

30 October 2023

Core business revenues + 15 % in Q1 Rest Assure[®] FDA submission lodged

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 September 2023 (Q1 FY24).

Financial Highlights

- Q1 FY24 revenue of \$21.4 million, +15.2% (+7.2% in constant currency) versus the previous corresponding period (pcp)
- The group’s quarterly performance was driven by strong revenue growth in Europe, reflecting the impact of an increased focus on sales and marketing initiatives and the trend of growing patient and medical clinical adoption of Continuous Open Airway Therapy (“OAT”) for the treatment of OSA
- SomnoMed’s FY24 guidance remains unchanged
- SomnoMed’s cash balance of \$14.8 million as at 30 September 2023
- A \$15.5 million capital raising was successfully completed in September 2023, which enabled the company to repay \$5 million of drawn debt on 22 September. Beyond strengthening the balance sheet, the Company will use the proceeds of the capital raising to provide additional working capital, drive organic growth and support the continued development and commercialisation of Rest Assure[®] in FY24

Operational Highlights for the Quarter

- All reports and documents required for a 510k FDA regulatory filing for the Rest Assure[®] technology in the United States have been completed and submitted. Commercialisation in the United States will commence once FDA approval is received
- With the Rest Assure[®] technology design now complete, SomnoMed anticipates that technology development spend will reduce over FY24, resulting in improved performance across a range of financial and cash metrics
- Total patients treated by SomnoMed worldwide now exceed 830,000

Commenting on the results, SomnoMed’s Managing Director, Mr Neil Verdal-Austin said: “SomnoMed’s core business performed well in the first quarter of FY24 with growth of 15% over the prior year.

The growth across the regions validates our strategic approach of being “treatment focused” as the organisation remains deeply committed to our dental customer and medical sector engagement. While continuing to address the key challenges and adoption to drive growth and further acceptance of OAT.

Meanwhile, the development of SomnoMed’s Rest Assure[®] technology reached a critical point during the quarter. After many years of diligent and painstaking work by our incredible R&D and Manufacturing teams, all design tests and documentation were completed. Our FDA 510k regulatory filing was made and we now await approval. We will be ready to commercialise the technology in the United States once these approvals are received.”

Financial Review

Q1 FY24 revenue of \$21.4 million, +15.2% (+7.2% in constant currency) versus pcp, reflects the continued strength of SomnoMed's core business.

Revenue (A\$000's)	Q1 FY24	Q1 FY23	% Change	% Change
	(A\$000's)	(A\$000's)	Actual	Constant Currency
Europe	11,601	9,679	+19.8%	+7.6%
North America	8,132	7,345	+10.7%	+6.6%
APAC	1,634	1,529	+6.9%	+6.8%
Total regional revenue	21,367	18,553	+15.2%	+7.2%

In a seasonally weaker quarter in the Northern Hemisphere summer, cash used in operations in Q1 was \$4.9 million, including one-off amounts totalling \$1.4m, which will not be repeated in subsequent quarters, and is down from \$5.6m used in Q1 FY23. The ongoing investment in R&D and CAPEX, primarily related to the development of SomnoMed's Rest Assure® technology, amounted to \$1.5 million.

Following the capital raise in September 2023, SomnoMed is sufficiently funded to execute on its growth priorities with an available cash balance of \$14.8 million and drawn debt of \$12.7 million as at quarter-end.

Operational Review

In Q1 FY24 SomnoMed retained its strong position in the OSA market in a seasonally weaker quarter. Business conditions improved across SomnoMed's key regions of North America, Europe and Asia Pacific and the Company believes that there is potential to further increase the addressable market by providing an alternative to the traditional default CPAP product.

Throughout Q1 FY24 the business 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 continued 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.

During Q1 FY24, the business hosted the SomnoMed Sleep Summit USA, which was a resounding success. This important conference brought together a range of medical and dental experts and strategic partnership groups to discuss and debate critical topics facing the industry. This event continues to be an industry benchmark well respected and well attended by leading medical and dental clinicians together with world renown sleep researchers. The quality of the speakers brings a renewed conviction to current customer groups while also forming new medical referral networks for the future.

Europe

European revenues rose +19.8% (+7.6% in constant currency) in Q1 FY24 versus pcp. Patient demand for the Company's OAT technology remains strong across Europe, driven by positive reimbursement trends and a growing acceptance of the benefits of improved compliance with the SomnoDent™ devices for mild and moderate OSA patients. The Q1 growth results were supported by strong performances from France, Sweden, Netherlands and Switzerland.

Europe remains a critically important region for SomnoMed and the previous quarter's revenue downturn in two core markets has been corrected. The Company will continue to focus its efforts on increasing sales and marketing initiatives to ensure ongoing strong product take-up and growth. Product development and technological innovation remains key to the continued success across the region.

North America

Q1 FY24 North American revenue rose +10.7% (+6.6% in constant currency) versus pcp. Sales of the SomnoDent Avant® continue to be impacted as the Company is yet to be granted full Medicare reimbursement coding, with subsequent applications having been made during the quarter.

SomnoMed remains confident that its competitive positioning in the North American market will continue to improve as the growing demand for OAT™ products remains positive, indicating that patients and physicians are looking at OAT™ as an alternate treatment path for mild and moderate OSA patients. Implementation of the two new partnership agreements recently signed with Nexus Dental and Rest Assured is underway with early results already been seen.

Asia Pacific

Asia Pacific quarterly revenues rose +6.9% (+6.8% in constant currency) versus pcp in Q1 FY24.

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® submission complete and lodged with the FDA

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.

In Q1 FY24, all reports and documents required for a 510k FDA regulatory filing for the Rest Assure® technology in the United States were completed and the application subsequently submitted. Commercialisation in the United States will commence once FDA approval is received. Due to the different regulatory classifications within Europe, the first sales of Rest Assure® in Europe are expected during Q2 FY24.

Quarterly payments to related parties and their entities

Cash outgoings for the quarter included payments of \$232,000 in relation to the Managing Director pursuant to his employment contract, and the payment of non-executive directors' fees.

As previously disclosed on 31 August 2023, TDM Growth Partners, in which Mr Hamish Corlett has a relevant interest, received a sub-underwriting fee in relation to the capital raising undertaken by the Company in the quarter. The payment of this sub-underwriting fee of \$57,073 was indirectly funded by the Company from the proceeds of the capital raising.

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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 830 000 patients in 28 countries. For additional information, visit SomnoMed at <http://www.somnomed.com.au>