



# Biotech Daily

Friday October 9, 2020

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market was flat on Friday October 9, 2020, with the ASX200 up 0.2 points to 6,102.2 points. Twenty-two of the Biotech Daily Top 40 stocks were up, 13 fell and five traded unchanged.

Antisense was the best, up 1.5 cents or 13.0 percent to 13 cents, with 2.1 million shares traded. Resonance rose 9.4 percent; Amplia and Uscom climbed more than five percent; both Alterity and Oncosil improved 4.2 percent; Osprey was up 3.7 percent; Immutep, Pharmaxis, Proteomics and Starpharma rose more than two percent; Avita, Genetic Signatures, Imugene, Neuren, Next Science, Orthocell, Prescient and Volpara were up more than one percent; with Cochlear, Medical Developments, Mesoblast and Opthea up by less than one percent.

Patrys led the falls, down 0.2 cents or 9.5 percent to 1.9 cents, with 14.6 million shares traded. Optiscan fell 4.2 percent. Actinogen and Kazia lost more than three percent; Impedimed, Nanosonics and Paradigm shed more than two percent; Clinuvel, CSL, Cynata and Dimerix were down more than one percent; with Polynovo, Pro Medicus, Resmed and Telix down by less than one percent.

## [DR BOREHAM'S CRUCIBLE: OVENTUS MEDICAL](#)

**By TIM BOREHAM**

**ASX code:** OVN

**Share price:** 24.5 cents; **Shares on issue:** 158,237,701; **Market cap:** \$38.8 million

**Chief executive officer:** Dr Chris Hart

**Board:** Dr Mel Bridges (chair), Dr Hart, Sue MacLeman, Paul Molloy, Sharad Joshi, Jake Nunn

**Financials (year to June 30 2020):** revenue \$419,298 (up 26%), loss of \$10.12 million (previously \$7.84 million deficit), cash on hand \$8.5 million

**Major identifiable holders:** Dr Chris Hart 16.8%, Tiga Trading (Thorney Group) 13.9%.

To those unfamiliar with sleep therapy, the two US professional bodies representing the somnolence-inducing profession sound as chalk-and-cheese as Monty Python's Judean People's Front and the People's Front of Judea.

But don't underestimate the differences between the American Academy of Sleep Medicine and the American Academy of Dental Sleep Medicine, which led to the bodies severing their formal affiliations late last year.

As Oventus founder and chief executive Dr Chris Hart explains, competitive tensions arose around the method of treating patients, the follow-up care and the associated revenue streams.

In essence, the sleep groups (sleep clinics and laboratories) fear that if they refer a client to a sleep dentist, they may never see the client (and their billings) again. Similarly, dentists fear that if they refer their patient for a sleep study, they may never see that client again, either. So, the dentists started doing their own home sleeping testing.

"The sleep docs weren't happy with that as they felt dentists were practicing medicine without a licence," says Dr Hart, a former dentist and obstructive sleep apnoea sufferer.

"The next thing you know is that ... their respective peak bodies officially separated, making it even less likely that they would work together."

To resolve the turf war Oventus is rolling out a program in US and Canada called Lab-in-Lab, by which sleep physicians and dentists can work in the one location and - crucially - share patient care and revenues.

Lab-in-Lab is a key strategic shift for the company, which earlier tried selling directly to dentists with little success. "We developed [the clinical model] because the sleep physicians are the ones who appreciate the physiology and are most likely to prescribe this technology and embrace it," Dr Hart says.

## **The size of the prize**

There's a lot at stake, given the incidence of obstructive sleep apnoea (OSA) in western nations. Synonymous with snoring, OSA happens when a person's throat is partly or completely blocked while they are asleep, causing them to stop breathing for up to 90 seconds.

Oventus estimates the sleep apnoea market is worth up to \$US7 billion (\$A9.8 billion) per annum globally, growing at a compound annual rate of 15 to 20 percent. The company cites a \$US2.4 billion "market opportunity" in the US alone.

