

## **ASX Release**

Brisbane 29<sup>th</sup> July 2016: Oral medical device company, Oventus Medical Limited (ASX: OVN) is pleased to release a copy of the presentation being delivered by Founder and Clinical Director, Dr Chris Hart at the 2016 Bioshares Investment Summit, in Queenstown, New Zealand.

Dr Hart was invited to deliver a presentation to an audience of Australian, New Zealand and international investors and life science analysts.

The Bioshares Annual Investment Summit is considered one of the leading forums for the life science industry..

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## 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>

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



**BETTER SLEEP, BETTER HEALTH**  
*and a* **BETTER LIFE**

<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.



## **Better Sleep, Better Health and a Better Life**



**OVENTUS™**

Bioshares 2016 Presentation – July 2016

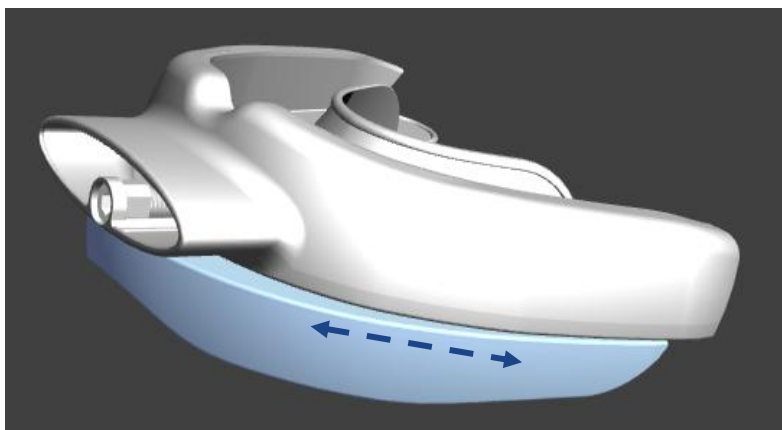
# About Oventus

Oventus is an Australian medical device company with a proprietary oral appliance for the treatment of *obstructive sleep apnoea*\* (OSA).

Our mission is to be a global leader in the treatment of OSA with an initial focus on those that cannot, or are not, treated effectively with existing treatments

Oral appliances with a revolutionary **airway** that addresses limitations with existing obstructive sleep apnoea\* (OSA) treatments including:

- Nose related issues such as irritation, congestion and obstruction
- High pressures from CPAP\*\* which can cause discomfort and dry mouth for patients
- Claustrophobia and leakage from CPAP masks leading to high non-compliance by patients.



\* Obstructive Sleep Apnoea (OSA) – repeated episodes of airway obstruction during sleep – is commonly associated with snoring but also has a direct link to more serious health issues

\*\* CPAP= Continuous Positive Airway Pressure

\*\*\*Titratable – the lower part of the appliance can be adjusted by the patient to optimise lower jaw position



