Company Announcement

Monday February 17, 2020

COMPUMEDICS ANNOUNCES MILESTONE US FDA APPROVAL FOR THE ORION LIFESPAN™ MEG

Highlights:

- **Compumedics' Neuroscan Orion LifeSpan™ MEG receives US Food and Drug Administration (FDA) approval in the United States, following installation at Barrow Neurological Institute in Arizona, USA**
- **Sites can now use the MEG for routine clinical examinations and bill for insurance reimbursement**
- **Significant milestone for the company's MEG sales and marketing efforts**
- **Company continues to actively pursue forty identified MEG opportunities around the world, with four opportunities substantively advanced**

Compumedics Limited (ASX: CMP) ("Compumedics" or **"Company")** is pleased to announce that on February 14, 2020, it received 510(K) clearance from the US Food and Drug Administration (FDA) for its Orion LifeSpan™ Magnetoencephalography (MEG) single Dewar system. This news follows the successful installation and first phase commissioning of the single Dewar Orion LifeSpan™ MEG at Barrow Neurological Institute (BNI) in Phoenix, Arizona, USA.

MEG is a neuroimaging technique for mapping brain activity by recording magnetic fields produced by electrical currents occurring naturally in the brain.

The MEG hardware approval comes in addition to the already approved components offered with the Orion LifeSpan™ by the company. These include the amplifiers, the simultaneous electroencephalogram (EEG) subsystem; and the fully integrated, state-of-the-art co-registration, neuroimage processing, and source estimation software known as CURRY – the world's gold standard for clinical MEG/EEG and neuroscience research and used by many of the existing installed MEG systems.

The FDA clearance now allows for routine clinical use of the single MEG device, primarily for epilepsy and pre-surgical brain function mapping. Furthermore, sites using the Orion LifeSpan™ may now

routinely bill both private and public insurance plans for MEG examinations, an important consideration when purchasing medical equipment. In the late 1980s there were about 200 or so MRI systems installed, like MEG today. These were largely used for research at that time before billable codes became available in the 1990's for MRI. There are about 36,000 MRIs installed globally today, with 2,000 to 3,000 MRI systems sold annually. The Company believes MEG may follow a similar trajectory over time.

With the FDA approval in place, Compumedics may now enter the lucrative US clinical market with its single Dewar MEG technology.

Each system will typically sell for around USD3m to USD4m, depending on specification. The dual adult/child Dewar is currently planned for installation in the coming months at BNI, with FDA submission for the dual Dewar to follow. Regulatory submissions for other territories are well advanced and are likewise expected to proceed smoothly.

Orion LifeSpan™ MEG technology has evolved from more than thirty years' experience with MEG and EEG technologies. Included are innovations in acquisition/analysis/visualisation software, highly sensitive magnetic field detectors and low-noise amplifier electronics, which have been developed at both the Korea Research Institute of Standards and Science (KRISS) and within Compumedics Neuroscan itself.

The Orion LifeSpan™ MEG allows for a unique dual-helmet sensing system, with one side optimised for adult MEG recordings and the other for paediatrics. The dual-helmet will be installed at BNI in coming months, with its FDA application to follow. Other ground-breaking features of the Orion LifeSpan™ MEG include advanced Superconducting Quantum Interference Device (SQUID) detectors for unparalleled sensitivity to brain signals; reduced operating cost from zero-loss helium reliquification with 24/7 operation; a fully integrated low-noise, high-density EEG monitoring system utilising the latest Compumedics/Neuroscan technology.

Dr David Burton, Chairman and CEO of Compumedics, said:

"Compumedics Neuroscan is very pleased to have achieved this important milestone for the Orion LifeSpan™ MEG. Receiving 510(K) clearance from the FDA, whilst expected, it is nevertheless satisfying and validating after all the R &D over many years. Much like MRI technology in the late 1980s which transitioned from research to clinical application, we expect MEG to follow a similar trajectory. In addition to the technical accomplishments achieved by the company and our partners at the Korea Research Institute of Standards and Science (KRISS), it represents a foundation for the commercialisation of our MEG technology. This market clearance will allow us to transition from product

development to full commercialisation. Compumedics continues to actively pursue 40 identified MEG opportunities around the world, with four opportunities substantively advanced."

About Compumedics Limited

Compumedics Limited [ASX: CMP] is a medical device company involved in the development, manufacture and commercialisation of diagnostics technology for the sleep, brain and ultrasonic blood-flow monitoring applications. The company owns US based Neuroscan and Germany based DWL Elektronishe 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 Compumedics Neuroscan Orion LifeSpan™ MEG:

Compumedics has overcome earlier MEG system barriers with the Compumedics Neuroscan Orion LifeSpan™ MEG's increased precision coupled with fully integrated CURRY software, the "gold standard" for brain signal analysis.

At the heart of the new Compumedics Neuroscan Orion LifeSpan™ MEG system is the patented Double Relaxation Oscillation Superconducting Quantum Interference Device (DROS SQUID) sensor, providing a new level of MEG sensitivity and spatial resolution.

Additionally, a unique dual-helmet dewar, enabling optimal brain signal localisation, applicable to the greater population including both adult and paediatric populations, is coupled to a vibration-free, vacuum-cooling system for virtually 100% coolant recycling, with continuous 24/7 operation. These advances contribute to transforming functional brain-health, but also provide a sustainable business model reinforced by high barriers of market entry, including patented technological and scientifically proven clinical deployment.

For further information please contact:

Dr David Burton
Executive Chairman, CEO Executive Director
Phone: + 61 3 8420 7300
Fax: +61 3 8420 7399

David Lawson
Chief Financial Officer
Phone: + 61 3 8420 7300
Fax: +61 3 8420 7399

Investor Relations, Media & PR enquires:

Rod North
Managing Director
Bourse Communications Pty Ltd
Phone: +61 3 9510 8309
Mobile: 0408 670 706

Richard Allen
Oxygen Financial PR
Ph: + 61 3 9915 6341
Mob: 0403 493 049