



26 July 2023

Company meets topline revenue guidance

SomnoMed Limited (ASX “SOM”, or the Company), a leading company in the provision of oral appliance treatment solutions for sleep-related breathing disorders and obstructive sleep apnea (‘OSA’), is pleased to provide its quarterly activities report for the period ended 30 June 2023 (Q4 FY23).

Financial Highlights

- FY23 [unaudited] revenue of \$83.6 million, +15% (+12% in constant currency) versus pcp and in line with guidance
- Q4 FY23 [unaudited] revenue of \$23.5 million, +10% (+3% in constant currency) versus the previous corresponding period (pcp)
- FY23 EBITDA guidance of \$2 million+ remains
- SomnoMed’s cash balance of \$12.0 million as at 30 June 2023

Operational Highlights for the Quarter

- The design and development of Rest Assure® continued with the company completing all necessary validation and verification tests required for a 510k FDA regulatory filing in the United States
- The regulatory filings will now be submitted, and approval is expected to be received within 120 days. Once approval has been granted, commercialisation will begin in the United States
- Management continued to focus on ensuring technical teams are in place and ready to commercialise Rest Assure® once approvals are granted
- Appointment of Mr Darren Collins as CFO
- Total patients treated by SomnoMed worldwide now exceed 810,000

Commenting on the results, SomnoMed’s Managing Director, Mr Neil Verdal-Austin said: “SomnoMed continued to grow in the quarter, and it was rewarding to see the Company meet our topline revenue guidance of 15%, albeit at the lower end for the financial year. However, the quarter’s results were disappointing, with lower-than-expected revenues across all regions. The impact of the changing Medicare reimbursement rules and coding structures for oral appliances in North America is now being felt across the industry. As our flagship product remains non-reimbursable under these rules, sales within this category underperformed in the quarter.”

“We have already submitted a new application for the full reimbursement coding for the SomnoDent Avant® while also challenging the outdated criteria used by the Centers for Medicare Services (CMS) contractor group Pricing, Data Analysis, and Coding (PDAC),” continued Mr Verdal-Austin.

“Europe’s lower than expected results were driven by revenue downturns in two core markets, with direct and specific actions now taken to correct this. APAC’s revenues, derived mainly from Australia, have slowed primarily due to lower patient volumes as the economy tightens with no reimbursement for oral appliance treatment available in that market.”

“Meanwhile, the development of SomnoMed’s Rest Assure® technology reached a critical point during the quarter. The validation and verification tests are now complete and making up part of the Design History File (“DHF”), which is needed as part of the documentation for the 510k FDA regulatory filings in the United States. We will be ready to commercialise the technology in the United States once these approvals are received.”

Financial Review

Full year FY23 revenue of \$83.6 million, +15% (+12% in constant currency) versus pcp, was in-line with guidance.

Revenue (A\$000’s)	12 months to 30 June 2023	12 months to 30 June 2022	% Change	% Change
	(A\$000’s)	(A\$000’s)	Actual	Constant Currency
North America	30,165	24,688	+22.2%	+13.4%
Europe	47,332	42,214	+12.1%	+11.8%
APAC	6,119	5,427	+12.8%	+13.5%
Total regional revenue	83,616	72,329	+15.6%	+12.5%
HIC ¹	-	251	NA	NA
Total group revenue	83,616	72,580	+15.2%	+12.1%

Quarterly revenue of \$23.5 million for Q4 FY23, +10% (+3% in constant currency) versus pcp, reflects the challenges described.

Revenue (A\$000’s)	Q4 FY23	Q4 FY22	% Change	% Change
	(A\$000’s)	(A\$000’s)	Actual	Constant Currency
North America	8,074	7,057	+14.4%	+6.7%
Europe	13,857	12,558	+10.3%	+2.5%
APAC	1,547	1,436	+7.7%	+7.9%
Total regional revenue	23,477	21,051	+11.5%	+4.3%
HIC ¹	-	251	NA	NA
Total group revenue	23,477	21,303	+10.2%	+3.0%

Cash flow from operations in Q4 FY23 was positive \$2.5 million, while the ongoing investment in R&D and CAPEX amounted to \$1.7 million. FY23 CAPEX investment totalled \$6.4 million, including the technology innovation spend of \$3.1 million, was in line with guidance.

SomnoMed has a cash balance of \$12 million and drawn debt of \$17.6 million as at 30 June 2023.

¹ HIC (Health Care Companies) Revenue is associated with allowances received in the Netherlands in FY22 which compensated SOM for a portion of lost managed care income in country due to COVID-19

Operational Review

SomnoMed has retained its strong position in the OSA market and will increase its total addressable market by providing an alternative to the traditional default CPAP recommendations by most sleep physicians.

The business has maintained its focus on tight cost management to protect and grow SomnoMed's margins. SomnoMed has implemented significant cost control measures in the core business, including a headcount freeze in all regions. Employee numbers are expected to be stable into FY24. The exception will be necessary manufacturing, engineering and electronic skills needed in the Philippines to launch Rest Assure® once regulatory approvals are received.

