Data-driven Oral Appliance Therapy

SomnoMed is a global manufacturer of oral appliance therapy (OAT) devices for the treatment of obstructive sleep apnea (OSA), with significant traction in multiple markets. The company recently unveiled its next-generation products which integrate biosensor and digital technologies, significantly expanding their clinical utility and medical value proposition to a broader range of healthcare practitioners and patients in the highly underpenetrated sleep apnea therapy market. Incorporating clinically meaningful analytics allows more targeted management and remote monitoring of patients and access to reimbursement opportunities.

Sleep apnea has serious comorbidities, but is underdiagnosed and often poorly managed

OSA is a common sleep-disordered breathing condition, characterised by frequent episodes of upper airway collapse during sleep, and linked to major comorbidities including cardiovascular and cerebrovascular diseases. However, lack of awareness of OSA and its consequences means many cases are undiagnosed, creating a larger and underpenetrated market opportunity.

Further, when OSA is diagnosed, nasal continuous positive air pressure (CPAP) is the gold standard non-surgical treatment option and is typically prescribed for all cases regardless of severity. However, poor ongoing patient compliance remains a hurdle to long-term management in many cases, as many patients find CPAP cumbersome.

Continuous Open Airway Therapy (COAT)™[1] is an attractive alternative to CPAP

Oral appliance therapy (OAT), such as SomnoMed's Continuous Open Airway Therapy (COAT™), uses an oral appliance to reduce upper airway collapse by advancing the mandible. This represents an attractive alternative treatment with better long-term compliance and similar effectiveness vs. CPAP for mild to moderate cases.

SomnoMed Ltd. designs, manufactures and sells premium oral appliances for the treatment of sleep-disordered breathing conditions. The company was founded in 1987 and is headquartered in Sydney, Australia. SomnoMed's SomnoDent™ suite of oral devices are FDA cleared for mild-to-moderate obstructive sleep apnea (OSA) and available in 28 countries across Europe, North America, and APAC.

Stock	SOM.ASX
Price	A$1.76
Market cap	A$146m
Valuation	A$3.20

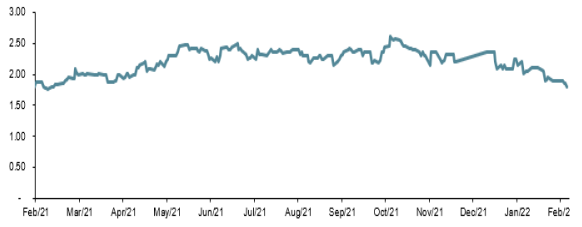
Company data	
Net cash	17.6m
Shares on issue	84.0m
Code ASX	SOM

Share price catalysts

1HCY22 - Completion of patient validation study

2H CY22- Regulatory submission for Rest Assure

SOM share price (A$)



Source: FactSet.

Chris Kallos, CFA
chris.kallos@mstaccess.com.au

Unveiling Rest Assure® – Data analytics redefine clinical utility and create SaaS potential

Despite ample clinical evidence supporting the use of OAT/COAT™ to treat mild to moderate OSA, objective real-time measures of 'in-the-mouth' compliance and efficacy monitoring have hindered optimisation of these devices. Rest Assure® sensor technology combined with SomnoMed's COAT™ adds rigour and delivers powerful real-time analytics which should build confidence among physicians in using OAT in first-line therapy for mild to moderate cases. Notably, Rest Assure® also opens the door to recurring revenues from potentially multiple end-users under a SaaS model.

Valuation: Base case 82% above current share price not including SaaS potential upside

We value SomnoMed at ~$269m, or $3.20 per share (undiluted), based on DCF methodology and assuming FDA clearance, using a probability of 70%, and subsequent launch of Rest Assure® in 1HCY23.

[1] COAT™, SomnoMed's branded OAT (oral appliance therapy) system, is a registered trademark owned by SomnoMed.

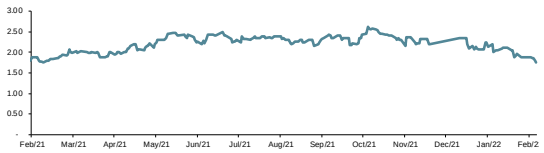
Financials

SomnoMed SOM-AU

Year end 30 June, AUD unless otherwise noted

MARKET DATA		
Price	**$**	**1.76**
52 week high / low	$	1.75-2.08
Valuation	**$**	**3.20**
Market capitalisation	$m	147.8
Shares on issue (basic)	**m**	84.0
Options / rights	m	4.2
Other equity	m	0.0
Shares on issue (diluted)	**m**	**88.2**

12-MONTH SHARE PRICE PERFORMANCE (A$)



INVESTMENT FUNDAMENTALS		FY20A	FY21A	FY22E	FY23E	FY24E
Reported NPAT	$m	(1.1)	(1.2)	(3.9)	1.8	4.4
Underlying NPAT	**$m**	**(1.1)**	**(1.2)**	**(3.9)**	**1.8**	**4.4**
Reported EPS (diluted)	¢	(1.7)	(1.4)	(4.7)	2.1	5.2
Underlying EPS (diluted)	**¢**	**(1.7)**	**(1.4)**	**(4.7)**	**2.1**	**5.2**
Growth	%		-13.3%	226.5%	-145.2%	146.4%
Underlying PER	x	**nm**	**nm**	**nm**	**83.0**	**33.7**
Operating cash flow per share	¢	8.2	3.5	(0.7)	7.3	9.9
Free cash flow per share	¢	5.3	(2.1)	(10.3)	2.5	5.1
Price to free cash flow per share	**x**	**33.1**	**nm**	**nm**	**70.6**	**34.4**
FCF Yield	%	3.0%	nm	nm	1.4%	2.9%
Dividend	**¢**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Payout	%	0.0%	0.0%	0.0%	0.0%	0.0%
Yield	**%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**	**0.0%**
Franking	%	0.0%	0.0%	0.0%	0.0%	0.0%
Enterprise value	**$m**	**125.1**	**129.1**	**137.7**	**135.6**	**131.3**
EV/EBITDA	x	28.3	33.5	349.2	17.7	13.0
EV/EBIT	x	93.7	13,908.3	(42.6)	54.4	25.7
Price to book (NAV)	x	4.1	4.6	5.2	4.9	4.3
Price to NTA	x	5.3	6.3	7.2	6.4	5.3

KEY RATIOS		FY19A	FY20A	FY21A	FY22E	FY23E
EBITDA margin	%	7.7	6.1	0.5	8.7	9.1
EBIT margin	%	2.3	0.0	nm	2.8	4.6
NPAT margin	%	nm	nm	nm	2.0	3.9
ROE	%	nm	nm	nm	5.9	12.8
ROA	%	nm	nm	nm	3.1	6.6
Net tangible assets per share	$	0.3	0.3	0.2	0.3	0.3
Book value per share	$	0.0	0.0	0.0	0.0	0.0
Net debt/(cash)	$m	(22.7)	(18.8)	(10.1)	(12.2)	(16.5)
Interest cover/ (EBIT/net interest)	x	104.4	2.3	nm	nm	nm
Gearing (net debt/EBITDA)	x	nm	nm	nm	nm	nm
Leverage (net debt/(net debt + equity))	x	nm	nm	nm	nm	nm

DUPONT ANALYSIS		FY19A	FY20A	FY21A	FY22E	FY23E
Net Profit Margin	%	nm	nm	nm	2.0	3.9
Asset Turnover	x	0.9	1.1	1.3	1.5	1.7
Return on Assets	%	nm	nm	nm	3.1	6.6
Leverage	x	1.8	1.7	1.9	1.9	1.9
Return on Equity	%	nm	nm	nm	5.9	12.8

KEY PERFORMANCE INDICATORS	FY19A	FY20A	FY21A	FY22E	FY23E
Regional sales					
North America	19.8	20.3	18.5		
Europe	38.8	32.4	38.8		
Asia Pacific	5.4	4.6	5.4		

HALF YEARLY DATA		2H21	1H22	2H22	1H23	2H23
Total Revenue	$m	31.9	33.9	38.2	44.0	44.0
Operating expenses	$m	(31.4)	(34.0)	(38.3)	(40.5)	(40.5)
EBITDA	$m	0.8	(0.4)	0.8	3.8	3.8
EBIT	$m	(1.2)	(2.3)	(0.9)	1.2	1.2
PBT	$m	(1.6)	(2.3)	(1.6)	0.9	0.9
Reported NPAT	$m	(1.7)	(2.9)	(1.0)	0.9	0.9

PROFIT AND LOSS		FY20A	FY21A	FY22E	FY23E	FY24E
Total Revenue	**$m**	**57.3**	**62.7**	**72.1**	**88.0**	**111.7**
Operating expenses	$m	(54.7)	(59.5)	(72.3)	(80.9)	(102.2)
EBITDA	**$m**	**4.4**	**3.8**	**0.4**	**7.7**	**10.1**
Depreciation & Amortisation	$m	3.1	3.8	3.6	5.2	5.0
EBIT	**$m**	**1.3**	**0.0**	**(3.2)**	**2.5**	**5.1**
Net interest	$m	0.0	0.0	0.0	0.0	0.0
Pretax Profit	**$m**	**0.7**	**(0.7)**	**(3.9)**	**1.8**	**4.4**
Tax expense	$m	(1.2)	(0.3)	0.0	0.0	0.0
Reported NPAT	**$m**	**(1.1)**	**(1.2)**	**(3.9)**	**1.8**	**4.4**
Weighted average diluted shares	m	63.1	78.4	84.0	84.0	84.0

GROWTH PROFILE		FY20A	FY21A	FY22E	FY23E	FY24E
Revenue	%	(2.7)	9.4	15.0	22.0	27.0
EBITDA	%	86.8	(13.0)	(89.8)	1,844.1	32.1
EBIT	%	45.5	(99.3)	(34,895.7)	(177.2)	104.6
Reported NPAT	%	1,012.9	147.1	263.9	(145.2)	146.4

BALANCE SHEET		FY20A	FY21A	FY22E	FY23E	FY24E
Cash	$m	30.2	21.1	12.5	14.6	18.9
Receivables	$m	7.6	10.6	12.1	14.8	18.8
Other	$m	2.5	2.5	2.8	3.3	4.1
Current assets	**$m**	**40.2**	**34.1**	**27.5**	**32.7**	**41.8**
PPE	$m	3.9	4.7	11.3	11.9	12.3
Intangible assets	$m	7.9	8.6	7.8	7.1	6.4
Right-of-use assets	$m	6.3	5.6	4.2	3.2	2.4
Other	$m	86.1	78.5	78.5	78.5	78.5
Non current assets	**$m**	**21.5**	**22.0**	**26.4**	**25.2**	**24.2**
Total assets	**$m**	**61.7**	**56.2**	**53.9**	**58.0**	**66.1**
Trade and other payables	$m	8.6	10.6	12.2	14.6	18.3
Borrowing and lease liabilities	$m	7.3	2.0	2.0	2.0	2.0
Other	$m	2.9	3.6	3.6	3.6	3.6
Current liabilities	**$m**	**18.8**	**16.2**	**17.8**	**20.2**	**23.9**
Borrowing and lease liabilities	$m	8.2	7.0	7.0	7.0	7.0
Other liability	$m	0.8	0.9	0.9	0.9	0.9
Non current liabilities	**$m**	**9.1**	**7.8**	**7.8**	**7.8**	**7.8**
Total liabilities	**$m**	**27.9**	**24.0**	**25.7**	**28.0**	**31.7**
Net assets	**$m**	**33.8**	**32.2**	**28.2**	**30.0**	**34.4**
Share capital	$m	73.9	74.3	74.3	74.3	74.3
Retained earnings	$m	(48.7)	(49.9)	(53.8)	(52.0)	(47.6)
Other	$m	8.6	7.8	7.8	7.8	7.8
Total equity	**$m**	**33.8**	**32.2**	**28.2**	**30.0**	**34.4**

