



Better Sleep, Better Health and a Better Life



OVENTUS™

Annual General Meeting – 21st November 2016

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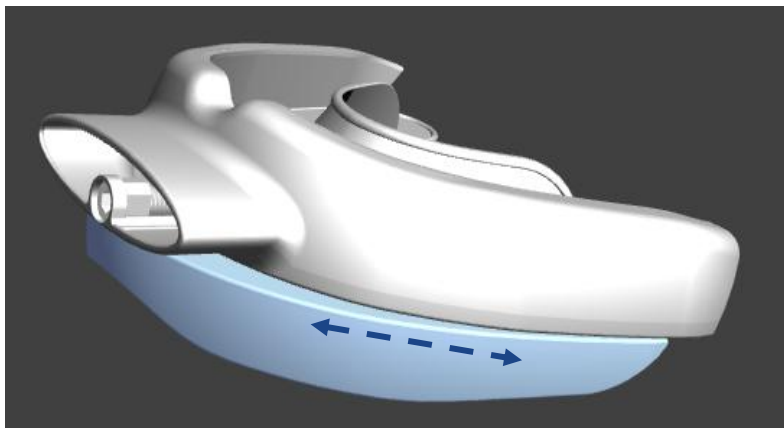
About Oventus

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

Our competitive edge

Oventus O₂Vent™



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

O₂Vent 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

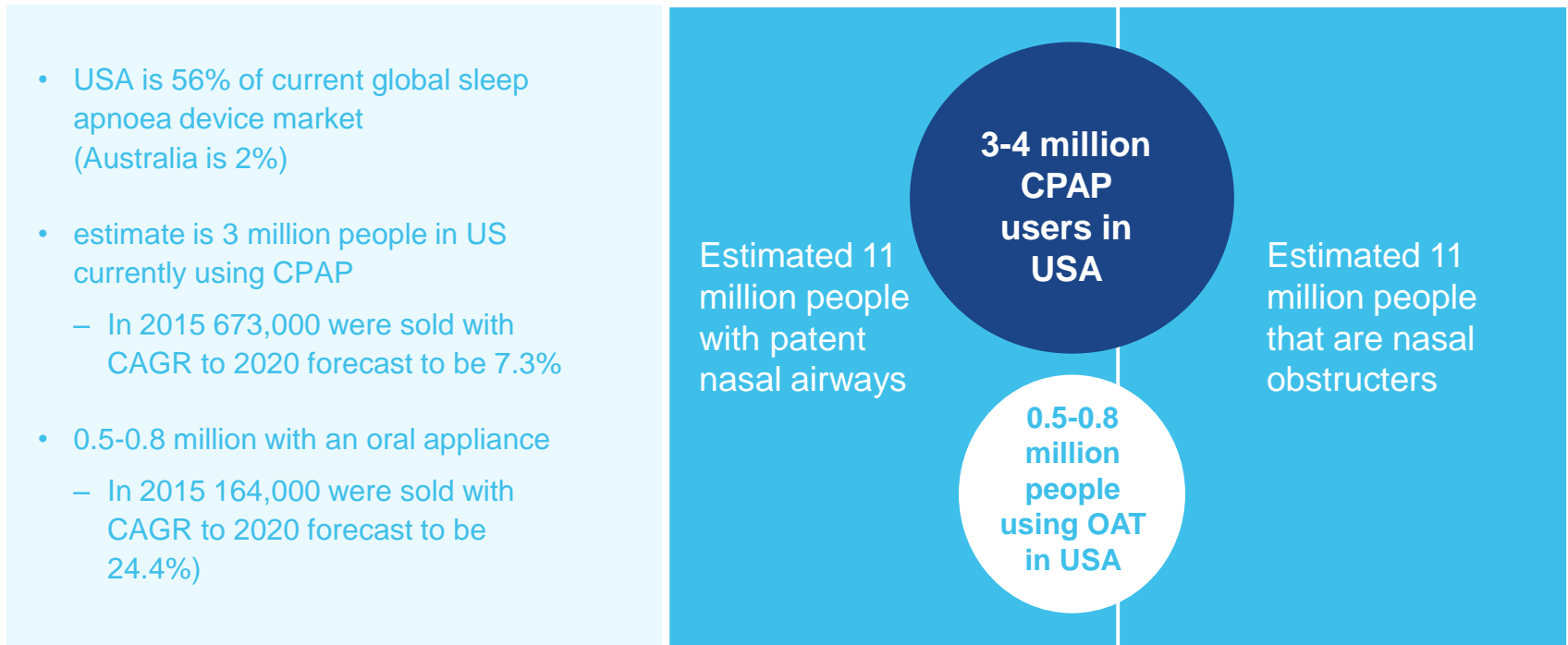
CPAP:

CPAP equipment including masks for moderate to severe sleep apnoea



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



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



Operations



Progress in the last year

“We have been setting up our quality and regulatory systems, manufacturing capability, distribution and marketing channels and generating further clinical data to enable sales. This has required a significant upfront investment. We expect this business development expenditure to taper until the end of FY17 while we simultaneously build sales with a significant reduction in investment in 1HFY18 on the back of further clinical data, maturation of sales and distribution arrangements, reducing R & D spend and accelerating sales growth”

Progress in the last year

Products

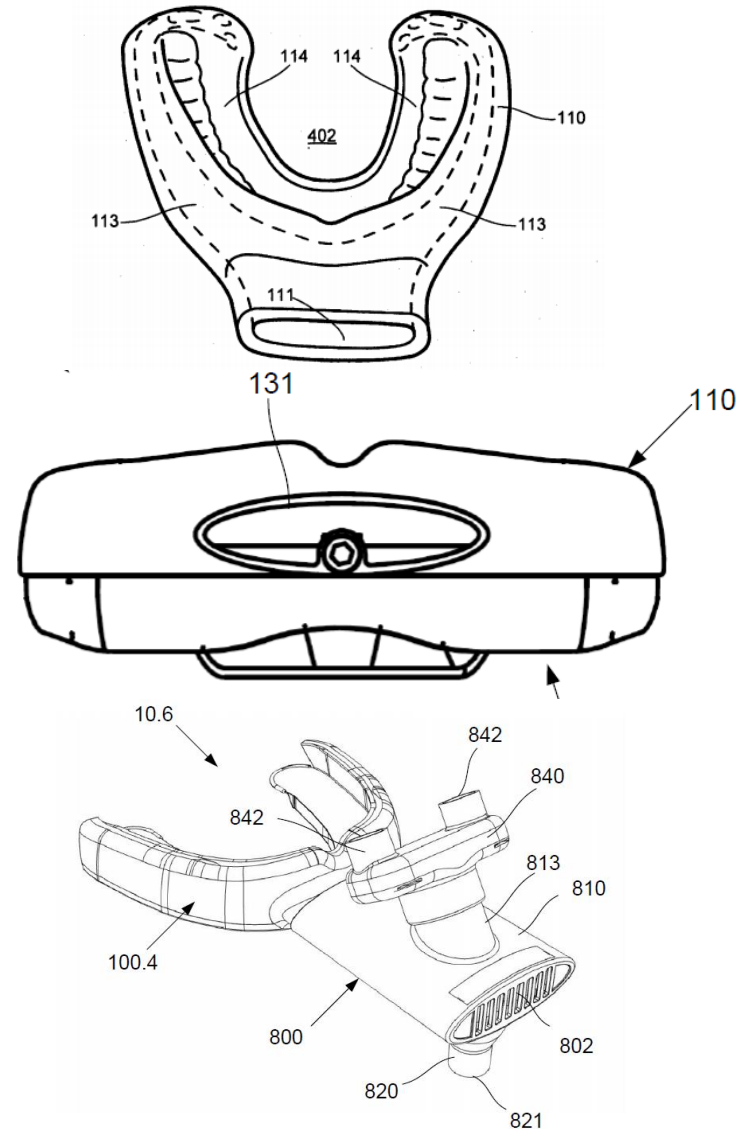
- Developed and launched in Australia a 2nd generation appliance the O₂Vent™ T – a titratable device allowing level of advancement to be easily adjusted
- Advanced the development of a version allowing PAP connection – first clinical evaluation recently undertaken with analysis still underway