With the preparation of the Rest Assure® DHF now completed, the Company's associated elevated investment technology development spend will reduce. This will result in an improved performance across a range of financial metrics as the technology is distributed into the market. It is expected that the first Rest Assure® commercial sales will take place in Q2 FY24 in Europe.

During Q4 FY23, SomnoMed attended and presented at the American Academy of Dental Sleep Medicine (AADSM) Conference in Philadelphia and the Associated Professional Sleep Societies (APSS) Conference in Indianapolis. SomnoMed received widespread validation of its connected technology pathway and was highlighted as a leader in the oral appliance field with a superior product range. Two significant partnerships were forged during the Conferences with two leading US based dental and digital platform solutions businesses, adding to SomnoMed's extensive network of providers.

North America

Q4 FY23 North American revenue rose 14% (7% in constant currency) versus pcp. Sales of the SomnoDent Avant® were heavily impacted by the lagged effect of changes made to PDAC reimbursement rules in the previous half year and the fact that the Company did not get full Medicare reimbursement coding approved for the SomnoDent Avant®. SomnoMed has included further detailed information in a new submission in the hope to achieve the full Medicare reimbursement.

SomnoMed remains confident that its competitive positioning in the North American market will continue to improve as the growing demand for COAT™ products remains positive and indicates patients and physicians are looking at COAT™ as an alternate treatment path for mild and moderate OSA patients.

Europe

While benefiting from positive reimbursement trends and a growing acceptance of the benefits of COAT™ technology for mild and moderate OSA patients, European sales were lower than expected in two core markets. As a result, European revenue rose 10% (3% in constant currency) versus pcp in Q4 FY23. Other standout performers continued across the region, with impressive growth rates from those with more recently approved oral appliance reimbursement schemes.

Asia Pacific

Asia Pacific quarterly revenues rose 8% (8% in constant currency) versus pcp in Q4 FY23. SomnoMed continued to focus on its clinical education program and investment in new sales and marketing resources to advance the adoption of oral appliances within the medical sector while facing the non-reimbursed challenges within a tightening economy.

Rest Assure® design, internal development and testing is now complete

The development process for Rest Assure® commenced in early 2020, with the aim of building a connected device providing nightly patient usage and treatment effectiveness data. The resulting Rest Assure® system includes a smart device with in-mouth sensors, cloud-based algorithms, the Rest Assure Healthcare Provider (HCP) portal for physicians and dentists to review patient data, and the Rest Assure® patient app.

The development of a first-in-class integrated hardware and software system of this nature is a monumental task for any healthcare company of our size. SomnoMed engaged Planet Innovation, a specialist medical device development company to provide support, with 40 specialist engineers and software developers supporting the project. To date, the Rest Assure project team has:

- Generated 240,000 individual documents that now define SomnoMed IP,
- Performed 300 different tests to confirm functionality, safety and durability of the Rest Assure® device and software
- Produced 335 test reports and supporting documents required by regulatory agencies

“I’m immensely proud of the Rest Assure® development team and what they have delivered over the last 3.5 years, and I want to thank everyone who has been involved in this milestone project,” noted Mr Neil Verdal-Austin. “With Rest Assure®, physicians and sleep dentists can work together to improve patient care using nightly data, and patients will be more involved in their treatment via the Rest Assure® App. Our physician and sleep dental customers continue to advise us that Rest Assure® will be a global game changer for oral appliance therapy.”

SomnoMed used the US FDA pre-submission process, which identified that 110 documents are required for the 510K submission. Except for one report from an external test house in the USA, these documents are complete, and the development of the 510k submission for Rest Assure® is underway by a specialist regulatory consultancy and is expected to be finalised during the August / September 2023 timeframe.

Commercialisation in the United States will commence once these approvals have been received. Due to the different regulatory classifications with Europe, first sales of Rest Assure® are expected during Q2 FY24.

Executive Management Changes

On 5 July, 2023 Mr Darren Collins was appointed SomnoMed CFO, effective 1 August 2023, replacing Mr Herve Fievet who had been in the role for more than 4 years. Mr Collins has extensive global financial market experience and a proven track record of driving transformational change and strategic growth.

Mr Collins has worked globally with both large (ASX listed) and smaller companies, including complex multinational organizations across diverse industries.

Quarterly payments to related parties and their entities

Cash outgoings for the quarter included payments of \$241,000 in relation to the Managing Director pursuant to his employment contract and the payment of non-executive directors’ fees.

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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 commercialised on the basis of extensive clinical research. Supporting independent clinical research, continuous innovation and instituting medical manufacturing standards has resulted in SomnoDent® becoming the state-of-the-art and clinically proven medical oral appliance therapy for more than 810 000 patients in 28 countries. For additional information, visit SomnoMed at <http://www.somnomed.com.au>