CASH FLOW		FY20A	FY21A	FY22E	FY23E	FY24E
Net loss for period	**$m**	**(1.1)**	**(1.2)**	**(3.9)**	**1.8**	**4.4**
Depreciation & Amortisation	$m	3.1	3.8	3.6	5.2	5.0
Changes in working capital	$m	2.7	0.1	(0.3)	(0.9)	(1.1)
Other	$m	0.5	(0.0)	0.0	0.0	0.0
Operating cash flow	**$m**	**5.2**	**2.7**	**(0.6)**	**6.1**	**8.3**
Payments for PPE	$m	(2.2)	(4.1)	(8.0)	(4.0)	(4.0)
Other	$m	0.4	(0.2)	0.0	0.0	0.0
Investing cash flow	**$m**	**(1.8)**	**(4.4)**	**(8.0)**	**(4.0)**	**(4.0)**
Equity	$m	16.3	0.4	0.0	0.0	0.0
Lease liability payments	$m	(1.8)	(2.4)	0.0	0.0	0.0
Net borrowing	$m	4.5	(4.8)	0.0	0.0	0.0
Financing cash flow	**$m**	**18.9**	**(6.8)**	**0.0**	**0.0**	**0.0**
Cash year end	**$m**	**30.2**	**21.1**	**12.5**	**14.6**	**18.9**
Free cash flow	**$m**	**3.4**	**(1.7)**	**(8.6)**	**2.1**	**4.3**

Source: Company, MST Access.

Investment Thesis: Enhancing Oral Appliance Therapy with Real-Time Data Analytics

Company Profile: Global Sleep Apnea Oral Device Manufacturer Goes Digital

SomnoMed designs, manufactures, and sells premium oral appliances for the treatment of sleep-disordered breathing conditions. The company was founded in 2004 and is headquartered in Sydney, Australia. It is vertically integrated with its own centralised manufacturing facilities in the Philippines.

The original technology was invented in the late 1990s by Sydney orthodontist Dr Richard Palmisano and incorporated a proprietary 'dorsal fin' design which was subsequently developed into other styles including the company's SomnoDent™ range of oral appliance therapy (OAT) devices[2].

New product development driven by innovation and evidence-based clinical research

SomnoMed listed on the ASX in August 2004, raising A$12m, with funds used to support new product development and international expansion commencing in 2006. The company has been an industry leader in terms of building awareness and driving adoption of OAT devices, branded by SomnoMed as COAT™ (Continuous Open Airway Therapy), as an alternative to CPAP. This leadership position has been instrumental in forging reimbursement policy in 8 countries.

Proprietary design and b-flex material add to product differentiation strategy

SomnoMed's SomnoDent™ range of oral devices is FDA cleared for mild-to-moderate obstructive sleep apnea (OSA) and fitted to around 675,000 patients (as at end-December 2021) in 28 countries across Europe, North America, and APAC. New product development has been driven by evidence-based clinical research (17 studies) and has led to a range of proprietary features that represent significant points of differentiation in terms of comfort and efficacy – key attributes valued by sleep physicians and dentists. This has underpinned improved rates of patient compliance when compared to CPAP.

'Rest Assure®' – New integrated biosensors with connected-care data analytics: Redefining business model, competitive advantage, value proposition to sleep physicians

Integration of data-driven technologies is reshaping the landscape for healthcare, including sleep apnea treatment. Greater connectivity is allowing real-time data collection and storage, which is enhancing the ability of healthcare providers to respond to patients' individual needs with a more targeted approach and building their confidence in the tools available.

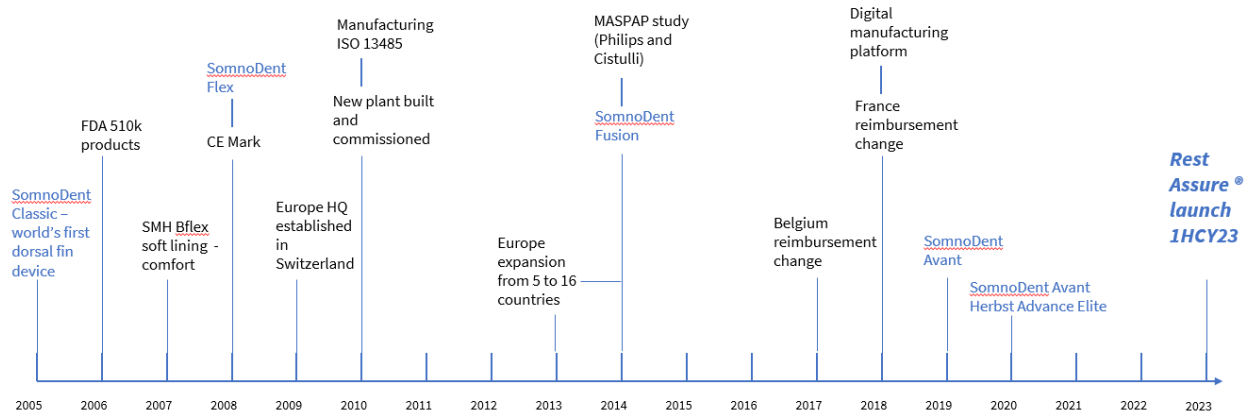
SomnoMed recently unveiled its next-generation product offering, Rest Assure®, which integrates miniature biosensors into its oral devices to record efficacy and compliance. This product suite, which combines the Rest Assure® sensor technology with SomnoMed's milled[3] oral appliances, will have a range of clinical benefits, such as expanded and real-time data capture. This should in turn encourage a larger number of sleep physicians to embrace and recommend OAT for mild to moderate cases of sleep apnea, rather than defaulting to the usual choice of CPAP. Features of the new product suite include:

- algorithms that track respiratory rate and sleep disturbances, as well as overall patient compliance with the therapy
- real-time analytics that use collected data to monitor the solution's effectiveness and patient compliance, expanding the value proposition to sleep physicians
- a connected platform that supports a multidisciplinary approach to manage sleep apnea and provides longitudinal quality of care, building the confidence of healthcare providers in COAT (vs CPAP).

[2] https://portal.unifiedpatents.com/patents/patent/US-6604527-B1. A number of terms are used for OAT devices. Note that the terms mandibular advancement device (MAD), mandibular advancement splint (MAS), and mandibular re-positioner appliance (MRA) are interchangeable. These are distinct from tongue-retaining devices (TRDs, which protrude the tongue instead of the mandible).

[3] Milling refers to a high-precision, fully digital manufacturing production process. In this process, already formed hard material is machined using rotary cutters to remove material, thereby forming the CAD designed product. This process brings additional strength and durability to the finished product.

Exhibit 1 – History of product innovation and global expansion – major milestones



Source: SomnoMed.

Recent Significant Events

- September 2019 – Launch of SomnoDent Avant
- October 2020 – Launch of SomnoDent Herbst Advance Elite
- February 2022 – Rest Assure® is unveiled

Potential Near-term Catalysts

We will watch the following potential near-term catalysts for SomnoMed stock:

- World Sleep meeting in March 2022 (a global scientific congress of ~2,000 physician attendees) and presentation of Rest Assure®
- Completion of patient validation study
- Updates on development of Rest Assure®
- Regulatory submission and clearance for Rest Assure®
- Changes to reimbursement policies for oral appliances
- Signs of increased awareness and diagnosis of OSA globally fuelling growth of addressable market
- Progress in penetrating sleep physician channels in first-line therapy settings

Financials – Investing in Rest Assure®

The company is increasing its investment in Rest Assure® and has provided the following full-year guidance which is incorporated into our forecasts: revenue growth of at least 15%; EBITDA breaking even; and cash investment in technology of $8m.

Valuation – Base case of $3.20 per share not including SaaS revenues

We think the integration of Rest Assure® technology with the SomnoDent™ product range radically changes the company's medical and economic value proposition given the benefits of increased connectivity across multiple stakeholders in the treatment of OSA and the prospect of improving patient adherence and therefore efficacy. These include physicians, dentists, payors, and patients. We see this as valuable to stakeholders and an attractive opportunity for SomnoMed to generate recurring revenues under a future SaaS model. As such, we value SomnoMed at $268.7m, or $3.20 per share, using DCF methodology.

Sensitivities and Risks

With products available in 28 countries and partial/full reimbursement established in many of these, the company is well positioned to both enhance its leadership position and redefine industry standards. Nonetheless, investors should remain mindful of several company-specific risks which could impact our forecasts and valuation, including product development risks and regulatory clearance of Rest Assure®, and adoption by sleep physicians as first line therapy.

Outlook: Transforming Oral Appliance Therapy for Sleep Apnea

Existing Product: Oral Appliances to Treat Sleep-Disordered Breathing

SomnoMed listed on the ASX in 2004 to commercialise and develop proprietary oral appliance technology invented in the late 1990s by Sydney orthodontist Dr Richard Palmisano to treat sleep-disordered breathing (SDB). SDB comprises all disease processes that cause abnormal breathing patterns in sleep, including obstructive and central sleep apnea (OSA and CSA) and hypoventilation syndromes which occur in sleep.

The history of mandibular advancement splint treatments

Oral appliance (splint) therapy has been used in dentistry since the early 1900s for a variety of disorders of the temporomandibular joint (which connects the jawbone to the skull), including those related to tooth-grinding[4]. Oral splints, specifically mandibular advancement devices (MADs), began to be used to treat sleep apnea in the late 1980s[5]. MADs comprise an upper and lower splint which move the lower jaw, carrying the tongue forward so that it is less likely to partially block or constrict the airway during sleep[6]. MADs have successfully treated orthodontic conditions, snoring, OSA and certain temporomandibular joint disorders.

SomnoDent ™ portfolio – proprietary features underpin strong product differentiation

Unique design. Dr Palmisano's patented invention used a novel 'dorsal fin' design with complementary upper and lower flanges/dorsal fins close to the posterior teeth, allowing mandibular advancement over a broad range of jaw openings. This unique design underpinned SomnoMed's OAT designs until the launch of SomnoDent Avant in 2019.

