29 April 2024

Continued revenue growth achieved despite manufacturing constraints

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 quarter ended 31 March 2024 (Q3 FY24).

Financial Summary

- Q3 FY24 revenue of $22.5 million, +11% (+6% in constant currency) versus the previous corresponding period (pcp)
- FY24 year-to-date revenue of $67.6 million, +12% (+7% in constant currency) versus pcp
- SomnoMed reconfirms the revised FY24 guidance of revenue growth of 6% - 9%, EBITDA[1] of $(1) - $0 million (excluding estimated $3 million of restructuring costs) and capital expenditure of $5 million
- The originally planned cost reductions announced at the AGM in November 2023, as well as additional cost reductions, are now in progress and will be completed by 30 June 2024
- SomnoMed had a cash balance of $9.1 million and drawn debt of $12.7 million as at 31 March 2024

Operational Comments for the Quarter

- Q3 FY24 revenue was constrained by manufacturing capacity limitations
- The two newly appointed co-CEO's visited the manufacturing facility in Manila in March 2024, as part of their initial discovery phase, to better understand the past production issues and delays in turn around times encountered in late 2023. During this visit, it became apparent that given the ongoing growth in demand for the Company's products, the facility was not able to reduce the backlog of orders
- It was assessed that the capacity of the facility was not capable of manufacturing enough volume to satisfy the increasing demand for the Company's products
- Total patients treated by SomnoMed worldwide now exceed 885,000

[1] EBITDA does not include AASB16 lease payments, share/option expenses, unrealised forex gain/(loss), discontinued operations and once off restructuring costs.

Capital Raise

Subsequent to the quarter end, the Company undertook a $22.6 million accelerated non-renounceable entitlement offer. The uses of capital are as follows:

Use of funds over the next 12 – 18 months	$m
Clean balance sheet and reduce costs (annual savings >$6.7m)	
Pay out Epsilon Debt Facility	*11.5*
Fund Cost reduction program	*3.0*
Investment into manufacturing capacity initiatives and Rest Assure® scalability	
Immediate investment into manufacturing facility and capacity	*2.0*
Investment in dedicated production line and process for scale-up of Rest Assure®	*3.0*
Exploration and potential pilot of second manufacturing facility	*2.0*
Subtotal	**21.5**
Transaction costs	1.1
TOTAL	**22.6**

- A cost reduction program has been actioned to deliver savings of at least $5 million p.a. commencing 1 July 2024, facilitated by a Q4 FY24 restructuring charge estimated to total $3 million
- Upon settlement of the Retail Component Offer on 7 May 2024, the Company expects to be in a position to repay its current debt facility in full, which is anticipated to save $1.7 million p.a. in interest costs
- Plans are currently being developed to provide additional manufacturing capacity in the short to medium term and on an ongoing basis.

The company announced the successful completion of the institutional component of its accelerated non-renounceable entitlement offer of new fully paid ordinary shares on 10 April 2024.

- Approximately 27.5 million new shares were issued to successful applicants under the Institutional Entitlement Offer on 16 April 2024 at an issue price of $0.21 per share, raising an aggregate of approximately $5.8 million. The Institutional Entitlement Offer had strong support from existing domestic and international institutional shareholders with a take-up rate of approximately 70.6%.

- The shortfall of $1.7 million (8.1 million shares) from the Institutional Entitlement Offer was placed to certain new and existing institutional investors. No shortfall shares were allocated to the sub-underwriter TDM Growth Partners Pty Ltd (a major shareholder of the Company).

Financial Review

Q3 FY24 revenue of $22.5 million, +11% (+6% in constant currency) versus pcp, was constrained by manufacturing capacity limitations with plans in place to address these constraints over the course of FY25.

Revenue (A$000's)	Q3 FY24 (A$000's)	Q3 FY23 (A$000's)	% Change Actual	% Change Constant Currency
Europe	13,684	11,840	16	9
North America	7,380	6,847	8	3
APAC	1,413	1,491	(5)	(5)
Total regional revenue	**22,477**	**20,178**	**11**	**6**

FY24 year-to-date revenue of $67.6 million, +12% (+7% in constant currency) versus pcp, reflects the headwind experienced from the constrained manufacturing capacity in both Q2 and Q3.

Revenue (A$000's)	9 months to 31 March 2024 (A$000's)	9 months to 31 March 2023 (A$000's)	% Change Actual	% Change Constant Currency
Europe	38,922	33,475	16	8
North America	24,016	22,091	9	6
APAC	4,653	4,573	2	2
Total regional revenue	**67,591**	**60,139**	**12**	**7**

Cash used in operations in Q3 was $2.1m while the ongoing investment in R&D and CAPEX, primarily related to the design and development of SomnoMed's Rest Assure® technology, amounted to $1.8 million.

SomnoMed had an available cash balance of $9.1 million and total drawn debt of $12.7 million as at quarter-end.

Operational Review

Revenue across all regions was adversely impacted by manufacturing capacity limitations.

Europe

European revenues rose 16% (+9% in constant currency) in Q3 FY24 versus pcp. The Q3 growth results were supported by strong performances from France, Germany, Sweden and Switzerland. 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.

North America

Q3 FY24 North American revenue rose 8% (+3% in constant currency) versus pcp and was impacted by the manufacturing constraints leading to delays in turnaround times.

SomnoDent Avant®, which is a product connected by straps, rather than hinges, continues to grow share despite the lack of Medicare reimbursement coding. To further improve access for all customers and patients, Somnomed has approached US Pricing, Data Analysis and Coding (PDAC) to approve Medicare reimbursement coverage.

A response was received from PDAC in April advising that they have not granted Somnomed's Avant® product the E0486 code for reimbursement due to perceived feature and function differentiation from the currently reimbursed Herbst-style device. In line with their process, we will be responding in writing to this notice in the next 45 days requesting that this decision is reviewed. Despite this development, SomnoMed continues to believe there is a path forward for a favourable outcome given there are precedent products with similar functions to Avant® for which the E0486 reimbursement code has been granted. Additionally, Somnomed confirms FY24 guidance does not include any financial impact resulting from a decision from PDAC.

Asia Pacific

Asia Pacific quarterly revenues fell 5% (-5% in constant currency) in Q3 FY24 versus pcp.

SomnoMed's results in Australia for Q3 were impacted by manufacturing capacity limitations.

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 FDA has completed its substantive review and in mid-March the Company received the FDA response on the submission. The Company is now working through the areas on which the FDA has requested further information or clarification and has 180 days in which to provide the FDA with a response.

Quarterly payments to related parties and their entities

Cash outgoings for the quarter included payments of a total of $1,207,569 to the former CEO and current Co-CEOs pursuant to their employment contracts, 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 885,000 patients in 28 countries. For additional information, visit SomnoMed at http://www.somnomed.com.au