



## **SomnoMed introduces Rest Assure<sup>®</sup>, an inbuilt, technology-enabled oral appliance**

**SomnoMed Limited (ASX “SOM”, or the Company)**, a leading company in the provision of treatment solutions for sleep-related breathing disorders and obstructive sleep apnea (‘OSA’), is pleased to introduce Rest Assure<sup>®</sup>, its first ever inbuilt technology-enabled oral appliance.

### Highlights:

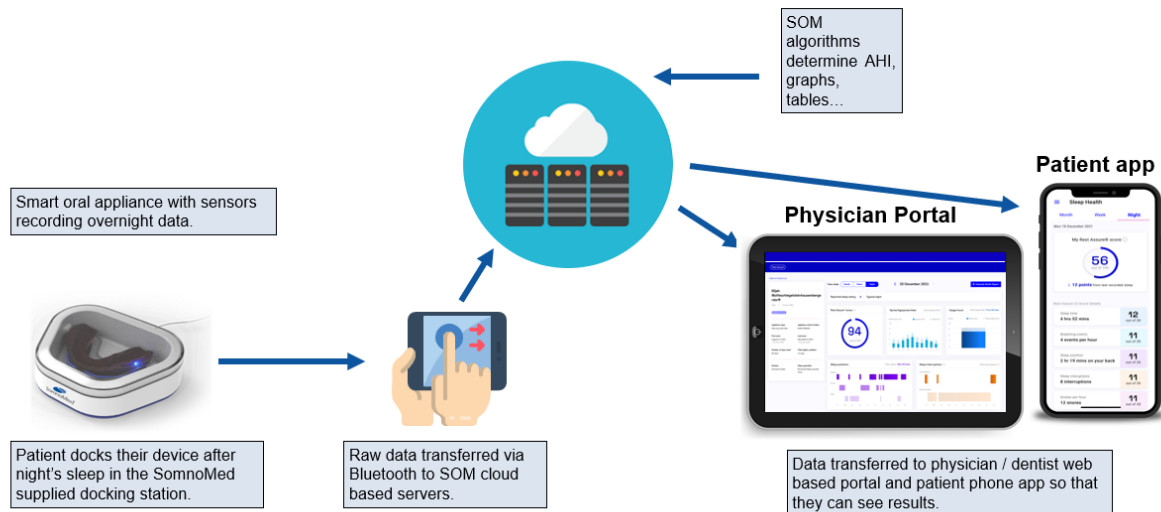
- Addresses the lack of overnight monitoring in continuous open airway therapy (‘COAT<sup>™</sup>’), which has been a major barrier to prescription and reimbursement rates to date
- Under the brand name Rest Assure<sup>®</sup>, sensors that measure treatment efficacy and adherence (usage) will be added to SomnoMed’s milled oral appliances
- Physicians and dentists will be able to view personalised data from their patients on a web-based portal, alongside a patient phone app that will allow patients to view their own sleep data
- This data will help support the effectiveness equation and drive acknowledgement of equivalent clinical effectiveness for COAT<sup>™</sup> and CPAP when considering both efficacy and compliance together
- Rest Assure<sup>®</sup> is expected to drive prescriptions, increased reimbursement and ultimately greater share of treatment prescriptions for COAT<sup>™</sup> versus CPAP

In 2019, SomnoMed commissioned specific market research with sleep physicians that demonstrated that the lack of objective usage and efficacy data from COAT<sup>™</sup> was a key barrier to prescribing oral appliances. In response, SomnoMed engaged Planet Innovation, a global leader in medical device and software development, to assist in developing sensors, algorithms and software to provide this data.

Currently, overnight data on usage and efficacy in the treatment of OSA is only available with CPAP devices. Ultimately, we expect that Rest Assure<sup>®</sup> data will help drive the acknowledgement of the clinical effectiveness for COAT<sup>™</sup> and drive greater share of therapy for COAT<sup>™</sup> versus CPAP. Once equivalent clinical effectiveness for COAT<sup>™</sup> and CPAP is quantified with objective data, this will pave the way for discussions on possible reimbursement increases for COAT<sup>™</sup>. Using Direct to Patient marketing, SomnoMed expects to build brand awareness with patients who will want to interact with the Rest Assure<sup>®</sup> patient app and request Rest Assure<sup>®</sup> by name from their sleep physician and dentist.

# How does Rest Assure® technology work?

Smart oral appliance and cloud based infrastructure



The Rest Assure® hardware and software is now in prototype stage, with a patient study underway to validate algorithms for efficacy and compliance. These algorithms were developed by correlating Rest Assure sensor signals and the NOX level 2 diagnostic sleep test (a portable Home Sleep Test that is a standard diagnostic test in sleep medicine). The results from this validation study will be presented at the World Sleep Meeting in Rome from March 11th-16th 2022 and will be included in CE mark and FDA regulatory submissions.

SomnoMed will continue to progress Rest Assure® towards commercial readiness. Key milestones for the remainder of FY22 include the completion of the patient study, final design for the docking station and sensor package and the selection of suppliers. In FY23, the Company will focus on the preparation and submission of regulatory documentation to the FDA, CE and TGA. Ultimate commercialisation of Rest Assure® will be subject to the review and approval by these relevant regulatory authorities.

**Commenting on the development of Rest Assure®, SomnoMed’s Managing Director, Mr Neil Verdall-Austin said:** “SomnoMed is extremely proud to bring to the sleep industry true technology that matters to patients and all treatment stakeholders. We believe SomnoMed’s Rest Assure® technology will empower patients to manage their own OSA treatment with a technology-enabled oral appliance providing measures of both efficacy and compliance. Whilst such data availability is standard for CPAP, having personalised treatment data, shared confidentially between clinicians and patients, is truly a first for oral appliances. We anticipate that over time, the data collected by Rest Assure® will demonstrate and establish the equivalent clinical effectiveness of COAT™ therapy and CPAP, driving prescriptions, increased reimbursement and ultimately greater therapy market share for COAT™ amongst the large population of patients suffering from sleep apnea.”

22<sup>nd</sup> February 2022

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This release has been approved by the Board of SomnoMed Limited.

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**About SomnoMed**

SomnoMed is a public company providing treatment solutions for sleep-related breathing disorders including obstructive sleep apnea, snoring and bruxism. SomnoMed was commercialized on the basis of extensive clinical research. Supporting independent clinical research, continuous innovation and instituting medical manufacturing standards has resulted in SomnoDent<sup>®</sup> becoming the state-of-the-art and clinically proven medical oral appliance therapy for more than 675,000 patients in 28 countries. For additional information, visit SomnoMed at <http://www.somnomed.com.au>