



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 28 April 2023.

4 May 2023

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28th April 2023

Growth momentum maintained

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 March 2023 (Q3 FY23).

Financial Highlights

- Q3 FY23 revenue of \$20.2 million, +16.3% (+13.4% in constant currency) versus the previous corresponding period (pcp), driven by strong demand from North American and European markets
- Year-to-date revenue of \$60.1 million, +17.3% (+15.9% in constant currency) versus pcp
- SomnoMed’s FY23 revenue guidance remains unchanged at between 15-20%, while the FY23 EBITDA guidance of \$2m+, also remains unchanged
- SomnoMed’s cash balance was \$14.6 million as at 31 March 2023

Operational Highlights

- The design and development of Rest Assure[®], the Company’s first ever in-built technology-enabled oral appliance, continued during the quarter with the remaining validation and verification tests now completed
- Ongoing focus on addressing the key North American supply chain and delivery issues that impacted the previous quarter has resulted in customers returning to SomnoMed for the industry’s superior quality oral appliance range
- The Company continues to proactively deliver a range of initiatives to secure our supply chain, with the aim of limiting any negative impact of inflation pressure on margins
- Total patients treated worldwide now exceed 790,000

Commenting on the results, SomnoMed’s Managing Director, Mr Neil Verdall-Austin said: “SomnoMed continued its growth momentum during the period, which reflects the ongoing demand for our oral appliance range coupled with the large addressable market in which we operate. Our March quarter performance benefited from a range of proactive measures taken to address the challenges across North America.

“The development of SomnoMed’s Rest Assure[®] technology continued during the quarter with the remaining validation and verification tests, being completed. These tests will now form part of the Design History File (“DHF”), which is required as part of the documentation for regulatory filings in most regions. We anticipate that the DHF should be finalised in the final quarter of FY23 (i.e. before June 2023). Following that, the FDA 510k application will be made. Once approvals are received, we will be ready to commercialise.”

Financial Review

Quarterly revenue of \$20.2 million for Q3 FY23, +16.3% (+13.4% in constant currency) versus pcp, reflects improved trading conditions in North America and continued growth in Europe with strong contributions from a broad set of countries, including the Netherlands and Sweden.

Revenue (A\$000's)	Q3 FY23	Q3 FY22	% Change	% Change
	(A\$000's)	(A\$000's)	Actual	Constant Currency
North America	6,847	5,763	+18.8%	+12.1%
Europe	11,840	10,191	+16.2%	+14.9%
APAC	1,491	1,389	+7.4%	+6.1%
Total group revenue	20,178	17,344	+16.3%	+13.4%

Year-to-date revenue of \$60.1 million, +17.3% (+15.9% in constant currency) on pcp, indicates strong performance momentum across all regions.

Revenue (A\$000's)	9 months to 31 Mar 2023	9 months to 31 Mar 2022	% Change	% Change
	(A\$000's)	(A\$000's)	Actual	Constant Currency
North America	22,091	17,631	+25.3%	+16.1%
Europe	33,475	29,656	+12.9%	+15.8%
APAC	4,573	3,991	+14.6%	+15.6%
Total group revenue	60,139	51,278	+17.3%	+15.9%

Cash flow from operations was breakeven in Q3 FY23, an improvement of \$2.2 million from pcp, while the ongoing investment in R&D and CAPEX amounted to \$0.7 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 its growth priorities with a cash balance of \$14.6 million as at 31 March 2023.

Operational Review

SomnoMed maintains a leadership position within the OSA market and will increase its total addressable market by providing an alternative to the traditional default CPAP treatment recommendation made by most sleep physicians.

In March, the SomnoMed Global Clinical Advisory Board held its first roundtable, bringing together some of the world's premier sleep physicians, dentists and ENTs with extensive clinical and research experience. The group discussed a wide range of issues currently impacting the sleep industry, validating SomnoMed's patient centric vision and multi-disciplinary approach to long term OSA care, as well as the Company's long-term strategic plans. Strong endorsement was received for Rest Assure®, the company's future connected oral appliance.

Clinical Advisory Board Member and Professor of Clinical Physiology at Grenoble Alpes University, Jean-Louis Pepin, said, *“I truly believe that SomnoMed is at a strategic crossroads with a unique opportunity to differentiate itself in the field of oral appliances by including objective measurement of adherence and assessment of residual events on therapy in a digital medicine solution for sleep apnea.”*

During Q3 FY23, members from the SomnoMed European team attended the Dutch Society of Dental Sleep Medicine (NVTS) Conference in Noordwijk. Here, SomnoMed was recognised as the leader in the oral appliance field with a superior product range, proprietary Comfort Liner and a “fit right first time” competitor advantage providing unparalleled retention and patient comfort.

North America

After experiencing a challenging end to Q2 FY23, North American revenue improved in Q3 FY23, rising 18.8% (12.1% in constant currency) on pcp. Areas of improvement included the hire of new logistics and supply chain staff in Dallas and the re-set of delivery and supply deadlines with SomnoMed logistic partners.

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. Rest Assure’s® ability to address the lack of overnight monitoring and objective data in COAT™ is expected to deliver better results to patients, while establishing a pathway towards prescription and reimbursement.

Europe

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.

European revenue continued to increase in Q3 FY23, primarily driven by outstanding performance from the Netherlands and Sweden, amongst others. Overall, revenue for the quarter rose +16.2% (+14.9% in constant currency) on pcp.

Asia Pacific

Asia Pacific quarterly revenues rose +7.4% (+6.1% in constant currency) on pcp. The company continued to focus on its clinical education program, as well as investment in new sales and marketing resources to advance the adoption of oral appliances within the medical sector. SomnoMed was also able to address the shortage of raw materials for the manufacture of SOMTabs (SomnoMed’s proprietary cleaning tablets).

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 now completed the remaining validation and verification tests required by regulatory authorities for commercial approval. These tests will form part of the final set of documentation required to complete the DHF, a necessary dossier for regulatory filings. We expect these regulatory filings to be completed during the first quarter of FY24.

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.

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

For further information please contact

Corporate

Mr. Neil Verdal-Austin

CEO SomnoMed

+61 406 931 477

Nverdal-austin@somnomed.com

Investors

Mr. Howard Marks

Automic Markets

+61 402 438 019

Howard.marks@automicgroup.com.au

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 790,000 patients in 28 countries. For additional information, visit SomnoMed at <http://www.somnomed.com.au>