



30 January 2024

Core business revenues +13% in first half as manufacturing capacity challenged during Q2

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 2023 (Q2 FY24).

Financial Summary

- Q2 FY24 revenue of \$23.7 million, +11% (+6% in constant currency) versus the previous corresponding period (pcp)
- First half FY24 revenue of \$45.1 million, +13% (+7% in constant currency) versus pcp
- A cost reduction program, announced at the AGM held in November, is now underway to strengthen margins and profitability. This program will eliminate significant costs in the second half to 30 June 2024
- SomnoMed's FY24 guidance remains unchanged
- SomnoMed has a cash balance of \$12.8 million and drawn debt of \$12.7 million as at 31 December 2023

Operational Comments for the Quarter

- Manufacturing capacity and hence the supply of finished product during Q2 was interrupted during November by milling machine downtime. A total of 8 out of 23 milling machines were out of commission for various mechanical reasons for a period of 2 weeks:
 - All issues have now been resolved and all milling machines are running at full capacity, with contingency plans now in place to ensure that this does not re-occur
 - An aggressive catch-up plan was implemented during December. We were able to ensure that all orders received up to early December were completed prior to the end of the quarter
- Total patients treated by SomnoMed worldwide now exceed 860,000

Commenting on the results, SomnoMed's Managing Director, Mr Neil Verdal-Austin said: "SomnoMed's core business was interrupted during the second quarter of FY24 with the unplanned and unexpected milling machine downtime. This reduced our growth run rate from 15% in the first quarter to 11% in the second quarter. While this was extremely disappointing, all the issues have been resolved and the manufacturing capacity has returned to 100%.

The orders received across all regions during the quarter continued to validate demand for our products and reaffirms our strategic approach of being focused on quality and our commitment to our dental customers and our medical sector engagement."

Financial Review

Q2 FY24 revenue of \$23.7 million, +11% (+6% in constant currency) versus pcp, hampered by manufacturing capacity constraints which have now been addressed.

Revenue (A\$000's)	Q2 FY24	Q2 FY23	% Change	% Change
	(A\$000's)	(A\$000's)	Actual	Constant Currency
Europe	13,638	11,956	+14.1%	+6.6%
North America	8,505	7,898	+7.7%	+6.6%
APAC	1,605	1,553	+3.4%	+3.6%
Total regional revenue	23,748	21,408	+10.9%	+6.4%

First half FY24 revenue of \$45.1 million, +13% (+7% in constant currency) versus pcp, reflects the headwind experienced from the constrained manufacturing capacity in the second quarter.

Revenue (A\$000's)	H1 FY24	H1 FY23	% Change	% Change
	(A\$000's)	(A\$000's)	Actual	Constant Currency
Europe	25,239	21,636	+16.7%	+7.1%
North America	16,236	15,244	+9.1%	+6.6%
APAC	3,239	3,082	+5.1%	+5.2%
Total regional revenue	45,115	39,961	+12.9%	+6.7%

Cash used in operations in Q2 was \$0.9m and is a substantial improvement from \$4.9m used in Q1 FY24. The ongoing investment in R&D and CAPEX, primarily related to the development of SomnoMed's Rest Assure® technology, amounted to \$0.7 million.

SomnoMed is sufficiently funded to execute on its growth priorities with an available cash balance of \$12.8 million and a total drawn debt of \$12.7 million as at quarter-end.

Operational Review

Despite the softer Q2 FY24 SomnoMed maintained its leadership position in the OSA market on a global basis. Trading conditions, including supply chain, improved across SomnoMed's key regions of North America, Europe and Asia Pacific. The Company firmly believes that there is a growing potential to further increase the addressable market by providing an alternative to the traditional default and lower compliance CPAP products.

Throughout Q2 FY24 SomnoMed began to implement its cost reduction plan to protect and grow SomnoMed's profitability. SomnoMed has implemented significant cost reduction measures in the core business, which are expected to take real effect in the 6 months from January to June 2024.

Europe

European revenues rose +14.1% (+6.6% in constant currency) in Q2 FY24 versus pcp. Ongoing positive reimbursement trends in Europe facilitate and help to drive a growing acceptance of the benefits of improved compliance with the SomnoDent™ devices for mild and moderate OSA patients. The Q2 growth results were supported by strong performances again from France, Sweden, Netherlands and Switzerland.

Europe continues to focus its efforts on increasing sales and marketing initiatives to ensure ongoing strong product take-up and growth. Systems development and the introduction of new "customer experience" teams are contributing to the continued success across the region.

North America

Q2 FY24 North American revenue rose +7.7% (+6.6% in constant currency) versus pcp. The disappointing results seen in Q2 were heavily impacted by the lagged delivery of finished goods due to the milling machine downtime. Planned sales for the quarter were lost to our competitors during this final quarter of the insurance year. At the same time the SomnoDent Avant® sales continue to be impacted by the awaited Medicare reimbursement coding. A new submission was made to PDAC during the quarter, which included new additional information requested.

SomnoMed remains confident that patients and physicians are looking at OAT™ as an alternate treatment path for mild and moderate OSA patients.

Asia Pacific

Asia Pacific quarterly revenues rose +3.4% (+3.6% in constant currency) versus pcp in Q2 FY24.

SomnoMed's results for Q2 were behind expectations for this region, exacerbated by the tightening economy in a non-reimbursed market.

Rest Assure® Update

As previously announced in Q1 FY24, the 510k FDA regulatory filing for the Rest Assure® technology in the United States was completed and submitted in October 2023. The submission is currently being reviewed. We anticipate an initial response from the FDA during Q3.

Commercialisation of Rest Assure® 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 when all end-to-end manufacturing quality processes are complete – this is expected in early Q4 FY24.

Quarterly payments to related parties and their entities

Cash outgoings for the quarter included payments of a total of \$246,660 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

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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 860,000 patients in 28 countries. For additional information, visit SomnoMed at <http://www.somnomed.com.au>