



# Biotech Daily

Friday November 30, 2018

*Daily news on ASX-listed biotechnology companies*

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- \* **ESENSE APPOINTS PIERS LEWIS CHAIR, AMIT EDRI DIRECTOR**

## MARKET REPORT

The Australian stock market fell 1.58 percent on Friday November 30, 2018 with the ASX200 down 91.2 points to 5,667.2 points. Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and four were untraded.

Factor was the best, up 0.1 cents or 50 percent to 0.3 cents, with 2.1 million shares traded. Reva climbed 14.3 percent; Optiscan was up 7.4 percent; Prescient improved 5.3 percent; Genetic Signatures, Osprey and Universal Biosensors were up more than four percent; Pharmaxis was up 3.6 percent; LBT, Neuren, Oncosil and Polynovo rose more than two percent; with Nanosonics and Pro Medics up more than one percent.

Admedus led the falls, down 0.8 cents or 14.3 percent to 4.8 cents with 5.6 million shares traded. Uscom lost 9.4 percent; Clinuvel, Compumedics, Impedimed and Opthea were down more than three percent; Airxpanders, Cochlear, Cynata, Immutep and Telix shed two percent or more; with CSL, Ellex and Medical Developments down more than one percent.

## 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 apnoea.

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.***

## MACH7 TECHNOLOGIES

Mach7 says that it has raised \$3 million in an “oversubscribed placement at 20 cents a share, an 11 percent discount to the closing share price on November 27, 2018.

Mach7 said that “leading healthcare investor” Australian Ethical participated in the raise. The company said that Australian Ethical had more than \$2 billion in funds under management, across superannuation and managed funds.

Mach7 said the proceeds would be used to accelerate recent contracts with the Hospital Authority Hong Kong and Sentara Healthcare, along with continued investment in its product development, sales and marketing as well as for general working capital.

Mach7 fell half a cent or 2.2 percent to 22 cents.

## MESOBLAST

Mesoblast chair Brian Jamieson says he will retire from the board at the end of March 2019.

In his chairman’s address to the annual general meeting, Mr Jamieson said that “as part of the process of moving towards a US-centric commercial organization, I will be retiring from the board at the end of March 2019 after completing the installation of a new chairman of your company”.

“This will facilitate a structured and progressive succession plan as we move into the commercialization phase,” Mr Jamieson said.

In a newspaper article published this morning, ahead of today’s annual general meeting, Mesoblast investor and Thorney Investments founder and executive director Alex Waislitz allegedly said he wanted to see “changes at board and management levels to help it achieve global success”.

A spokesman for Mr Waislitz said that Mr Waislitz was “not referring to [Mesoblast chief executive Prof] Silviu Itescu”.

“Mr Waislitz wants to see Silviu better supported,” the spokesman said.

The spokesman said that there was a need for further changes.

Mesoblast was up one cent or 0.8 percent to \$1.325 with 1.8 million shares traded.

## MESOBLAST

The Mesoblast annual general meeting passed all resolutions but with strong dissent against the remuneration report, for the second year in a row.

The remuneration report narrowly avoided a ‘first strike’, with 39,864,196 votes (23.4%) against the report and 130,815,008 votes (76.6%) in favor.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for reelection.

The company’s most recent Appendix 3B new issue announcement said that Mesoblast had 482,639,654 shares on issue, meaning that the votes against the report amounted to 8.3 percent of the company, sufficient to requisition extraordinary general meetings.

Last year, the Mesoblast meeting passed all resolutions but with 28,085,191 votes or 19.0 percent dissent against the remuneration report (BD: Nov 16, 2017).

Today, the company said that the issue of options to directors faced more than 14.3 percent dissent at the meeting, but the issues of shares to Novaquest and the election of chairman Brian Jamieson and directors Joseph Swedish, Shawn Tomasello and Michael Spooner were passed overwhelmingly.

## GENETIC SIGNATURES

Genetic Signatures has a remuneration report first strike with the annual meeting voting 19,093,528 votes (31.0%) against the report and 42,557,268 votes (69.0%) in favor. Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed, the directors must stand for re-election at a subsequent meeting within 90 days.

Genetic Signatures said that the issue of options to chief executive officer Dr John Melki was passed overwhelmingly and the re-election of Michael Archer were unopposed. The company said that a resolution to increase the share issue capacity was withdrawn prior to the meeting.

According to its most recent Appendix 3B new issue announcement, Genetic Signatures had 104,026,937 shares on issue, meaning that the votes against the remuneration report amounted to 18.35 percent of the company, sufficient to requisition extraordinary general meetings.

Genetic Signatures was up three cents or 4.55 percent to 69 cents.

## OPTISCAN IMAGING

Optiscan says its annual general meeting faced up to 32.5 percent opposition to the issue of 1,940,000 free "performance rights" and 12,800,000 options to three directors.

Optiscan's meeting results said the strongest opposition was to the issue of 8,000,000 options to chair Darren Lurie with 66,105,003 votes (32.5%) against and 137,178,453 votes (67.5%) in favour.

The company said that the issue of 1,100,000 rights to Mr Lurie, 660,000 rights and 4,800,000 options to Dr Phillip Currie, 180,000 rights to Graeme Mutton, as well as the re-election of Dr Currie and the 10 percent placement facility were opposed by similar margins, with the remuneration report passing with 145.0 million votes in favour and 9.8 million votes against.

In October Optiscan said that options would vest in four tranches over 30 months with an eight cent price hurdle for the first three tranches and a 10 cents price hurdle for the last tranche, with the first two tranches exercisable at five cents, the third tranche at 6.5 cents and the final tranche at eight cents, by May 31 and November 30, 2022 and May 31 and November 30, 2023 (BD: Oct 30, 2018).

