

# OT Bio

Developed by The George Washington University

# Technology Summary

- ▶ Obstructive sleep apnea (OSA)
  - ▶ highly prevalent sleep breathing disorder
  - ▶ occurring in about 24% of men and 9% of women in the US
- ▶ OSA increases the risk of
  - ▶ hypertension, cardiac arrhythmias, myocardial ischemia, and ventricular hypertrophy leading to a 3-fold increase in cardiovascular mortality
- ▶ No FDA approved pharmacological or other non-device based approaches to reduce the frequency or duration of obstructive events has been successful
- ▶ Untreated sleep apnea causes \$3.4 billion in additional medical costs in the U.S
- ▶ Intranasal Oxytocin therapy
  - ▶ Natural neuropeptide
  - ▶ FDA approved for use in childbirth

# Challenges with current therapies

- ▶ Few effective treatment options for sleep apnea other than positive airway pressure (CPAP or autoPAP) devices
- ▶ Despite the risks of OSA, CPAP is often discontinued because it is intrusive and poorly tolerated
- ▶ Approximately half of all patients with OSA **discontinue CPAP use** entirely or use it for less than 4 hours each night



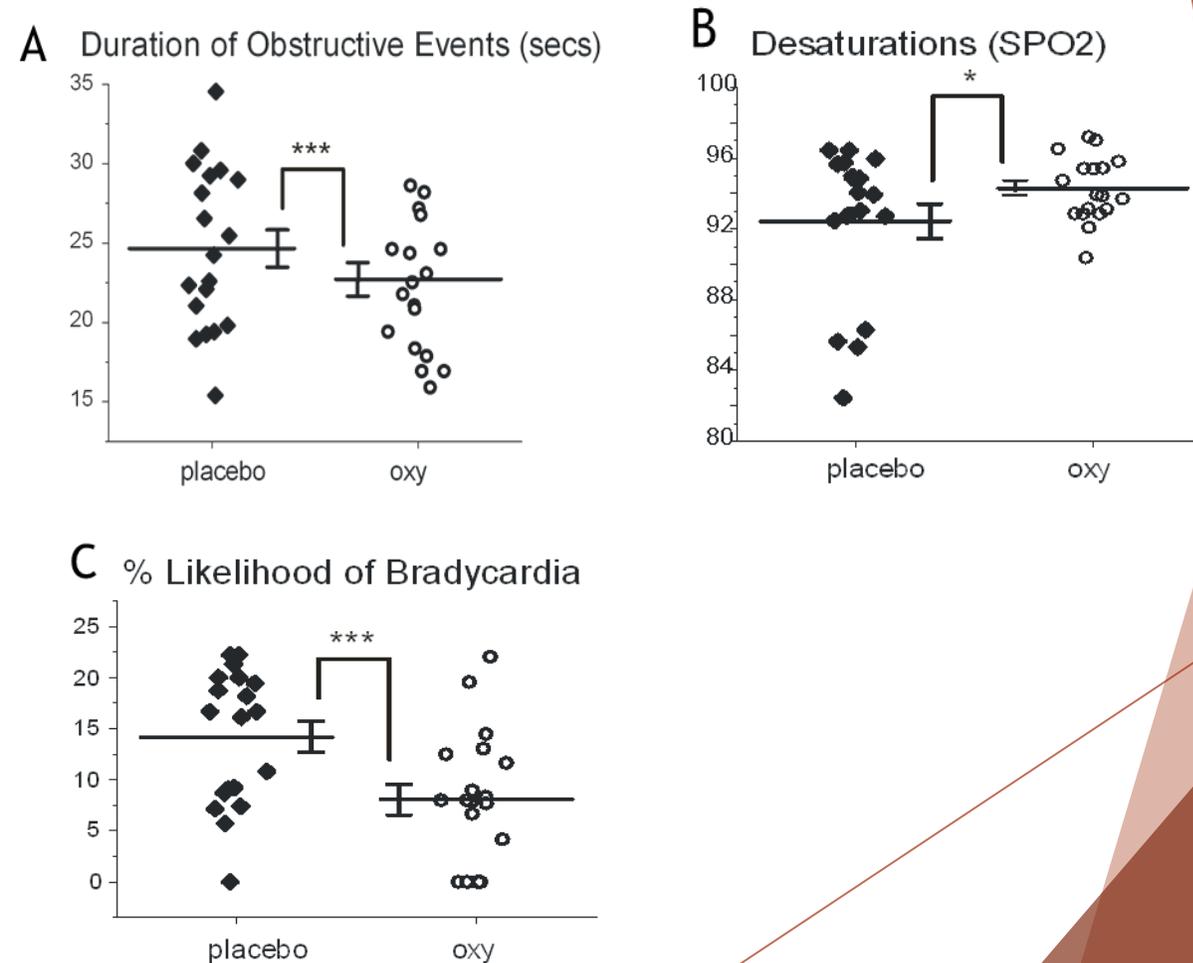
# OT Bio Solution

- ▶ Intranasal administration of oxytocin help patients with OSA
- ▶ Nasal administration of Oxytocin reduces
  - ▶ 1) duration of obstructive events
  - ▶ 2) level of oxygen desaturation
  - ▶ 3) abnormal heart rate fluctuations
- May be used as a substitute for CPAP in patients with mild OSA and provide cardio protection
- In combination with CPAP for severe OSA to decrease severity of obstructions, increase sleep satisfaction and CPAP compliance



# Randomized, Double-Blinded Cross-Over Study with 19 OSA Subjects

- ▶ Oxytocin significantly decreased the duration of obstructive events
- ▶ Oxytocin decreases desaturations in obstructive events
- ▶ Oxytocin decreases chance of bradycardia accompanying obstructive events



# How big is the market?

- ▶ OSA prevalence of about 16% in US
- ▶ The **annual economic cost** of moderate - severe OSA in the United States is **\$65 - \$165B**, which is greater than asthma, heart failure, stroke and hypertensive disease (\$20B to \$80B)

## In addition to medical costs:

- ▶ OSA-related traffic accident (*excluding medical costs*):  
\$10 - \$40 Billion