# Treatment



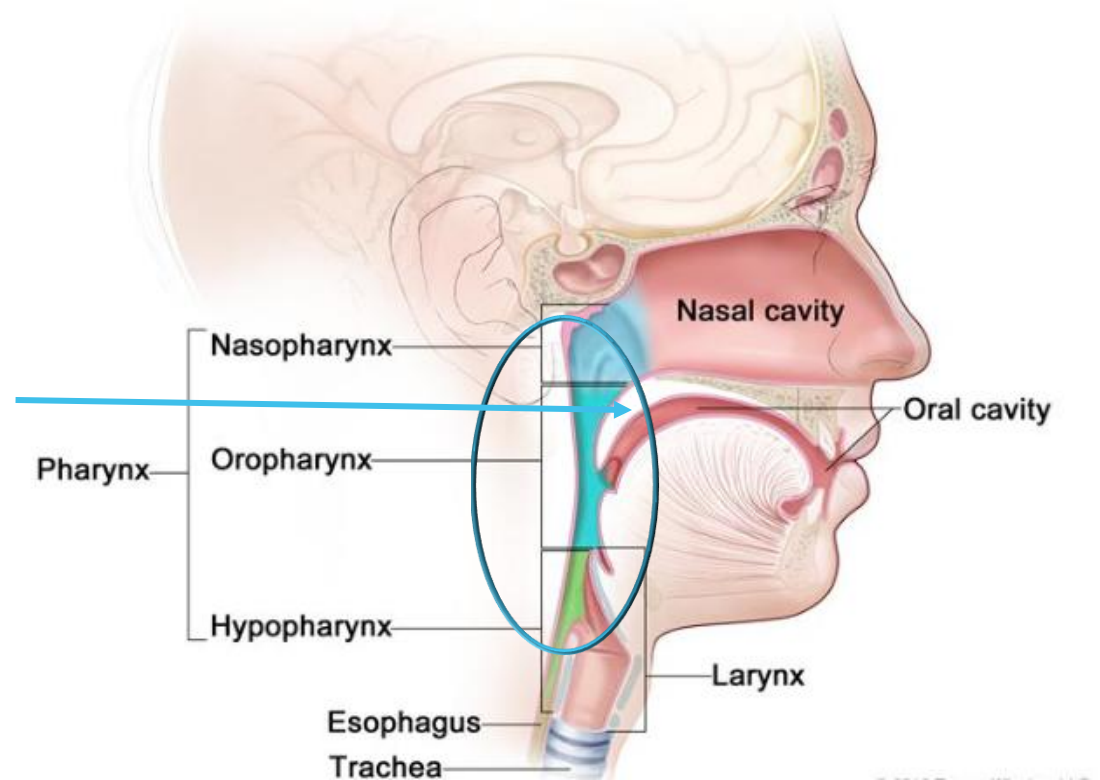


# Sources of Obstructions

## Structures in the airways

Collapse occurs here due to negative pressure created by increased respiratory effort to overcome resistance of the upper airway

It is estimated that 50% of OSA sufferers also suffer from nasal congestion and nasal congestion is implicated in the aetiology of OSA and is a major reason for non-response to and non-compliance with existing treatments