The company's flagship product, SomnoDent Avant, is an intraoral device for the treatment of snoring and mild to moderate OSA in patients 18 years of age or older. The appliance functions as a mandibular positioner, which acts to increase the patient's pharyngeal space and improves their ability to exchange air during sleep (see 'Understanding Sleep Apnea and the Challenges in its Treatment', below). The SomnoDent appliance consists of two generic splints which fit over the upper and lower teeth, with the lower splint holding the mandible (lower jaw) in a forward position using an advancement mechanism. The patient thus gains additional pharyngeal space, which reduces their symptoms of sleep apnea.

Material advantage. Durability and comfort are key drivers of efficacy for OAT, but traditionally these two characteristics have been somewhat in conflict. A hard material is more durable but less comfortable; a softer device is comfortable but may not retain its fit and effectiveness. SomnoMed's b-flex Comfort Liner™ is a proprietary soft lining material, developed in house, that the company believes will fix this problem: the b-flex material provides a soft inner cushion for the teeth, making the device comfortable, while an acrylic exoskeleton is used on the outside of the device, making it durable. These two layers have been developed in tandem to bond together seamlessly.

Exhibit 2 – SomnoMed oral appliance range currently on the market

	bflex Comfort liner	CAD/CAM appliance (reduces bulk and increases comfort)	Pre-cured material for increased strength and durability	Unique strap design that holds mouth closed for additional efficacy	Allows side to side movement of upper/lower jaw – more comfortable
Herbst Advance	NO	NO	NO	NO	NO
SomnoDent Classic	NO	NO	NO	NO	NO
SomnoDent Flex	YES	NO	NO	NO	NO
SomnoDent Fusion	YES	NO	NO	NO	NO
SomnoDent Herbst Advance Elite	YES	YES	YES	NO	NO
SomnoDent Avant	YES	YES	YES	YES	YES

Source: SomnoMed.

[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3760352/

[5] Mandibular advancement splints for the treatment of obstructive sleep apnea; Chan et al (2021).

[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5803051/).

New SomnoMed Product Suite, 'Rest Assure®': Oral Appliances Get Smart

New sensors support advanced real-time analytics and personalised monitoring

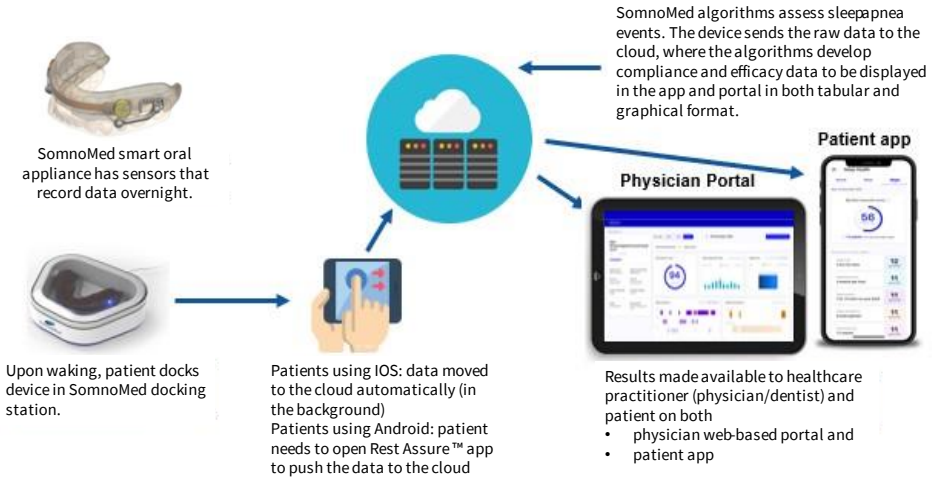
SomnoMed's release of Rest Assure® heralds a new era for the company and creates a potential first-mover advantage in oral appliance therapy more broadly. The digitisation of oral appliances is a major innovative step for the category and a significant new point of differentiation for the company. This should enhance brand recognition and demand for prescribing by name from sleep physicians and support a potential first-mover advantage in smart oral appliance therapy for SomnoMed in a multi-disciplinary setting.

Rest Assure® addresses previous limitations of oral appliances and delivers a common platform for physicians and dentists, thereby facilitating multidisciplinary treatment protocols more closely and giving sleep physicians confidence in the efficacy of COAT™.

SomnoMed's Rest Assure® platform has three key elements which support connectivity between patient, physician, and dentist (see Exhibit 3):

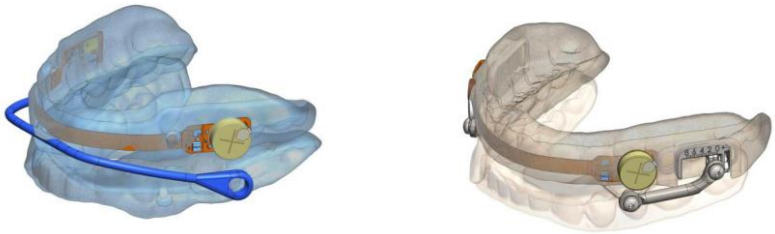
- **sensors** that determine in-mouth efficacy and compliance for SomnoMed's oral appliances
- a patient **phone app** enabling patients to monitor their own therapy
- a **web-based portal** for physicians/dentists to review treatment, enabling a multi-disciplinary team approach.

Exhibit 3 – Rest Assure® system – how it works



Source: SomnoMed.

Exhibit 4 – First two sensor-integrated products– Rest Assure® Avant (left) and Rest Assure® Elite (right)



Source: SomnoMed.

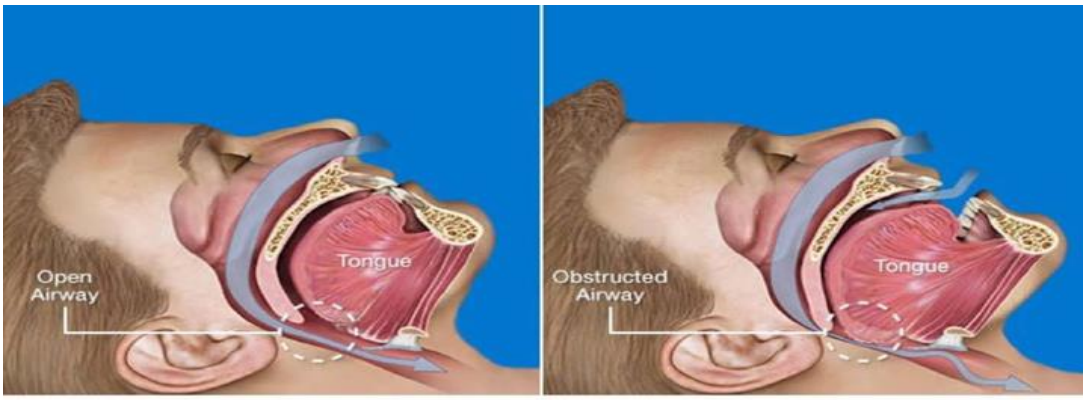
Understanding Sleep Apnea and the Challenges in its Treatment

The condition: an underdiagnosed problem with many adverse health consequences

What is obstructive sleep apnea (OSA)? Simply put, patients with sleep apnea repeatedly stop and start breathing while sleeping. Sleep apnea is further differentiated into obstructive sleep apnea (OSA) and central sleep apnea (CSA). Collectively, OSA and CSA – in addition to sleep-related hypoventilation – are referred to as sleep disordered breathing (SDB) or sleep apnea[7].

Physiologically, OSA occurs when muscle tissue, such as the tongue or soft palate, relaxes and collapses in the rear of the throat, blocking the airway momentarily and cutting off breathing. OSA is the most common type of sleep apnea, according to the American Sleep Apnea Association (ASAA). Patients with OSA have repeated episodes of partial or complete obstruction of the throat (upper airway) during sleep and can stop breathing for more than a minute and up to 60 times a night, or more than 100 times per hour in severe cases. Often, the patient is unaware of their condition.

Exhibit 5 – Non-obstructed airway (left); Obstructed airway (right)



Source: SomnoMed.

What are the risk factors? The main risk factor is extra weight/obesity, with ageing also a key factor. While more men experience OSA, the risk for women increases after menopause. Other risk factors include facial or upper airway abnormalities, drug, tobacco and alcohol use, conditions including Down syndrome and diabetes, congestion, swollen tonsils/adenoids, an underactive thyroid, larger neck size, and family history.

What are the symptoms? OSA can significantly reduce oxygen levels in the body and disrupt sleep. Signs include loud snoring, observed episodes of stopped breathing during sleep, and waking abruptly with gasping or choking. The patient may wake with a dry mouth, sore throat, or headache, and may experience daytime sleepiness, difficulty concentrating, mood changes, high blood pressure and decreased libido.

How is it assessed? After a physician or dentist identifies symptoms, diagnostic tests (sleep studies) are typically performed to grade the severity of the condition. The tests can be done at home absent significant co-existing conditions[8]. Otherwise, overnight polysomnography[9], which is the standard diagnostic test for OSA[10], can be conducted in a clinical sleep lab to measure the frequency of apneas (pauses in breathing) and hypopneas (shallow breathing) during sleep. The Apnea-Hypopnoea Index (AHI) counts the apneas and hypopneas per hour of sleep, then clinically grades the presence and severity of OSA from normal (< 5 events/hour) to severe (> 30 events/hour).[11]

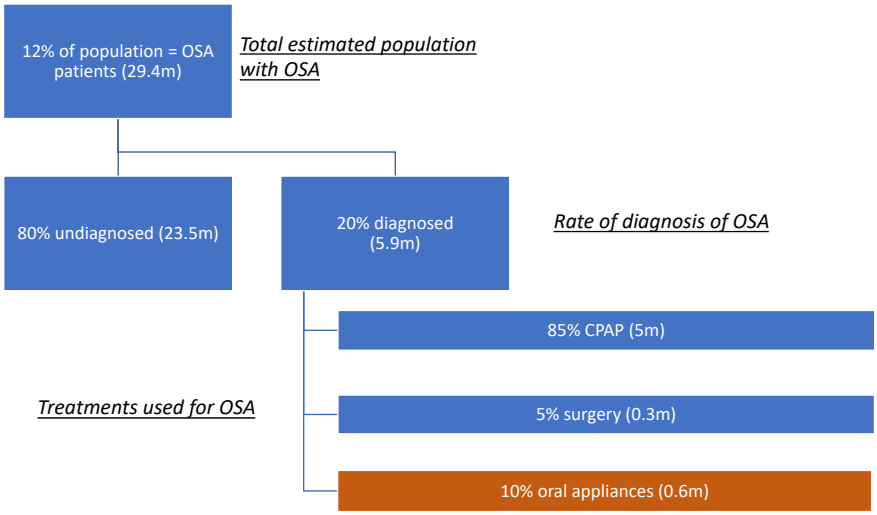
[7] https://www.acc.org/latest-in-cardiology/articles/2015/06/25/08/24/evolving-relationship-between-sleep-disordered-breathing-and-stroke
[8] Co-existing conditions include opiate use, known/suspected history of stroke, neuromuscular or pulmonary disorder with hypoventilation, or congestive heart failure. https://www.nejm.org/doi/full/10.1056/NEJMcp1816152
[9] Polysomnography (a sleep study) is a comprehensive test used to diagnose sleep disorders. It records brain waves, blood oxygen level, heart rate, breathing, and eye and leg movements. https://www.mayoclinic.org/tests-procedures/polysomnography/about/pac-20394877#:~:text=Polysomnography%2C%20also%20called%20a%20sleep,leg%20movements%20during%20the%20study
[10] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2727690/
[11] https://www.sleepapnea.org/what-does-ahi-represent/

While prevalence is high, diagnosis and treatment remain comparatively low

OSA is conservatively estimated[12] for 30–49-year-olds at 3% (women)/10% (men), and 50–70-year-olds at 9% (women)/17% (men) – including an estimated ~24m undiagnosed Americans. A lack of awareness of OSA and its consequences has resulted in poor diagnosis rates, and a large percentage of the patient population is untreated. According to BIS Research, 33% of patients diagnosed with OSA have mild sleep apnea that could become critical if untreated.

