



# Biotech Daily

Friday October 8, 2021

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market was up 0.87 percent on Friday October 8, 2021, with the ASX200 up 63.4 points to 7,320.1 points. Eighteen of the Biotech Daily Top 40 stocks were up, 19 fell and three traded unchanged.

Nova Eye was the best, up 2.5 cents or 6.6 percent to 40.5 cents, with 34,155 shares traded. Actinogen, Genetic Signatures, Impedimed and Patrys climbed four percent or more; Alterity and Osprey were up more than three percent; Immutep, Kazia, Orthocell, Prescient, Resonance and Starpharma rose two percent or more; Polynovo was up 1.45 percent; with Cochlear, CSL, Mesoblast, Pro Medicus, Proteomics and Volpara up by less than one percent.

Pharmaxis led the falls, down one cent or 7.4 percent to 12.5 cents, with 832,361 shares traded. Uscom lost 7.1 percent; Amplia, Antisense, LBT and Optiscan fell more than four percent; Clinuvel, Dimerix, Paradigm and Universal Biosensors were down more than three percent; Telix shed 2.6 percent; Compumedics, Cynata, Imugene and Neuren were down one percent or more; with Avita, Medical Developments, Nanosonics, Next Science and Resmed down by less than one percent.

## [BIOTECH CALL TO ARMS: DAVID BLAKE - UPDATE](#)

At the time of publication, the fundraiser for Bioshares co-founder David Blake has raised more than \$113,000 (BD: Oct 1, 2021).

We were hopeful as the pledges came in over the weekend that we might come close to the \$90,000 target and were pleased to be more than halfway on Monday morning.

By Wednesday we had reached \$60,000, and mail-outs from Ausbiotech and Bio-Melbourne Network triggered a further surge, exceeding the target on Thursday morning.

We would like to thank everyone who has donated to support David and his family and remind those who have not as yet, that the Gofundme page remains open.

To donate, go to: <https://gofund.me/9c2dff05>.

The funds will make a huge difference allowing David to be cared-for at home with his family. It is an honor to report that the Australian biotechnology sector is different from most others with such a display of kindness and compassion. Thank you all.

**David Langsam**  
Editor

## [DR BOREHAM'S CRUCIBLE: SOMNOMED](#)

**By TIM BOREHAM**

**ASX code:** SOM

**Share price:** \$2.35; **Shares on issue:** 82,759,315; **Market cap:** \$194.5 million

**Chief executive officer:** Neil Verdal-Austin

**Board:** Guy Russo (chair), Mr Verdal-Austin, Amrita Blickstead, Hilton Brett, Hamish Corlett, Michael Gordon, Karen Borg

**Financials: (year to June 30 2021):** revenue \$62.7 million (up 9%), underlying earnings before interest, tax depreciation and amortization \$3.9 million (down 17%), net loss after tax \$1.2 million (previous \$438,000 deficit), cash \$21.1 million (down 30%), debt \$2.35 million (down 68%)

**Identifiable major holders:** TDM Growth Partners 26.8%, Australian Ethical 11.07%, Dottie Investments (Peter Howarth) 7.9%, Fidelity 7.6%.

Somnomed chief Neil Verdal-Austin readily concedes the established treatment for obstructive sleep apnoea (OSA) is highly effective, which may seem a strange message from the world's biggest supplier of the (mouthguardy) alternative technique.

The reason is that compliance rates for the standard-of-care, continuous positive airways pressure (CPAP) is notoriously low with 70 percent of patients discarding the requisite pumps and masks within months.

So, it's a bit like saying that anti-Covid masks work well when they're not dangling under one's chin (no judgments, not at all. Not here.)

Unlike CPAP, Somnomed's continuous open airway therapy, or COAT, does not require unwieldy masks and pumps.

"Somnomed's plan is to grow that sector so that a far greater number of patients are treated for OSA," Mr Verdal-Austin says.

But how?

Somnomed's master strategy to increase adoption revolves around a mystery new technology platform due to be unveiled by the end of the year.

Aimed at winning over US insurers, the "transformational technology" will enable Somnomed to better position oral appliances against CPAP.

Mr Verdal-Austin describes it as an "integrated automated tech platform that creates a data driven ecosystem."

Um - we're none the wiser either. But we shouldn't have long to wait, with an investor tell-all planned before the year is out.