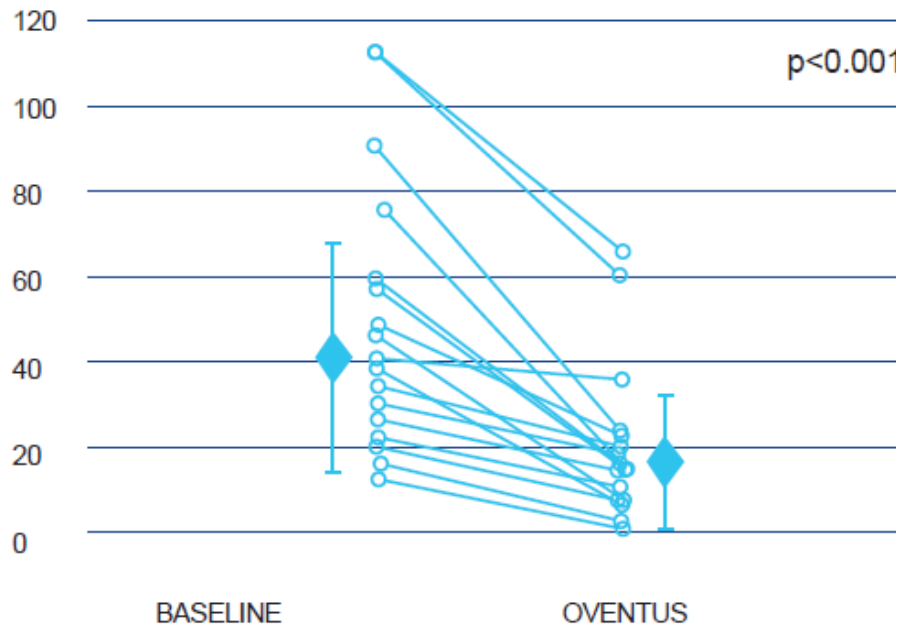
# Our competitive edge

*Oventus O<sub>2</sub>Vent™*

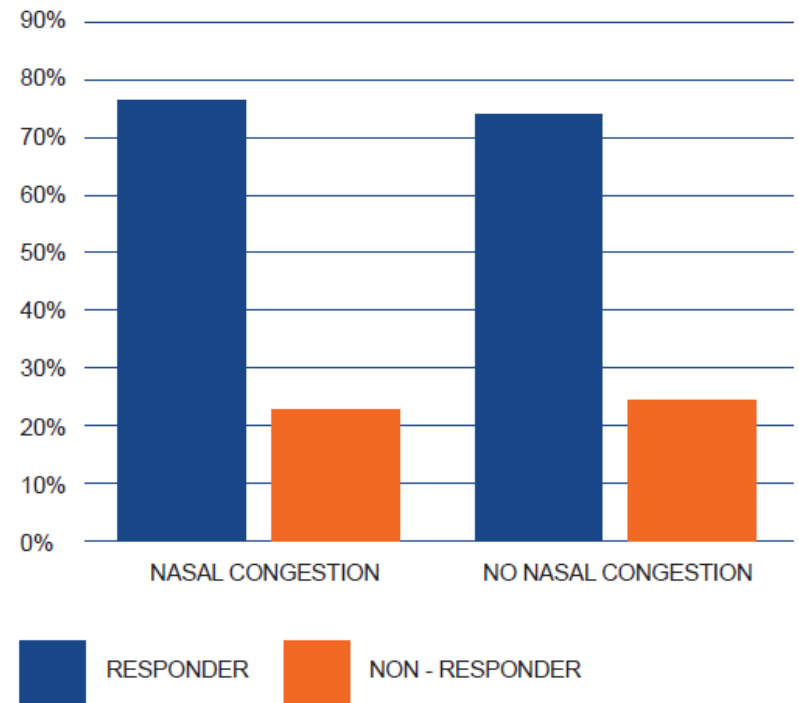


# Clinical Trial Results

AHI at baseline and with Oventus treatment



Response Rate by Nasal Congestion





# Comparison to other treatments (Oventus 62.5% reduction in AHI)

- MAD review (Marklund ERJ 2012)
  - MAD -19 studies reduction in AHI of 55%
  - CPAP – 8 studies reduction in AHI of 83%
  
- CPAP non-adherence rate (< 4 h of nightly use 70% of nights) between 46–83% (Weaver 2008)
  
- Surgical Modifications Review (Caples Sleep 2010)
  - UPPP – 13 studies reduction in AHI of 33%
  - RFA – 8 studies reduction in AHI of 34%
  - Maxillo-Mandibular Advancement – 9 studies reductions in AHI of 87%
  - Multilevel surgery – 34 studies reduction in AHI of 56% (Verse 2008)



## Market Overview & Opportunity



# The total addressable market in US

- 22 million people with sleep apnoea in USA compared to 800,000 in Australia
- 80% of these not treated
- nasal obstructers are a large unmet need

- USA is 56% of current global sleep apnoea device market (Australia is 2%)
- estimate is 3 million people in US currently using CPAP
  - In 2015 673,000 in were sold with CAGR to 2020 forecast to be 7.3%
- 0.5-0.8 million with an oral appliance
  - In 2015 164,000 were sold with CAGR to 2020 forecast to be 24.4%)

Estimated 11 million people with patent nasal airways

**3-4 million  
CPAP  
users in  
USA**

Estimated 11 million people that are nasal obstructers

**0.5-0.8  
million  
people  
using OAT  
in USA**

\*From Sleep Apnea Diagnostic & Therapeutic Devices Market – Global End-user Analysis, Competitive Landscape & Forecast to 2020 MarketsandMarkets 2015

# Product Positioning

There is a growing need for an alternative to CPAP

Current oral appliances gaining acceptance but not suitable for severe sleep apnoea OR nasal obstructors

## O<sub>2</sub>vent device can bridge this gap

Standalone oral appliance for mild to moderate / **severe CPAP Intolerant** sleep apnoea –

Better comfort, reduced apnoeas

CPAP connection instead of a mask for severe to very severe sleep apnoea – (in development)