Despite the prevalence of OSA, penetration of the addressable market by medical instrument manufacturers is estimated[13] at only 20%. This has been due to several factors, including historically cumbersome diagnostic procedures and products, coupled with a relative lack of strong clinical data required to increase the clinical relevance of the condition to support evidence-based practices by physicians.

Exhibit 6 – Only 2% of the estimated patient population in the US is being treated with OAT, given low levels of diagnosis as well as an overwhelming use of CPAP over other therapies



Source: Frost & Sullivan/American Academy of Sleep Medicine 2016.

Why it matters – hidden long-term health consequences and costs associated with OSA

Untreated OSA is linked to a higher risk of physical (high blood pressure, stroke, heart attack, diabetes) and mental disorders (depression, cognitive impairment). It also increases the risk of work-related and motor accidents due to daytime sleepiness (assessed by Epworth Sleepiness Scale) caused by sleep deprivation.

Beyond the hidden costs of lost productivity and accidents, there is mounting evidence linking OSA with comorbidities such as diabetes, stroke, heart disease, and hypertension. Direct costs of better-understood comorbidities, including medical expenses and hospital admission (Exhibit 7), can be significant.

Exhibit 7 – Direct costs of OSA comorbidities

Comorbidity	# People in US with undiagnosed OSA and Comorbidity (m)	Costs* (US$b)
Hypertension	14.1	5.4
Heart Disease	3.1	6.7
Diabetes	5.6	6.4
Asthma and other Breathing Disorders	5.9	2.6
Insomnia	6.8	2.1
Depression, Anxiety and Other Mental Health Problems	8.7	7.1
Total		**30.3**

Source: Frost & Sullivan/American Academy of Sleep Medicine 2016. *Costs include medication and healthcare utilisation.

[12] https://www.nejm.org/doi/full/10.1056/NEJMcp1816152

[13] Frost & Sullivan/American Academy of Sleep Medicine 2016, *Hidden Health Crisis Costing America Billions*

Large and Growing Market Opportunity: Mild to Moderate Sleep Apnea Needs a Better (More Personalised) Solution

Mild to moderate obstructive sleep apnea a large cohort – undiagnosed and untreated

The term 'sleep disordered breathing' covers a range of breathing disturbances at night, the most common of which is obstructive sleep apnea (OSA), but also including central sleep apnea, hypoxemia, and hypoventilation. Distinguishing the clinical presentation of each patient population, and degrees of severity within OSA itself, is not always straightforward given numerous comorbidities and the sometimes overlapping and non-specific nature of many of the symptoms and other possible causes (obesity, age).

OSA patients can live asymptomatically with precursors of the disease (habitual snoring, excessive daytime sleepiness, witnessed apneas) for years, unaware that their breathing is affected and not seeking medical help or being referred for evaluation. This limits an accurate assessment of the true prevalence of OSA in the general population and explains why current consensus levels of undiagnosed patients are as high as ~80%.

As such, estimates of the prevalence of OSA vary significantly in the literature. Overall, OSA is estimated to affect 3–9% of the general population[14]. According to Frost & Sullivan[15], the prevalence of OSA in the US is about 29.4m adults or approximately 12% of the adult population. However, findings from studies into comorbidities suggest that the prevalence of some degree of OSA in the adult population could be as high as ~25%, and as much as 45% in obese subjects[16].

Awareness of OSA growing and increasing understanding of mild and moderate forms

OSA severity is currently clinically graded using the AHI[17] into mild (AHI ≥ 5, but < 15 per hour), moderate (AHI ≥ 15, but < 30 per hour), and severe (AHI ≥ 30 per hour). According to the Wisconsin Sleep Cohort Study the prevalence of moderate or severe OSA[18] is estimated at about 6% of US adults. This compares with almost 17% of adults estimated to have mild to moderate sleep apnea.

We expect increasing awareness of OSA (supported by improving physiological assessments, more consistent definitions using body mass index, and growing understanding of the link with comorbidities) will increase identification, diagnosis, and treatment of mild to moderate forms of the disease. Thus, we see the widespread adoption of consumer-facing lifestyle applications and devices, used to track heart rate, breathing patterns and sleep, as positive.

We expect demand for treatments of OSA (across all levels of severity) to grow given currently low rates of penetration and the following drivers:

- increasing prevalence of obesity in developed countries
- an ageing population
- genetic drivers of facial and upper-airway morphology
- health economics of untreated OSA and shift to value-based healthcare payor models.

[14] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4992257/

[15] Frost & Sullivan/American Academy of Sleep Medicine 2016, *Hidden Health Crisis Costing America Billions*

[16] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3021364/#:~:text=It%20is%20possible%20that%20obesity,upper%20airway%2C%20predisposing%20to%20apnea.

[17] Apnea-hypopnoea index (AHI): the number of complete (apneas) or incomplete (hypopneas) obstructive events per hour of sleep

[18] The Wisconsin Sleep Cohort (WSC) is an ongoing longitudinal study of the causes, consequences, and natural history of sleep disorders, particularly sleep apnea. The WSC uses overnight in-laboratory sleep studies (in-patient studies at the University of Wisconsin - Madison ICTR's CTRC) conducted with a baseline sample of 1,500 Wisconsin state employees, assessed at four-year intervals (https://sleepdata.org/datasets/wsc).

Current therapies and treatments: patients desperately need an alternative to CPAP

In addition to changes such as weight loss or sleep positioning, treatment options (in order of least to most invasive, as well as least to most expensive) include:

- OAT (oral appliance therapy)/COAT™ (Continuous Open Airway Therapy), currently used for 8–9% of newly diagnosed cases: moves the mandible forward to open the airway and free airflow
- CPAP (continuous positive airway pressure), currently 90%: applies air pressure to the upper airway to keep it open during sleep
- UPPP[19] (surgery), currently 1–2%: an invasive option that is generally a 'last resort'.

CPAP is overwhelmingly the most used therapy for newly diagnosed cases of OSA. It is the leading treatment for OSA and typically recommended as first-line therapy. Nonetheless, and despite advances in masks and machine technologies, patient adherence remains a major issue in the long-term management of OSA with CPAP. This is due to the significant negative impact that CPAP treatment has on a patient's comfort during sleep. Put simply, if a patient feels that their therapy is interfering with their sleep, they will often not use it.

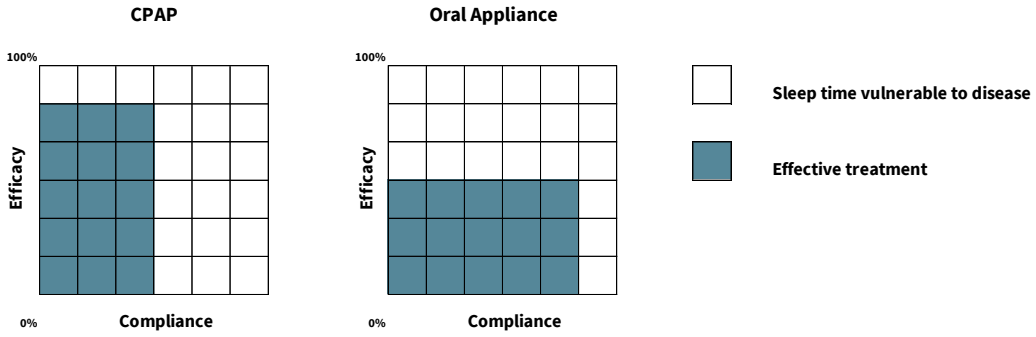
Three key opportunities exist to move more patients into OAT

Opportunity 1: Undiagnosed OSA patients. With undiagnosed OSA patients estimated at 80% of the total prevalence of the disease, the challenge for all players including SomnoMed involves raising awareness of both the problem and the benefits of treatment. The success of CPAP manufacturers such as ResMed has raised the awareness of OSA in the general population through continued investment in clinical research proving efficacy and driving adoption. Similarly, SomnoMed has established a clear strategic position through a primarily dentist-led business model to date and investment in clinical research, allowing it to drive adoption through clinical evidence and to build a formidable brand position in the industry.

Opportunity 2: OSA patients who could get equally good outcomes with OAT (effectiveness equation). While CPAP treatment is considered the gold standard for all severities of OSA, mounting evidence shows that OAT is a valid alternative in mild to moderate cases. The key metric for assessing a treatment is its **effectiveness**, defined as 'how well an intervention performs in the real world where conditions are not controlled', as opposed to its **efficacy**, which measures 'how well an intervention works under ideal circumstances' (Sutherland et al 2015)[20]. These measures differ due to patient compliance with the use of their device: e.g., frequency and duration of use, proper care for the appliance, and appropriate positioning.

In short-term randomised control studies comparing CPAP and OAT overall, Sutherland et al (2015) found no difference between CPAP and OAT treatments in health-related quality-of-life outcomes and short-term effects on blood pressure.

Exhibit 8 – SomnoMed's COAT™ device leads to higher effectiveness, even with lower efficacy, because of superior patient compliance – overall, a better result for many patients with mild to moderate OSA



Source: Efficacy and Effectiveness in OSA Treatment—Sutherland et al.

[19] Uvulopalatopharyngoplasty (UPPP) is a procedure that removes excess tissue in the throat to make the airway wider. The aim of UPPP is to allow air to move through the throat more easily when breathing, reducing the severity of obstructive sleep apnea (OSA).
[20] Sutherland K, Phillips CL, Cistulli PA. Efficacy versus effectiveness in the treatment of obstructive sleep apnea: CPAP and oral appliances. *Journal of Dental Sleep Medicine* 2015;2(4):175–181.

