

ASX Release

## Oventus Quarterly Business Review – Q3 FY2018

### Highlights

- Receipts from customers from sales of Oventus' O<sub>2</sub>Vent™ totalled \$101,881 in the March quarter, up from \$35,386 in the December 2017 quarter following the commencement of initial sales and marketing by Modern Dental Group in the Dentist channel in January
- Cost reduction program underway with R&D spend reducing as clinical trials are concluded, expected to kick in in the second half of calendar 2018
- Analysis of clinical trial data in progress with results from an additional 79 patients expected to be released in current June quarter
- Operational team bolstered in North America with appointment of Robin Randolph as Vice President of Marketing and Operations; and Greg Eaton as Vice President of Sales
- Government Research and Development tax incentive cash rebate of \$966,233, received in January 2018
- Oventus remains in a strong cash position with \$11.89m as at 31 March 2018

Brisbane, Australia 23 April 2018: Oventus Medical Ltd (ASX: OVN) (Oventus, the Company) announces its Appendix 4C Report for the three-month period ending 31 March 2018 (Q3 FY2018) and is pleased to provide a review of progress made during the quarter.

### Quarterly sales

Receipts from customers totalled \$101,881 in the March quarter, up 188% from \$35,386 in the December 2017 quarter (Q2 FY2018).

The increase in sales represents the beginning of Phase 3 activities in January 2018 involving the commencement of initial sales and marketing of Oventus products under the Modern Dental Group (Modern) manufacturing and distribution agreement into the Dental channel.

Founder and Clinical Director, Dr Chris Hart commented, "While we are still in the early stages of rolling out under the Modern agreement, the go to market activities undertaken by Modern in the Dental channel are now starting to have an impact on sales.

Along with our recently increased sales capability in the US, early feedback and progress in the Sleep channel indicates that we will be well positioned to start better driving sales in the second half of calendar 2018. A European launch is planned by the second half of calendar 2018."

### Operational staff appointments

Oventus is building out its operational, sales and marketing capability in North America to support the Modern dental implementation and the introduction of the Sleep channel products.

Ms Robin Randolph was recently appointed VP Marketing and Operations North America. Robin has over 30 years of experience in the sleep industry in the US. She worked with ResMed for twelve years

leading national accounts management and payee initiatives, as Director of Channel Management and then Director of Sleep Initiatives. She worked with Fisher and Paykel for eight years as the marketing manager for North America. As VP of operations and sales at MD Sleep/Cardiosom, she managed a large network of sleep clinics and durable medical equipment (DME) distributors. She also worked at Metamason Inc, a medtech start up developing 3D printed CPAP mask technology as the Chief Marketing Officer.

From her experience in these senior roles, Robin brings a deep knowledge base and skillset across all facets of the US sleep industry including sleep lab business operations, contracts, DME arrangements, diagnostic and therapeutic stakeholder engagement, KOL development, sales and marketing strategy development and implementation, clinical and sales training, new technology development and commercial launches of new technologies.

Dr Hart commented, "We are very excited that Robin is joining Oventus to speed up our adoption in a market as crucial as the US."

Robin Randolph, VP Marketing and Operations commented, "I was inspired to join Oventus because of the leadership and culture that is driven by creativity, innovation and clinical excellence. With products like the Oventus O<sub>2</sub>Vent™, bridging the gap between CPAP and standard oral appliances, we can drive positive change for patients suffering from OSA every single day."

Additionally, Greg Eaton has joined Oventus as VP of Sales with twenty years of experience in the sleep industry having taken on senior sales management roles with Resmed as a district sales manager, with DeVilbiss Healthcare as VP of Respiratory Sales and with Breas Medical as VP of Sales-Sleep.

Both Robin and Greg bring with them a wealth of knowledge and experience. Together they have developed and are now implementing a sales strategy for the Sleep channel to run in tandem with the distribution agreement in the Dental channel with Modern Dental Group to drive referrals for Oventus' 'Airway Technology' in both the Dental and Sleep channels. They are also working to introduce Oventus' 'Airway Technology' to industry stakeholders such as sleep alliances, payers and government bodies.

### **Dental channel – product roll out with Modern Dental**

Execution of the Modern agreements (signed in mid 2017) in the dental channel in the United States and Australia is well underway, with roll-out activities being completed under a three phased approach.

Phases 1 and 2 of the Modern manufacturing and distribution agreements were completed in the December 2017 quarter.

In the March 2018 quarter, Phase 1 testing of the manufacturing and logistics process under this agreement was completed and this has now moved into production. As a result of the Phase 1 activities, manufacturing of polymer inserts for Oventus devices fitted with the O<sub>2</sub>Vent™ airway is now being managed by Modern and finished devices are being shipped by Modern directly to customers.