No mask, lower pressures

### Oral appliances:

Mandibular advancement devices for mild to moderate sleep apnoea



Unmet customer needs –  
nasal obstructors and non  
compliant CPAP users

### CPAP:

CPAP equipment including masks for moderate to severe sleep apnoea





## Oventus' Business Operations





# Current Business Overview

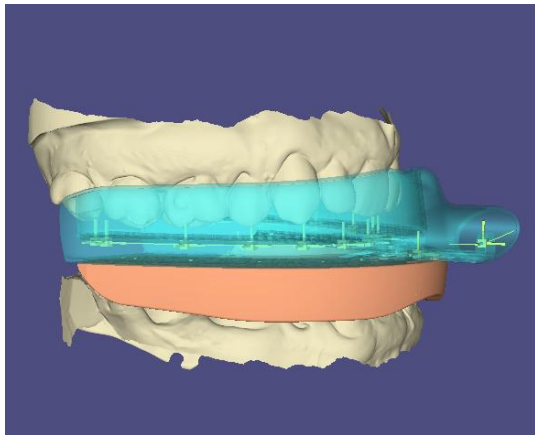
Department	Product/Activity	4Q2015-16	1Q2016-17	2Q2016-17
Product Development	O <sub>2</sub> Vent Trial		In select clinics in Australia	On market in Australia
	O <sub>2</sub> Vent Titratable	In select clinics in Australia	On market in Australia	On market in USA
	O <sub>2</sub> Vent Plus (Tongue Retaining)	In select clinics in Australia	On market in Australia	
	O <sub>2</sub> Vent PAP (CPAP connection)	Proof of concept	Development	Development
Manufacturing	New facility Brisbane	Plan developed for overseas rollout	Begin execution of overseas plan	Execution of overseas plan
	ISO Accreditation		Audit	Accreditation
	3D printing setup	Printer delivered	In production	
Regulatory	510k first product submitted	510k approval of Mono appliance	Titratable submitted in US	Titratable approved in US

- O<sub>2</sub>Vent™ Mono (on market) – a stand-alone oral appliance for the treatment of sleep apnoea and snoring and can be adjusted in the clinic by the clinician
- O<sub>2</sub>Vent™ (delivered to first patients) - a stand-alone oral appliance for the treatment of sleep apnoea and snoring and can be adjusted by the patient as well as the clinician
- O<sub>2</sub>Vent™ Plus (advanced stage of development) – a stand-alone device with an incorporated tongue retaining component for patients with specific tongue anatomy
- O<sub>2</sub>Vent™ PAP (early stage of development) – an oral appliance that connects to a Continuous Positive Airway Pressure (CPAP) machine for severe sleep apnoeics

# Products and Manufacturing

## Scalable Manufacturing

- Digital records
- Proprietary appliance design software
- 3D printing of appliances
  - Current titanium printer now in-house
  - Contract manufacturing discussions underway to enhance scalability
- Insert manufacture



Proprietary Design Software



Titanium 3D printer



Insert Manufacture

# Intellectual Property – Strong IP position

Core patent issued in  
Aust & National  
phase overseas:

WO 2012/155214

Inventor  
Dr Chris Hart

Title: Breathing  
assist device

PCT / AU2015  
/050144:


Breathing Assist  
Device covers  
numerous design  
aspects and additive  
manufacturing

Provisional  
July 2015:

Breathing Assist  
Device with Tongue  
Retaining Device

Provisional  
March 2016:

Titratable design with  
an airway– allows  
lower jaw adjustment  
by the patient

- 
- Proprietary design software
  - Online portal for patient management
  - Patient data/registry
  - Trade Mark lodged: O<sub>2</sub>Vent™

