

# BETTER SLEEP, BETTER HEALTH and a BETTER LIFE

### **ASX Release**

# Oventus 4E – Platform in place for accelerated growth

# **Key Points:**

- Successful IPO Raised \$12 million strong institutional support
- Received FDA clearance for O<sub>2</sub>Vent<sup>TM</sup> Mono device
- Launched next generation O<sub>2</sub>Vent<sup>TM</sup> T device in Australia
- Manufacturing scale up in place
- Strong interest generated at major US sleep conference
- Early sales revenue encouraging
- Awaiting FDA clearance on 2<sup>nd</sup> device
- Technology breakthrough in our airway

Brisbane, Australia 25th August 2016: Medical device sleep apnoea and snoring disorder company Oventus Medical Ltd. (ASX: OVN) releases its first 4E. The company has established a platform for accelerated growth following a successful IPO raising \$12 million and is reporting encouraging early revenue.

Oventus is focused on developing and producing oral appliances to treat obstructive sleep apnoea and snoring, especially in people who cannot be, or are not effectively treated with existing devices or therapies.

CEO Neil Anderson said, "The Company's devices are 3D printed and feature a unique airway that channels air to the back of the throat, bypassing oral obstructions that cause sleep apnoea and snoring. We have established state of the art systems and processes that will drive growth for the company going forward."

Oventus has reported early revenues of \$540,164 for the 12 months to June 30, 2016 and achieved significant milestones which are driving the company forward.

The company received clearance from the US Food and Drug Administration (FDA) for its first generation device, the  $O_2Vent^{TM}$  Mono, and has made an application for its second generation titratable device, the  $O_2Vent^{TM}$  T.

Oventus launched the  $O_2Vent^{TM}$  T in Australia and enrolled the first patient in a 40 patient clinical trial of the device. The trial will produce data around the comfort, safety and efficacy of the  $O_2Vent^{TM}$  T, as well as the comfort and efficacy of the inclusion of an airway into an oral appliance. Oventus has a unique position with a patent protected device in the growing sleep disorder market.



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A Scientific Advisory Committee of sleep, dentistry and ear, nose and throat experts has been established in Australia to advise on clinical trial design for Oventus' current and future products.

Clinical Director and founder Dr Chris Hart said: "We believe obstructive sleep apnoea is a serious medical condition that requires a multidisciplinary approach to treatment. We look forward to working with the committee so that our devices achieve maximum patient benefit."

Oventus has also established a 3D titanium printing facility at CSIRO in Melbourne and a production operation in Brisbane for polymer inserts and packaging.

The company is also making significant progress driving awareness for its products with attendance at Sleep 2016, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society. There was considerable interest among attendees of Oventus' technology and its potential to treat obstructive sleep apnoea.

#### -ENDS-

For more information please contact:

Dr Mel Bridges, Chairman: M: 0413 051 600 (+61413051600)

Gavin Lower, WE Buchan: P: 03 8866 1215 or M: 0414 796 726

#### **About Oventus**

Oventus is a Brisbane 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 counterintuitive, the device actually prevents oral breathing. 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, OSA, 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>



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

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

#### OVENTUS MEDICAL LIMITED Appendix 4E Preliminary final report 30 June 2016

#### 1. Company details

Name of entity: Oventus Medical Limited

ACN: 608 393 282

Reporting period: For the year ended 30 June 2016
Previous period: For the year ended 30 June 2015

#### 2. Results for announcement to the market

Revenues from ordinary activities	up	859%	to	\$ 540,164
Loss from ordinary activities after tax attributable to the owners of Oventus Medical Limited (the Company)	up	1196%	to	(2,341,078)
Loss for the year attributable to the owners of Oventus Medical Limited	ир	1196%	to	(2,341,078)
			30 Jun 2016 Cents	30 Jun 2015 Cents
Basic earnings per share Diluted earnings per share			(5.37 (5.37	, ,

30 June 2015 amounts shown above have been adjusted for share restructure and consolidations.

#### 3. Commentary on results for the year

The loss for the consolidated entity after providing for income tax amounted to \$2,341,078 (30 June 2015: loss of \$180,579)

During the 2015 and 2016 financial years the Company operated mainly as a research and development company. During this premarketing phase the Company has been focused on the development of the O2Vent™ device, ensuring it meets the relevant technical requirements for sale as a medical device in Australia and overseas, and can be manufactured in an efficient and quality assured manner while meeting the targeted gross profit margin.