Studies comparing a range of oral appliances against no treatment in mild to moderate OSA show that oral appliances are effective in terms of both cost and clinically important improvements[21]. Separately, OAT showed continued efficacy due to compliance with two-thirds of patients even after three years of treatment.[22]

Opportunity 3: OAT in second-line settings as rescue treatment for failed CPAP/unsuccessful surgery patients. OAT has emerged as a second-line, non-invasive alternative to CPAP for (1) patients who do not tolerate or comply with CPAP[23]; (2) patients who have undergone surgery to remove throat tissue which hasn't resolved the OSA; (3) those who need a temporary alternative to CPAP. Exhibit 9 shows the difference in the two types of equipment – clearly, OAT is significantly less cumbersome.

As discussed above, although studies have consistently supported CPAP's superior *efficacy* on objective polysomnographic parameters, poor compliance remains a major challenge for long-term CPAP use in real-world settings. Despite advances in nasal mask technology, difficulties may stem from physical or psychological discomfort and/or lifestyle or social considerations. This strongly affects the *effectiveness* of CPAP treatment in many cases and means that a significant number of OSA patients are not getting any treatment for their condition. Sutherland et al (2015) state that, probably due to this lower CPAP compliance, 'the superiority of CPAP in terms of efficacy is generally not carried through to actual health outcomes of treatment'. In fact, 46–83% of CPAP patients are reported to be non-adherent, when 'adherent' is defined as greater than 4 hours of nightly use.

Common CPAP-related problems, which can lead to low compliance or CPAP refusal, include

- **discomfort:** intolerance of CPAP pressure/interface, discomfort due to limitations on sleep position
- **physical symptoms:** nasal problems (eg dry nose, nasal congestion, post-nasal drip), dry mouth
- **psychological symptoms:** claustrophobia during CPAP usage, difficulty falling asleep
- **unintentional removal** of CPAP during sleep.

For these patients, OAT can make the difference between having OSA treated or untreated.

Exhibit 9 – CPAP device (left) vs. OAT device (right): CPAP is significantly more cumbersome

Source: SomnoMed.

Various surgical procedures including UPPP are available to treat patients with mild OSA who have surgically correctible anatomical abnormalities contributing to upper airway collapse during sleep in one of three major regions of obstruction (nasal cavity, retropalatal and retro lingual). However, isolated nasal surgery has been found generally not to resolve OSA given other contributing factors. In addition, OSA patients typically have a higher risk of complications from surgery under general anaesthesia.

21 https://thorax.bmj.com/content/69/10/938

22 Factors influencing oral appliance adherence: A systematic review: Johal et al (2021)

23 How to treat patients that do not tolerate continuous positive airway pressure: Vanderveken and Hoekema (2010)

Digital Strategy – Rest Assure® Realigns Patient Pathway, Transforms Business Model and Builds Brand Equity

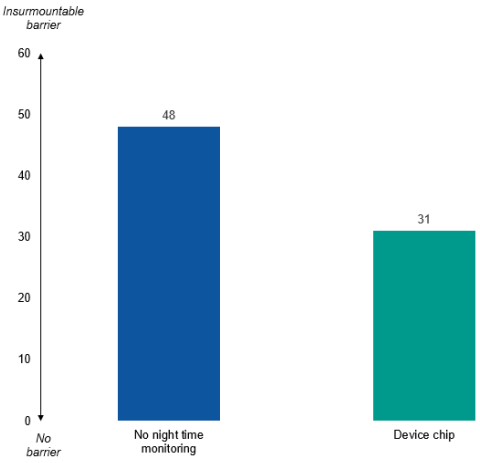
Data validates 'effectiveness equation' for physicians and supports a multi-disciplinary approach with dentists

Lack of objective, personalised OAT monitoring has hurt the category to date. Rest Assure® delivers in-built technology that allows the personalised and objective overnight monitoring of OAT that has been lacking in the category. The lack of this monitoring up to now has resulted in:

- lower acceptance and adoption of COAT™
- lower reimbursement for COAT™ over a 5-year period
- lower utilisation of COAT™ to treat OSA in first-line settings.

Exhibit 10 highlights previous shortcomings of the SomnoMed range according to US sleep physician surveys. Notably, these findings suggest around a third of sleep physicians surveyed would consider prescribing OAT if an overnight monitoring solution was available.

Exhibit 10 – US sleep physician research – barriers to COAT™ prescription (100 = insurmountable barrier)



Source: Survey conducted by MedSurvey, Nov 2019; commissioned and paid for by SomnoMed.

Rest Assure® delivers objective data-driven OAT to clinicians and paves the way for a cloud-connected multi-disciplinary approach with dentists. The ability of SomnoMed's new technology to analyse, store and access patient data from the cloud facilitates adoption by sleep physicians and builds confidence in the use of the technology as a first-line therapy in mild to moderate OSA alongside CPAP, addressing a major weakness in the current patient pathway and raising the prospect of monetising data through a future SaaS model.

Exhibit 11 – Rest Assure® and CPAP go head-to-head

	Usage	Efficacy	Sleep Position Prone/Supine	Treatment Interruptions	Respiratory Rate
CPAP 	Time the device is connected to patient (software algorithm detects breathing)	Surrogate AHI from ventilation, validated by comparing to diagnostic sleep test	Not specified	Mask removal	Breathing algorithm
Rest Assure® 	Remove from dock, temperature sensor detects device in mouth, other sensors activated	Surrogate AHI validated by comparing to diagnostic sleep test (Validation study in progress)	Determined by sensors in device	Patient moving into a vertical position (sitting or standing up), removing the device from mouth	Jaw movement algorithm

Source: SomnoMed.

New technology adds scientific rigour to objective measures of compliance and efficacy. The current multidisciplinary approach to managing SDB with oral appliances relies heavily on the dentist to custom

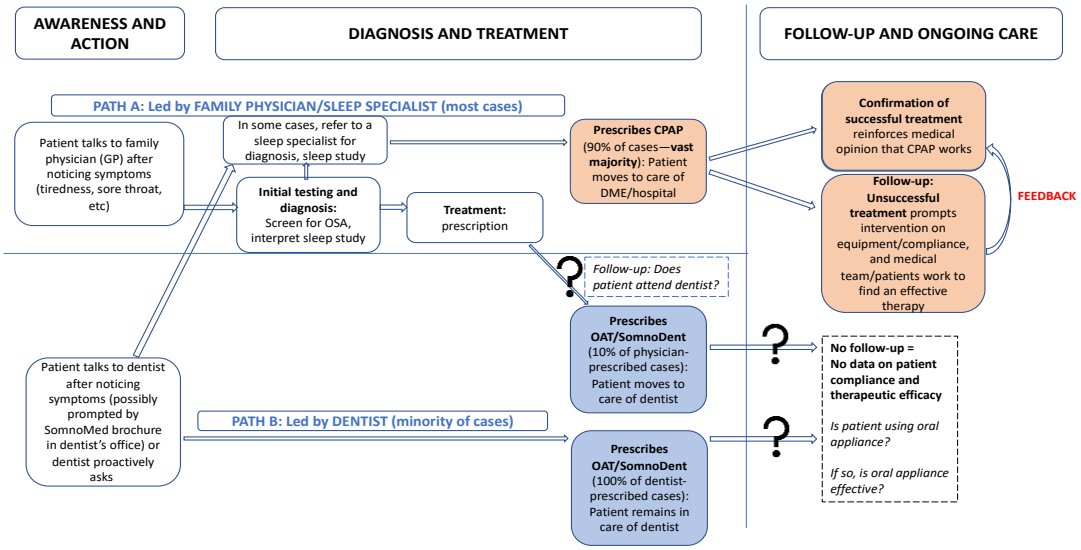
make and titrate (calibrate and fit) the device, as well as to maintain compliance. Adding rigour to measures of compliance and efficacy should increase the clinical utility of OAT and the confidence amongst sleep physicians to prescribe this treatment as a first-line therapy.

The new model: plugging the leaks to attract and retain many more patients to OAT

Potential OAT patients 'leak' from the system in several places in the current pathway (see Exhibit 12).

- The vast majority of OSA patients are immediately prescribed the default therapy, CPAP, often without the potential benefits of OAT being considered. In some situations, a family physician may have low awareness of the OAT option. CPAP failures are rarely treated with OAT.
- As patients are unaware of OAT as an option, they may not ask for it.
- If a patient is referred to a dentist to explore OAT, there is no link between the referring doctor and the dentist, and thus no confirmation that the patient attended the dentist appointment.
- At this point, the dentist 'owns' the patient relationship and has a full choice of OAT brands.
- If a dentist does prescribe OAT, there is almost no ongoing treatment monitoring (and no ongoing payment for doing so). Furthermore, no information is provided to healthcare providers or health insurers about treatment success or failure, and all parties (including the patient) do not have data on efficacy or compliance. This contrasts with CPAP monitoring, which is reimbursed in the US.

Exhibit 12 – Current patient pathway



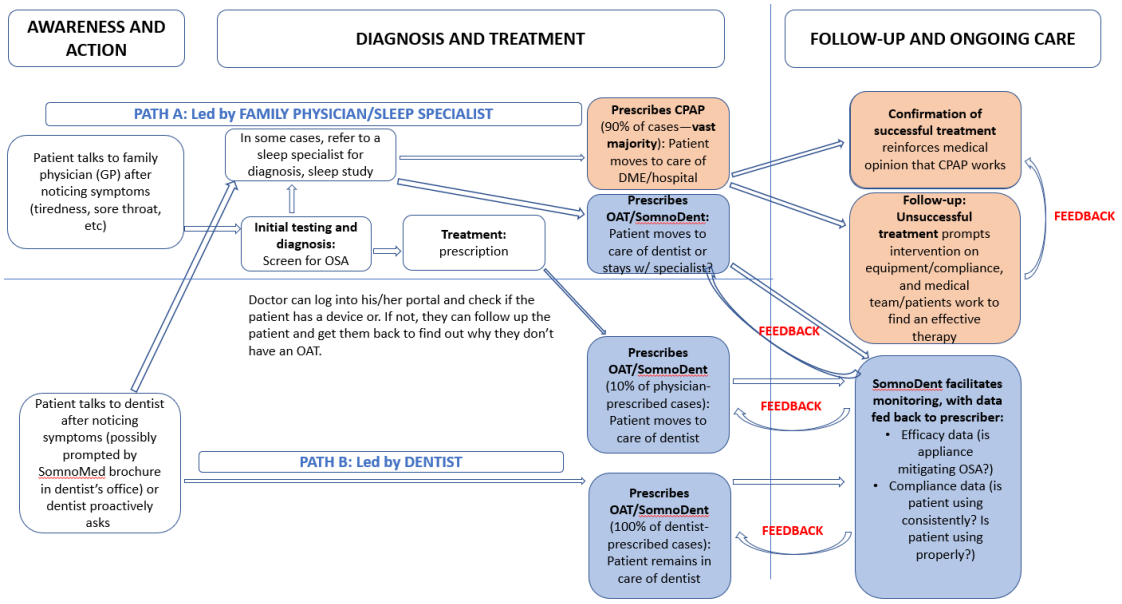
Source: SomnoMed.

SomnoMed aims to create a new model that plugs these leaks (see Exhibit 13).