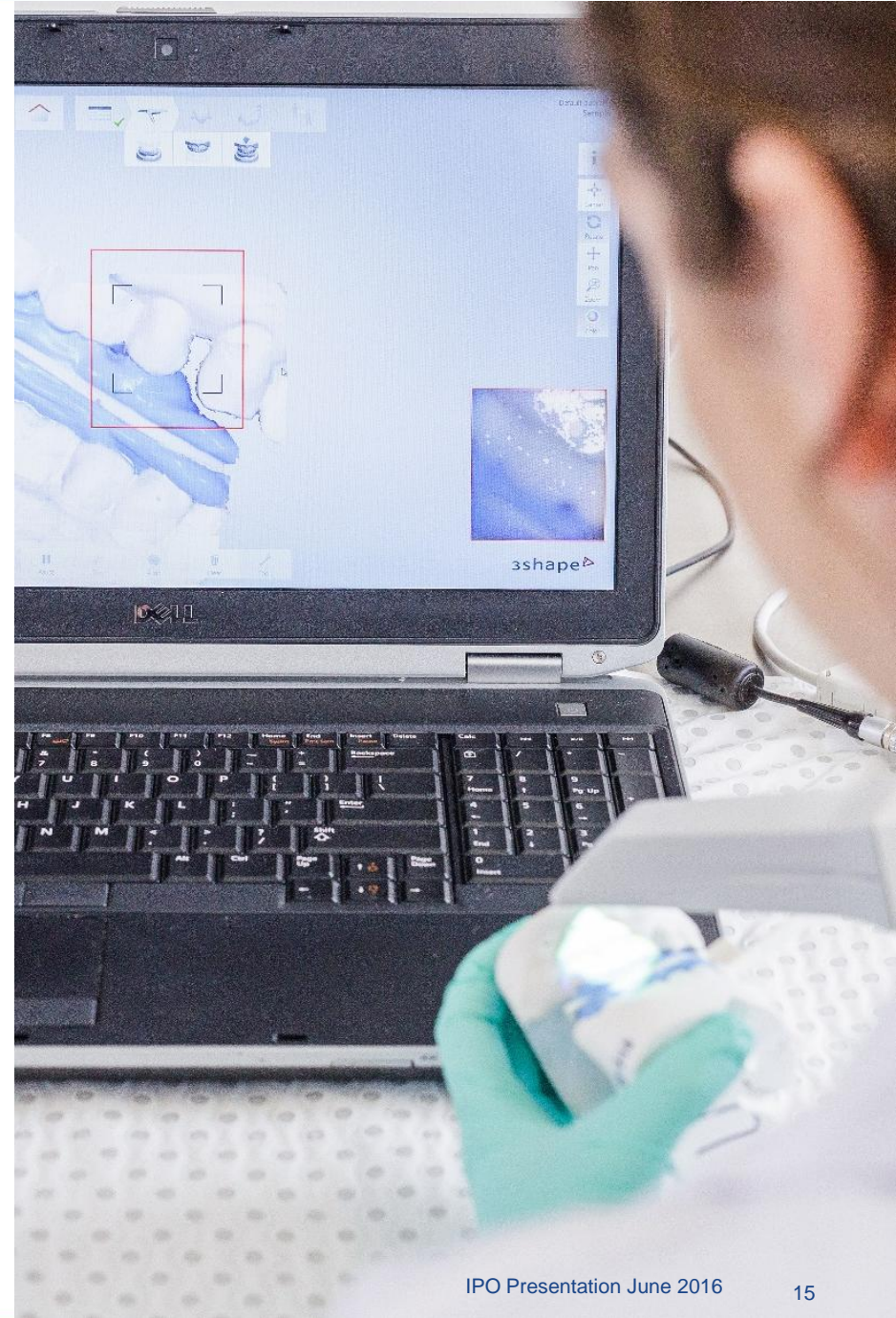
# Regulatory and Reimbursement

## Regulatory

- TGA Class 1 in Australia - allows access to European and some Asian markets (registration in November 2014)
- FDA 510k (Class II) clearance in USA (secured in March 2016)

## Reimbursement

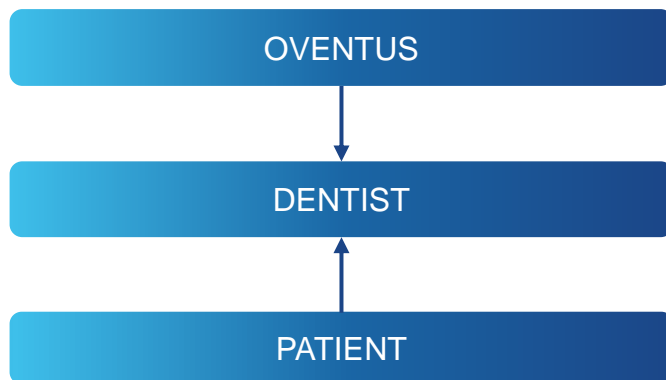
- Partially covered by private insurance in Australia (dental) – rebate of 30-50%
- Separate code for USA reimbursement
- Opportunity to apply for dedicated code in USA
- Favourable reimbursement in specific European countries