The company's most recent Appendix 3B new issue announcement said that Optiscan had 432,678,800 shares on issue, meaning that the votes against Mr Lurie's options amounted to 15.3 percent of the company, sufficient to requisition extraordinary general meetings.

Optiscan was up 0.4 cents or 7.4 percent to 5.8 cents.

## AVITA MEDICAL

Avita has requested a trading halt pending an announcement regarding "a potential capital raise".

Trading will resume on December 4, 2018 or on an earlier announcement.

Avita last traded at 8.2 cents.



## [NUHEARA](#)

Nuheara has requested a trading halt “pending [the] release of an announcement regarding a capital raising”.

Trading will resume on December 4, 2018 or on an earlier announcement.

Nuheara last traded at 7.8 cents.

## [OPTHEA](#)

BVF Partners and Mark Lampert say their Opthea 37,705,918 share-holding has been diluted from 16.39 percent to 15.12 percent following the recent exercise of options. Earlier this week, Opthea said it had raised \$13.3 million through the exercise of options issued in 2014 (BD: Nov 28, 2018).

Opthea fell two cents or 3.5 percent to 55 cents.

## [TPI \(TASMANIAN POPPY INDUSTRIES\) ENTERPRIZES](#)

Thorney Opportunities says it has increased its substantial shareholding in TPI from 9,889,957 shares (12.20%) to 11,349,996 shares (14.00%).

The Melbourne-based Thorney said that between August 24 and November 28, 2018 it bought 942,898 shares at “market prices” but failed to provide the cost of the shares as required under the Corporations Act 2001 and related company TIGA Trading acquired a further 517,141 shares, also at “market prices”.

The company said the shares were held by Thorney Opportunities, Thorney Investment Group, TIGA Trading Pty Ltd and Jamahjo Pty Ltd.

TPI was unchanged at \$1.24.

## [RHINOMED](#)

Rhinomed says it has appointed Sean Slattery as its chief financial officer effective from December 1, 2018 and will lose US head of sales and marketing Shane Duncan.

Rhinomed said Mr Slattery had more than 20 years of experience as a director, company secretary and chief financial officer with Unscriptd, Powerwrap and Accendre Pty Ltd, and previously was Cybertrust Australia’s financial director.

The company said that Mr Slattery held a Bachelor of Science from Maryland’s Salisbury University and a Master of Taxation from the University of Melbourne.

Rhinomed says its Americas head of sales and marketing Shane Duncan was returning to Australia and would “leave the company to pursue other opportunities”.

The company said its major US accounts would be managed by the US account teams.

Rhinomed chief executive officer Michael Johnson said Mr Duncan “helped spear our entry in the US and built a strong team on the ground to support our [more than] 9,000 store network”.

The company said that “following an internal review” of its Australian and New Zealand program, it was “resuming control of wholesaling and distribution of Mute that was previously conducted by BOC in the Australian and New Zealand markets”.

Rhinomed said that “all existing retail and wholesaling accounts will be serviced by Rhinomed directly” and it expected a positive impact on revenue.

The company said it would move its US office from Cincinnati, Ohio to New York in early 2019, coinciding with “the increase in activity with new medical marijuana licensing partner Columbia Care, as well as the planned growth in US based consumer health market”.

Rhinomed was up half a cent or 2.4 percent to 21.5 cents.

## PHYLOGICA

Phylogica says chief executive officer Dr Rohan Hockings has been appointed a directors, replacing chief scientific officer Dr Robert Hayes.

Phylogica said that the changes were “part of the company’s preparation for commercialization of its cell penetrating peptide platform on the back of a series of major technical milestones scheduled for delivery between now and mid-2019”.

“The milestones will address the critical question of the efficacy of the company’s platform in animal models of human disease across a range of drug cargoes and target tissues,”

The company said.

Phylogica said its board comprised chairman Alan Tribe and directors Dr Rohan Hockings, Dr Bernard Hockings and Sahm Nasser.

Phylogica was unchanged at 2.9 cents.

## GENERA BIOSYSTEMS

Genera says that 10-year, non-executive director David Symons has resigned, effective from today.

Genera said that Mr Symons was “transitioning to a new executive role which precludes external directorships”.

The company said that early next year it would review the board’s composition and the skills needed “with a view to appropriate renewal”.

Genera was untraded at 16 cents.

## ESENSE-LAB

Marijuana company Esense says it has appointed Piers Lewis as chairman and former Israeli Special Air Force Unit major Amit Edri as a non-executive director.

Esense said that Mr Lewis and Mr Edri had “significant corporate experience which would aid in accelerating the company’s commercialization of its innovative plant-based products”.

The company said that Mr Lewis had more than 20 years’ experience in finance, banking, management and mergers and acquisitions in the resources, banking and technology sectors in Australia, Asia and Europe.

Esense said that Mr Lewis was currently a director Dawine and Cycliq Group and was Grange Resources and Ultima United company secretary.

The company said that in 2011, Mr Lewis founded advisory firm Smallcap Corporate.

Esense said that Mr Lewis held a Bachelor of Commerce from the University of Western Australia.

The company said that Mr Edri had experience in the medicinal cannabis industry and had been a consultant for several companies, and was previously the chief operating officer of an unnamed Israeli medical cannabis processor.

Esense said that in 2013 Mr Edri founded the Vaporizers medical marijuana company.

Esense was up 0.4 cents or 11.8 percent to 3.8 cents.