



Revenues on track despite COVID-19 disruptions, with new technology-enabled appliances in development

SomnoMed Limited (ASX "SOM", or the Company), a leading company in the provision of treatment solutions for sleep-related breathing disorders and obstructive sleep apnea ('OSA'), is pleased to provide its report for the half-year ended 31 December 2021 and a further update on the development of its technology-enabled oral sleep appliance.

Overview

- Revenue of \$33.9 million for 1H FY22 (1H FY21: \$30.8 million), an increase of 10% (11% in constant currency) as global business conditions continued to improve, mainly in our North American markets
- SomnoMed continues to forecast +15% revenue growth for FY22
- Group gross margin of 62% (1H FY21: 59%)
- EBITDA¹ fell to \$0.2 million (1H FY21: \$3.2 million), driven by investment in future growth initiatives including in-device technology developments and the expansion of marketing and sales networks
- Net cash outflow for the period of \$3.7 million (1H FY21: outflow of \$4.5 million)
- Total patients treated worldwide now exceeds 675,000
- Cash of \$17.6 million as at 31 December 2021, and well managed as the business invests in its transformational technology initiatives with total investment in technology for 1H FY22 of \$3 million
- Undrawn debt facilities of \$5 million remain

SomnoMed introduces technology-enabled oral sleep appliance Rest Assure®

- Rest Assure® is an inbuilt technology-enabled oral appliance for the treatment of sleep-related breathing disorders and obstructive sleep apnea
- Rest Assure® addresses the lack of overnight monitoring in continuous open airway therapy ('COAT™'), which has been a major barrier to prescription and reimbursement rates to date
- Physicians and dentists will be able to view personalised data from their patients on a web-based portal, alongside a patient phone app that will allow patients to view their own sleep data
- This data will help support the effectiveness equation and drive acknowledgement of equivalent clinical effectiveness for COAT™ and CPAP when considering both efficacy and compliance together
- Rest Assure® is expected to drive prescriptions, increased reimbursement, and ultimately greater share of treatment prescriptions for COAT™ versus CPAP

¹ EBITDA does not include share/option expenses, unrealised forex gain/(loss) and discontinued operations

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Commenting on the results, SomnoMed's Managing Director, Mr Neil Verdal-Austin said: "SomnoMed continues to deliver good revenue growth despite the ongoing COVID-19 issues in some markets. Our vision of providing an effective long-term treatment for patients who suffer from the effects of OSA remains front and centre, alongside a strategic development program to address the lack of objective data for oral appliance therapy. As foreshadowed at the end of January, we are incredibly pleased to announce further details on our new technology-enabled oral appliance."

"SomnoMed is truly leading the way with this commitment to the industry through our innovation and transformational product development to deliver a connected oral sleep appliance, providing objective data and empowering all stakeholders and patients to manage their own OSA treatment. SomnoMed is focused on driving significant change and investing in our future growth plans that will enhance and build upon our leading competitive advantage to deliver better health outcomes for our patients," Mr Verdal-Austin added.

"In addition to this, SomnoMed has also recently announced the formation of three regional Clinical Advisory Boards who will begin to guide our clinical direction and future research. The assembly of this esteemed group of experienced and credentialed leaders within the sleep industry has been a pleasure to bring together. Our valued clinical heritage will be further enhanced as this group works alongside us to craft our future research plans," commented Mr Verdal-Austin.

"Operationally, we continue to see positive momentum across our key trading markets. We posted record sales numbers during the period in North America and still delivered growth across both Europe and APAC where the impacts of COVID-19 are still being felt. Additionally, we continue to engage with authorities globally to drive positive reimbursement trends which allow SomnoMed's oral appliance range to be available as a long-term cost-effective treatment option for OSA patients. The momentum we have seen across our business in the first half of the year continues to provide the confidence to maintain our FY22 guidance of at least 15% revenue growth," noted Mr Verdal-Austin.

Financial Review

Net revenue of \$33.9 million increased 10% versus the previous corresponding period as the ongoing rolling impact of the COVID-19 pandemic continued to drive mixed financial and operational performance across the various markets. During the period, Europe and APAC were impacted by the recent wave of Omicron, whilst North America remained largely resilient due to the positive seasonal insurance benefits driving a strong end to the calendar year.

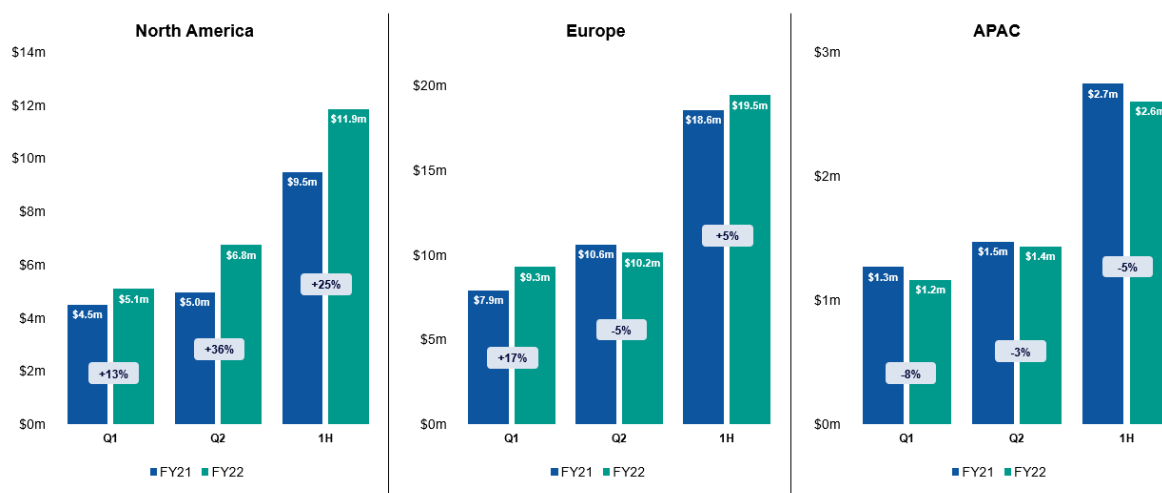
SomnoMed generated an EBITDA¹ for the first half of \$0.2 million (1H FY21: \$3.2 million). The reduction in EBITDA was driven by investment into growth initiatives, including development of in-device technology, expansion of marketing and sales force networks and an increase in medically targeted advertisement and marketing communication.