The significant factors underlying the operating performance were as follows:

- 1. A new product O2Vent<sup>TM</sup> Titratable was developed and brought to market in Australia. Other proof of concept projects were advanced, such as the Positive Airway Pressure Connection to an O2Vent<sup>TM</sup> Titratable.
- 2. Pilot manufacturing has been established and is ready for expansion. This includes the following:
  - a. Melbourne the Company have leased space from the CSIRO, employed staff and acquired equipment including a 3D printer for printing titanium and polishing equipment;
  - b. Brisbane the Company has established its production setup for producing polymer inserts, packaging and dispatch; and
  - c. The development of the Company's Enterprise Resource Planning (ERP) system is underway and is due for completion during the 2016 calendar year.
- 3. A pilot marketing launch has been completed on O2Vent<sup>™</sup> Mono. As a result to Company earned \$540,614 in revenue in 2016.

Development expenditure totalling \$991,131 has been capitalised in the balance sheet. This amount is shown net of research and development tax concessions received or receivable totalling \$730,037. Development expenditure is expected to increase in the 2017 year as a result of new products being developed, clinical trials for new products and the ongoing collection of clinical data on existing product use.

The consolidated entity had an excess of current liabilities over current assets of \$664,213 at 30 June 2016. It had the following measures in place at 30 June 2016 to ensure it continued to meet its obligations:

- 1. The directors had agreed to provide loan funding to the consolidated entity and at 30 June 2016 had advanced \$762,422, which was included in current liabilities; and
- 2. The Company had entered into an underwriting agreement at 30 June to raise \$12 million.

Subsequent to the end of the financial year Oventus Medical Limited raised \$12 million, less transaction costs of \$1.04 million, by the issue of 24,000,000 fully paid ordinary shares at an issue price of \$0.50 per share.

#### OVENTUS MEDICAL LIMITED Appendix 4E Preliminary final report 30 June 2016

### 4. Expected future developments

The following factors are likely to affect the results of the consolidated entity in the future:

- A research and development project for the 3D printing of inserts is currently underway. When implemented this is anticipated
  to lead to a significant reduction in productions costs compared to the current manufacturing process.
- 2. A new method for polishing titanium printed appliances is being implemented, which is expected to increase the efficiency of production. This process is due to be implemented in the first half of the 2017 financial year.

5. Net tangible assets		Reporting period Cents	Previous period Cents
Net tangible assets per ordinary sec	curity	1.39	(233.81)
	rther 24 million shares after year end raising \$10.96 m ue results in net tangible assets per ordinary security o		costs. Adjusting the
6. Control gained over entities			
Name of entities	Oventus Manufacturing Pty Ltd	Oventus CRM Pty	Ltd
Date control gained	28 September 2015	23 September 201	5
Contribution of such antities to the	reporting entity's profit/(loss) from ordinary activities		\$
before income tax during the year	eporting entity's promotioss, non-ordinary activities		(2,181,381)
Profit/(loss) from ordinary activities before income tax of the controlled entity (or consolidated entity of entities) for the whole of the previous year			(180,579)
7. Loss of control over entities			
Name of entities (or consolidated en	ntity of entities)		
Not applicable			
8. Dividends			
Current period There were no dividends paid, reco	mmended or declared during the current year.		
Previous period There were no dividends paid, reco	mmended or declared during the previous year.		
9. Dividend reinvestment plans			
Not applicable.			
10. Details of associates and join	t venture entities		
Not applicable			

### 11. Foreign entities

Details of origin of accounting standards used in compiling the report

Not applicable.

### OVENTUS MEDICAL LIMITED Appendix 4E Preliminary final report

### 12. Attachments

The Preliminary Final Report of Oventus Medical Limited for the year ended 30 June 2016 is attached.

# 13. Audit qualification or review

This Preliminary Final Report for the year ended 30 June 2016 is based on accounts which are currently being audited by the company's independent auditor, PKF Hacketts Audit.

# 14. Signed

Signed \_\_\_\_\_

Date: 25 August 2016

Mel Bridges Director Sydney

# OVENTUS MEDICAL LIMITED ACN 608 393 282

Preliminary Final Report 30 June 2016

# OVENTUS MEDICAL LIMITED Preliminary Final Report Contents 30 June 2016

#### Contents

Statement of profit or loss and other comprehensive income	6
Statement of financial position	7
Statement of changes in equity	8
Statement of cash flows	9
Notes to the financial statements	10

#### **General information**

The financial statements cover Oventus Medical Limited as a consolidated entity, consisting of Oventus Medical Limited **(the Company)** and the entities it controlled at the end of, or during, year. The financial statements are presented in Australian dollars, which is Oventus Medical Limited's functional and presentation currency.

