



**Wilsons  
Drug and Device Conference  
October 2023**

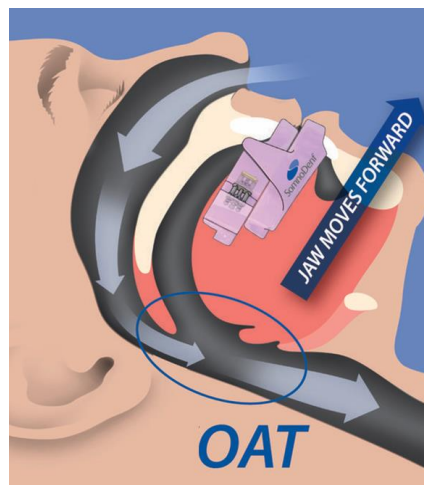
**Mark Harding  
Senior Vice President  
Global Marketing and R&D.**

**Significant TAM:**  
Almost 1 billion people globally suffer from OSA<sup>1,2</sup>

- OSA is highly prevalent and undiagnosed medical condition, associated with cardiovascular and metabolic diseases
- SOM's TAM continues to grow as national health bodies learn more about OSA and the long-term health risks of OSA

**SOM - only global player in OAT**

- Operating in 28 countries (17 with direct sales teams) .
- 8 regional hubs delivering support to local dental and medical customers.
- ISO 13485 certified manufacturing facility in the Philippines. Upgrading to MDSAP level certification over the next 2 years.



- Oral Appliance Therapy (OAT) is an effective alternative to CPAP for mild/ moderate OSA and is preferred by patients when they try both therapies.<sup>1</sup>
- Greater compliance rates of OAT results in comparable improvements in quality-of-life and cardiovascular measures<sup>3</sup>
- However, today OAT only represents 10.6% of TAM for OSA devices.

**Robust, clinical research is at the core**

- SomnoMed's product suite and technology is based on long-running investment in research and development in Australia.
- High quality clinical research, real world evidence and health-economics provide the foundation for governments and insurers to use OAT as first line therapy (as in the Netherlands and Sweden).

**SOM is the leading provider of OAT to treat OSA globally**

- ~830,000 patients being treated by SOM OAT devices
- Global leader in the design, manufacture and distribution of OAT devices since inception 19 years ago
- Competitive differentiation via b-flex comfort liner that creates superior comfort and improved compliance to therapy.