- SomnoMed's direct-to-patient (DTP) interface encourages patients to screen for OSA on the company's website, using increased awareness and engagement to drive action.
- The SomnoMed ecosystem also allows patients to be screened by a GP, sleep physician (SP), pharmacist, or dentist, in person or via telemedicine. This allows SomnoMed to 'own' the patient flow. This also facilitates much better integration with the primary care physician.
- Rest Assure® provides efficacy and compliance information to the patient, dentist, insurance company and SP with ongoing monitoring and assistance, supporting longer-term therapy.
- The healthcare provider receives payment for monitoring patient through reimbursement.
- The cost is lower: the cost per patient is 2-10x more for CPAP than OAT globally.
- SomnoMed will position Rest Assure® as the go-to brand, with 100% of CPAP failures to be treated with COAT™.

Reimbursement impact of new model. Currently reimbursement for OAT varies by country (SOM is in 28 countries), with Northern Europe providing the most given its socialist healthcare models. Creating objective health economic metrics provides a compelling argument to payors in other geographies, such as Medicare and insurers in the US, for reimbursement of OSA in first-line settings.

Exhibit 13 – SomnoMed's proposed model – plugging the leaks to attract and retain OAT patients



Source: SomnoMed.

Algorithm validation/usability study read out expected in 2HFY22

Findings from a 31-patient algorithm validation trial are expected in 2HFY22. If positive, these should provide clinical validation of the algorithm used in Rest Assure™. The study, completed in October 2021, compared the Rest Assure® algorithm with output from the NOX sleep test[24]. Its secondary aim is to confirm ease of use, comfort, and preference vs. the current COAT™ device.

Details of the study:

- 30 different patients currently using SOM device (~480 hours of sleep)
- Rest Assure® algorithms compared with output from NOX sleep test
- Currently underway, conducted by Prof. Peter Cistulli (University of Sydney – Faculty of Medicine)
- Confirm ease of use, comfort, and preference vs. current COAT™ device
- Study to be presented at World Sleep Meeting, Rome, March 11–16, 2022
- Study results will be included in CE and FDA regulatory submissions

Intellectual Property and History of Technological Development

Exhibit 14 – SomnoMed granted patents

Reference	Description	Filing Date	Expiry Date
US D718449 S1	Set of oral appliances	23-Nov-11	25-Nov-28
US D718448 S1	Set of oral appliances	23-Nov-11	25-Nov-28
US D725783	A rail for adjustable anchoring of dental appliances	01-Oct-13	31-Mar-29
002317792-0001	A rail for adjustable anchoring of dental appliances	30-Sep-13	30-Sep-38
002491266-0001	An adjustable anchor for dental appliances	26-Jun-14	26-Jun-39
002491266-0002	An adjustable anchor for dental appliances	26-Jun-14	26-Jun-39
D738511 S	An adjustable anchor for dental appliances	16-May-14	16-May-39
PCT/DE2012/000314	Fusion HOF1	26-Mar-12	26-Mar-32

Source: SomnoMed.

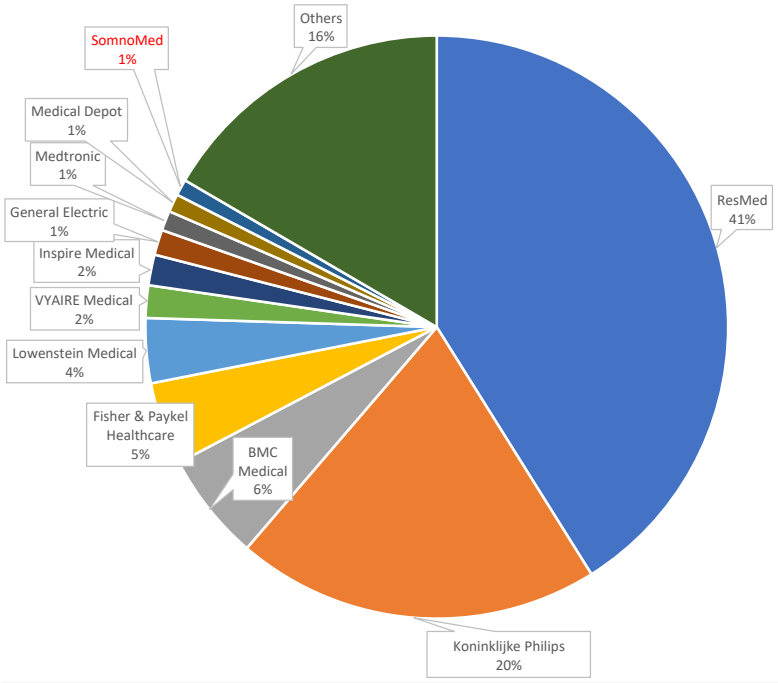
[24] The Nox Sleep Test is a Type II, portable Home Sleep Test and a standard diagnostic test in sleep medicine.

Competitive Landscape[25] – CPAP (90%) vs Oral Appliances (10%)

The global competitive landscape for sleep apnea devices and platforms is highly concentrated and dominated by three major medical device manufacturers: ResMed, Koninklijke Philips N.V., and Fisher and Paykel Healthcare Limited, reflecting the heavy use of CPAP treatment as first-line therapy for most newly diagnosed cases of OSA. These three companies hold approximately 41%, 20%, and 5% of the overall market respectively (BIS Research). SomnoMed has 0.86% of the global OSA market.

Notwithstanding the emergence of novel therapeutics and new entrants[26], oral appliances as a segment represent around 10% of non-invasive treatment modalities.

Exhibit 15 – Global sleep apnea devices and platforms market (2019), valued at US$7b in FY2021



Source: BIS Research. Note: Numbers are rounded to closest whole percentage point.

Mandibular Advancement Device Market – Forecast CAGR of 10% to 2030

SomnoMed is the global leader with around 39% of the oral appliance segment based on FY19 total revenue of A$59m. Other companies in the oral appliance segment, all with lower market shares than SomnoMed's, include Airway Management, Braebon Medical Corporation, Dental Arts Laboratories, Inc., Glidewell, ProSomnus Sleep Technologies, and Oventus. The segment is forecast to see a CAGR of 10% in 2021–2030, growing from US$152m to US$360m in the period (BIS Research estimates).

Exhibit 16 – Direct oral appliance competitors

Mandibular Advancement Device Companies	Global market share
Braebon Medical Corporation	0.11%
Glidewell	0.86%
SomnoMed	0.86%
ProSomnus Sleep Technologies	n/a
Dental Arts Laboratories, Inc.	n/a
Oventus	n/a

Source: BIS Research.

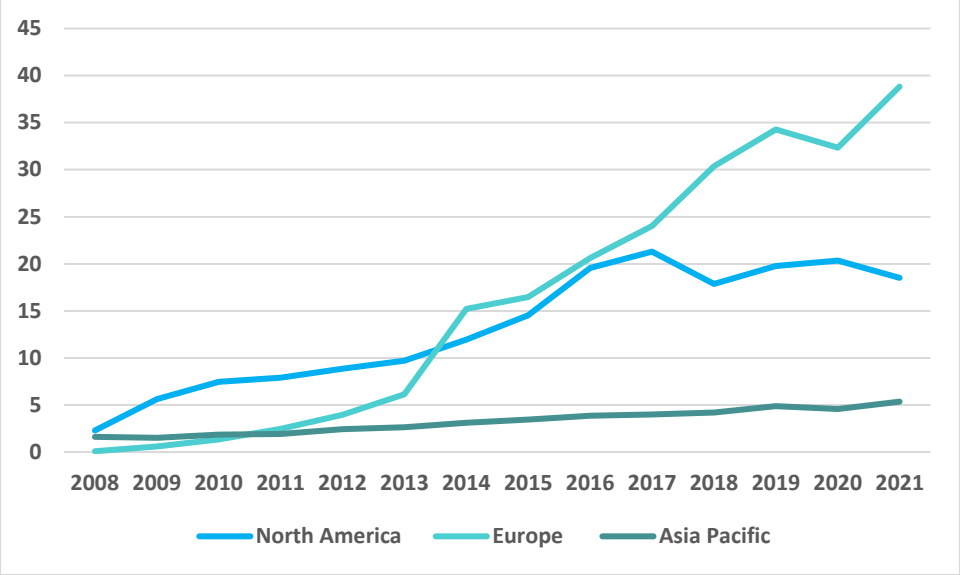
[25] Surgery accounts for around 1% of the total sleep apnea market and is not considered explicitly here.

Financials – Investing in Technology

SomnoMed listed in 2004, with a focus on further developing its proprietary technology in oral appliances for the treatment of sleep disordered breathing, specifically OSA. It has subsequently achieved a global corporatised leadership position in a market segment which still is to a large extent a cottage industry. SomnoMed's global strategy underpinned rapid international expansion commencing in the mid-2000s with the US market, resulting in cumulative unit sales across 28 countries of 675,000 as at end-December 2021.

The company segments its reporting across the three broad geographies of North America, Europe, and Asia Pacific, which in FY21 comprised 30%, 62% and 9% respectively of group revenues. Organic growth at a country level has been largely driven by levels of reimbursement. This has seen growth in revenues vary across the three geographies with 10-year CAGRs to FY21 for North America of 9%, Europe 32%, and Asia Pacific 11%. On a consolidated basis, this equates to a 10-year revenue CAGR to FY21 of ~18%. Europe is the most important contributor to group revenues driven largely by the reimbursement status of OAT (device and dental component) in the key markets of Germany, Holland, Norway, Belgium, France, Switzerland, and Sweden where share of the OSA market by oral appliances rivals that of CPAP for mild to moderate cases.

Exhibit 17 – Growth of SomnoMed's global business by revenue ($m)



Source: Company reports, MST Access.

1H22 results – Mixed globally given the impact of Omicron wave; North America a highlight: SomnoMed reported 1H22 results on 22 February 2022 with revenues of $33.9m, up 10% on the previous corresponding period (pcp). This was driven by improving global business conditions, mainly in North American markets where the company increased revenue by 25% over the pcp driven by positive insurance benefits. In contrast, the recent wave of Omicron weighed on Europe and APAC performances, with year-on-year regional sales increasing 5% and decreasing 2%, respectively.

Gross margin for the group in 1H22 was 62%, compared with 59% in 1H21, continuing the upward trend of recent years supported by digital manufacturing efficiencies. Adjusted EBITDA for 1H22 was $0.2m, compared with $3.2m in 1H21, reflecting the significant investment into various growth initiatives during the period. This included development of in-device technology, expansion of marketing and sales force networks and an associated increase in medically targeted advertisement and marketing communication contributing to net cash outflow of $3.7m. Total investment in technology in 1H22 was $3m.

Strong balance sheet: The company's balance sheet remains strong with net cash of $17.6m as of 31 December 2021 and undrawn debt facilities of $5m.

Full-year guidance: Management provided the following full-year guidance which is incorporated into our forecasts: revenue growth of at least 15%; EBITDA breaking even; and cash investment in technology of $8m.

