

ASX Release

O₂Vent T launched in USA – first orders received

Key Points:

- **All preparations for US launch of O₂Vent completed – first orders now received.**
- **Official launch at G'day USA event in San Francisco on 21st January, 2017 to be attended by a representative from the Department of Industry, Innovation and Science and local clinicians including dentists and sleep clinicians.**
- **Dr Chris Hart (Oventus Clinical Director) to present pilot clinical results on “maskless CPAP” – (results currently being analysed and to be the subject of a separate announcement). This is a key future product for Oventus and is designed to compete in the lucrative CPAP¹ market.**

Brisbane 18th January, 2017: Oventus Medical is pleased to announce that the O₂Vent T has been launched in the USA. Records for the first saleable product have been received and appliances have entered manufacturing.

Oventus CEO, Neil Anderson said: “A key use of funds from our ASX listing in July 2016 was to prepare for, and undertake a launch of the O₂Vent in the USA – a major market² for the treatment of obstructive sleep apnoea (OSA). After a lot of work from the Oventus team, it gives me great pleasure to announce that these preparations are now complete and we have received our first orders.”

In the last six months, launch preparations included:

- Submission of US 510k and FDA clearance for our launch product O₂Vent T
- ISO 13485 medical device accreditation for the company's quality management system for the design, development and manufacture of oral appliances in the treatment of sleep apnoea.
- Set up of a US subsidiary Oventus Medical USA in Delaware.
- Launch of a cloud based ERP³ system linking the US subsidiary to the Oventus Medical financial management system. The ERP system includes manufacturing, patient and customer management and Advanced Partner Centres (APC) (for individual clinical sites) that accesses only their own Patient records. The APC is compliant with HIPAA⁴ – a key requirement for managing patient records in the US.
- Setup of 5 beta (pilot) sites for delivery in various US locations. Clinicians have been trained, records have been taken and evaluation appliances successfully delivered to a small number of subjects.
- Partnering with a dental laboratory (FDA registered contractor manufacturer) to receive patient records. The partner laboratory will be scanning models, checking appliances and delivering to clinical customers. The appliances will be manufactured in the Oventus manufacturing facility in Australia.

- Preparations will culminate with an official launch event at a G'day USA in San Francisco on 2st January 2017 celebrating Australian innovation. There will be presentations from a representative of the Department for Industry, Innovation and Science, Lindsay Adler the CSIRO General Manager Global Operations, key US clinicians, Dr Chris Hart (Oventus Clinical Director) and Elise Hogan (Oventus VP for Sales, Marketing and Commercialisation). The event will be attended by sleep physicians/pulmonologists, general dentists and tech leaders.
- Dr Hart will present on the Oventus technology and initial clinical results on validation of the airway and CPAP requirements when connected to the Oventus appliance airway. This is a key study as it sets the future direction of the company's product portfolio and the company strategy. The results will be announced soon.

Oventus plans for the first half of the 2017 calendar year are to register additional products with the FDA, gather further clinical evidence to validate the benefit of the unique Oventus airway and to complete the US pilot launch - readying for an expanded US launch in the 2nd half of the 2017 calendar year.

Footnotes:

1. Continuous positive airway pressure therapy (CPAP) uses a machine to help a person who has obstructive sleep apnea (OSA) breathe more easily during sleep.
2. In the US it is estimated that there are 22 million people with Obstructive Sleep Apnoea and at least 80% are either out of treatment (eg non-compliant with other treatments) or have not been treated. (From Sleep Apnea Diagnostic & Therapeutic Devices Market – Global End-user Analysis, Competitive Landscape & Forecast to 2020 MarketsandMarkets 2015)
3. ERP or Enterprise Resource Planning is a business process management software that allows an organisation to use a system of integrated applications to manage the business and automate many back-office functions related to technology, manufacturing, customer management and financial management.
4. HIPAA, the Health Insurance Portability and Accountability Act, sets the standard for protecting sensitive patient data. Any company that deals with protected health information (PHI) must ensure that all the required physical, network, and process security measures are in place and followed.

-ENDS-

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About Oventus

Oventus is a Brisbane (Queensland, Australia) based medical device company that is commercialising a suite of oral appliances for the treatment of sleep apnoea and snoring. Unlike other oral appliances, the Oventus devices have a unique and patented airway within the device that delivers air to the back of the mouth bypassing multiple obstructions from the nose, soft palate and tongue. They are particularly designed for the many people that have nasal obstructions and consequently tend to mainly breathe through their mouth. While it may seem counter-intuitive, the device actually prevents oral breathing. The O₂Vent is designed to allow nasal breathing when the nose is unobstructed, but when obstruction is present, breathing is supplemented via the airways in the appliance.

According to a report published by the Sleep Health Foundation Australia, an estimated 1.5 million Australians suffer with sleep disorders and more than half of these suffer with obstructive sleep apnoea.¹

Continuous positive airway pressure (CPAP) is the most definitive medical therapy for obstructive sleep apnoea, OSA, however many patients have difficulty tolerating CPAP². Oral appliances have emerged as an alternative to CPAP for obstructive sleep apnoea treatment.³

¹ *Deloitte Access Economics. Reawakening Australia: the economic cost of sleep disorders in Australia, 2010. Canberra, Australia.*

² *Beecroft, et al. Oral continuous positive airway pressure for sleep apnea; effectiveness, patient preference, and adherence. Chest 124:2200–2208, 2003*

³ *Sutherland et al. Oral appliance treatment for obstructive sleep apnea: An updated Journal of Clinical Sleep Medicine. February 2014.*