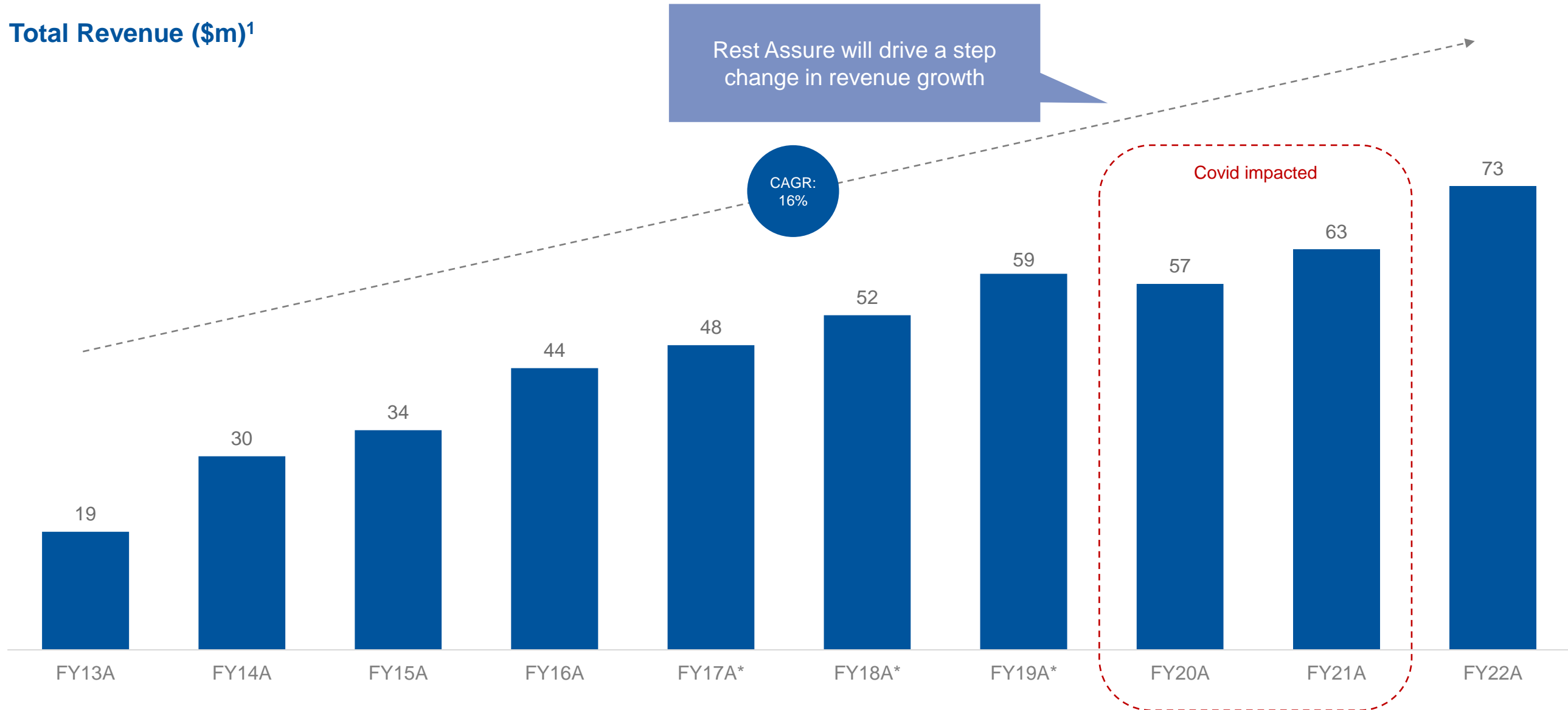
**Leading management team and board**

- More than 100 years of collective medical device experience of senior management team.
- Highly engaged board and a passionate management team

1. A. V. Benjafield et. al. Estimation of the global prevalence and burden of OSA: a literature-based analysis. *Lancet Respiratory Medicine*. Aug 2019; 7(8): 687-698, Philips et.al *Am J Respir Crit Care Med* Vol 187, Iss. 8, pp 879–887,  
 2. U. Devaraj et. al. Undiagnosed OSA and Postoperative Outcomes: A Prospective Observation Study: *Respiration* (2017) 94(1): 18-25  
 3. H. U. Dissanayake et. al. Obstructive sleep apnea therapy for cardiovascular risk reduction–Time for a rethink? *Clinical Cardiology*. Dec 2021; 44(12): 1729-1738