Phase 2 activities have included updating marketing collateral, training of sales representatives and setting up for continuation of service with Oventus' existing dental customers who will now be managed through Modern. While this is a continuing process of ongoing training and implementation,

Modern is now well positioned in the US and Australia to support customers in their delivery of Oventus devices to patients.

Phase 3 of the manufacturing and distribution agreements is currently being executed, with Modern commencing initial sales and marketing of Oventus products in January 2018.

### **Sleep clinician channel – product roll out**

With the clinical evidence building to support Oventus' 'Airway Technology' as a new treatment modality for Obstructive Sleep Apnoea (OSA), additional sales capability to introduce Oventus to key stakeholders and early adopters in the Sleep channel is an important part of the sales strategy.

Initial discussions with key opinion leaders and significant sleep groups about Oventus' sleep treatment platform in both the Australian and US markets have proven positive.

Several significant groups are in the process of adopting the technology as part of their treatment options for their patients. They can see how the technology may benefit a proportion of their patients for whom traditional oral appliance therapy or CPAP therapy may not be achieving optimal outcomes.

Informing sleep physicians as gatekeepers of the industry of the benefits of Oventus' technology is critical for the adoption as a standard of care for their patients. This is a long term strategy to drive adoption of both the Sleep channel products such as the CPAP interface (O<sub>2</sub>Vent™ Connect) which is in the late stages of development and also for the referral of patients for Oventus' O<sub>2</sub>Vent™ line of oral appliances (currently manufactured in titanium variations and a nylon version is in late stage R&D).

Licensing and partnering discussions for Oventus' Sleep channel technologies are underway to reduce the costs associated with launching and to provide a streamlined path to market.

### **Product development**

Product development has been guided by clinical trial results and on market feedback on the existing range of devices. Efforts to bring Oventus' products to market, specific to the Sleep channel has also been progressing well.

In response to feedback from clinicians we have undertaken a significant review of the O<sub>2</sub>Vent™ T and O<sub>2</sub>Vent™ W devices to make them easier to adjust, more robust, more ergonomic and smaller, and therefore more user friendly for both patients and clinicians. Additionally, the development of the nylon O<sub>2</sub>Vent™ appliances, in bespoke and temporary appliance formats, which are ultralight weight and much lower cost to produce, is ahead of schedule.

These improvements to the range of O<sub>2</sub>Vent™ oral appliances are intended to increase the rate of adoption and significantly reduce manufacturing costs. Development of the temporary nylon device has taken longer than expected due to technical challenges that Oventus is working to overcome in partnership with the CSIRO. Good progress is now being made on this product.

The O<sub>2</sub>Vent Connect - CPAP interface development is on track. As part of its development there was a need to control exhalation through the Oventus' O<sub>2</sub>Vent™ airway which resulted in the development of a peak end expiratory pressure (PEEP) valve to fit within the O<sub>2</sub>Vent™ 'duck bill' of the airway. The PEEP valve, when implemented within the duck bill of the O<sub>2</sub>Vent™, may further increase the efficacy

of the Oventus Airway in the O<sub>2</sub>Vent™ range of oral appliances for a number of patients. Further investigations are under way.

These developments, combined with the growing body of clinical evidence, positions Oventus well for the developing discussion on partnering and licensing the Sleep channel products.

**Clinical trials and presentation of data in scientific forums**

To date, data has been collected and analysed across 50 patients over four clinical studies, all consistently showing strong clinical efficacy of the O<sub>2</sub>Vent™ oral appliance.

Oventus is currently analysing data collected from a further 79 patients across three clinical studies which concluded in late 2017 and early 2018. Following release of this data, Oventus’ O<sub>2</sub>Vent™ will have been trialled in over 120 OSA sufferers with the aim of validating the Oventus’ ‘Airway Technology’ for use in both oral appliances and as a CPAP interface.

Final results are expected in the following timeframes:

Trial name	Expected date of final data
<b>OVEN-003 ‘Brisbane’ study</b>	Calendar Q2 2018
<b>OVEN-004 ‘Perth’ study</b>	Calendar Q3 2018
<b>OVEN-005 ‘Sydney’ study</b>	Calendar Q2 2018

Results are expected to be in line with results from previous studies with Oventus’ ‘Airway Technology’. These results indicate the ‘Airway Technology’:

1. Improves outcomes for oral appliance therapy compared to mandibular advancement alone
2. Provides increased efficacy in more severe OSA sufferers and in those with increased nasal resistance
3. Can treat patients with increased nasal resistance and soft palate collapse as effectively as those without these issues
4. Reduces PAP pressure requirements when used in a CPAP interface (O<sub>2</sub>Vent Connect)
5. Allows mouth breathing while delivering nasal CPAP, eliminating the need for full face masks

This is a departure from current outcomes for existing oral appliance and CPAP therapy in the market and supports the use of Oventus’ ‘Airway Technology’ in a large number of patients that may not respond to existing technologies, reinforcing the indication for Oventus’ ‘Airway Technology’ in approximately half of OSA sufferers. This represents a significant clinical benefit and a major commercial opportunity for the Company.