The preliminary financial statements were authorised for issue, in accordance with a resolution of directors, on 25 August 2016. The directors have the power to amend and reissue the financial statements.

# OVENTUS MEDICAL LIMITED Statement of profit or loss and other comprehensive income For the year ended 30 June 2016

	Consolidated	
	2016 \$	2015 \$
Sales revenue	540,164	56,303
Less: Expenses		
Manufacturing costs - Pilot phase	512,007	63,043
Marketing, website and logo expenses	341,266	41,325
Accounting and legal fees	195,774	29,702
Employee and contractors expense	822,380	45,821
Premises rental expense	85,620	6,383
Information technology costs	137,542	12,839
Insurance expense	26,297	12,086
Depreciation and amortisation	197,470	6,490
Other expenses	575,757	19,804
Total expenses	2,894,113	237,493
Operating loss before interest and tax	(2,353,949)	(181,190)
Interest revenue	12,871	611
Loss before income tax expense	(2,341,078)	(180,579)
Income tax expense	-	-
Loss for the period	(2,341,078)	(180,579)
Other comprehensive income for the period		
Total comprehensive loss	(2,341,078)	(180,579)

# OVENTUS MEDICAL LIMITED Statement of financial position As at 30 June 2016

		Consolidated	
	Note	2016	2015
		\$	\$
Current assets			
Cash and cash equivalents		161,114	42,876
Trade and other receivables		220,304	57,108
Other current assets		648,348	3,060
Total current assets	_	1,029,766	103,044
Non-current assets			
Non-current assets			
Property, plant and equipment		1,427,298	3,616
Intangible assets	3	1,270,978	953,666
Total non-current assets		2,698,276	957,282
	_		
Total assets	_	3,728,042	1,060,326
Current liabilities			
Trade and other payables		1,655,614	830,132
Employee entitlements		38,365	-
Total current liabilities		1,693,979	830,132
Non-current liabilities			
Other liabilities		97,724	78,156
Total non-current liabilities	_	97,724	78,156
Total liabilities	_	1,791,703	908,288
	_	, , , , , , , , , , , , , , , , , , , ,	
Net assets	=	1,936,339	152,038
Equity			
Share capital	4	4,426,703	342,857
Reserves	•	41,533	-
Accumulated losses		(2,531,897)	(190,819)
Total equity	_	1,936,339	152,038
	=		

# OVENTUS MEDICAL LIMITED Statement of changes in equity For the year ended 30 June 2016

	Contributed Equity \$	Share Based Payments Reserve \$	Accumulated Losses \$	Total \$
Balance at 1 July 2014	342,857	-	(10,240)	(10,240)
Profit / (loss) for the period		-	(180,579)	(180,579)
Total comprehensive income for the year		-	(180,579)	(180,579)
Balance at 30 June 2015	342,857	-	(190,819)	152,038
Balance at 1 July 2015	342,857	_	(190,819)	152,038
Profit / (loss) for the year Other comprehensive income	-	-	(2,341,078)	(2,341,078) -
Total comprehensive income for the year	-	-	(2,341,078)	(2,341,078)
Transactions with owners in their capacity as owners: Contributions of equity, net of transaction costs and tax Share based payments	4,083,846	- 41,533	- -	4,083,846 41,533
Total transactions with owners in their capacity as owners:	4,083,846	41,533	-	4,125,379
Balance at 30 June 2016	4,426,703	41,533	(2,531,897)	1,936,339

# OVENTUS MEDICAL LIMITED Statement of cash flows For the year ended 30 June 2016

	Con	
Note	2016 \$	2015 \$
Cash flows from operating activities		
Receipts from customers	509,373	39,473
Payments to suppliers and employees	(2,244,878)	(194,168)
Interest received	12,871	611
R&D tax concession received	255,609	78,156
Interest paid	(319)	-
Net cash outflow from operating activities	(1,467,344)	(75,928)
Cash flows from investing activities		
Payments for property, plant and equipment	(1,694,384)	(2,987)
Payments to cash deposit	(92,385)	-
Payments for intangible assets	(974,146)	(500,325)
Net cash outflow from investing activities	(2,760,915)	(503,312)
Cash flows from financing activities		
Proceeds from issue of shares, net of transaction costs	4,125,379	239,999
Proceeds from borrowings from directors and related entities	221,118	381,691
Net cash inflow from financing activities	4,346,497	621,690
Net increase in cash held	118,238	42,450
Cash and cash equivalents at the beginning of the year	42,876	426
Cash and cash equivalents at the end of the year	161,114	42,876

The above statement of cash flows should be read in conjunction with the accompanying notes.