# Growth Track Record

Total Revenue (\$m)<sup>1</sup>



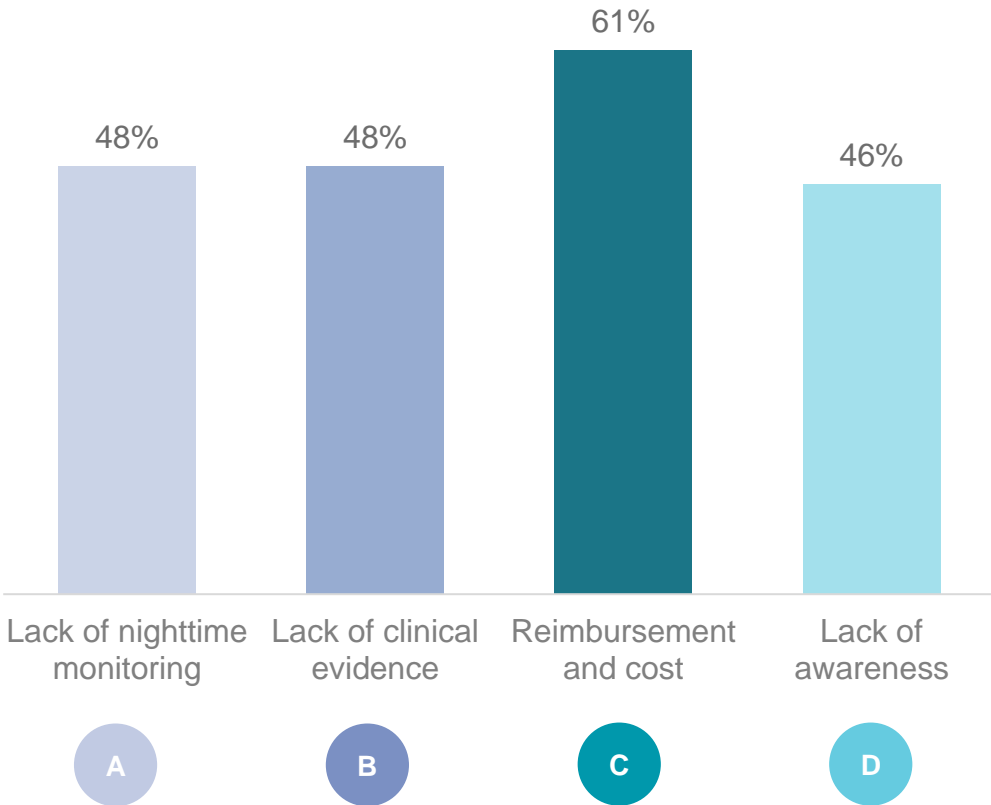
1. Core SOM revenues only. Excludes revenues from Renew Sleep Services (RSS). RSS was in operation from FY17, and closed halfway through FY19

# Rest Assure - Addressing barriers to OAT prescription



# How does Rest Assure address OAT barriers?

**SOM market research: Key barriers to prescribing OAT  
242 Sleep Physicians - conducted in Oct 2019**



**A**  
Lack of night-time monitoring

- Currently physicians don't know if a patient has an oral device, if they're wearing it and if it's working. They know this with CPAP
- Rest Assure provides all night, every night monitoring of OAT treatment efficacy and adherence to therapy with a medical device customised for each patient

**B**  
Lack of clinical evidence

- Current clinical evidence supporting OAT is based on small patient population studies. Limited real-world data.
- Rest Assure enables continuous large scale data collection via regional data registries, at much lower cost than clinical studies.
- Rest Assure will be integrated into clinical trials to demonstrate effective oral device design of SOM products

**C**  
Reimbursement and cost

- For patients in therapy, over 5 years, CPAP is reimbursed 2-10 x the price of OAT (depending on the market).<sup>1</sup>
- 50% of patients may not be using CPAP at 2 years.<sup>2</sup>
- Rest Assure will track compliance and provide objective, real world effectiveness (adherence and efficacy) data of OAT patients to insurance companies and payors **on their patients**

**D**  
Lack of awareness of OAT as an alternative

- CPAP is considered the gold standard and the "go to" therapy to treat OSA
- Increasing focus on "personalised medicine" and involving patient in decision making
- Rest Assure will convince both physicians and patients of the effectiveness of OAT
- Rest Assure opens Direct to Patient marketing channel for SOM

1. SOM internal data.  
2. Hwang D et al. PATTERNS OF LONG-TERM CPAP ADHERENCE: A 3-YEAR FOLLOW-UP FROM THE TELE-OSA STUDY, SLEEP, Volume 42, Abstract 0518, 2019

