



26<sup>th</sup> July 2022

## SomnoMed posts record Q4 and delivers on FY22 revenue guidance

**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 June 2022 (Q4 FY22).

### Highlights

- Record quarterly revenue of \$21.3 million for Q4 FY22, +32% (+32% in constant currency) versus the previous corresponding period (pcp). On an underlying basis, when excluding the Q4 FY21 COVID-19 related HIC<sup>1</sup> allowance, Q4 FY22 revenue was up +36% (+37% in constant currency) versus pcp
- Full year unaudited revenue of \$72.6 million, up +16% (+17% in constant currency) versus pcp and above guidance of +15% growth for FY22. On an underlying basis, when excluding the COVID-19 related HIC<sup>1</sup> allowance, FY22 revenue was up +19% (+20% in constant currency) versus pcp
- FY22 guidance of breakeven EBITDA<sup>2</sup> remains
- The record quarter reflects the impact of successful sales and marketing initiatives in all regions, with business conditions improving and the overall trend of patient activity and engagement with their medical clinician normalising post COVID-19
- Total patients treated worldwide now exceeds 715,000
- Development of Rest Assure<sup>®</sup>, the Company’s first ever in-built technology-enabled oral appliance progressed during the quarter, with the second patient validation study now complete
- SomnoMed had available cash of \$15.6 million as at 30 June 2022
- Subsequent to 30 June 2022, SomnoMed secured new debt funding of \$16 million (net \$11m after repaying HSBC), which delivers sufficient capital to support the ongoing growth within the core business and to complete the development of the new technology, Rest Assure<sup>®</sup>

**Commenting on the results, SomnoMed’s Managing Director, Mr Neil Verdal-Austin said:** “I am exceptionally pleased that the Company has met our FY22 revenue guidance and immensely proud that we delivered a record \$21.3 million of revenue in the June quarter.”

“The improving sales levels SomnoMed is experiencing have been driven by a combination of the strong 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 to focus on delivering a quality treatment solution for patients with mild to moderate OSA. The sales momentum we have achieved over recent quarters continues to demonstrate the sound fundamentals of the core business and the large growth opportunity for oral appliance solutions in the treatment of obstructive sleep apnea, globally.”

“These results validate our strategy and confirm, once again, that the exceptional ‘first time fit’ quality and durability of our product range is superior within the marketplace and preferred by clinicians and patients world-wide.”

<sup>1</sup> HIC (Health Care Companies) Revenue is associated with allowances received in the Netherlands which compensates SOM for a portion of lost managed care income in the country due to COVID-19

<sup>2</sup> EBITDA as adjusted does not include share-based payments, discontinued operations, and other expenses

“Our recent attendance at a range of sleep conferences across Europe and the USA have highlighted the growing demand from patients, sleep physicians and other providers, for new technologies that provide an alternative to CPAP where the ongoing, low compliance rates are just not acceptable anymore.”

“We are also acutely aware of the current global economic environment and the impact of supply chain issues, rising inflation and interest rates on costs. SomnoMed continues to proactively drive a range of initiatives to secure our supply chain and ensure we limit any negative impact on our own cost structures, so that we protect margins and cash flow.”

“The development of SomnoMed’s Rest Assure® technology has progressed during the quarter, with our second patient validation study now complete. We anticipate that, once launched and over time, the data collected by Rest Assure® will demonstrate and establish the true clinical effectiveness of Continuous Open Airway Therapy™ (COAT™), driving prescriptions, increased reimbursement and ultimately greater OSA therapy market share.”

“As we move into FY23 we have strong revenue momentum, an increasing rate of patient engagement, a passionate and energized global team, a strengthened balance sheet and an exciting technology development in Rest Assure®, which all leave the Company poised to deliver solid growth in the year ahead. I look forward to providing more formal FY23 guidance with our FY22 financial results release in August.”

## Financial Review

Quarterly revenue of \$21.3 million for Q4 FY22, +32% (+32% in constant currency) versus pcp represents the highest quarterly revenue the Company has ever recorded. This reflects the sales success of both AVANT™ and Herbst Advance Elite™ and the investment the Company has made into sales teams and business development channels in all regions, allowing the Company to penetrate the sector more deeply and drive growth.

The revenue growth posted in both North America and Europe continued, with the momentum seen in those regions during the year driven by the continued normalisation of the impacts of COVID-19 on the healthcare market.

Revenue (A\$000's)	Q4 FY22	Q4 FY21	% Change
	(A\$000's)	(A\$000's)	
Europe	12,558	9,178	+37%
North America	7,057	4,955	+42%
APAC	1,436	1,335	+8%
<b>Total regional revenue</b>	<b>21,051</b>	<b>15,468</b>	<b>+36%</b>
HIC <sup>1</sup>	251	700	-64%
<b>Total group revenue</b>	<b>21,303</b>	<b>16,169</b>	<b>+32%</b>

<sup>1</sup> HIC (Health Care Companies) Revenue is associated with allowances received in the Netherlands in FY21 which compensated SOM for a portion of lost managed care income in the country due to COVID-19

<sup>2</sup> EBITDA as adjusted does not include share-based payments, discontinued operations, and other expenses

Full year unaudited revenue of \$72.6 million, up +16% (+17% in constant currency) versus pcp and above guidance for FY22. EBITDA<sup>2</sup> guidance remains at breakeven for FY22 and will be detailed in the upcoming FY22 financial results release in August.