# Value Chain

- Oventus conducts marketing programs through online presence, relationships with sleep groups and direct dentist interaction to raise awareness of device
- Dentist prescribes Oventus device for patient
- Oventus sells device to dentist for ~\$895 per device with anticipated GP of 75% (once scaled)
- Dentist sells device to patient for \$1800-\$2200 including clinical delivery

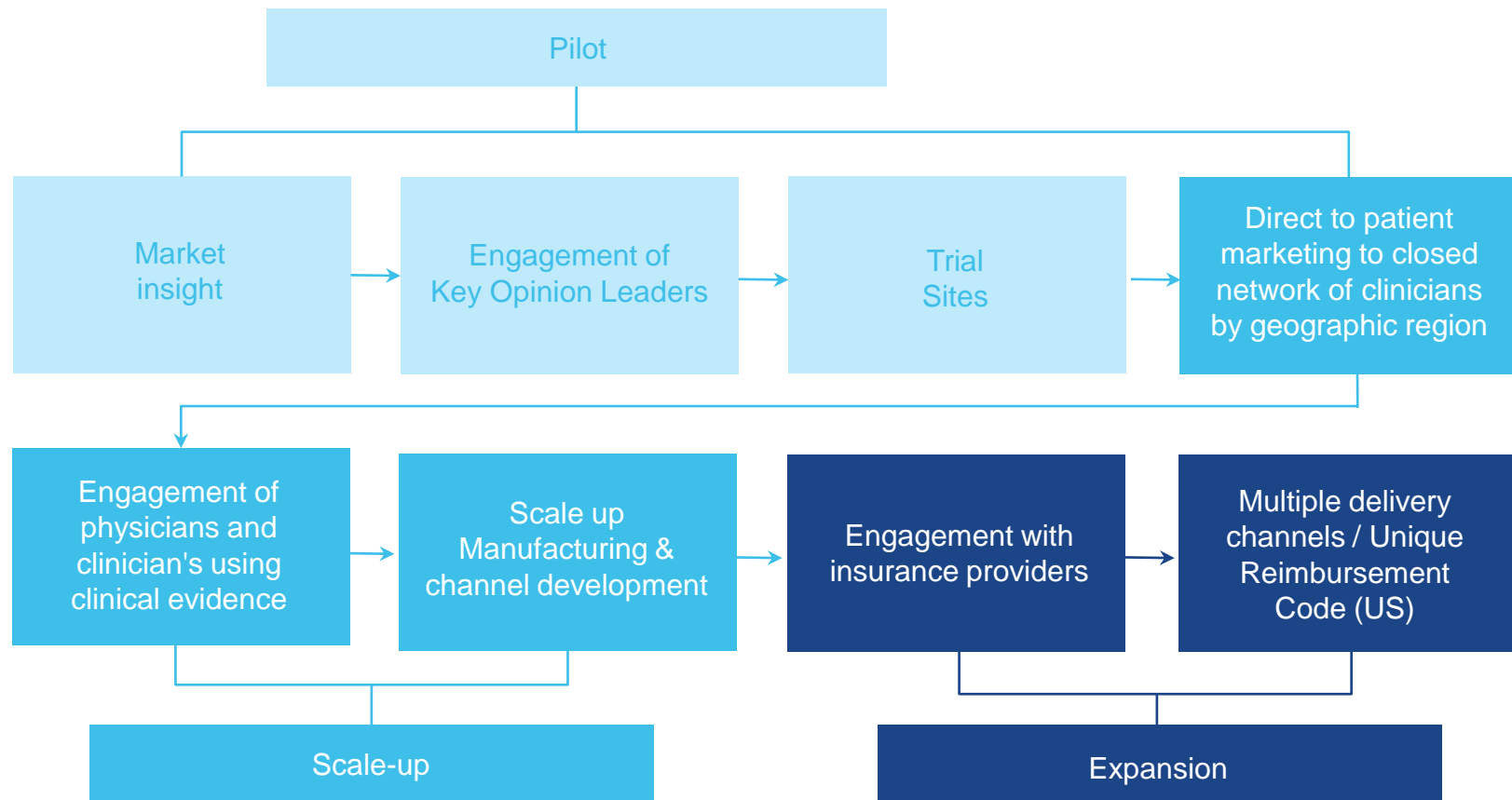


“... clinical data has shown that the O<sub>2</sub>Vent is more effective in treating OSA...and has an effect on oxygen levels comparable to CPAP”

– Dr Chris Hart, *Oventus founder and Clinical Director*



# Path to Market – pilot → scale-up → expansion



# Path to Market – indicative timing

Region	Stage	2H2016	1H2017	2H2017	1H2018	2H2018
Australia	Pilot	Completed				
	Scale-up					
	Expansion					
USA	Pilot					
	Scale-up					