# Intended market rollout strategy

## Steps to market

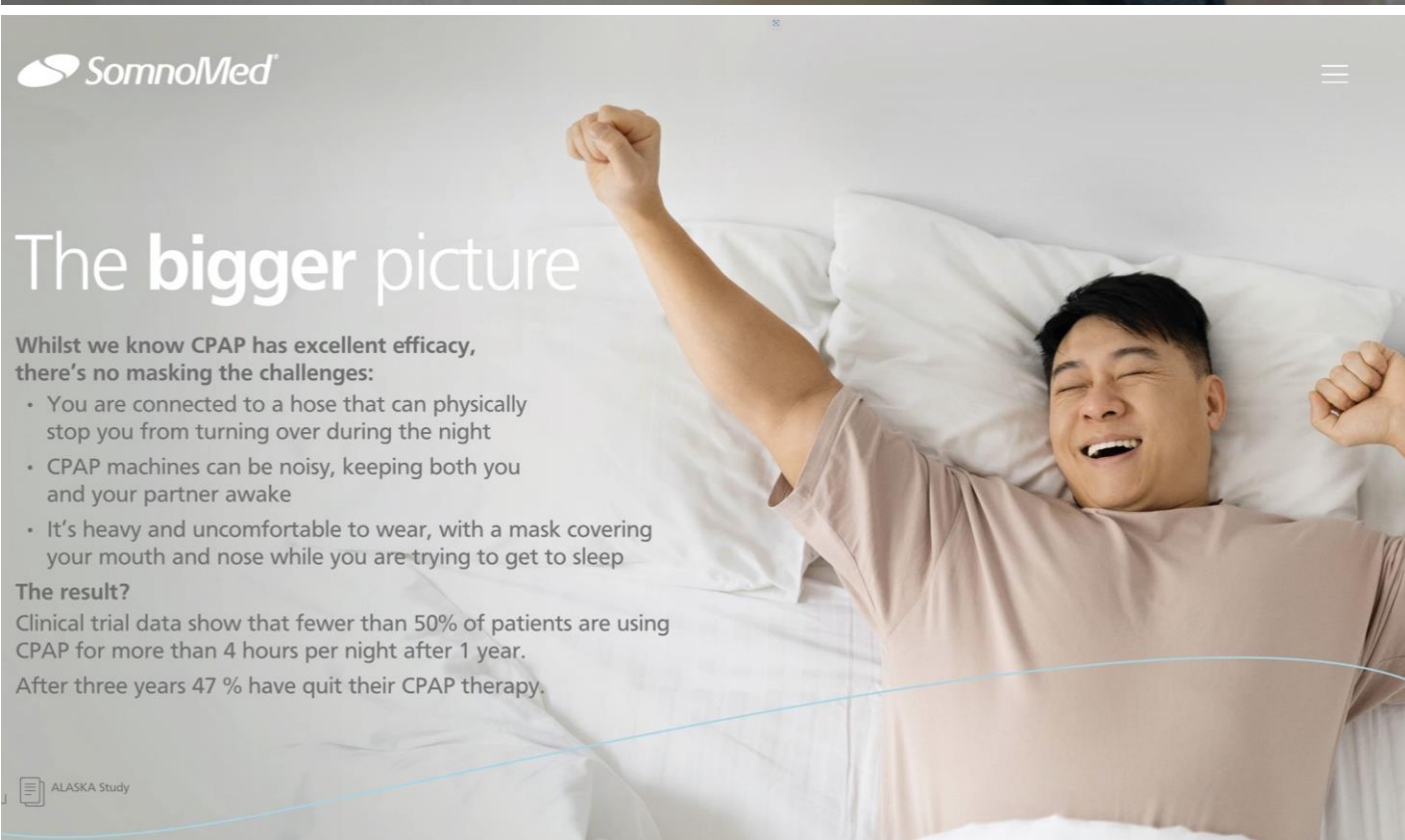
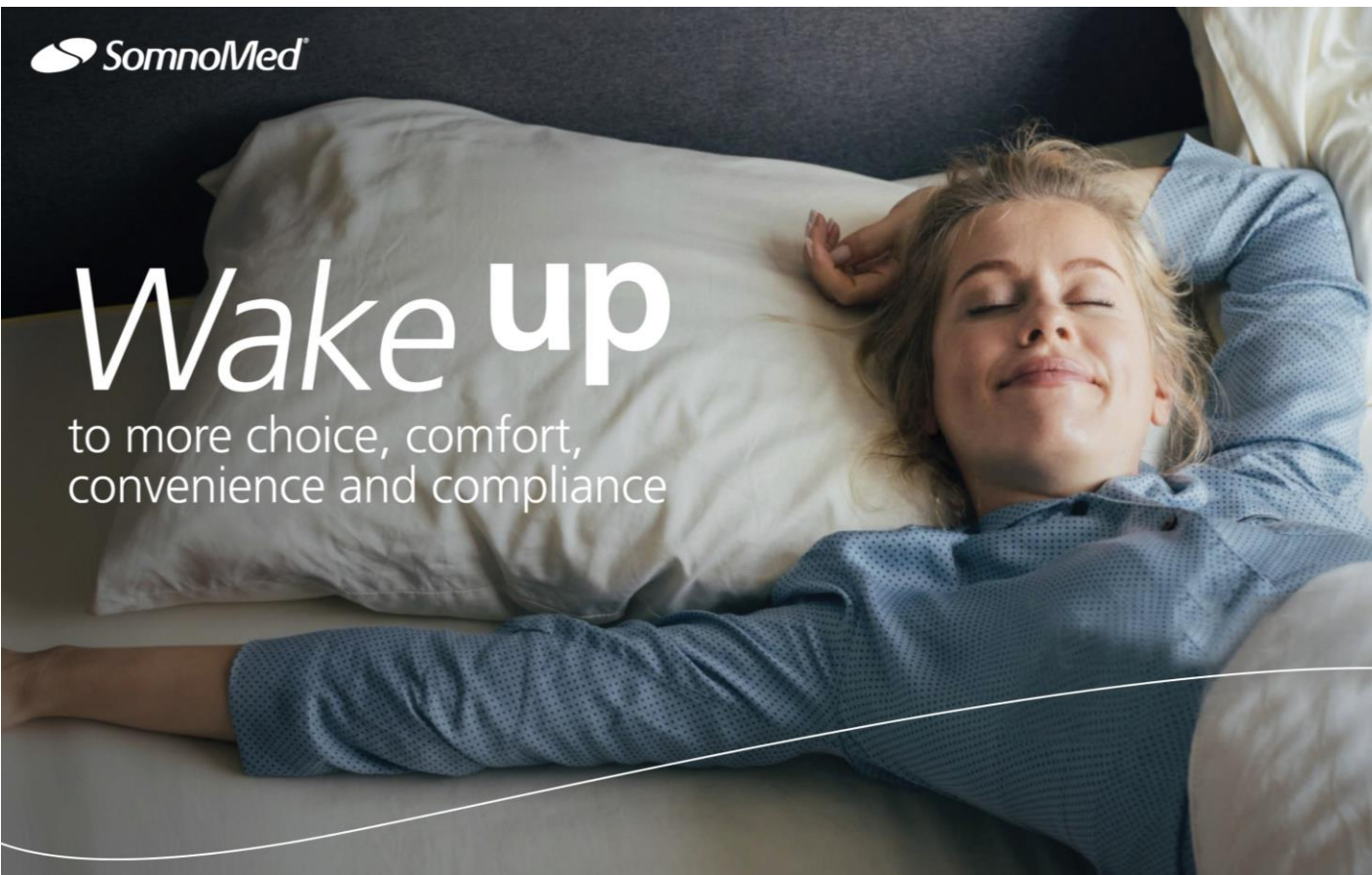