Mouthguard-like oral appliance therapies (OATs) are touted as a cheaper and less cumbersome alternative to continuous positive airways pressure (CPAP) the pump-and-mask standard of care pioneered by Australia's Resmed.

"Normally a mouthguard can treat 50 percent of sleep apnoea patients, we have increased that to about 80 percent," says Dr Hart. "We are seeing a dramatic improvement in efficacy; it's like having a CPAP in your pocket."

About 80 percent of cases are undiagnosed, probably because the sufferers are asleep and can't hear their own vociferous eruptions. Learned articles note that obesity causes obstructive sleep apnoea, with 70 percent of sufferers (or culprits?) being men.

## **Taking a PEEP at Oventus**

The founder of the Lifetime Smiles dental chain, Dr Hart devised a mouthguard to increase airflow to the lungs and bypass obstruction sites including the nose, tongue and soft palate. The device also deploys a technique called positive end expiratory pressure (PEEP).

Dr Hart's prototype model was effective but bulky, so he teamed up with technologist Neil Anderson and the Commonwealth Scientific and Industrial Research Organisation, to develop a 3-D-printed version that was 60 percent smaller.

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

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. Oventus listed in July 2016, raising \$12 million at 50 cents apiece for a total market valuation of \$36 million.

In July 2017, the FDA approved O2Vent, a mouth guard with a titanium breathing channel (duckbill). Then came O2Vent Optima, a lighter nylon version followed by O2Vent/Exvent (with an additional valve that enhances PEEP).

The FDA approved O2Vent Optima, the company's current product on market, in September last year.

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 science of snoring**

Severe snoring is no laughing matter and is linked to morbidities such as diabetes, hypertension, heart disease, stroke, workplace health and safety.

Obstructive sleep apnoea (OSA) happens when airways collapse during sleep, either at the nose, the tongue base, the side walls, the epiglottis or the uvula – the soft palate (the ‘boxing bag’ at the back of the throat).

In the US, there are 35 million CPAP patients, which helps to explain Resmed’s multi-billion-dollar success. Of every 100 patients diagnosed with OSA, 35 will refuse CPAP treatment outright. Of the 65 who try it, 50 will take it home and half of those will quit within a year.

The O2Vents refine the action of a normal mouthguard, which brings the jaw forward to stop the tongue from flopping back and falling into the airway.

“By putting in a ‘second nose’ into the airway we allow the air to flow below those obstructions around the tongue and into the back of the throat,” Dr Hart says. “You breathe out against these little holes and that resistance leads to pressure gradient building up in the airway.”

He says the main anatomic reasons oral devices fail is because of a blocked nose or other obstruction, leading to mouth breathing.

“The valve takes the problem and turns it into the therapy itself,” Dr Hart says. “It regulates the patient’s own breathing and diverts some of the air back into the airway to stabilize it.”

Oventus claims an 80 percent clinical success rate compared with 50 percent for standard mouthguards.

## **The dentists and the sleep makers can be friends**

In the company’s words, the Lab-in-Lab program allows sleep physicians and dentists “to deliver care collaboratively and profitably.”

The Lab-in-Lab model involves the sleep doc doing the initial consultation, with the in-house dentist providing the device and handling reimbursement. The sleep doc then does a follow-up consultation. The patient benefits from not having to make multiple visits to the dentist.

In creating Lab-in-Lab, the company needed to navigate 25 regulations across 50 US states which, in effect, prevent the parties from practicing together. "We figured a way to do that across all 50 states," Dr Hart says. "It does take 20 or 30 separate agreements to do that, I must add."

In many states, the dentist can send an assistant to operate the scanner that images the patient's mouth. In the remaining jurisdictions a dentist is required to do it.

The company had a decent head of steam initially, signing up 57 sites after launching the scheme last October. The sites are contracted to order a minimum of either 10 or 20 devices a month and first revenues flowed in during December and continued to build until March this year, when you-know-what happened (see below).

### **Meanwhile ...**

The pandemic means that half of Oventus's patient dealings are over the 'phone or online, via "clinical educators".

