



# Sommetrics

## Welcome to our Investor Webinar

*We'll be starting shortly*



FROST & SULLIVAN

**Visionary Innovation  
Leadership Award**

Acute Airway Management

GLOBAL

# Our Agenda

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## ▶ **Sommetrics Today**

- ▶ What does your Company look like?
- ▶ Who are the key people?
- ▶ What are our near-term goals?
- ▶ Why is sleep apnea such an important target?

## ▶ **aerSleep II – our lead product for sleep apnea**

- ▶ How does it work?
- ▶ Is it safe? Will people wear it?
- ▶ What are its competitive advantages?
- ▶ How will we make it for the upcoming pivotal trial?
- ▶ Are our quality systems adequate?

# Our Agenda (cont.)

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## ▶ **Clinical-Regulatory Update**

- ▶ Where are we with FDA?
- ▶ What does the Breakthrough Device Designation mean?
- ▶ What does our pivotal clinical trial entail?

## ▶ **Current Financing**

- ▶ How much have we raised?
- ▶ For what purpose?
- ▶ What is the current investment opportunity?

## ▶ **Q&A**

# Sommetrics Today

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- ▶ **We are a lean organization**

- ▶ Employ 10 personnel covering key functions of a larger organizations (Engineering/Development, Clinical, Regulatory, Quality and Finance/Administration)

- ▶ **Our facility**

- ▶ We have extra-capacity for future commercial activities and a favorable lease (the owner is a Board member and investor)

- ▶ **Key people**

- ▶ We believe all our employees are essential to our success
- ▶ You will meet some of them during today's presentations

- ▶ **Our primary focus is obtaining FDA clearance to market aerSleep to treat sleep apnea**

- ▶ This requires engineering and clinical-regulatory support as well as adequate quality systems and sufficient finances



# The Importance of Sleep Apnea

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- ▶ **The most common chronic respiratory disease worldwide**
  - ▶ About **1 billion** adults afflicted
  - ▶ Fewer than 5% receiving adequate treatment
- ▶ **Medical need is enormous**
  - ▶ First line therapy with CPAP works in most people but most people don't like it and don't use it
  - ▶ Untreated, sleep apnea reduces life expectancy and predisposes to stroke, heart attacks and other significant health problems
- ▶ **Commercial opportunity is one of the largest in healthcare**
  - ▶ Treatment of sleep apnea is highly cost-effective
  - ▶ As a result, common interventions like CPAP are reimbursed
  - ▶ The US is the largest market, which underlines the importance on FDA market clearance
  - ▶ Largest “pure play” public companies are: ResMed (at 5/10/21: ~\$3.1B rev/~\$28.1B market cap/~9x rev)& Inspire (~\$115M rev/~\$4.9B market cap/~43x+ rev!)

# We Continue to Build an Impressive Patent Portfolio

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- ▶ **33 international patents (10 US) allowed/granted from 8 patent families**
  - ▶ Validity of seminal US patent challenged by major competitor and granted by USPTO with only small wording change
- ▶ **Granted patents cover multiple attributes of aerSleep product and expire from 12/2027 to 11/2037**
- ▶ **Hold exclusive licenses to worldwide patents/patent applications and improvements for vacuum micropump from TTP-Ventus (expiring 2029 to 2035) and to new interface foam technology from ISL, LLC**
- ▶ **Trademarks granted on Sommetrics, aerSleep, aerFree, aer+ in multiple countries**

# aerSleep II – Our Lead Product

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# Solution: aerSleep<sup>®</sup>, superior treatment for sleep apnea

First fully integrated product that is unlike and better than anything on the market.

- ▶ Cordless neck collar which opens the airway
- ▶ Integrated vacuum pump
- ▶ Comfortable, easy to use and very portable
- ▶ Preferred by user and bed partner
- ▶ Monitoring capabilities
- ▶ Unlike CPAP, does not create infectious aerosols





# CPAP – The Competition

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# Our Quality Systems

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- ▶ **We are compliant with the major global quality requirements for medical devices: ISO-13485**
- ▶ **We have also passed an audit to the standards of the Medical Device Single Audit Program (MDSAP)**
  - ▶ Successfully audited for Canada and Australia

# Clinical-Regulatory

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# Clinical-Regulatory Status Report - FDA

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- ▶ **In 2020, the FDA designated aerSleep II as a “breakthrough” medical device**
  - ▶ In recognition of its unique and innovative features capable of addressing a critical unmet need for a life-threatening condition (sleep apnea)
  - ▶ This entitles aerSleep II to:
    - Priority review status
    - May allow for immediate coverage/reimbursement from the Centers for Medicare & Medicaid Services (CMS)
- ▶ **A detailed application for an Investigational Device Exemption (IDE) was submitted to FDA in March**
  - ▶ Approval is required to launch our pivotal trial
  - ▶ *The IDE was approved on April 23 (!)*

# SOM-029 – Our Pivotal Trial

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## ▶ Key Study Components

- ▶ Target population: adults with moderate to severe sleep apnea who are unable to use CPAP
- ▶ Primary safety and effectiveness endpoints assessed after 24 weeks of home use
- ▶ Patterned after successful study previously completed in Canada (lowers risk)

## ▶ Study logistics

- ▶ Goal is to have data on 79 subjects at 24 weeks
- ▶ Expect this will require enrolling about 200 people at 10 clinical sites in the U.S. (academic and community based)
- ▶ Two Core Labs to independently review sleep studies and ultrasound images

## ▶ Study refinements to accommodate COVID

- ▶ Most study visits to be done remotely via telehealth
- ▶ All sleep studies performed at home

# Current Financing

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# Financing Opportunity: \$16M Series C Preferred

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- ▶ **Seeking to raise remaining \$5.5M**
  - ▶ \$10.5M raised in first close early February
  - ▶ Added new/key investors including our new Director, Dr. Thomas Haider
- ▶ **Proceeds of the \$10.5M already raised will be mainly used to fund the FDA Pivotal trial**
- ▶ **Additional \$5.5M funding for:**
  - ▶ Product development initiatives (\$1.0M)
  - ▶ Commercial preparation (\$2.5M)
  - ▶ Reserve/general corporate purposes (\$2.0M)
- ▶ **Pro-rata investments**
  - ▶ Contact the Company to provide an investor statement/pro-rata calculation

# Q&A

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# Sommetrics

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**Thank you for joining us!**

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