

Somfit® Receives FDA Clearance to Market in the USA

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

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“

Compumedics can now begin executing its commercialisation strategy to capitalise on the under penetrated sleep market with an initial focus on Home Sleep Testing (HST), then onto other opportunities.”

David Burton

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.

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