Revenue (A\$000's)	12 months to 30 June 2022	12 months to 30 June 2021	% Change
	(A\$000's)	(A\$000's)	
Europe	42,214	36,769	+15%
North America	24,688	18,506	+33%
APAC	5,427	5,369	1%
<b>Total regional revenue</b>	<b>72,329</b>	<b>60,644</b>	<b>+19%</b>
HIC <sup>1</sup>	251	2,062	-88%
<b>Total group revenue</b>	<b>72,580</b>	<b>62,706</b>	<b>+16%</b>

Cashflow from operations was a positive \$3.3 million for the quarter (positive \$1.8 million for FY22), due to the strong sales momentum seen in both Q3 and Q4, as well as effective cash management and collections to year end.

Investment in R&D continues with total cash expenditure during the quarter of \$1.5 million specifically related to our technology investment. The FY22 technology investment has been approximately \$7.8 million, primarily associated with the development of Rest Assure<sup>®</sup> and under the guidance provided of \$8 million. The investment in Rest Assure<sup>®</sup> and our other growth initiatives is supported by our balance sheet position and positive cash generation in Q4 FY22.

Subsequent to June 2022, SomnoMed secured new debt funding of \$16 million (net \$11m after repaying HSBC), which delivers sufficient capital to support the ongoing growth within the core business and to complete the development of the new technology, Rest Assure<sup>®</sup>.

## 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.

SomnoMed's position in the oral appliance sector within the OSA market remains strong, with the potential to further increase the addressable market by providing an alternative to the traditional default CPAP recommendation by most sleep physicians. The Company continues to experience positive engagement within the medical sector, which is driving further acceptance of COAT<sup>™</sup>.

### North America

The North America market experienced another positive quarter with a +42% (+33% in constant currency) revenue increase versus pcp. This is driven by increased investment in sales and marketing efforts in the region driving greater demand for the product range, especially for the AVANT<sup>™</sup> and Herbst Advance Elite<sup>™</sup>. Direct and targeted 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 superior comfort and retention.

<sup>1</sup> HIC (Health Care Companies) Revenue is associated with allowances received in the Netherlands which compensates SOM for a portion of lost managed care income in the country due to COVID-19

<sup>2</sup> EBITDA as adjusted does not include share-based payments, discontinued operations, and other expenses

## Europe

Revenue for the quarter was \$12.6 million, up +37% (+43% in constant currency) versus pcp. Patient demand for the Company's COAT™ technology remains strong across core countries within Europe driven by strong positive reimbursement trends and a growing acceptance of the benefits of COAT™ technology for mild and moderate OSA patients.

Sales volume growth for the quarter in each of the 7 main European countries in which we trade were over +20% versus volumes in the prior corresponding quarter, reflecting deeper penetration into both core and new markets where SomnoMed has been the leading COAT™ treatment solution for some time.

## Asia Pacific

Asia Pacific quarterly revenues were up +8% (+8% in constant currency) versus pcp. After the extended impact of COVID-19 on revenues in the first half, recovery in the second half was strong. 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.

## **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.

Although the Rest Assure® hardware and software is in prototype stage, the design is now complete, and a vendor is manufacturing the docking station and sensor components. The second patient validation study has also been completed. These study results are currently being analysed and will be submitted for publication in a scientific sleep journal later this calendar year to confirm the algorithms needed to objectively measure efficacy and compliance to ensure long term therapy effectiveness. Patient feedback was also collected during this study, with 29/30 patients able to connect their device to the patient App and dock their device using simple written instructions only, showing the Rest Assure® system is easy to use. All patients in the study expressed a desire to continue COAT™ therapy with Rest Assure® when the device is launched.

The Rest Assure® project remains on schedule, with SomnoMed's focus now on the preparation of documentation required for regulatory submissions to the FDA (USA), TGA (Australia) and for CE marking (Europe). Rest Assure® will be commercialised once these approvals are received.

The Company attended the American Academy of Sleep Medicine (AASM) 'SLEEP 2022' conference in Charlotte USA during the quarter. AASM SLEEP 2022 is a leading conference for sleep physicians, sleep medical prescribers and researchers in North America focusing on all aspects of sleep, sleep disorders, screening, pharmaceuticals, technology platforms, tele-medicine, diagnostics, and treatment. The conference with approximately 3,500 delegates allowed the Company to showcase its best-in-class oral appliance treatment solution while also engaging in a range of collaborative interactions and meetings with various industry players. The feedback on the Rest Assure® technology was overwhelmingly positive.

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

[Nverdalaustin@somnomed.com](mailto:Nverdalaustin@somnomed.com)

**Investors**

Mr. Craig Sainsbury

Market Eye

+61 428 550 499

[Craig.sainsbury@marketeye.com.au](mailto:Craig.sainsbury@marketeye.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<sup>®</sup> becoming the state-of-the-art and clinically proven medical oral appliance therapy for more than 715,000 patients in 28 countries. For additional information, visit SomnoMed at <http://www.somnomed.com.au>