**Cost Reduction**

As Oventus transitions from being a predominantly R&D focussed company to a sales oriented company, sales channel investment is required to increase the rate of adoption of our products.

There will be some one-off structural costs associated with this transition in the current June quarter however the Company aims to offset this with cost savings elsewhere as R&D spending falls along with the finalisation of outsourcing manufacturing.

While cash burn is expected to remain similar to previous quarters through to the end of the June quarter, a key focus for the company will be cost reduction in the second half of calendar 2018 as significant R&D projects and the restructure to focus on sales are completed.

#### **R&D tax incentive**

A \$966,233 cash refund was received from the Australian Taxation Office under the Federal Government's Research and Development (R&D) Tax incentive scheme in January.

#### **Investor engagement**

In January 2018, Dr Chris Hart presented at the Biotech Showcase during JP Morgan Healthcare week in San Francisco. In addition to this presentation, he held a number of meetings with US and Australian investors during the visit.

In February, Oventus presented to shareholders and investors in Brisbane at Tattersall's Club. The presentation can be viewed as an ASX announcement and on the Oventus website in the Investor section under 'Presentations'.

Immediately after the quarter, Oventus relaunched the 'Investor' and 'News & Media' sections of our website.

Visit our website to learn more about Oventus and our engagement activities with investors, shareholders and in the media. We also encourage those shareholders interested in following our progress to sign up for our Email Alerts service via this link: <http://oventus.com.au/investors/>.

#### **Cash position**

As at 31 March 2018, the Company maintained a solid cash position of \$11.89m.

#### **Outlook**

Looking forward, Oventus will be well positioned to start better driving sales in the second half of calendar 2018. Key developments expected across the coming quarters include:

- Increasing sales of the titanium O<sub>2</sub>Vent™ oral appliance in both Australia and US through the Modern channel as a wider rollout is undertaken.
- Continuing commercialisation activities around a number of late state R&D projects including the O<sub>2</sub>Vent™ Connect – CPAP interface and the nylon O<sub>2</sub>Vent™ appliances.
- Clinical trial results across three studies to be released in the current June quarter from the 'Brisbane', 'Sydney' and 'Perth' studies covering over 70 patients, further building on the clinical body of evidence on the Oventus 'Airway Technology'.

Oventus invites you to follow our progress via our website at [www.oventus.com.au](http://www.oventus.com.au).

—ENDS—

For more information, please contact:

Mr Neil Anderson, Managing Director and CEO: M: 0403 003 475

Jane Lowe, IR Department: M: 0411 117 774 or [jane.lowe@irdepartment.com.au](mailto:jane.lowe@irdepartment.com.au)

## About Oventus

Oventus is a Brisbane, Australia, based medical device company that has commercialized and brought to market a new **sleep treatment platform** for the treatment of sleep apnoea and snoring that enhances the treatment outcomes of both oral appliance therapy and CPAP therapy through increased efficacy and greater adherence.

**Oral appliance:** Oventus' unique and patented 'Airway Technology' incorporated into an oral appliance, the O<sub>2</sub>Vent™, bypasses multiple levels of breathing obstruction including the nose, soft palate and tongue.

Our appliances are particularly designed for sufferers with nasal obstructions, soft palate collapse and who consequently tend to breathe through their mouth while sleeping.

In action, when nasal obstruction is present, breathing is supplemented through the O<sub>2</sub>Vent™'s integrated 'Airways' delivering air to the back of the mouth while maintaining an oral seal, stabilizing the tongue base, bypassing obstructions in the nose and soft palate and reducing the collapsibility of the upper airway. However, when the nose is unobstructed, the O<sub>2</sub>Vent™ allows for natural nasal breathing.

**'O<sub>2</sub>Vent™ Connect' Positive Airway Pressure (PAP) Connection:** Severe sleep apnoea sufferers who have traditionally used a CPAP machine and full facemask can use Oventus' O<sub>2</sub>Vent™ oral appliance to interface with CPAP reducing operating pressure by around 66%, eliminating the need for straps and allowing physiologic mouth breathing while delivering CPAP. This has allowed for a re-design of the CPAP delivery system which is far less intrusive (without full face mask and straps), called the 'O<sub>2</sub>Vent™ Connect'.

Oventus' O<sub>2</sub>Vent™ Connect' attaches to the front of the O<sub>2</sub>Vent™, thereby doing away with the full face mask, while bringing air from the CPAP machine to the nasal opening at lower pressure.