	Expansion					
Europe	Pilot					
	Scale-up					
	Expansion					From 2019
Asia Pacific	Pilot					
	Scale-up					
	Expansion					From 2019

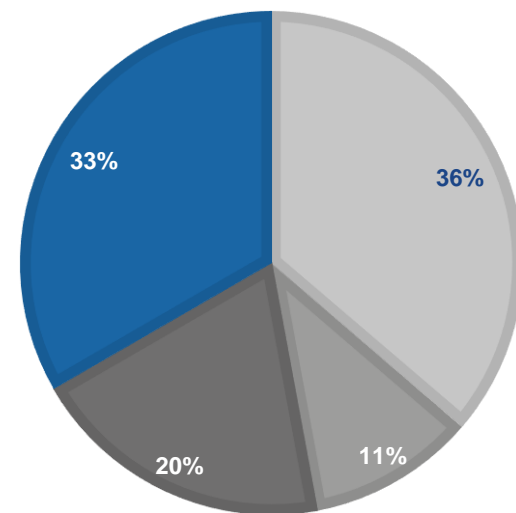
# Capital Structure

Terms of Offer	Details
Offer Price per Share	\$0.50
Total number of Shares offered under this Prospectus*	24,000,000
Total number of Shares on issue following the Offer*	72,000,000
Amount to be raised under the Offer*	\$12,000,000
Market capitalisation at the Offer Price Post-IPO*	\$36,000,000

\* anticipated and without reference to the prospectus

# Shareholding Information

Shareholding	Pre IPO	IPO	Post-IPO	%
Dr Chris Hart Founder (1)	26,126,513	0	26,126,513	36.3%
Board & Management	7,778,315	*	7,778,315	10.8%
Pre IPO Investors (2)	14,095,171	*	14,095,171	19.6%
IPO Investors		24,000,000	24,000,000	33.3%
Total	48,000,000	24,000,000	72,000,000	100.0%