Valuation:
Rest Assure® Paves the Way to Recurring Revenues in a SaaS Model

We think the integration of Rest Assure® technology to the SomnoDent product range radically changes the company's medical and economic value proposition given the benefits of increased connectivity across multiple stakeholders in the treatment of OSA and the prospect of improving patient adherence and therefore efficacy. These include physicians, dentists, payors, and patients. We see this change as valuable to stakeholders and an attractive opportunity for SomnoMed to generate recurring revenues under a future SaaS model.

Base case valuation of $3.20 includes Rest Assure® but excludes SaaS revenue potential

We value SomnoMed at $268.m, or $3.20 per share (undiluted), or $3.05 (fully diluted given outstanding options of 4.198m) using DCF methodology. Key assumptions of our base case include:

- FDA clearance Rest Assure® risk adjusted using a probability of 70%
- Rest Assure® launch in 1HCY23
- No currency impacts

Bull case valuation of $5.84 includes SaaS revenues (risk adjusted at 50%)

Our bull case has SomnoMed valued at 490.5m, or $5.84 per share (undiluted), or $5.56 (fully diluted given outstanding options of 4.198m) using DCF methodology. Key assumptions of our bull case include:

- Rest Assure® data to be monetised under SaaS model risk adjusted using a probability of 50%
- SaaS to be introduced in 2HCY23
- Annual SaaS revenues of $240 per device achieved based on $20 per month.
- No currency impacts

Exhibit 18 – Base-case DCF valuation and key metrics

		Jun-21 2021	Jun-22 2022	Jun-23 2023	Jun-24 2024	Jun-25 2025	Jun-26 2026	Jun-27 202
EBIT	A$m	0.0	(3.2)	2.5	5.1	8.5	12.1	16.5
Tax at standard rate	A$m		0%	0%	0%	0%	0%	0%
Post-tax EBIT	A$m	**0.0**	**(3.2)**	**2.5**	**5.1**	**8.5**	**12.1**	**16.5**
Depreciation & Amortization	A$m	3.8	3.6	5.2	5.0	4.9	4.8	4.7
Post-tax cash flow	A$m	**3.9**	**0.4**	**7.7**	**10.1**	**13.4**	**16.8**	**21.2**
Less capex	A$m	(4.1)	(8.0)	(4.0)	(4.0)	(4.0)	(4.0)	(4.0
Less change in working capital	A$m	0.1	(0.3)	(0.9)	(1.1)	(1.5)	(1.6)	(2.1
Free cash flow	A$m	**(0.2)**	**(7.9)**	**2.8**	**5.0**	**7.9**	**11.2**	**15.2**
Discount coefficient	years		0.4	1.4	2.4	3.4	4.4	5.4
Discounted cash flow	A$m		**(7.6)**	**2.4**	**4.0**	**5.7**	**7.4**	**9.0**
Sum of discount streams	A$m	65.3						
Terminal growth	%	2.0%						
Future value into perpetuity	A$m	443.9						
NPV of terminal value	A$m	184.6						
PV of cash flows	A$m	249.9						
PLUS: Value of investments	A$m	-						
LESS: Net debt	A$m	(18.8)						
Equity value	**A$m**	**268.7**						
Ordinary shares	m	84.0						
Value per share	**A$**	**3.20**						

Source: MST Access.

Exhibit 19 below contains our key DCF assumptions used in both our base and bull case scenarios.

Exhibit 19 – Key DCF assumptions

Risk free rate	%	5.00%
Equity beta	x	1.41
Equity risk premium	%	6.00%
Cost of equity	%	13.5%
Debt	%	31%
Equity	%	69%
Interest rate	%	3.0%
Tax rate	%	30%
WACC	%	10.0%

Source: MST Access.

Sensitivity analysis

In our view, Rest Assure® will be a game changer for the company and the industry in a highly underpenetrated market. However, the uncertain nature around the extent of change makes our assumptions on discount and terminal growth rates difficult to quantify definitively. As such, we provide a sensitivity matrix (see Exhibit 20) to highlight the impact of discount rate and terminal growth rate assumptions to our base-case valuation.

Exhibit 20 – Sensitivity impact of terminal growth rate and discount rate assumptions on our SomnoMed valuation

Terminal growth rate \ WACC	3.200	7.0%	8.0%	9.0%	10.0%	11.0%	12.0%	13.0%
0%		4.24	3.60	3.10	2.72	2.40	2.15	1.94
1%		4.79	3.98	3.38	2.93	2.56	2.27	2.04
2%		5.57	4.50	3.74	3.20	2.76	2.42	2.15
3%		6.73	5.22	4.23	3.54	3.00	2.61	2.29
4%		8.67	6.31	4.90	3.99	3.32	2.84	2.46
5%		12.55	8.12	5.91	4.63	3.74	3.13	2.68

Source: MST Access.

Sensitivities and Key Risks

SomnoMed will launch its new technological platform Rest Assure®, pending FDA approval, from a unique position of strength. With products available in 28 countries and partial/full reimbursement established in many of these, the company is well positioned to both enhance its leadership position and redefine industry standards. Nonetheless, investors should remain mindful of several company-specific risks which could impact our forecasts and valuation.

Development and Regulatory Approval Risk Associated with Rest Assure®

Sensor technology has advanced significantly in recent years with the proliferation of smart devices and wearables. Nonetheless, this is a novel application for oral appliances which does involve development risk and the need for associated regulatory approval to allow commercialisation. These include exceeding the estimated or budgeted costs of development and unexpected delays in development timelines.

Adoption by Sleep Physicians as First-line Therapy

Confidence by sleep physicians to include oral appliances in first-line therapy for mild to moderate cases will depend on clinical validation and experience with the product, which will take robust data and time to build. Notwithstanding the global acceptance of CPAP therapy in first-line treatment, the evolution of OAT for sleep apnea now spans several decades and has been largely driven by innovation at the level of dentists across the globe. This has led to the proliferation of oral appliance designs and inconsistent outcomes which has historically undermined confidence in the category to sleep physicians. We expect the enhancement of SomnoMed's technology with real-time analytics will enhance differentiation of the product.

Pricing – Limited Control Over Pricing to End Patients in the US Market

Related to competitive forces, and because of the cottage industry history of oral appliances and the role of dentists in their development and distribution, pricing has not been consistent across all markets. This inconsistent pricing has distorted the cost–value proposition in some markets and made OAT more expensive appear less competitive compared with CPAP for mild to moderate cases of OSA.

Reimbursement

Reimbursement for both sleep testing and oral appliances is a key driver of demand; however, this varies from country to country. For example, full reimbursement is in place in many Scandinavian countries as compared to partial reimbursement in Mediterranean and Asian countries, including Australia.

Product Liability

SomnoMed could be exposed to product liability claims or other lawsuits resulting from inappropriate medical treatment and/or serious side effects or harm being caused to a patient. However, the company has to date never been subject to such action despite treating over 600,000 patients.

Foreign Exchange Risk

All SomnoMed's production and over 92% of its sales and revenues take place outside Australia. Although the company does not actively hedge its currency exposure, it benefits from a natural hedge, given the number of countries and local currencies in which it operates. However, this does not eliminate foreign exchange risk completely.

Board and Management

Directors

Guy Russo, Chairman. Mr Russo has a strong commercial and customer-focussed background in Australia and internationally. In addition to his role as Chairman of SomnoMed, he is Chairman of Guzman y Gomez Mexican Kitchen (GYG), Australia's fastest-growing restaurant business. He is a Non-executive Director of Scentre Group (ASX: SCG), which owns and operates Westfield Living Centres in Australia and New Zealand, and is Chairman of OneSky, an international charity for children living in poverty in Asia. Mr Russo also previously led the Wesfarmers Department Store Division, a role in which he helped turn Kmart into the country's largest and most profitable retail department store. He has been a member of YPO (www.ypo.org) since 2006, has served as a member of the Business Council of Australia, and has won industry awards for leadership in diversity in employment.

Neil Verdal-Austin, CEO and Managing Director. Mr Verdal-Austin has served as the company's CEO since November 2018. His experience includes previous roles in medical device companies in South Africa, the UK and Australia spanning over 25 years. He has held various roles in SomnoMed throughout the company's businesses in Europe, the US and Asia-Pacific.

Amrita Blickstead, Non-Executive Director. Ms Blickstead is the Chief Operating & Marketing Officer at eBay Australia and New Zealand as well as a member of the Executive Leadership Team, a role in which she leads Strategy, Operations, Marketing, Buyer Loyalty, Advertising, Monetisation & Consumer Selling. Her nearly 10 years at eBay has given Ms Blickstead deep e-commerce experience covering multiple roles including leading Small & Medium Business, Shipping, and Cross Border Trade. Ms Blickstead was previously a management consultant with Port Jackson Partners and has had roles in the medical device and pharmaceuticals industries. She won the *Australian Financial Review* BOSS Awards for Young Executive of the Year in 2019.

Hilton Brett, Non-Executive Director. Mr Brett is an Operating Advisor at TDM Growth Partners (TDM), a private global investment firm founded in 2004 with offices in Sydney and New York. He is a Non-Executive Director of Guzman y Gomez (GYG) and Pacific Smiles Ltd (PSQ: ASX). Prior to joining TDM, Mr Brett was the co-CEO of Accent Group Limited (AX1), formerly RCG Corporation Ltd, the regional leader in the retail and distribution of performance and lifestyle footwear in Australia and New Zealand. Mr Brett has over 25 years' experience as CEO of multiple consumer businesses with proven skills in growing the businesses and delivering strong returns for shareholders.

Hamish Corlett, Non-Executive Director. Mr Corlett is a founder and director of TDM Growth Partners. TDM made its first investment in SomnoMed in 2010 and has been a substantial shareholder since 2012. Prior to TDM, Mr Corlett worked as an Investment Manager at global fund manager Caledonia Investments. He also worked in London in an operating role for an e-commerce start-up and in Sydney at Caliburn Partnership (now Greenhill) in corporate advisory. He is a Non-Executive Director of Tyro Payments Ltd (ASX: TYR) and QBiotics Group Limited.

Michael Gordon, Non-Executive Director. Mr Gordon was most recently the CFO of Rokt, a high-growth marketing technology company with more than US$200m in revenue, more than 300 employees, and offices in Sydney, New York, Tokyo, Singapore and Auckland. He remains as an advisor to Rokt. Mr Gordon was previously the Group CFO and MD of Group Services for Greenlit Brands Pty Limited. Prior to Greenlit Brands, Mr Gordon spent ten years with PricewaterhouseCoopers in South Africa, the UK and Australia specialising in the retail industry with experience in audit, taxation M&A and IPOs.

Karen Borg, Non-Executive Director. Ms Borg has held senior roles in FTSE 100–250 medical device, technology, consumer products and government services organisations. She is currently CEO of Catholic Healthcare Ltd and prior to this was the CEO of Healthdirect and the inaugural CEO of Jobs for NSW. She has also served as President (Asia Pacific & Middle East) of ResMed (ASX: RMD) and held several senior roles with Johnson & Johnson Medical Devices in Australia and the US. Ms Borg is on the Board of Optiscan Ltd (ASX: OIL) and was previously on the Board of The North Foundation and Interim Chair of the Australian Vaccine Research Alliance. She was a NSW finalist for Telstra Business Woman of the Year 2017.

