidis, PhD, Chairman, Chief Executive Officer & President 18+ years experience in biomedical research; Two awards from the Alzheimer's Association Fellow of the Science and Engineering Council and the Wellcome Trust



Hamish McArthur, PhD, Manufacturing Chief Officer, Executive with 33 years biologics experience within Pfizer, directly involved in numerous approved products.



J. Wesson Ashford, MD, PhD, Chief Medical Officer Clinical Professor (affiliated), Department of Psychiatry & Behavioral Sciences, Stanford University, Scientific Advisory Board Member and Chair of the Memory Screening Advisory Committee of the Alzheimer's Foundation of America.



**Jukka Karjalainen, MD, PhD,** *Chief Operating Officer.*Experience in pharmaceuticals and medical devices and clinical drug development from Phase I to Phase IV



James Harris, MBA, Chief Financial Officer 20+ years experience in startups, licensing and biosimilars.



Jane Johnston, PhD, VP of Operations
18+ years of research in cellular neuroscience



## **Board of Directors & Advisors**

**Directors** 



Nikolaos Tezapsidis, PhD (Chair) Neurotez



J Wes Ashford, MD, PhD Stanford U/ Neurotez



James Harris III, MBA
Healthcare Economics /Neurotez



Thomas J Humphries, MD

36 years of experience in Pharma and Biotech; 225+ papers published; Retired as a Colonel after 26 years in the Navy and Airforce



**Bob Oliver, MBA** 

MBA in Marketing from the Haub School of Business at Saint Joseph's University; President and CEO of Otsuka America Pharmaceutical, Inc.; VP and Global Business Manager for Oncology at Wyeth

#### **Advisors**

Julio Licinio, MD, FRANZCP

SVP and Dean at SUNY

Arthur Klausner, MBA

Director at Monopar Therapeutics

Steven Jacobsen, PhD

CEO at ALSP Inc

Daniel P. van Kammen, MD, PhD

**CNS Pharma** 

Gil Block, MD

CMO at Neuraltus, Inc

Robert Winkler, MD

CMO at Stealth Biotech

Kent Iverson, BS

Pharmaceutical Advisors

Lex Van der Ploeg, PhD

CSO at Rhythm Pharma



## **Forward-Looking Statement**

Our discussion may include predictions, estimates or other information that might be considered forward-looking. While these forward-looking statements represent our current judgment on what the future holds, they are subject to risks and uncertainties that could cause actual results to differ materially. You are cautioned not to place undue reliance on these forward-looking statements, which reflect our opinions only as of the date of this presentation. Please keep in mind that we are not obligating ourselves to revise or publicly release the results of any revision to these forward-looking statements in light of new information or future events. Throughout presentation, we will attempt to present some important factors relating to our business that may affect our predictions. You should also review our most recent SEC filings for a more complete discussion of these factors and other risks, particularly under the heading "Risk Factors."



## **Service Providers**

#### **Corporate Lawyer**

Ernest Stern
 Culhane Meadows
 5008 Scarsdale Road
 Bethesda, MD 20816

#### **CPA Firms**

#### 2020

Joel Liebman
 Liebman Goldberg & Hymowitz, LLP
 595 Stewart Avenue – Suite 420
 Garden City, NY 11530

#### 2021

Jason M. Tyra, CPA, PLLC 1700
 Pacific Avenue, Suite 4710 I Dallas, TX 75201

#### **Bank**

Santander Bank

Bank Address: Santander Bank, N.A.,601 Penn Street, Reading, PA 19601

Beneficiary: Neurotez Inc.



## **SUMMARY**

- Repurposing MYALEPT, an approved drug, as Memtin<sup>TM</sup>
- Team: Top-Notch Leaders in Academia and Pharmaceutical Industry
- Drug is an endogenous protein naturally transported into the brain with receptors in the hippocampus (area affected by disease)
- Data from thousands of patients supporting an association of the drug to protection against Alzheimer's
- Data from preclinical studies demonstrating efficacy as a disease modification entity
- Perfectly positioned to allow early intervention and prevention therapy for those at risk (because of its safety profile)
- Novel use patents issued in US, Japan, China, Australia, S Africa and have pending in Europe, Canada and India, protection until 2029
- Drug as a biologic, will get 12 y of market exclusivity from approval in the US (similar provisions ex-US)
- Drug can be produced cost-effectively and in large batches in Ecoli
- Treatment will be combined with diagnostic tests (plasma leptin)/apoE4)
- Can be subject to accelerated approval, using protein as a surrogate marker as an endpoint, can cut clinical development costs by 10s of \$millions and time by 3-4 years.



