



The following updated Quarterly Activities Report includes details of “quarterly payments to related parties and their entities” as was disclosed in the Company’s Appendix 4C released on 30 January 2023.

1 February 2023



30 January 2023

## Second quarter revenue growth of 17% to \$21.4 million

**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 31 December 2022 (Q2 FY23).

### Financial Highlights

- Q2 FY23 revenue of \$21.4 million, +16.6% (+14.0% in constant currency) versus the previous corresponding period (pcp)
- Year-to-date revenue of \$40.0 million, +17.7% (+17.1% in constant currency) versus pcp
- North America experienced a challenging last month to the quarter, with increased competition and supply chain issues, including reduced availability of manufacturing and logistic staff
- Europe Q2 FY23 revenue of \$12.0 million, +17.7% (+19.8% in constant currency) versus pcp, was driven by robust growth in the Netherlands and Sweden
- SomnoMed’s FY23 revenue guidance has been revised to between 15-20% while the FY23 EBITDA guidance of \$2m+, remains unchanged
- SomnoMed’s cash balance was \$16.9 million as at 31 December 2022

### Operational Highlights

- Total patients treated worldwide now exceed 760,000
- The design and development of Rest Assure®, the Company’s first ever in-built technology-enabled oral appliance, continues with the majority of tests completed and documents prepared for regulatory submissions
- The Company continues to proactively deliver a range of initiatives to secure our supply chain, with the aim to limit any negative impact of inflation pressure on margins

**Commenting on the results, SomnoMed’s Managing Director, Mr Neil Verdal-Austin said:** “Revenue in the first half of \$40 million was up over 17% on the prior corresponding period, demonstrating continued strong growth in SomnoMed’s oral devices range. SomnoMed’s performance at the end of the December quarter, however, was impacted by increased competition and logistics difficulties across North America. The Company continued to focus on delivering strong financial growth, increasing the awareness of COAT™ for the treatment of OSA and developing our technology-enabled oral appliance Rest Assure®.”

“We continue to invest in the business, both in terms of new technology development and business operations, all aimed at ensuring that SomnoMed grows market share within the broader sleep apnea treatment market. Europe produced strong results this quarter, while our central manufacturing team made important advances in all digital processes and documentation in readiness for the Rest Assure® full commercial launch once approvals have been received.”

“Over the past several years we have continued to see ongoing demand for COAT™ devices in the treatment of obstructive sleep apnea. Although some supply chain issues still remain, we have also seen macro-economic pressures, staff shortages and lower-priced competitive products in the USA, begin to affect the business. As a consequence, the revenue guidance has been revised to between 15-20%, with no change to the EBITDA guidance of \$2m+.”

## Financial Review

Quarterly revenue of \$21.4 million for Q2 FY23, +16.6% (+14.0% in constant currency) versus pcp, reflects the lower contribution from North America. This was somewhat offset by a stronger quarter in Europe, with revenues in the Netherlands and Germany being particularly strong.

Revenue (A\$000's)	Q2 FY23	Q2 FY22	% Change	% Change
	(A\$000's)	(A\$000's)	Actual	Constant Currency
North America	7,888	6,762	+16.7%	+6.4%
Europe	11,956	10,156	+17.7%	+19.8%
APAC	1,554	1,435	+8.2%	+9.0%
<b>Total group revenue</b>	<b>21,398</b>	<b>18,354</b>	<b>+16.6%</b>	<b>+14.0%</b>

Year-to-date revenue of \$40.0 million, +17.7% (+17.1% in constant currency) on pcp, indicating a robust performance across all regions.

Revenue (A\$000's)	6 months to 31 Dec 2022	6 months to 31 Dec 2021	% Change	% Change
	(A\$000's)	(A\$000's)	Actual	Constant Currency
North America	15,233	11,867	+28.4%	+18.0%
Europe	21,636	19,464	+11.2%	+16.2%
APAC	3,082	2,602	+18.4%	+19.6%
<b>Total group revenue</b>	<b>39,951</b>	<b>33,933</b>	<b>+17.7%</b>	<b>+17.1%</b>

Cash flow from operations was a positive \$1.3 million, while the ongoing investment in R&D and CAPEX amounted to \$2.7 million during the quarter. The Company maintains the forecast for FY23 EBITDA of at least \$2 million with a CAPEX investment c.\$7 million, which includes the expected technology innovation spend of c.\$3 million.

SomnoMed remains well funded to execute on our growth priorities with a cash balance of \$16.9 million as at 31 December 2022, including \$6 million of the final debt funding drawn down during Q2 FY23.

## Operational Review

SomnoMed's position within the OSA market remains strong, with the potential to further increase the addressable market by providing an alternative to the traditional default CPAP recommendations by most sleep physicians.

SomnoMed remains “treatment focused” in its approach and provides a best in class, superior comfort, “fit right first time” and durable oral appliance for the treatment of OSA. The Company has continued to experience positive engagement within the medical sector, which is driving further acceptance of COAT™.

## North America

North America experienced a challenging end to Q2 FY23 with increased competition, somewhat exacerbated by rising inflation impacting some consumer spending. Early indications of this change in consumer spending and delaying non-critical medical treatments, should be temporary and directly linked to the general economic pressures felt in the region. The region was also impacted towards the end of the quarter by a range of supply chain issues temporarily opening the door to lower priced competitors, including logistic staff unavailability in the wake of the COVID-19 pandemic.

SomnoMed continues to monitor the competitive activity and is optimising its response, asserting the superior fit and long-term therapeutical benefits of its products, in order to increase sales and margins in the region.

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. We believe Rest Assure's® ability to address the lack of overnight monitoring and objective data in COAT™ will deliver better results to patients, while establishing a pathway towards prescription and reimbursement. This should dramatically improve the Company's competitive positioning in the North American market.

## Europe

Higher European revenue in Q2 FY23 was primarily driven by the strong performance from the Netherlands and Sweden. Overall, revenue for the quarter jumped +23.5% from Q1 FY23 (+16.4% in constant currency) and increased +17.7% (+19.8% in constant currency) on pcp. Patient demand for the Company's COAT™ technology remains strong across Europe driven by positive reimbursement trends and a growing acceptance of the benefits of COAT™ technology for mild and moderate OSA patients.

## Asia Pacific

Asia Pacific quarterly revenues rose +8.2% (+9.0% in constant currency) on pcp. While non-device revenues were impacted by a shortage of SOMTabs (SomnoMed's proprietary cleaning tablets) due to a global shortage of raw materials, 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.

## **Rest Assure®**

SomnoMed introduced Rest Assure®, its first ever in-built technology-enabled oral appliance, in February 2022. Rest Assure® aims to address the lack of overnight monitoring and objective data in COAT™, which has been a major barrier to prescription and reimbursement rates to date.

The Rest Assure® project team has completed the majority of tests and documentation required by regulatory authorities for commercial approval. A small number of validation and verification tests required by regulatory authorities remain outstanding, and these activities are now a priority for SomnoMed's R&D team to complete in Q3. Once this final testing and necessary documentation required for regulatory authorities is complete, submissions (where required) will be filed in Q3 FY23.

Rest Assure® will be commercialised once these approvals are received.

## **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.

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

**For further information please contact**

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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 760,000 patients in 28 countries. For additional information, visit SomnoMed at <http://www.somnomed.com.au>