**Clinical trials:** Over 50 patients to date have shown Oventus' O<sub>2</sub>Vent™ is successful in treating Obstructive Sleep Apnoea (OSA) by an additional 30-50% and that snoring was either eliminated or significantly reduced, when compared to mandibular or "jaw" advancement oral appliances which primarily reduce tongue based breathing obstruction. The positive results included those sufferers who had nasal obstructions and mainly breath through the mouth.

**Market:** 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.<sup>1</sup>

Continuous positive airway pressure (CPAP) is the most definitive medical therapy for obstructive sleep apnoea, however many patients have difficulty tolerating CPAP<sup>2</sup> due to discomfort caused from high operating pressure and low tolerance for a full face mask.

**The Oventus oral appliance 'Airway Technology' in the O<sub>2</sub>Vent™ when incorporated with Oventus' 'O<sub>2</sub>Vent™ Connect' allows sufferers to breathe physiologically through the mouth or through the**

nose whilst simultaneously delivering CPAP. Mild sufferers are able to solely wear the O<sub>2</sub>Vent™ oral appliance.

Further information can be found on our website: <http://oventus.com.au/how-it-works/>.

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

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

## Appendix 4C

### Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

**Name of entity**

OVENTUS MEDICAL LIMITED

**ABN**

12 608 393 282

**Quarter ended ("current quarter")**

31 MARCH 2018

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	102	251
1.2 Payments for		
(a) research and development	(615)	(1,746)
(b) product manufacturing and operating costs	(161)	(542)
(c) advertising and marketing	(197)	(273)
(d) leased assets	-	-
(e) staff costs	(552)	(1,800)
(f) administration and corporate costs	(446)	(1,339)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	69	128
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	966	966
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(834)</b>	<b>(4,355)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	(48)	(124)
(b) businesses (see item 10)	-	-
(c) investments	-	-

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
(d) intellectual property	(103)	(145)
(e) other non-current assets	-	-
<b>2.2</b> Proceeds from disposal of:		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-
(d) intellectual property	-	-
(e) other non-current assets	-	-
<b>2.3</b> Cash flows from loans to other entities	-	-
<b>2.4</b> Dividends received (see note 3)	-	-
<b>2.5</b> Other (provide details if material)	-	-
<b>2.6</b> <b>Net cash from / (used in) investing activities</b>	<b>(151)</b>	<b>(269)</b>

<b>3.</b> <b>Cash flows from financing activities</b>		
3.1 Proceeds from issues of shares	-	8,332
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	-	-
3.4 Transaction costs related to issues of shares, convertible notes or options	-	(466)
3.5 Proceeds from borrowings	-	-
3.6 Repayment of borrowings	-	-
3.7 Transaction costs related to loans and borrowings	-	-
3.8 Dividends paid	-	-
3.9 Other (provide details if material)	-	-
<b>3.10</b> <b>Net cash from / (used in) financing activities</b>	<b>-</b>	<b>7,866</b>

<b>4.</b> <b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of quarter/year to date	12,874	8,647
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(834)	(4,355)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(151)	(269)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	-	7,866

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
4.5	Effect of movement in exchange rates on cash held	-	-
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>11,889</b>	<b>11,889</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	11,889	12,874
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>11,889</b>	<b>12,874</b>

**6. Payments to directors of the entity and their associates**

- 6.1 Aggregate amount of payments to these parties included in item 1.2
- 6.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

**Current quarter  
\$A'000**

37

-

Payment of directors' fees.

**7. Payments to related entities of the entity and their associates**

- 7.1 Aggregate amount of payments to these parties included in item 1.2
- 7.2 Aggregate amount of cash flow from loans to these parties included in item 2.3
- 7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

**Current quarter  
\$A'000**

-

-

8. <b>Financing facilities available</b> <i>Add notes as necessary for an understanding of the position</i>	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1 Loan facilities	-	-
8.2 Credit standby arrangements	-	-
8.3 Other (please specify)	-	-
8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.		

--

9. <b>Estimated cash outflows for next quarter</b>	\$A'000
9.1 Research and development	(500)
9.2 Product manufacturing and operating costs	(190)
9.3 Advertising and marketing	(250)
9.4 Leased assets	
9.5 Staff costs	(600)
9.6 Administration and corporate costs	(450)
9.7 Other (provide details if material)	(160)
<b>9.8 Total estimated cash outflows</b>	<b>(2,150)</b>

10. <b>Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)</b>	Acquisitions	Disposals
10.1 Name of entity		
10.2 Place of incorporation or registration		
10.3 Consideration for acquisition or disposal		
10.4 Total net assets		
10.5 Nature of business		

**Compliance statement**

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.



Sign here: .....  
(Director/Company secretary)

Date: 23 APRIL 2018

Print name: NEIL ANDERSON

**Notes**

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.