## Nikolaos Tezapsidis President & CEO

Neurotez, Inc.

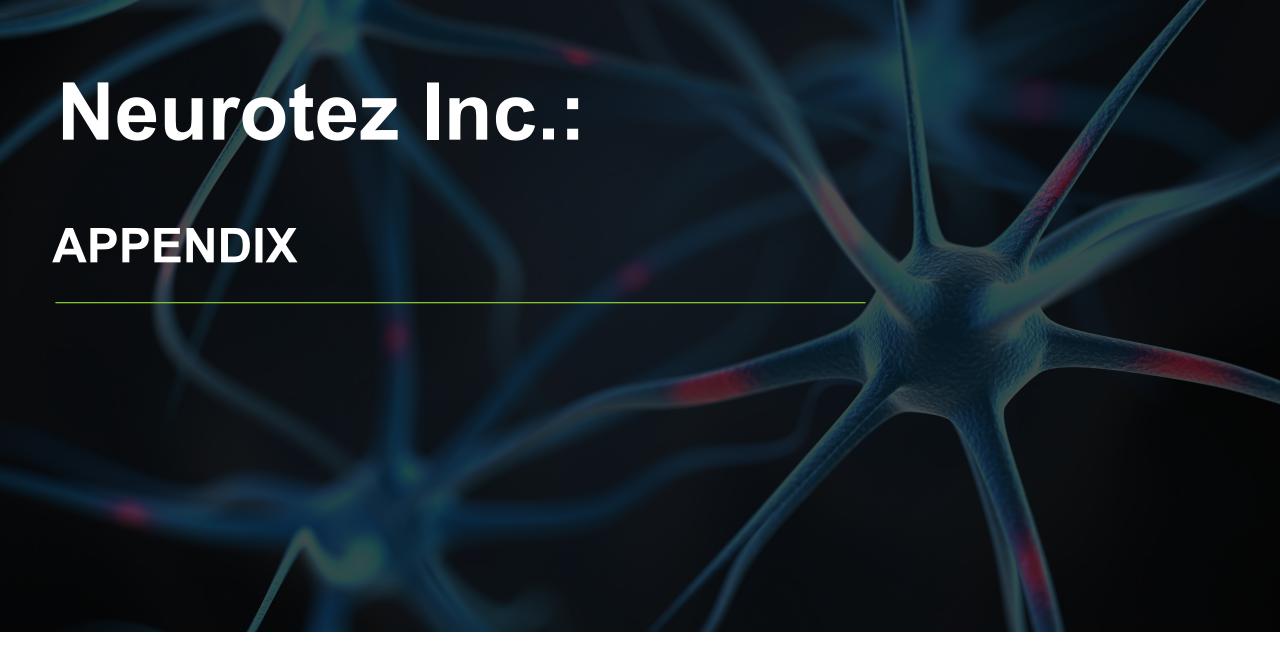
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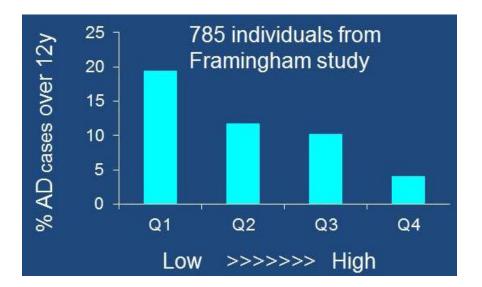




## **Studies: Serum Leptin Levels in Elderly and Prognosis**

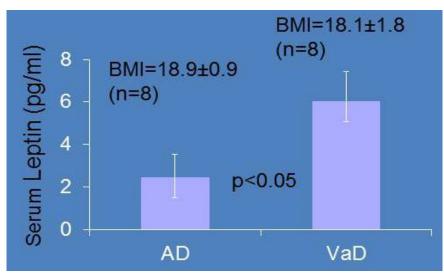
In elderly, higher serum Leptin is associated with a lower risk for Alzheimer's disease and dementia

Lieb et al, JAMA, 2009



For BMI<25, patients with AD have lower serum Leptin levels compared to patients with Vascular Dementia (VaD)