This telehealth channel has resulted in an 80 percent conversion rate, in terms of patients making follow-up appointments. While the patient's gob has to be scanned physically, remote imaging techniques may make a personal visit redundant.

Oventus has also developed a home-care model, to be expanded in the next quarter, allowing patients to be treated anywhere, anytime.

### **Finances and performance**

Oventus recorded underwhelming revenue of \$419,000 for the year to June 30 2021, with cash burn of \$10.1 million.

But is the company about to bite into something much bigger, thanks to Lab-in-Lab?

On Dr Hart's sums, the 57 sites would deliver \$13.6 million of annualized revenue, based on a minimum order of 20 units per month. The company so far has launched 27 sites, which would equate to \$6.8 million annualized, once fully operational.

In the Covid-19 wash-up, only a dozen clinics are seeing patients, with across-the-board North American patient volumes reportedly down 50 percent.

"We are opening, or re-opening, three to four sites a month and as patient flow returns, we would expect revenue to grow in a similar fashion - if not a little faster - quarter on quarter."

"We are pretty much where we hoped to be had Covid not occurred."

The Oventus units sell for \$800 apiece wholesale, with the entire consulting and fitting process reimbursable on average to the tune of \$2,000.

The company also will deploy a subscription model - \$200 a year - for the consumable items such as valves and connector bands, which need to be replaced four times a year.

In May and June, Oventus raised \$6.65 million: \$4.65 million in a placement and \$2 million in a capped share purchase plan, both at 24 cents per share.

The company also raised \$9.3 million in a placement in July last year. Both efforts were supported by institutional holders including the Thorney Group's Tiga trading.

Oventus shares peaked at 81 cents in early October last year and then slumped to a low of 18 cents on March 23, at the height of the Covid-19 crisis.

### **Dr Boreham's diagnosis:**

Dr Hart says the company's workmanlike objectives include extending telehealth, reducing lead time to revenue and reducing cost of goods sold from 40 per cent to 20 percent over the next six months.

The company also has "tens and millions" of revenue under negotiation.

A device iteration, Exvent shortly will be subject to an FDA 510k application.

"The tech speaks for itself, so really it's about implementation, growing out these clinics, optimizing revenue from these sites and then reducing our cost base to ensure great profit margins," Dr Hart says.

We stress that Oventus hardly has the market to itself. One rival is its bigger ASX counterpart Somnomed, which markets its Somnodent device to 445,000 patients across 28 countries. Oral appliances account for only 10 percent of the obstructive sleep apnoea market, so Oventus is clearly still in growth phase.

The annual recurring revenue from the in-place Lab-in-Lab centres suggests the company should be turning over millions, rather than a few hundred thousand. Given the handsome margins on the devices, a maiden profit should also be on the cards.

"It's still small numbers but we are growing reasonably quickly and we don't need a heck of a lot to make money," Dr Hart says.

When we last covered the stock in October 2018 - yes, it's been a while - Dr Hart said that with the company moving from blue sky to marketing phase, "our job now is to generate revenue and gain some market share."

Nothing's changed, so carry on ...

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. While not a registered sleep therapist either, he has been known to bore readers to snores***

## [PROTEOMICS INTERNATIONAL LABORATORIES](#)

Proteomics says it will partner with the Queensland Institute of Medical Research Berghofer to improve detection of oesophageal adenocarcinoma.

Proteomics said it would combine its Promarker biomarker protein diagnostic technology with the Institute's biomarkers to develop a simple blood test for oesophageal adenocarcinoma, the most common oesophageal cancer in Australia.

The company said that if the 12-month collaboration was successful, it would have the rights to licence the blood test for international commercialization.

Proteomics said the test could be offered to patients with Barrett's oesophagus, a pre-malignant condition associated with an increased risk of oesophageal cancer, caused by acid reflux damage to the oesophagus, and affecting about two percent of the population. The company said it was recommended that people with Barrett's oesophagus were screened for pre-cancerous cells as often as every three months, and if discovered early, the pre-cancerous cells could be treated to prevent oesophageal cancer.