Progress in the last year

Intellectual property

- Platform patent protecting the novelty of the airway was issued by the Australian patent office
- Lodged an additional provisional patent for the titratable appliance
- More recently lodged a provisional patent protecting numerous aspects of connection to a Positive Airway Pressure machine



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

Provisional
October 2016:

Combination
device with both
PAP connection
and airway/
mandibular
advancement

- 
- Proprietary design software
 - Online portal for patient management
 - Patient data/registry
 - Trade Mark lodged: Logo and O₂Vent™

Progress in the last year

Regulatory for O₂Vent™ T

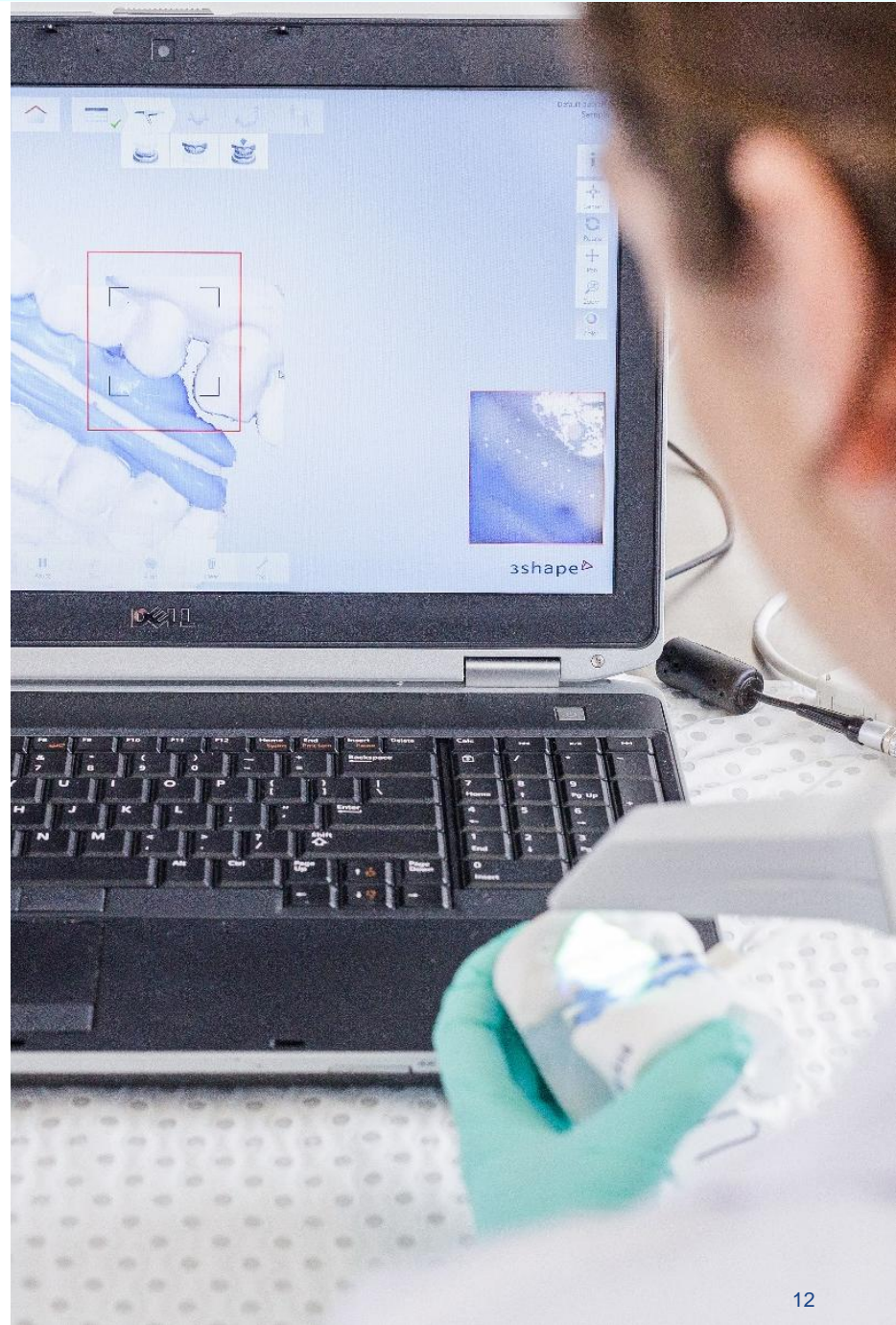
- US FDA 510k clearance secured September 2016
- Australian TGA registration in June 2016 - allows access to European and some Asian markets