- ▶ OSA-associated workplace accidents (*excluding traffic accidents and medical costs*):  
\$5 - \$20 Billion
- ▶ OSAS-related lost productivity costs driven by absenteeism:  
\$5 - \$15 Billion

# Competition

- ▶ CPAP therapy (non-compliance a problem)
- ▶ Several meta-analyses showed that the overall impact of CPAP on BP is modest (~2 mmHg)
- ▶ Patients on CPAP may still be at risk of heart failure
- ▶ CPAP Insurance coverage is based on Apnea Hypopnea Index (AHI)
  - ▶ AHI must at least 15 events per hour
- ▶ Apnea Hypopnea Index
  - ▶ average number of combined apneas and hypopneas per hour

None/Normal	AHI is <5 per hour
Mild	AHI ≥5 per hour, but <15 per hour
Moderate	AHI ≥15 per hour, but <30 per hour
Severe	AHI ≥30

# The Team



- ▶ **David Mendelowitz, Ph.D.**
- ▶ Interim Chair, Department of Pharmacology and Physiology
- ▶ Professor, Pharmacology and Physiology
- ▶ Research Interest: autonomic and respiratory control of brainstem cardiovascular function



- ▶ **Vivek Jain, M.D.**
- ▶ Associate Professor of Medicine
- ▶ Director, GW Sleep Disorders Center
- ▶ Research Interest: sleep disorders

# The ASK

- ▶ What we are looking for:
  - ▶ Serial entrepreneur with potential for CEO role
  - ▶ Investment / Financing
- ▶ Is there a market for the newly developed Oxytocin Therapy?
  - ▶ Yes, in sleep apnea and other respiratory disorders for which limited treatment options are available.
  - ▶ Oxytocin is safe and marketed, requiring only a small investment for a new indication and long term studies
  - ▶ Additional IP for targeting heart failure separately from OSA
- ▶ How far from evaluation of the technology in patients?
  - ▶ We have completed pilot acute human trials, including a double-blinded placebo controlled study.
  - ▶ We would like to perform a chronic human trial.

# Closing

- ▶ Intranasal oxytocin therapy platform can treat Obstructive Sleep Apnea (OSA) and Heart Failure
- ▶ Safe treatment already FDA approved for childbirth and tested in humans for OSA
- ▶ Oxytocin therapy for sleep apnea and associated heart failure protected by an issued patent and patent application with allowed claims
- ▶ Oxytocin therapy for heart failure protected by a patent application
- ▶ *OT Bio* team of clinician and scientist with strong and unique expertise to make the Oxytocin therapy successful in the treatment of Sleep Apnea