



27 April 2022

Strong revenue growth and continued positive momentum seen in all key markets

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 2022 (Q3 FY22).

Highlights

- Revenue of \$17.3 million for Q3 FY22, +10% (+9% in constant currency) versus the previous corresponding period, or +21% (+20% in constant currency) on an underlying revenue basis when excluding the one-off COVID-19 related HIC¹ allowance received in the Netherlands during Q3 FY21
- Year to date revenue of \$51.2 million, up 14% (+15% in constant currency) versus the previous corresponding period
- Business conditions continue to improve across all regions as the trend of patient activity and engagement with their medical clinician normalises post COVID-19 impacts
- Total patients treated worldwide now exceed 695,000
- Development of Rest Assure[®], the Company’s first ever in-built technology-enabled oral appliance continued during the quarter. The Company attended the World Sleep 2022 conference, where Rest Assure[®] received strong positive feedback. The international patent application for Rest Assure[®] technology was completed.
- FY22 guidance reaffirmed for revenue growth of at least 15% and breakeven EBITDA²
- Cash available of \$14.8 million as at 31 March 2022

Commenting on the results, SomnoMed’s Managing Director, Mr Neil Verdal-Austin said: “After a period of COVID-19 led volatility in trading and activity levels, it is exceptionally pleasing to have delivered another positive quarterly result. The improving sales levels SomnoMed is experiencing have been driven by a combination of the strong momentum in underlying business activity levels across our key markets and the results of the deliberate investments we made through 2021 to expand our sales and marketing teams and focus on our medical initiative. The sales momentum we have achieved over recent quarters continues to demonstrate the sound fundamentals of the business and the large growth opportunity for oral appliance solutions in the treatment of obstructive sleep apnea.”

“The development of SomnoMed’s Rest Assure[®] technology continued during the quarter with the lodgement of our patent application and the continuation of our patient validation study. The Rest Assure[®] technology was extremely well received at World Sleep 2022 with strong positive feedback. We anticipate that, over time, the data collected by Rest Assure[®] will demonstrate and establish the clinical effectiveness of Continuous Open Airways Therapy (COAT[™]), driving prescriptions, increased reimbursement and ultimately greater therapy market share for COAT[™].”

1. During Q3 FY21, the company recognised an allowance received from the HICs (Health Care Companies) in the Netherlands as \$1.4 million in revenue. This allowance compensated SOM for a portion of lost managed care income due to COVID-19 in this country. These sums have been partly used to compensate suppliers forming part of the managed care scheme; the impact on profit was detailed in FY21 results.
2. EBITDA as adjusted does not include share-based payments, discontinued operations and other expenses
3. Net cash is defined as gross cash, less commercial borrowings and COVID-19 related government loans

“As we move towards the end of the fiscal year, we reiterate our guidance for FY22, remain focused on sales growth, increasing awareness and driving the acceptance and adoption of COAT™ treatments across our core regions. We will also continue to execute on our Rest Assure® development milestones.”

Financial Review

Q3 FY22 unaudited revenues of \$17.3 million were up 10% (+9% in constant currency) versus the previous corresponding period, or up 21% (+20% in constant currency) on an underlying revenue basis when excluding the one-off COVID-19 related HIC¹ allowance received during the previous corresponding period in the Netherlands.

The revenue growth posted in both North America and Europe continued the momentum seen in those regions during the prior quarter as the impacts of COVID-19 on the clinical, hospital and patient market continued to normalise.

Revenue (A\$000's)	Q3 FY22	Q3 FY21	% Change
	(A\$000's)	(A\$000's)	
North America	5,763	4,054	+42%
Europe	10,191	9,009	+13%
APAC	1,389	1,289	+8%
SOM CORE	17,344	14,352	+21%
HIC ¹	-	1,362	
TOTAL	17,344	15,714	+10%

Year to date revenue of \$51.3 million, up 14% (+15% in constant currency) on the previous corresponding period, showing the strong recovery in the global business during the current financial year.

Revenue (A\$000's)	9 months to 31 March 2022	9 months to 31 March 2021	% Change
	(A\$000's)	(A\$000's)	
North America	17,631	13,551	+30%
Europe	29,656	27,591	+7%
APAC	3,991	4,034	-1%
SOM CORE	51,278	45,176	+14%
HIC ¹	-	1,362	
TOTAL	51,278	46,538	10%

Cashflow from operations was negative \$2.2 million, due mainly to seasonally lower collections against payments of \$1.2 million for annual insurance, legal and audit fees, and a \$0.5 million increase in stock and inventory to provide for global supply disruptions.

