

ASX Release

## Oventus Quarterly Business Review – Q2 FY2019

### Highlights

- Sales and marketing of Oventus' 'Sleep Treatment Platform' as a new treatment modality shifted to focus on the sleep channel as Modern Dental distribution agreement moves to non-exclusive in the US
- Manufacturing, customer care and distribution processes reorganised and streamlined to enable better service and delivery times
- Reduced fixed costs in business by 15-20% by outsourcing all manufacturing moving forward to CY2019
- Non-Executive Director appointment to the Board, Mr Sharad Joshi, US based with deep medical technology experience
- New O<sub>2</sub>Vent Optima™ nylon device launched in Australia post quarter end; to be followed by launch in Canada during calendar Q2 and US once US 510(k) FDA approval is received
- Oventus cash position remains solid with \$7 million at bank as at 31 December 2018

Brisbane, Australia 29 January 2019: Oventus Medical Ltd (ASX: OVN) (Oventus, the Company) announces its Appendix 4C Report for the three-month period ending 31 December 2018 (Q2 FY2019) and is pleased to provide a review of progress made during the quarter.

### Quarterly sales commentary

Receipts from customers for the sale of Oventus' O<sub>2</sub>Vent™ devices for the treatment of Obstructive Sleep Apnoea (OSA) totalled \$47,000 (Q2 FY2019), compared to \$107,000 in the September quarter (Q1 FY2019) and \$37,000 in the FY2018 corresponding period (Q2 FY2018). Cash receipts from customers for the December quarter were impacted by seasonality and a delay in payments to Oventus by distribution partner, Modern Dental. Post the quarter, the outstanding payments totalling \$20,000 were received and will therefore be included in the Q3 FY2019 cash flow reporting.

### Manufacturing and distribution

The distribution agreement between Oventus and Modern Dental became non-exclusive at the end of the December quarter, enabling the opportunity to launch sales and distribution in the sleep channel with a direct-to-customer sales approach and US based manufacturing and distribution. The sleep channel is of particular interest to Oventus as the Company's core technology is recognized by sleep physicians as a new treatment modality which has the ability to deliver significantly improved clinical outcomes to their patients.

In order to facilitate early sales with US sleep groups and to streamline communication leading to a further reduction in delivery times, the Company is also setting up online order entry, along with direct distribution, customer care and outsourced manufacturing in the US. This will enable Oventus to provide customers with US manufactured O<sub>2</sub> Vent T and W oral devices until 510(k) US Food and Drug Administration (FDA) regulatory clearance for Optima™ is granted.

### **Australian Optima™ product launch**

The Company was delighted to announce the formal launch of its nylon O<sub>2</sub> Vent Optima™ device in Australia in January, following a successful controlled pilot release with patients in the December quarter.

The O<sub>2</sub> Vent Optima™ is the newest product in the O<sub>2</sub> Vent® oral device range. It offers a new treatment alternative for the potentially fatal condition, obstructive sleep apnoea (OSA). The O<sub>2</sub> Vent Optima™ is a customised 3D printed nylon oral appliance that advances the jaw forward to open the airway and incorporates the Oventus proprietary Airway Technology to improve the effectiveness of oral appliance therapy. This device is lighter than the original O<sub>2</sub> Vent® technology and less complex to make. The combination of reduced material costs and lower manufacturing times brings down the cost of goods and shortens delivery times of devices to customers.

There has been a lot of early interest from Australian clinicians in the Optima™. Combined with the changes made to manufacturing outlined earlier in this report, Oventus expects the interest in Optima™ to translate to an improvement in sales during the March FY2019 quarter and remains confident about sales revenue for calendar 2019.

### **US and Canada sales, marketing and Optima™ product launch**

Under the leadership of VP Marketing and Operations, Robin Randolph, the US team is building relationships with national sleep groups and physician networks who know exactly those patients currently outside of care for obstructive sleep apnoea, due to their refusal of, or inability to tolerate continuous positive airway pressure (CPAP). A significant social media campaign will soon commence that will funnel the struggling and CPAP-failed patients into a network finder, where patients can receive education, direction and a conduit to locate providers that are trained and aligned with the Oventus product line.

A controlled market release of Optima™ in Canada is nearing completion with early success demonstrating strong product adoption and patient acceptance. The commercial market launch in Canada is planned for early February. The US Optima™ launch is expected to follow once regulatory clearance is received from the US FDA.

Reception to the Optima™ and the strong clinical evidence differentiating Oventus Airway Technology as a new treatment modality by the US sleep community has been exceptional. The Company expects that once these groups are familiar with the technology and Optima™ is in market in the US sleep channel, sales will ramp.