# OVENTUS MEDICAL LIMITED Notes to the financial statements 30 June 2016

#### Note 1. Significant accounting policies

These preliminary statements have been prepared in accordance with the ASX listing rules and do not include all the notes of the type normally included in annual financial statements. Accordingly, these financial statements are to be read in conjunction with the financial statements for the year ended 30 June 2015 and half year ended 31 December 2015 and any public announcements made by the company during the interim reporting period in accordance with the continuous disclosure requirements of the Corporations

The principal accounting policies adopted are consistent with those of the previous financial year and corresponding interim reporting period, unless otherwise stated.

The Company was incorporated on 23 September 2015. At the same time Oventus CRM Pty Ltd was incorporated as a wholly owned subsidiary of the Company. On 28 September 2015, the Company acquired all the issued shares in Oventus Manufacturing Pty Ltd, the consideration being the issue of 74,375,000 fully paid shares in the Company **(the Restructure)**. Oventus Manufacturing Pty Ltd is the operating company in the consolidated entity. Oventus Medical Limited and Oventus CRM Pty Ltd have not traded during the year.

As the shareholders of Oventus Manufacturing Pty Ltd prior to the Restructure were the same as the shareholders of the Company on completion of the Restructure, the Restructure has been treated as a "common control transaction" which does not meet the requirements of a "business combination" as set out in AASB 3 Business Combinations. Accordingly, no additional intangible assets (including any goodwill) have been recognised on completion of the Restructure.

These financial statements have been prepared to reflect the on-going results of Oventus Manufacturing Pty Ltd for the year ended 30 June 2016 on a pooling-of-interests method. The comparative information represents the financial results as though the Restructure had occurred as at 1 July 2014.

#### Note 2. Events after the reporting period

Subsequent to the end of the financial year Oventus Medical Limited raised \$12 million, less transaction costs of \$1.04 million, pursuant to its offer under a prospectus dated 8 June 2016 by the issue of 24,000,000 fully paid ordinary shares at an issue price of \$0.50 per share. Oventus Medical Limited was admitted to the Official List of ASX limited on 18 July 2016 and official quotation of its securities commenced on 19 July 2016.

Trade and other payables as at 30 June 2016 includes \$762,422 of loans from directors. These have been repaid in full subsequent to year end, following the share issue detailed above.

# Note 3. Intangible assets

	Conso	lidated
	2016	2015
	\$	\$
Patents, trademarks and licences at cost	208,595	113,083
Accumulated amortisation	(9,802)	(4,496)
	198,793	108,587
Software at cost	168,033	3,355
Accumulated amortisation	(16,616)	(839)
	151,417	2,516
Development at cost	991,131	764,407
Accumulated amortisation	(70,363)	-
	920,768	764,407
Total intangible assets	1,270,978	875,510

Development costs are shown net of amounts received subject to the research and development tax concession. In the consolidated entity's financial statements for the year ended 30 June 2015 and the half-year ended 31 December 2015 the development costs were shown gross and the amounts received subject to the tax concession were shown as deferred income in liabilities. The reclassification shows the net cost of development activities. There is no impact of the change on the profit or loss for each period.

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# OVENTUS MEDICAL LIMITED Notes to the financial statements 30 June 2016

Note 4. Share capital

	2016	2016	2015	2015
	Number of Shares #	Value of Shares \$	Number of Shares #	Value of Shares \$
Opening Balance	342,857	342,857	342,857	342,857
Issue of shares in Oventus Medical Limited on restructuring of company	(342,857)	-	-	-
Shares issued in consideration of initial investment in Oventus Manufacturing Pty Ltd	74,375,000	-	-	-
Ordinary shares issued: 28 September 2015	625,000	100,000	-	-
30 November 2015	20,650,000	4,130,000	-	-
Consolidation of shares	(47,650,000)	-	-	-
Share issue costs	-	(146,154)	-	-
At reporting date	48,000,000	4,426,703	342,857	342,857

Following the share issue referred to in note 2 above, the total number of shares in issue has increased to 72 million shares and total contributed equity has increased to approximately \$15.3 million after deducting share issue costs.

The consolidated entity has 3,362,258 (2015:nil) options on issue at reporting date. These were issued in accordance with terms of the Employee Share Option Plan. The total value of the options was calculated to be \$363,406, as determined by an independent valuation. The value of the options will be brought to account over the vesting periods of two or three years.