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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Oventus Medical

By TIM BOREHAM

ASX Code: OVN

Share Price: 29 cents; **Shares on issue:** 105,939,212; **Market Cap:** \$30.7 million

Chief executive officer: Dr Chris Hart

Board: Dr Mel Bridges (chairman), Dr Chris Hart, Neil Anderson (chief technology officer), Sue MacLeman

Financials (September quarter): receipts \$107,000, cash burn \$1.79 million, cash balance \$8.3 million*, estimated current quarter cash outflows \$2.175 million

Year to June 30, 2018: revenue \$272,322 (down 39%), loss of \$5.87 million (previously \$6.51 million loss), cash of \$9.89 million

Identifiable major holders: Dr Chris Hart 25.05%, Tiga Trading (Thorney Investments) 13.15%, Neil Anderson 5.51%, Mobius Medical Investments 3.52%

* The company received a \$1.04 million research and development refund in early November.

To sleep, perchance to dream, pondered a melancholy Hamlet before meeting his end in rather messy circumstances.

For the millions of chronic snorers and their spouses, hopefully it won't come to that. But night after night of poor sleep can be quite debilitating and in its extreme form obstructive sleep apnoea (OSA, which includes snoring) can even be fatal.

The home-grown Resmed has made a global business from its OSA treatment based on devices that deliver continuous positive air pressure (CPAP) through a pump and face mask.

But it's increasingly evident that many instances of OSA can be remedied with oral mouth-guard style devices at a fraction of the price.

Through its original device O2Vent and improved versions that it's rolling out, Oventus is targeting a global sleep apnoea market of \$US6 billion to \$US7 billion, growing at a compound annual rate of 15 to 20 percent.

According to Oventus, 80 percent of cases are undiagnosed, probably because the sufferer (or should that be culprit?) is not awake to hear himself/herself snoring.

Sleep Health Foundation Australia claims that more than 1.5 million Australians have sleep disorders, more than half for OSA.

"We have seen dramatic improvement in patients in our clinical trials," says CEO and co-founder Dr Chris Hart.

"The technology in these devices eliminates the need for full face masks and greatly improves medication for the majority," Dr Hart says. "We have been consistently delighted with the results."

About Oventus

The devices are the brainchild of Dr Hart, a dentist who founded the Lifetime Smiles dental chain.

An OSA sufferer himself, Dr Hart deployed his superior knowledge of complex upper airway physiology to build a prototype device consisting of a modified mouth guard and saliva tubes.

"It worked very well but it was a bulky piece of plastic and expensive to make," he says.

Dr Hart hooked up with Neil Anderson, a technologist and the founder of the once ASX-listed Cathrx (Mr Anderson was Oventus's founding chief executive officer and has moved to the position of chief technology officer).

With the help of the Commonwealth Scientific and Industrial Research Organisation, they developed a 3-D-printed version that reduced the size of the device by 60 percent.

Oventus was formed in 2015 and raised \$4.15 million in a private round, backed by fund management heavyweights including Thorney Investments, Regal Funds Management and former Packer family lieutenant Ashok Jacob. Later, former Macquarie Bank head Allan Moss joined the register.

Approved by the Australian Therapeutic Goods Administration in 2015, the original Oventus Clearway was sold through pop-up stores, selling directly to patients.

The venture proved an instant money spinner but it wasn't quite what Dr Hart, who had just sold Lifetime Smiles to National Dental Care, had in mind.

The backers opted for an initial public offer, and with biotech doyen Dr Mel Bridges as chairman, Oventus listed in July 2016, raising \$12 million at 50 cents apiece for a total market valuation of \$36 million.

Strategy U-turn

Oventus is targeting the US market, in particular sleep clinics and sleep doctors. It is also targeting four dental service organizations (that is, agglomerated dental practices) that account for 30,000 outlets across 33 states.

Oventus's original emphasis was on selling through dentists but the company realized that sleep physicians and sleep clinics were the real gatekeepers through which it could reach patients.

"The dentists didn't understand the technology. They viewed it as another mouth guard rather than a sleep management tool," says Dr Hart.

Targeting the sleep specialists makes sense. After all, a sleepless soul probably will consult their doctor and be referred to a specialist, rather than a dentist.

Nonetheless, in mid-2017 Oventus struck a distribution deal with the Hong Kong-based Modern Dental Group, the world's biggest supplier of dental prosthetics. The compact involves Modern Dental distributing the O2Vents across dental channels exclusively in the US and non-exclusively elsewhere. In the US, Modern Dental accounts for 25 percent of all dentists.