## Rest Assure Marketing strategy



- Rest Assure will be marketed as a premium OAT product, where local reimbursement allows
- Rest Assure will launch first in countries where it is classified as a Class I medical device with supportive physician/ dental partners
- Rest Assure will seek 510(k) premarket authorisation from the US FDA with the submission based on an existing predicate device
- Will be launched at dental sleep clinics in the US that are paired with strong supporting sleep physician relationships/referrals
- Rest Assure classified as a Class IIa medical device by the TGA.

# Rest Assure enables DTP marketing.



## Pre-Rest Assure DTP pilots.

- Direct to Patient (DTP) campaigns in Facebook in US and ANZ conducted to test DTP systems (using Salesforce/ Marketo)
- Campaigns direct patients to “Find A Provider” on SOM website, linking patients with dentists using SOM devices
- Campaigns targeting OSA sufferers who have stopped using CPAP have positive ROI

## Local DTP marketing (focus on US market)

- Local campaigns driving patients to dentists have been shown to increase dentist loyalty to SOM
- DTP marketing to users of Rest Assure to encourage them to “refer a friend” and leave testimonials
- Exploring DTP campaigns to current users of SOM devices to upgrade to Rest Assure

## OSA Market Overview

### Treatment landscape

3 primary treatment options currently available to treat Obstructive Sleep Apnea (OSA)

**1**

**OAT**

Oral Appliance Therapy (OAT) works by moving the mandible forward, opening the airway and removing any airflow restriction.

- High compliance
- Moderate efficacy
- Low - moderate 5yr cost
- Low invasiveness

**2**

**CPAP**

Continuous Positive Airway Pressure applies air pressure to the upper airway to keep the airway open to enable normal breathing while asleep.

- Low - moderate compliance
- High efficacy
- Moderate 5yr cost
- Moderate invasiveness

**3**

**Surgical Procedures including Hypoglossal Nerve Stimulation**

Invasive option considered as a last resort for severe OSA.

- Moderate - high compliance
- Moderate - high efficacy
- Very high 5yr cost
- High invasiveness

## SomnoMed Overview

### Market

Almost 1 billion people suffer from OSA globally. The most popular form of OSA treatment (CPAP) reports low compliance which impacts their overall effectiveness.

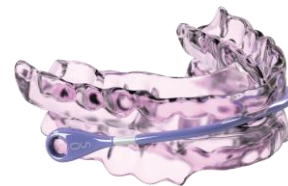
Uptake of OAT is driven by the acceptance, awareness and adoption of medical professionals prescribing the treatment.

### SomnoMed mission

To advance the adoption, acceptance and treatment of oral sleep apnea therapies by patients, medical specialists, dentists and insurers

### SomnoMed products

#### SomnoDent OAT devices



Current SomnoMed OAT devices have been used by ~830k patients globally

#### Rest Assure



SOM's OAT devices measure night to night compliance and efficacy, soon to be released to market

## Market Opportunity

### Growth opportunity

#### Raise awareness

- OAT is considered 2<sup>nd</sup> line therapy for mild-moderate OSA in most markets, with the OAT segment estimated to account for 10.6% of SOM's global TAM (CPAP largely taking the remaining market share)<sup>1</sup>
- In markets where OAT devices are 1st line therapy for mild-moderate OSA (Sweden, The Netherlands), OAT has an equal market share with CPAP (~45%+)

#### Launch Rest Assure

- Rest Assure enables continuous monitoring and data capture from patients, addressing the lack of night-time monitoring - a key barrier to OAT prescription.
- Rest Assure will provide the market with real world evidence and data to demonstrate the effectiveness and comfort (adherence) of OAT, increasing:
  - Awareness, acceptance and adoption of OAT and the likelihood of Rest Assure being prescribed by physicians; and
  - The likelihood that Rest Assure is considered as first line therapy and reimbursed by payors.
  - Awareness of Rest Assure as an alternative to CPAP, especially where SOM can deploy DTP marketing.

1. In the direct markets that SOM operates in, assuming SOM can address at least 69% of CPAP users.



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