Quality Management

- Audit recently completed by TUV SUD for MDSAP (Medical Device Single Audit Program) – Australia, USA, Europe, Canada, Japan and Brazil

Reimbursement

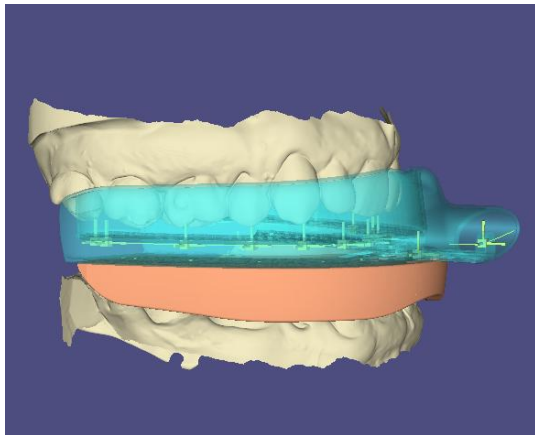
- Partially covered by private insurance in Australia (dental) – rebate of 30-50%
- Separate code for USA reimbursement
- Opportunity to apply for dedicated code in USA
- Favourable reimbursement in specific European countries



Progress in the last year

Scalable Manufacturing

- Use of digital records
- Proprietary appliance design software
- 3D printing of appliances
 - Current titanium printer now in-house in rented space at CSIRO Clayton
- Insert manufacture in Brisbane facility
 - Contract manufacturing discussions underway to enhance scalability
 - Developing 3D printing of inserts for future end to end “smart manufacturing”



Proprietary Design Software



Titanium 3D printer



Insert Manufacture



Clinical



Progress in the last year

Clinical

- Formed a multi disciplinary Scientific Advisory Committee
 - Prof Bill Coman (ENT)
 - Prof Peter Eastwood (Sleep Researcher)
 - Prof Jeremy Goldin (Sleep Physician)
 - Dr Karen McCloy (Dentist)
- First trial completed and submitted for peer review
- Presented Clinical data
 - American academy of Sleep Medicine
 - Australasian Sleep Association
- Launched clinical trial into the efficacy and compliance of the O₂Vent™ T and the effect of an airway incorporated into an oral appliance
- Completed a pilot study on the effect of the incorporation of an airway into an oral appliance on pressures in the upper airway and pressure requirements when used as a CPAP interface
 - Promising early data
 - Further analysis underway with completion by Q3CY17

Clinical Evidence

Initial clinical trial verified by Mobius Medical (a Clinical Research Organisation) and biostatistician showed:

- The O₂Vent™ can treat nasal obstructors as effectively as those with no nasal obstruction – market currently unmet.
- The O₂Vent™ is more effective in the moderate to severe range of sleep apnoea compared to other oral appliances increasing the addressable market for oral appliance therapy by 30 per cent.
- The O₂Vent™ is more effective than other oral appliances and has a higher “mean disease alleviation”* than CPAP.
- The O₂Vent™ has a lower time under 90% O₂ saturation – this means more consistently normal blood oxygen levels
- In the trial, 100% of patients experienced a significant improvement in snoring and 82% eliminated it completely when using the O₂Vent™