Power et al, Dementia, 2001



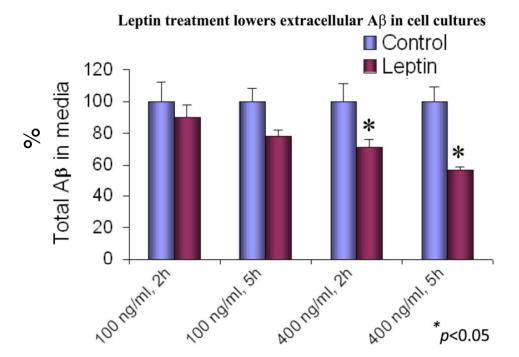
FOR INVESTOR DISCUSSIONS ONLY



## **Studies:** Leptin Targets Amyloid Beta and Tau Protein

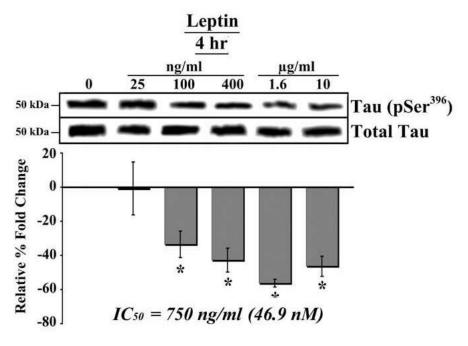
#### **Amyloid Plaques**

- Inhibition of amyloid beta (Aβ)
- Up-regulation of Aβ uptake
- Reduction of brain levels of Aβ
- Reduction of plaque density



#### **Neurofibrillary Tangles**

- Reduction of phosphorylation of tau protein in vitro and in vivo
- Phosphorylation of tau protein precedes the formation of neurofibrillary tangles





## **Studies:** Leptin Improves Memory in AD Animal Models

**Animal studies: Behavioral (CRND8)** 

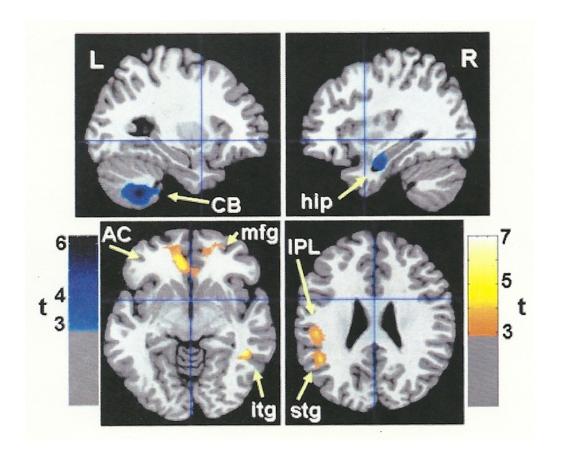


## **Studies: Direct Evidence for a Causation**

# Cognitive benefits in humans: treating leptin deficiency in adults and young"

- Behavioral changes after 2 wks, Licinio et al (2004)
- Leptin Replacement increases Gray matter concentration in Leptin (-) adults, Matochik et al (2005)
- Plasticity of Gray Matter changes following Leptin discontinuation
   / reinitiation in Leptin (-) adults, London et al (2011)
- Leptin Replacement improves Cognitive Development in Leptin
   (-) young, Paz-Filho et al (2008)

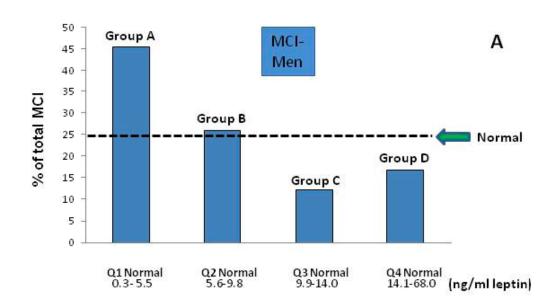
(Licinio's interventional clinical studies)

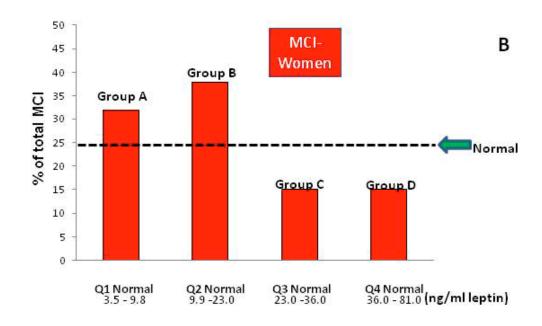




## **Studies: Serum Leptin Levels in MCI**

Approximately 70% of MCI Subjects Have Plasma Leptin Values Lower than the Median Leptin Value of Normal Elderly. (Neurotez)







## See attached documents