Key Management

Neil Verdal-Austin, CEO and Managing Director (see profile above in Board section).

Hervé Fievet, Chief Financial Officer. Mr Fievet's international experience includes complex strategic projects involving finance, IT, HR, customer service, manufacturing, and the supply chain. Mr Fievet has broad industry experience spanning medical, pharmaceutical, cosmetics, manufacturing, automotive, as well as social media, commercialisation, IT and legal services. Previous roles have included management of large teams both globally as with SOGEFI Group and in Australia as with Fabre Australia.

Mark Harding, SVP, Global Marketing. Mr Harding is an accomplished Medical Device executive, with 30 years of experience in sales, product development, reimbursement, and marketing. Previously, he worked with Baxter Healthcare in a local marketing role, with ZimmerBiomet in Australia and Asia based marketing roles, and with AtCor Medical in both global marketing and Europe/Asia sales roles. Before joining SomnoMed in 2019, Mr Harding was a consultant working in medical device reimbursement. He was promoted to his current position, SVP Global Marketing/R&D, in January 2021.

Mathew Conlon, EVP, Sales & Marketing – North America. Mr Conlon has been in the medical devices business for 30+ years, 16 of which were spent in commercial leadership roles at Respironics, Inc (prior to its acquisition by Philips). At Respironics, Mr Conlon helped to introduce and establish non-invasive ventilation as a new standard of care in the acute care setting; to grow the OSA diagnostic and PAP treatment market through DME channels; and to expand asthma and allergy solutions into retail channels. Mr Conlon led the successful reorganisation of SomnoMed's North American business unit and now is building and leading a commercial team to drive awareness and adoption of OAT in the medical community through strong collaboration with the company's network of sleep dentists.

Marco van Kleef, VP Sales & Marketing – Europe. After working for a small medical wholesaler during the 1990s, Mr van Kleef joined Tyco Healthcare (Covidien) in 2001 in a hospital and home care medical device sales role. He assumed national and international responsibility for respiratory home care products (oxygen therapy and CPAP devices). Following the divestiture of Puritan & Bennett home care products, he led different sales & marketing teams in key European countries in the critical care area (ICU and anaesthetics). After Medtronic acquired Covidien in 2015, he worked as EU Marketing Director, Business Leader for the Restorative Therapies Group (Spine, Neuromodulation, ENT) in the Netherlands, then led a large cluster of countries in patient monitoring and respiratory interventions, before joining SomnoMed in November 2021.

Paul Cottee, VP – APAC. Mr Cottee joined SomnoMed in April 2018 and is a marketing and sales leader with more than 20 years of medical device experience. He has previously had roles at Zimmer Biomet, Kimberley Clark, Becton Dickinson and Johnson & Johnson. Mr Cottee has a proven history of successfully managing complex businesses in both small and large multi-national organisations. He has held roles of increasing responsibility across the Asia-Pacific region that have provided him with exposure to a wide range of global commercial experiences.

Christopher Bedford, VP, Research & Development. Mr Bedford has worked within the healthcare industry and dental technology field for more than 25 years. Educated in dental technology in Sydney, he joined SomnoMed as a founding employee, and has built its global production and manufacturing platform to establish the company as the market leader in quality, reliability and innovation. Serving as a senior executive on the corporate team, Mr Bedford's responsibilities span global production and technology, innovation and new product development, regulatory, quality and clinical research. He continues to work closely with regional partners globally to develop the business and educate and train partners throughout the treatment pathway on new products and related research and help develop new business. He is also the inventor of numerous published and pending patents in the biomedical space.

Appendix 1 – Shareholder Register and Institutional Support

Exhibit 21 –Top 20 shareholders (as at 27 August 2021)

Ordinary Shareholders	Number	Percentage
HSBC Custody Nominees (Australia) Limited	30,014,342	36.27%
National Nominees Limited	9,616,815	11.62%
Smartequity EIS Pty Ltd	4,666,768	5.64%
Dottie Investments Pty Ltd	3,650,487	4.41%
Citicorp Nominees Pty Limited	2,847,531	3.44%
Belgove Pty Ltd	2,553,265	3.09%
Howarth PAF Pty Ltd <The Howarth Foundation A/C>	2,156,722	2.61%
Ginga Pty Ltd	1,799,045	2.17%
BNP Paribas Nominees Pty Ltd <ACF Clearstream A/C>	1,301,292	1.57%
BNP Paribas Nominees Pty Ltd <IB AU Noms Retail Client DRP>	1,206,009	1.46%
P Neustadt Holdings Pty Ltd <Belgove Super Fund A/C>	1,082,171	1.31%
Timbina Pty Ltd <Timbina Super Fund A/C>	1,073,764	1.30%
Sandhurst Trustees Ltd <Endeavour Asset Mgmt MDA A/C>	942,419	1.14%
REM Medical Pty Ltd <Cocoon Super Fund A/C>	800,641	0.97%
Golden Words Pty Ltd	775,399	0.94%
Thirty Sixth Vilmar Pty Ltd	561,148	0.68%
J P Morgan Nominees Australian Pty Limited	546,841	0.66%
Mr Edward Palmisano	534,631	0.65%
The Mulloon Institute Ltd	533,048	0.64%
Howarth PAF Pty Ltd <Howarth Charitable Fund A/C>	523,771	0.63%
TOTAL	**67,186,109**	**81.18%**

Source: SomnoMed.

Appendix 2 – Global Sleep Apnea Market Overview

Exhibit 22 – Global emerging sleep apnea devices and platforms market (by product type)

Therapeutic

Positive Airway Pressure Devices

Continuous Positive Airway Pressure (CPAP) Devices

Bilevel Positive Airway Pressure (BPAP) Devices

Facial Interfaces

Full Face Masks

Nasal Masks

Nasal Pillow Masks

Oral Appliances

Mandibular Advancement Devices

Tongue Retainers

Emerging Therapeutic Devices

Neurostimulator

Wearables and Other Therapeutic Devices

Adaptive-Servo Ventilators*

primarily used for the treatment of central sleep apnea.

Diagnostic and Monitoring

Polysomnography Devices

Clinical Polysomnography Devices

Ambulatory Polysomnography Devices

Home Sleep Testing Devices

Pulse Oximeters

Actigraphy Devices

Sleep Screening and Monitoring Devices and Solutions

Emerging Sleep Screening and Monitoring Devices and Solutions

Source: BIS Research, MST Access.

Disclaimers

MST Access is a registered business name of MST Financial Services Pty Ltd (ACN 617 475 180 "MST Financial") which is a limited liability company incorporated in Australia on 10 April 2017 and holds an Australian Financial Services Licence (Number: 500 557). This research is issued in Australia through MST Access which is the research division of MST Financial. The research and any access to it, is intended only for "wholesale clients" within the meaning of the Corporations Act 2001 of Australia. Any advice given by MST Access is general advice only and does not take into account your personal circumstances, needs or objectives. You should, before acting on this advice, consider the appropriateness of the advice, having regard to your objectives, financial situation and needs. If our advice relates to the acquisition, or possible acquisition, of a financial product you should read any relevant Product Disclosure Statement or like instrument.

This report has been commissioned by SomnoMed Limited and prepared and issued by Chris Kallos of MST Access in consideration of a fee payable by SomnoMed Limited. MST Access receives fees from the company referred to in this document, for research services and other financial services or advice we may provide to that company. The analyst has received assistance from the company in preparing this document. The company has provided the analyst with communication with senior management and information on the company and industry. As part of due diligence, the analyst has independently and critically reviewed the assistance and information provided by the company to form the opinions expressed in the report. Diligent care has been taken by the analyst to maintain an honest and fair objectivity in writing this report and making the recommendation. Where MST Access has been commissioned to prepare content and receives fees for its preparation, please note that NO part of the fee, compensation or employee remuneration paid will either directly or indirectly impact the content provided.

Accuracy of content: All information used in the publication of this report has been compiled from publicly available sources that are believed to be reliable, however we do not guarantee the accuracy or completeness of this report and have not sought for this information to be independently verified. Opinions contained in this report represent those of MST Access at the time of publication. Forward-looking information or statements in this report contain information that is based on assumptions, forecasts of future results and estimates of amounts not yet determinable, and therefore involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of their subject matter to be materially different from current expectations.

Exclusion of liability: To the fullest extent allowed by law, MST Access shall not be liable for any direct, indirect or consequential losses, loss of profits, damages, costs or expenses incurred or suffered by you arising out or in connection with the access to, use of or reliance on any information contained in this report. No guarantees or warranties regarding accuracy, completeness or fitness for purpose are provided by MST Access, and under no circumstances will any of MST Financials' officers, representatives, associates or agents be liable for any loss or damage, whether direct, incidental or consequential, caused by reliance on or use of the content.

General Advice Warning

MST Access Research may not be construed as personal advice or recommendation. MST encourages investors to seek independent financial advice regarding the suitability of investments for their individual circumstances and recommends that investments be independently evaluated. Investments involve risks and the value of any investment or income may go down as well as up. Investors may not get back the full amount invested. Past performance is not indicative of future performance. Estimates of future performance are based on assumptions that may not be realised. If provided, and unless otherwise stated, the closing price provided is that of the primary exchange for the issuer's securities or investments. The information contained within MST Access Research is published solely for information purposes and is not a solicitation or offer to buy or sell any financial instrument or participate in any trading or investment strategy. Analysis contained within MST Access Research publications is based upon publicly available information and may include numerous assumptions. Investors should be aware that different assumptions can and do result in materially different results.

MST Access Research is distributed only as may be permitted by law. It is not intended for distribution or use by any person or entity located in a jurisdiction where distribution, publication, availability or use would be prohibited. MST makes no claim that MST Access Research content may be lawfully viewed or accessed outside of Australia. Access to MST Access Research content may not be legal for certain persons and in certain jurisdictions. If you access this service or content from outside of Australia, you are responsible for compliance with the laws of your jurisdiction and/or the jurisdiction of the third party receiving such content. MST Access Research is provided to our clients through our proprietary research portal and distributed electronically by MST to its MST Access clients. Some MST Access Research products may also be made available to its clients via third party vendors or distributed through alternative electronic means as a convenience. Such alternative distribution methods are at MST's discretion.

Access and Use

Any access to or use of MST Access Research is subject to the Terms and Conditions of MST Access Research. By accessing or using MST Access Research you hereby agree to be bound by our Terms and Conditions and hereby consent to MST collecting and using your personal data (including cookies) in accordance with our Privacy Policy (https://mstfinancial.com.au/privacy-policy/), including for the purpose of a) setting your preferences and b) collecting readership data so we may deliver an improved and personalised service to you. If you do not agree to our Terms and Conditions and/or if you do not wish to consent to MST's use of your personal data, please do not access this service.