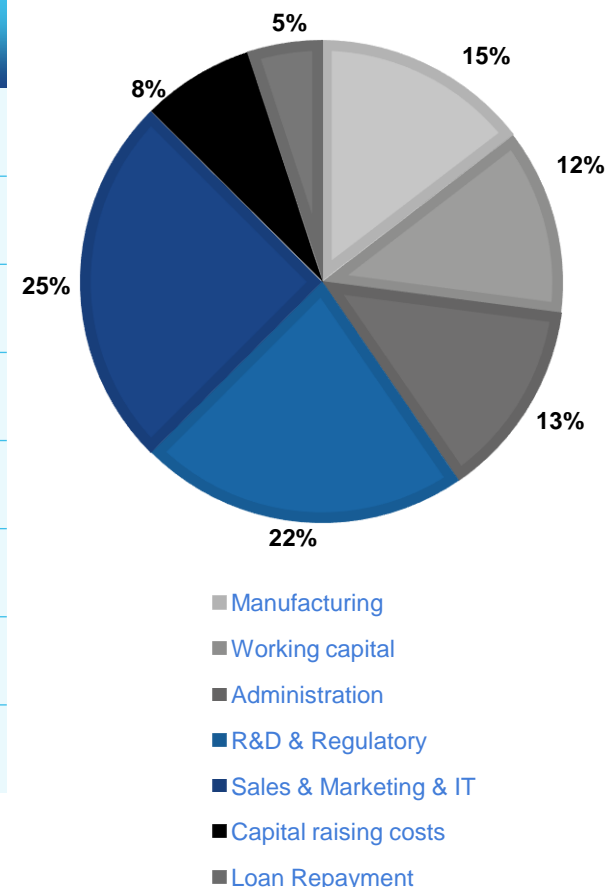


- Dr Chris Hart Founder (1)
- Board & Management
- Pre IPO Investors (2)
- IPO Investors

- \* To Be Advised regarding shares to be acquired at IPO
- 39,061,024 Shares (which represent 54.25% of the Shares on issue following completion of the Offer) are subject to mandatory escrow for 24 months from the date of Oventus' listing on the ASX (in respect of founders) and until 19 November 2016 (in respect of other shareholders). 8,938,976 Shares (which will represent 12.42% of the Shares on issue following completion of the Offer) are subject to voluntary escrow until 1 March 2017.

# Use of Funds

Expenditure	\$ spend
Manufacturing	\$1,750,000
Working Capital	\$1,500,000
Administration & Corporate	\$1,600,000
Product Development* & Regulatory	\$2,650,000
Sales & Marketing & IT	\$3,000,000
IPO	\$900,000
Loan Repayment to Chris Hart	\$600,000
Total	\$12,000,000



- \* ~78% clinical trials and ~22% product development
- The above table is a statement of current intentions as at the date of this Prospectus. As with any budget, intervening events (including trial success or failure) and new circumstances have the potential to affect the manner in which the funds are ultimately applied. The Board reserves the right to alter the way funds are applied on this basis.
- In addition to funds raised under the Offer, Oventus has access to a range of sources to meet its anticipated expenditure, including cash at bank, net cash flows from manufacturing and selling the Company's products, debt and equity funding options available to it as an ASX listed company following the Offer. Oventus may also seek additional funding in the form of state and federal government grants and concessions to assist with the development of its medical devices.



# Board and Management



Dr Mel Bridges,  
Non-executive  
Chairman

- Extensive experience as an Executive and Company Director in healthcare, agricultural technology, drug development, pathology, diagnostics and medical devices.
- Has successfully raised in excess of \$300M investment capital in the healthcare/biotech sector and been directly involved in over \$1B in merger and acquisition and related transactions



Ms Sue MacLeman,  
Non-executive Director

- Very broad commercial experience in multiple companies – currently CEO of the Medical Technology and Pharmaceutical Industry Innovation Growth Centre.
- Underpinned by graduate qualifications in pharmacy and post graduate qualifications in corporate governance, commercial law, business administration and marketing.



Mr Steve Denaro  
Company Secretary

- Experienced Company Secretary and Chief Financial Officer of various public companies and with major chartered accountancy firms in Australia and the UK
- Bachelor of Business in Accountancy, Graduate Diploma in Applied Corporate Governance and is a member of the Institute of Chartered Accountants in Australia & New Zealand,

## Board and Management (cont.)



Dr Chris Hart,  
Clinical Director

- Experienced dentist with extensive business experience
- Heads up clinician engagement for the delivery of the Oventus appliances
- Inventor of the core design
- Executive Director



Mr Neil Anderson,  
Managing Director & Chief  
Executive Officer

- Experienced CEO, project manager, materials scientist and entrepreneur
- In-depth skills and knowledge of medical device commercialisation – in the field for over 30 years
- Has managed the R&D, manufacturing process and regulatory
- Executive Director



Ms Elise Hogan,  
VP of Sales and Marketing

- Elise has over 20 years' experience as a medical device executive leading the sales, marketing and commercialisation teams in Australia, New Zealand, UK, and Asia
- Previously Vice President, Oceania and Asia for LivaNova and was responsible for the establishment and growth of the Australian subsidiary, and numerous product launches and geographical expansion throughout Asia and Australia/New Zealand