With its development work beyond new iterations of the core product, Oventus is transitioning from a research and development phase to marketing and sales.

A second nose

Oventus describes its O2Vent technology as a "second nose" based on mandibular advancement, which simply means pushing the lower jaw (the mandible) forward to allow more air to the back of the throat when nose-breathing.

The company's devices allow air to flow to the back of the mouth unobstructed, while maintaining an oral seal and a stable jaw position. The breathing avoids obstructions created by the nose, soft palate and tongue.

The device allows for nasal breathing, but when the snoz is obstructed the breathing is supplemented by the airways in the appliance.

Oventus started the year with its standard O2Vent, a mouth guard with a titanium breathing hole (duckbill), which the US Food and Drug Administration approved in July 2017. But the company is rolling-out new, improved versions of the O2Vent.

These include a nylon rather than titanium version, O2Vent Optima, which is “lighter and more aesthetically pleasing”. The TGA approved these units in October this year.

O2Vent/Exvent is an additional valve that enhances positive end-expiratory pressure (PEEP).

Exvent is due for release by the end of 2018, as is the Optima.

In late stage development, O2Vent Connect is a continuous positive airways pressure system which connects with an air pump, allowing for its use without a full-face mask.

Also in the lab is O2Vent Onepap, a PEEP valve for patients who stubbornly breathe through their nose despite mounting obstacles. The air pressure created ensures a transition to mouth-breathing as the patient snoozes on like Rip van Winkle.

Silencing the snores

So far Oventus has trialled 170 sleepless candidates across four trials for obstructive sleep apnoe.

The result is that more than 75 percent of these patients benefit from Oventus’s devices “across the full spectrum of disease severity”.

The results to date suggest that the standard O2Vent is helpful in 41 percent of cases. But this rises to 54 percent with O2Vent Optima (nylon) and to 78 percent with O2Vent/Exvent.

With the Connect, 100 percent of patients experienced an improvement in their sleep.

Results from another 120 patients are pending, but then that’s about it for the clinical program except for some more work on the Onepap device.

Finances and performance

The Oventus IPO raising of \$12 million has been supplemented by two further capital raisings totaling \$12.6 million. With cash of around \$8.3 million, the company considers itself adequately funded as it ramps up revenue.

Dr Hart said the company’s fixed costs were far too high, resulting in a decision to outsource manufacturing. With the reduced manufacturing costs and tapering research and development, the company expects to reduce cash burn by 15 to 20 percent by the end of next year.

Using nylon rather than titanium will reduce the cost of the units by about \$200, which is a decent saving in the context of the devices selling for about \$750 per unit.

Oventus’s revenue of \$272,000 in 2017-’18 was 39 percent lower than previously. Dr Hart admits the Modern Dental tie up, effective from February this year, “has not racked up sales as much as we would have liked”.

Dr Hart notes that the higher rate of reimbursement for oral appliances over CPAP means that the former is more attractive to clinicians than the latter.

“There will be a tipping point where the profession realizes the technology is more effective,” he says.

Over the last 12 months Oventus shares have traded as high as 73 cents (November 7 2017) and as low as 24 cents (September 13 this year). They peaked at 95 cents on July 20, 2016.

Dr Boreham’s diagnosis:

Oventus is hardly Robinson Crusoe in the oral sleep device sphere. Look no further than more established ASX counterpart Somnomed, which markets its Somnodent device to 445,000 patients across 28 countries.

Somnomed posted quarterly revenue of \$14.8 million up 14 percent but made an operating loss of \$5.76 million, the result of “disappointing” results from Renew Sleep Solutions, its chain of US sleep centres.

Rhinomed has a market cap of \$30 million and sells its Mute range of plastic nasal dilators for snoring and sleep apnoea (soon to come with its own medical marijuana eluting system) and posted revenue up 26 percent to \$2.2 million for the year to June 30, 2018

Also with a \$30 million market cap, compared to just over \$100 million for Somnomed, Oventus isn’t exactly extravagantly priced.

But with the company entering the marketing phase and saying 'bye-bye' to the blue sky, it’s time to deliver on the top line.

“We now have a device with double the success rate of any device in the market,” Dr Hart says.

“Our job now is to generate revenue and gain some market share.”

For Oventus, success depends on the sleep specialists not dismissing the company as just another mouth guard maker.

“We launched as an oral appliance company but in reality we are now an airway management company,” Dr Hart says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His spouse snores like a steam train, but he isn’t sure that an O2Vent is the ideal Christmas present.