### **Operations restructured to reduce fixed costs**

A key area of focus for the Company for the past two quarters through to the end of December 2018 has been on restructuring operations to reduce fixed costs, eliminate inefficiencies and focus on the most likely market segments in which sales volumes will ramp. Costs in the business have been reduced 15-20%.

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

A \$1.039m cash refund for research activities in FY2018 was received from the Australian Taxation Office under the Federal Government's Research and Development (R&D) Tax incentive scheme in November 2018.

### **Non-Executive Director appointment**

In December 2018, Mr Sharad Joshi was appointed to the Board as Non-Executive Director. US based, Sharad brings extensive experience in the medical technology sector with a biomedical engineering background and strong experience in launching medical devices in the North American market. He has also had exposure to the sleep market, extensive experience with IP, management, regulatory approvals, sales and marketing of medical devices including launch, capital raising and investor relations.

His appointment will complement the September 2018 appointment of Oventus' US Medical Technology Advisory Board, which is comprised of a number of leading sleep physicians and advisors bringing expertise in the North American market. The MTAB and board experience are pivotal elements in Oventus' go to market strategy.

### **Outlook**

The Company expects sales of Optima™ in Australia to continue to grow, and to see Optima™ launch in Canada within the coming weeks. Sales of the O<sub>2</sub>Vent T and W devices in the US will remain around current levels until Optima™ is available (pending 510(k) regulatory clearance from the US FDA).

A new product within Oventus' 'Sleep Treatment Platform', the ExVent™ - a peek end expiratory pressure valve which has been shown in clinical trial settings to treat over 75% of patients when used in conjunction with the O<sub>2</sub>Vent® devices – is expected to be launched in Australia and Canada in Q1 CY2019. ExVent™ further extends the efficacy of the O<sub>2</sub>Vent oral devices and improves treatment outcomes of the Oventus 'Sleep Treatment Platform' to CPAP like levels for the majority of patients. This new treatment modality is highly anticipated by the sleep community and is potentially transformational for the Company.

In line with this outlook management have significantly reduced fixed costs and R&D spend to focus on building revenue and to ensure enough cash runway to reach cashflow breakeven. Oventus board and management believe that 2019 will be a pivotal year for the Company.

—ENDS—

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

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### **About Oventus**

Oventus is a Brisbane based medical device company that is commercialising a unique treatment platform for the treatment of sleep apnoea and snoring. Unlike other oral appliances or CPAP interfaces, the Oventus devices have a unique and patented airway within the treatment platform that allows air to flow to the back of the mouth unobstructed while maintaining an oral seal and stable

jaw position, bypassing multiple obstructions from the nose, soft palate and tongue, reducing airway collapsibility and managing mouth breathing while maintain a stable airway with or without nasal CPAP. 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 counterintuitive, this technology actually manages mouth breathing by converting it to device breathing and normalising ventilation. The O<sub>2</sub>Vent™ 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.<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>. Oral appliances have emerged as an alternative to CPAP for obstructive sleep apnoea treatment.<sup>3</sup>

<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*

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

## 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 December 2018

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (6 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	47	154
1.2 Payments for		
(a) research and development	(454)	(782)
(b) product manufacturing and operating costs	(157)	(205)
(c) advertising and marketing	(51)	(349)
(d) leased assets	-	-
(e) staff costs	(958)	(1,801)
(f) administration and corporate costs	(760)	(1,145)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	27	103
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,125	1,125
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,181)</b>	<b>(2,900)</b>

<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	(99)	(122)
(b) businesses (see item 10)	-	-
(c) investments	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
	(d) intellectual property	(36)	(243)
	(e) other non-current assets	(17)	(30)
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	400
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	<b>Net cash from / (used in) investing activities</b>	<b>(152)</b>	<b>5</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of shares	-	-
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	-	-
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)	-	-
3.10	<b>Net cash from / (used in) financing activities</b>	<b>-</b>	<b>-</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	8,333	9,895
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,181)	(2,900)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(152)	(5)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.5	Effect of movement in exchange rates on cash held	-	-
4.6	<b>Cash and cash equivalents at end of quarter</b>	<b>7,000</b>	<b>7,000</b>

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	7,000	8,333
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>7,000</b>	<b>8,333</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**

48  
-

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>	<b>\$A'000</b>
9.1 Research and development	(160)
9.2 Product manufacturing and operating costs	(147)
9.3 Advertising and marketing	(189)
9.4 Leased assets	-
9.5 Staff costs	(960)
9.6 Administration and corporate costs	(293)
9.7 Other (provide details if material)	(141)
<b>9.8 Total estimated cash outflows</b>	<b>(1,890)</b>

10. <b>Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)</b>	<b>Acquisitions</b>	<b>Disposals</b>
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:   
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(Director/Company secretary)

Date: **29 January 2019**

Print name: **Dr. Chris Hart**

### 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.