O₂Vent™ Mono - First Generation

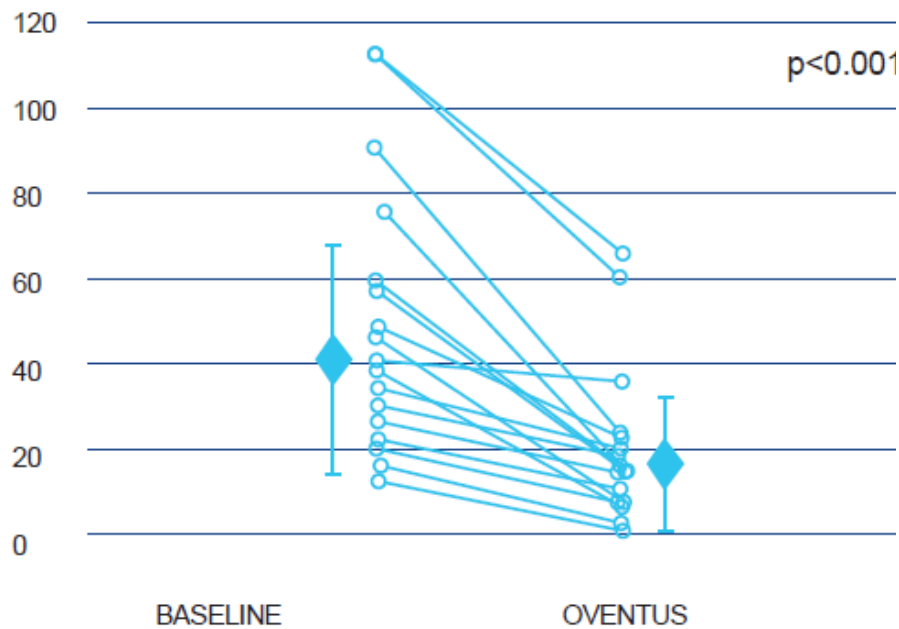


O₂Vent™ Titratable - 2nd Generation

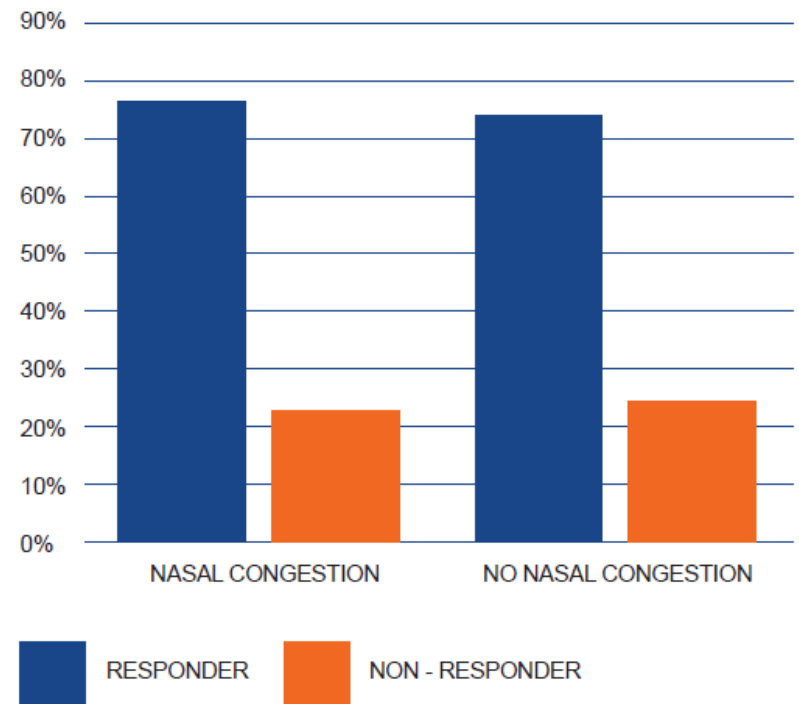
* Mean disease alleviation = Efficacy times compliance

Clinical Trial Results

AHI at baseline and with Oventus treatment



Response Rate by Nasal Congestion





Market Development



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

Progress in the last year

Market Development

- Australia
 - Focus has been to setup sales channels and clinical collaboration in Australia for ramping up sales in 2017
 - Now have over 40 dentists delivering Oventus Devices
 - Piloted distribution through dental corporate groups to increase coverage
 - Engaged multiple sleep groups to collaborate on sleep testing and clinical trials
- USA
 - Focus has been on engaging key opinion leaders with clinical evidence and building relationships with selected clinicians to pilot launch the O₂Vent™ T in the US ahead of a wider scale up in 2H CY17
 - Set up 5 initial clinical beta sites in a variety of market segments and socioeconomic demographics for market testing and product feedback and refinement for the US market
 - First patient records now received with initial US revenue anticipated to be booked in December
 - Relationships with educators and key opinion leaders developed
 - US clinical trial in planning



Thank you!