Net cash outflow for the period of \$3.7 million (1H FY21: \$4.5 million) was primarily due to the expenditure on the above-mentioned growth initiatives.

The balance sheet position remains strong with net cash of \$17.6 million as at 31 December 2021. The robust cash position has allowed management to drive forward with product innovation and advancements to improve customer experience, drive market penetration and set the company up to benefit from the continued normalisation in market conditions.

Investment in technology development continues with total investment specifically related to this of \$3 million for 1H FY22.

Total regional revenues by quarter



Operational Review

Whilst business operating conditions improved in 1H FY22, the Company remains aware of ongoing challenges with the recent Omicron wave and its impact on access to prescribers and hospitals within the health sector.

The Company continues to drive strong engagement within the medical sector, with many in-person and virtual activities, educational events, and congresses during the first half. Our focus on presenting the patient centric benefits of COAT™ continues to strengthen SomnoMed's position within the broader OSA market, with the potential to further increase the size of the addressable market by providing an alternative to the traditional default CPAP recommendations by sleep physicians regardless of the severity of OSA being treated. The Company has continued to deliver product on time, navigating supply and manufacturing challenges due to COVID-19 with minimal impact over the half.

Revenue (A\$000's)	1H FY22	1H FY21	% Change
North America	11,867	9,497	25%
Europe	19,464	18,582	5%
APAC	2,602	2,745	-2%
Total	33,934	30,824	10%

North America

Revenue for the half was \$11.8 million, up 25% versus the previous corresponding period (up 20% in constant currency terms). During the half, the Company was focused on building up and resourcing our North American operation, with an increase in its sales and business development resources to leverage the current market opportunity.

The recent global CPAP machine shortage has added to that opportunity to engage with those patient groups that may benefit from SomnoMed's product offering. Demand for the Herbst Advance Elite™ was strong in the North American market during the period, and the product continues to increase in contribution to our revenue results.

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Europe

Revenue from European operations was up moderately over the previous period, with \$19.4 million of revenue generated for the half as positive reimbursement trends offset the impacts of COVID-19 on activity levels.

Most of SomnoMed's markets within Europe were affected by COVID-19 in some way during the period. Holland, Belgium, Norway, France, UK and Switzerland were heavily impacted in Q2 FY22, while others were less so. In the latter part of the half, hospitals and doctors focused much of their attention to COVID-19 patients and patient treatments, and final fittings through our dental partners were also affected with many patient appointment cancellations.

This region remains pivotal to the group with market leadership positions in all key markets. Investment in additional resources will be made as both the medical and dental sectors begin to see what is possible with the new technology and the data that would be derived.

Asia Pacific

Asia Pacific revenues declined 2% over the previous period to \$2.6 million, primarily due to the impacts of COVID-19 lockdowns and the recent Omicron wave across Australia. During the half, SomnoMed continued with its clinical education program and its investment in operational system improvements to support the future growth.

SomnoMed introduces Rest Assure®

SomnoMed's aim is to ensure that all treatment stakeholders, including patients, can access overnight data on oral appliance treatment effectiveness. Currently, overnight data on usage and efficacy in the treatment of OSA is only available with CPAP. To address the lack of objective data, SomnoMed has developed Rest Assure®, an inbuilt technology enabled oral device.

Ultimately, we expect that Rest Assure® data will help drive the acknowledgement of the clinical effectiveness for COAT™ and drive greater share of therapy for COAT™ versus CPAP. Once equivalent clinical effectiveness for COAT™ and CPAP is quantified with objective data, this will pave the way for discussions on possible reimbursement increases for COAT™. For further information please see ASX Release "SomnoMed introduces Rest Assure®, an in-built, technology-enabled oral device" 22 February 2022.

Outlook

The Company remains optimistic about trading activity levels and the outlook for the second half of FY22. SomnoMed is committed to its technological transformation and its FY22 guidance²:

- Revenue growth of at least 15%
- EBITDA¹ breaking even as SomnoMed invests for future growth (assuming no change to the current COVID-19 environment in all trading markets)
- Cash investment (non-P&L) in technology innovations is expected to be c.\$8 million

1. EBITDA does not include share/option expenses, unrealised forex gain/(loss) and discontinued operations
2. Assumes no change to the current COVID-19 environment in all trading markets

Investor Webinar

The Company will provide an investor webinar to discuss the half year results and provide further insight into the technology innovations currently underway. To register please follow the link below.

Date: Tuesday 22nd February 2022

Time: 11:00am AEDT

Registration Link:

https://webcast1.boardroom.media/watch_broadcast.php?id=62045d87954d7

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This release has been approved by the Board of SomnoMed Limited.

22nd February 2022

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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 commercialized 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 675,000 patients in 28 countries. For additional information, visit SomnoMed at <http://www.somnomed.com.au>