QIMR researcher Prof Michelle Hill led the team that discovered the biomarkers and said the blood test "could fundamentally change oesophageal cancer screening".

"At the moment, patients have to undergo an invasive endoscopy, with a camera passed down their throat to look for changes in the oesophagus tissue and a biopsy taken," Prof Hill said.

"It's uncomfortable for patients, requires specialist expertise, and comes with some risk of perforation and bleeding," Prof Hill said.

Proteomics managing-director Dr Richard Lipscombe said that "the new technology aimed to identify the five percent of people most at risk of oesophageal adenocarcinoma and prioritize treatment for those patients".

"It has huge potential to bring down the overall number of endoscopy procedures, limit unnecessary patient discomfort and reduce the burden on the health system," Dr Lipscombe said.

Proteomics was up 1.5 cents or 2.6 percent to 59.5 cents.

## [ANTERIS TECHNOLOGIES \(FORMERLY ADMEDUS\)](#)

Anteris says early results from a human trial of its Duravr aortic valve have "exceeded ... what is normally expected following a surgical aortic valve replacement".

Anteris said that data presented at a meeting of the European Association for Cardio-Thoracic Surgery showed that the Duravr valve was easy to use and could restore normal pre-disease haemo-dynamics.

Lead surgeon of the study Prof Bart Meuris said that the "early results support the clinical hypothesis that Duravr, due to its anatomically correct design and the superior anti-calcification treatment of Adapt [tissue], will be an important addition for the treatment of severe aortic stenosis in the future".

Anteris chief executive officer Wayne Paterson said the "results are extremely important because they demonstrate improved haemo-dynamics over currently available commercial products".

"This data is essential as we move towards further study approvals from the US Food and Drug Administration and other regulators," Mr Paterson said.

Anteris said the Duravr had ongoing development programs, including animal studies for transcatheter heart valve replacement and could offer a more durable option for improving acute and long-term outcomes for patients with aortic valve diseases.

Anteris was up nine cents or 2.3 percent to \$4.01.

## OPTISCAN IMAGING

Optiscan says feedback from the US Food and Drug Administration has indicated that its Invivage oral cancer screening microscope is on-track for 510(k) submission.

Optiscan said the FDA provided “affirmative responses” regarding the proposed product code, primary predicate device and use of its Convivo digital confocal microscope as a reference device.

The company said the next step was the clinical study for the efficacy of the Invivage device with a topically applied imaging agent at Melbourne Dental School.

Optiscan said the study and third-party validation would begin by the end of the year and it expected to complete the 510(k) submission in “the first half of 2021”.

Optiscan fell half cent or 4.2 percent to 11.5 cents.

## MEMPHASYS

Memphasys said its Felix sperm separation device is on-track for sales this year in “less regulated markets,” with the final verification and validation tests underway.

Memphasys said the potential markets for sales of the Felix in-vitro fertilization device included Japan, Canada, New Zealand and India.

The company said the verification and validation tests were required before sales could begin and were expected to be completed “by late November”.

Memphasys said that it had adopted better medical grade materials for two components of the Felix disposable cartridge for stronger compliance with biocompatibility regulations.

Memphasys was up half a cent or five percent to 10.5 cents with 2.2 million shares traded.

## DORSAVI

Dorsavi has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company’s share price rose 36.1 percent from 3.6 cents yesterday

October 9, 2020 to 4.9 cents today and noted a significant increase in the trading volume.

Dorsavi fell 0.4 cents or 8.7 percent to 4.2 cents with 5.5 million shares traded.

## ANTEOTECH

Anteotech says shareholders will vote to issue 6,900,000 options to chair Jack Hamilton and directors Geoff Cumming, Matthew Sanderson and Chris Parker.

Anteotech said it proposed to issue 2,400,000 options to Mr Hamilton and 1,500,000 options each to Mr Cumming, Mr Sanderson and Mr Parker.

