

ASX Release

4th December 2023

Somfit® Receives FDA Clearance to Market in the USA

Key Highlights:

- **Significant addressable market in the USA between USD110m-180m in potential revenue, which Compumedics will target 10% to 30% of within the next 24 months**
- **USA has approximately 3,000 sleep centres & 15 major Independent Diagnostic Testing Facilities (IDTF's)**
- **Home sleep testing (HST) market is estimated at two million studies per annum**
- **FY24 guidance reaffirmed as revenues of more than \$44m and EBITDA of more than \$5m**

Compumedics Limited (ASX: CMP) ("Compumedics" or "Company") is pleased to announce the US Food & Drug Administration (FDA) has cleared the Somfit device to be marketed in the USA. This marks the achievement of another significant strategic milestone for the Somfit technology platform in one of the world's largest sleep markets. The commercialisation of Somfit in Australia was previously reported (ASX announcements on 3rd & 7th July 2023) with \$1.2m of sales orders taken to date. Compumedics can now begin its commercialisation activities in the key USA market, following the initial successful validation and commencement of sales activities for Somfit in the Australian market, since the beginning of the 2024 financial year.

The home sleep testing (HST) market in the USA, which the Somfit is primarily targeted at, is estimated to be about two million studies per annum. Given the pre-FDA market research activities undertaken by Compumedics, this represents a potential new addressable market of between USD110m and USD180m a year in potential new and incremental SaaS (software as a service) revenues to Compumedics. The revenue assumption is based on pre-FDA market research activities with existing HST providers in the USA market, which included potential pricing for the Somfit platform, should they switch to Somfit once FDA clearance was achieved. The revenue assumption is for the full market opportunity of about 2m studies per year, using differing pricing points based on volumes of studies achieved. Compumedics will target to achieve between 10% and 30% of the addressable market over the next 24 months.

Compumedics has pre-emptively appointed a number of new sales staff in the USA to commence initial commercialisation activities and will be actively pursuing several focused opportunities available to it following the FDA clearance. CMP believes the Somfit technology platform offers a clear competitive advantage, and superior value to alternate technologies on the market in the USA, by being highly scalable, offering a clinical grade technology for use in the home, greater convenience and ease of use for the patients, along with an overall reduced cost.

The go-to market strategy has, to-date, been developed around an initial focus in Australia, targeting three main areas:

- The existing Obstructive Sleep Apnea (OSA) Home Sleep Testing (HST) market (Medicare are currently evaluating the suitability of the Somfit Pro for claiming MBS Code 12250 with a decision expected in Q1 CY2024)
- The primary care market for sleep screening and OSA diagnosis (CMP now have, by their own internal estimates, 75% market share in this area in Australia)
- Supporting the diagnosis of Insomnia and circadian rhythm disorders (The initial product for this segment will be available in Q1 CY2024)

This initial Australian focus has allowed CMP to further refine the initial design through high volume local testing.

In commenting on this significant milestone for Compumedics, Executive Chairman & CEO, Dr David Burton said:

“Following FDA clearance for the Somfit device in the USA, Compumedics can now begin executing their commercialisation strategy to capitalise on the under penetrated sleep market with an initial focus on Home Sleep Testing (HST), before addressing other opportunities.”

Compumedics anticipates further announcements as it continues its commercialisation activities for Somfit in Australia and now the USA.

Compumedics reaffirms FY24 guidance of revenues of at least \$44m and EBITDA of at least \$5m.

About Compumedics Limited

Compumedics Limited (ASX: CMP) is a medical device company involved in the development, manufacture, and commercialisation of diagnostics technology for sleep, brain, and ultrasonic blood flow monitoring applications. The Company owns US based Neuroscan, and Germany based DWL Elektronische GmbH. In conjunction with these two subsidiaries, Compumedics has a broad international reach, including the Americas, Australia and Asia Pacific, Europe, and the Middle East.

Executive Chairman Dr. David Burton founded Compumedics in 1987. In the same year the Company successfully designed and installed the first Australian, fully computerised sleep clinic at Epworth Hospital in Melbourne. Following this early success, Compumedics focused on the development of products that sold into the growing international sleep clinic and home monitoring markets.

Compumedics listed on the Australian Securities Exchange in 2000. Over the years, Compumedics has received numerous awards, including Australia’s Exporter of the Year, and has been recognised as a Top 100 Innovator by both German and Australian Governments.

About the Somfit technology

The Somfit technology comprises of a number of market-specific and disorder-specific diagnostic products which offers several advantages to organisations operating in the sleep diagnostic space:

- **Highly scalable:** quality health SaaS business model
- **Clinical grade data in an at-home device:** Light and comfortable for the patient while enabling collection of high-quality signals to provide medical-grade (reimbursable) data

- **Greater convenience:** At-home monitoring eliminates the need for patients to travel to a hospital or sleep clinic, which can be time-consuming and inconvenient.
- **Reduced cost:** At-home monitoring is less expensive than hospital monitoring, as it eliminates the need for hospital staff and facilities.

Somfit technology products have received regulatory clearance for sale in Australia, New Zealand, the EU and the USA. These products open several new and incremental revenue streams to Compumedics in device sales, consumables and SaaS.

The Somfit and Somfit Pro Systems

Somfit – 4 components, **Somfit Pro** – 5 components



A single-use adhesive-gel electrode. This is worn on the patient's forehead and collects the physiological data.



The Somfit® device, which is pressed onto the electrode. The Somfit houses the sensors and transmits the data to the App via Bluetooth. Somfit can collect up to 12 hours of data.



The Respfit® device, which is located on the Thoracic belt houses the ECG, Airflow, chest movement and position body sensors and transmits the data to the App via Bluetooth.



The Somfit® App
This is used to control the Somfit and to transmit the study data to be processed.



The Profusion Nexus360™
cloud-based data management and reporting system.

Consumable revenue

Capital cost or built into SaaS fees

Recurring SaaS fee to access

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Authorised for lodgement by Compumedics Limited's Board of Directors