Investment in R&D continues with a total cash expenditure during the quarter of \$3.4 million specifically related to our technology investment. The year-to-date technology investment is approximately \$6.3 million, primarily associated with the development of Rest Assure®. The Company continues to guide to a cash investment in technology initiatives of \$8 million in FY22. The investment in Rest Assure® and our other growth initiatives is supported by our balance sheet position and the expected positive cash generation in Q4 FY22. The Company has cash available of \$14.8 million as at 31 March 2022, which includes \$6.7m of borrowings, of which \$2.4m is long-term. The net cash³ at the end of the period was \$8 million.

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Operational Review

Business conditions continued to improve across SomnoMed's key regions of North America, Europe and Asia Pacific as the impacts of COVID-19 on the medical sector and broader dental community continued to reduce.

The Company has continued to experience positive engagement within the medical sector, which is driving further acceptance of COAT™. 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.

North America

The North America market experienced another positive quarter with a +42% increase in revenues on the previous corresponding period (+35% in constant currency). These record results were driven by increased investment in sales and marketing efforts in the region driving demand for the product range, especially the Avant and Herbst Advance Elite™.

Marketing campaigns focused on the Company's proprietary B-Flex comfort liner continue to be successful, highlighting the importance of this material that provides both comfort and retention.

Europe

The impacts of COVID-19 on most of SomnoMed's markets within Europe reduced during the period, leading to an increase in activity levels on a year-on-year basis. Revenue for the quarter was \$10.2 million, a +13% increase on the previous corresponding period (+15% in constant currency) when excluding the effect of HIC¹ on Q3 FY21.

Across six of the Company's core countries within Europe, we have seen a >20% increase in volumes over the prior corresponding period for the quarter, reflecting deeper penetration of these markets where SomnoMed has been the leading COAT™ treatment solution for some time. The quarter saw record unit sales achieved in March, with positive reimbursement initiatives contributing to the significant progress made in Germany.

Asia Pacific

Asia Pacific quarterly revenues increased +8% on the previous corresponding period as the impact of COVID-19 lockdowns and the recent Omicron wave across Australia resided. SomnoMed continued with its clinical education program and the investment in new sales and marketing resources to advance the adoption of oral appliances within the medical sector.

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Rest Assure®

SomnoMed introduced Rest Assure®, its first ever in-built technology-enabled oral appliance, in February 2022 with the aim of addressing 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® hardware and software is in prototype stage, with a patient validation study underway to confirm algorithms for efficacy and compliance in order to objectively measure therapy effectiveness.

In March, SomnoMed presented the technology at World Sleep 2022 in Rome, Italy. The conference, attended by approximately 2,200 delegates, is the premier global gathering of the sleep market's leading scientific researchers, investigators, writers, thought-leaders, teachers, clinical professionals and commercial industry players. The in-person meeting brought SomnoMed's staff, customers, partners and colleagues together for the first time in over 2 years. The platform allowed SomnoMed to introduce Rest Assure® to the market, with positive feedback from participants.

The international patent application for the Rest Assure® technology was lodged for all commercial jurisdictions in which we currently sell and trade our clinically proven state-of-the-art SomnoDent® oral appliance.

SomnoMed will continue to progress Rest Assure® towards commercial readiness. Key milestones for the remainder of FY22 include the final design for the docking station and sensor package and the selection of contract manufacturers and suppliers. In FY23, the Company will focus on the preparation and submission of regulatory documentation to the FDA, CE and TGA. Rest Assure® will be commercialized once these approvals are received.

SomnoMed attends World Sleep introducing Rest Assure®, its first ever in-built technology-enabled oral appliance



Outlook

- With improving business conditions across the globe, the Company remains optimistic about trading activity levels and the outlook for FY22. The Company is committed to its technological transformation and FY22 guidance (assuming no change to the current COVID-19 lockdowns and restrictions in all trading markets)
- Revenue growth of at least 15%
- EBITDA² breaking even as SomnoMed invests for future growth (expected to rebound in FY23 and beyond)
- Cash investment (non-P&L) in technology innovations is expected to be c.\$8 million

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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 695,000 patients in 28 countries. For additional information, visit SomnoMed at <http://www.somnomed.com.au>