The company said the options would vest in three equal tranches exercisable at 30 percent, 50 percent and 100 percent premia to the 30-day volume weight average to the date of issue, respectively, expiring within three years.

Anteotech said the annual general meeting would vote to adopt the remuneration report, re-elect director Mr Sanderson and approval a 10 percent placement facility.

The meeting will be held online on November 12, 2020 at 10am (AEDT).

Anteotech was up one cent or 12.2 percent to 9.2 cents with 17.2 million shares traded.



### EMYRIA (FORMERLY EMERALD CLINICS)

Emyria says shareholders at its annual general meeting will vote to issue up to 8,500,000 options to directors in lieu of cash bonuses.

Emyria said it proposed to issue 4,000,000 options to managing-director Dr Michael Winlo, 2,000,000 options to medical director Dr Alistair Vickery, 1,500,000 options to director Matt Callahan and 1,000,000 options to director Prof John Tooke.

The company said the options would vest in three tranches within two years of the grant date, exercisable at 11.7 cents each and expiring after four years.

Emyria said the proposed issue sought “to align the efforts of the directors in seeking to achieve growth of the share price and in the creation of shareholder value ... [and] incentivizing with options is a prudent means of conserving the company's available cash”.

The company said shareholders would vote to adopt the remuneration report, re-elect director Prof Tooke, approve a 10 percent placement facility and ratify the prior issue of placement shares.

The meeting will be held at the offices of BDO Tax Agents 38 Station Street, Subiaco, Perth, Western Australia on November 13, 2020 at 9am (AWST).

Emyria fell 0.1 cents or 1.2 percent to eight cents.

### MEDIBIO

Medibio says its annual general meeting will vote to issue managing-director Claude Solitario and Jennifer Solitario 14,150,000 options

Medibio said that Ms Solitario's 2,900,000 short-term bonus options would be exercisable at the 5-day volume-weighted average price to October 1, 2020 by October 6, 2023, while Mr Solitario's options would be exercisable at the 30-day volume-weighted average price to the date of grant within five years.

The company said that shareholders would vote to adopt the remuneration report, re-elect Melanie Leydin as a director, ratify the prior issue of shares and options approve amendments to the constitution and approve the 10 percent placement capacity.

The virtual meeting will be held on November 12, 2020 at 11am.

Medibio was unchanged at 1.1 cents with 7.5 million shares traded.

### STARPHARMA HOLDINGS

Allan Gray Australia says it has reduced its substantial shareholding in Starpharma from 45,058,767 shares (12.09%) to 43,597,242 (10.82%).

The Sydney-based Allan Gray said that between September 17 and 25, 2020 it sold 1,461,525 shares for \$2,451,473 or an average of \$1.68 a share.

Starpharma was up three cents or two percent to \$1.515.

### STARPHARMA HOLDINGS

Fidelity International Limited (FIL) says it has increased its substantial shareholding in Starpharma from 26,141,471 shares (7.02%) to 33,514,716 shares (8.32%).

The Sydney and Hong Kong-based FIL said that between September 15 and October 6, 2020 it bought 7,373,245 shares at prices ranging between \$1.50, as part of the company's \$5 million share plan, and \$1.6989 a share (BD: Sep 30, 2020).

## CRESO PHARMA

Creso says it has a second purchase order of \$C138,960 (\$A146,811) from Nova Scotia Liquor Corporation for its Ritual Green brand recreational marijuana.

Last month, Creso said the initial purchase order from Nova Scotia Liquor Corp, made through its wholly owned subsidiary Mernova Medicinal, was for \$C180,000 of two Ritual Green marijuana strains, HPG13 and Lemon Haze (BD: Sep 30, 2020).

Today, the company said it believed that the second purchase order was “early confirmation of the success of the Ritual Green brand” and anticipated that additional orders would be received in the coming weeks for existing and new strains.

Creso was up 0.2 cents or 6.45 percent to 3.3 cents with 61.25 million shares traded.