## **Emerging from the shadows of the pandemic**

The Covid-19 scoreboard shows that most life sciences companies weathered the pandemic reasonably well, or else they benefited because they were part of the solution (such as testing and vaccines).

Somnomed was not one of them: the sleep sector was affected enormously because patients were denied access to sleep physicians, the company's key source of referrals.

Meanwhile sleep physicians, who are respiratory doctors (pulmonologists, if you must) were being shifted to deal with emergency Covid patients.

Unlike CPAP giant Resmed, Somnomed didn't have air pumps which it could convert to ventilators to keep critically ill Covid patients alive.

"A healthcare device company doesn't do to well during a pandemic," Mr Verdal-Austin says.

"It's been a tough time, there's no doubt about that. You can see and read it in the communications from ourselves and others in the market."

## **Sleepers, awake!**

Now, the first rays of recovery are emerging, as evidenced by the company's second (June) half revenue rebound (see 'finances and performance' below).

Mr Verdal-Austin describes the North American recovery as "outstanding", while the company is also emerging from access issues in Europe (where the sleep docs are hospital-based rather than in private practice).

In the US, a product recall from CPAP provider Philips Respironics has benefited Somnomed, but has also created chaos for US sleep clinics.

He describes conditions as "unpredictable and lumpy as things change week to week", but increased vaccination rates are likely to contain the risks and spur sales growth.

Indeed – we're all hoping on the power of the vaccine to restore some semblance of normality.

## **A COAT of many colors**

Somnomed's COAT device is a mandibular advancement splint that moves the lower jaw slightly forward, keeping the airway open at all times.

Think of it as a posh mouthguard.

Somnomed sells in 28 countries and has treated 620,000 patients, including failed CPAP users and previously untreated users.

Somnomed listed in August 2004, raising \$12 million at 30 cents apiece.

The company initially was based on a device called the Somnomed MAS (mandibular advancement splint), invented by Sydney retired consultant orthodontist and champion rower Dr Richard Palmisano, who died in 2009.

Somnomed underwent several strategy iterations, most notably a hasty and costly retreat from its chain of direct-to-patient US sleep diagnostic centres, Renew Sleep Centres (RSS).

Somnomed opened its first RSS centre in December 2016 but abandoned the strategy in December 2018, having opened only four of the intended 16 outlets.

The core problem, in short, was a change to health insurance policies that increased patients' out-of-pocket expenses and reduced reimbursement rates for Somnomed

The RSS fiasco saw the departure of US-based CEO Derek Smith, who was replaced by Mr Verdal-Austin, the company's long time CFO and chief operating officer.

Somnomed's chairman Guy Russo is a revered figure in retail land, having run the Kmart and Target chains and McDonald's Australia. He currently chairs the Mexican food chain Guzman y Gomez so there's never a shortage of takeaway burritos at board meetings.

### **Putting the bite on distribution**

As evidenced by the RSS experiment, the problem for sleep appliance makers is that distribution channels are inherently indirect. The sleep physicians do the diagnosing and prescribing, but the dentist does the fitting and invoices the customer.

With the exception of mouthguards for teeth grinding (bruxism), the dentist doesn't initiate the sale.

Given mouth appliances are much cheaper than CPAP and just as effective in many cases, the vexing question is why COAT accounts for only eight to 10 percent of the obstructive sleep apnoea (OSA) market.

"It's fraught with complication because there are myriad variables," Mr Verdal-Austin says.

"History shows that doctors default to CPAP and sometimes it's been the only treatment. They didn't consider the patient versus the treatment."

He says the situation is changing because of raised awareness and education and continuing research to highlight the virtues of COAT.

Somnomed, meanwhile has built a network of around 25,000 dentists who are wise to the virtues of COAT.

### **What's next?**

Somnomed is now in second-generation stage with its appliance called Herbst Advance, which is more comfortable and lasts longer than Advant 1.0.

The mouthguard works with a titration action (the moving forward of the jaw) and is made of a soft inner liner material, rather than hard acrylic.

In Europe patients pay around EUR1,000 (\$A1,390), which includes diagnosis and fitting.

In the US this 'all in' cost is more like \$US2,000 to \$US3,000, while in Australia it's more like \$A1,800.

Somnomed itself receives about 500 for each device and by 500 we mean Euros, US dollars or Aussie dollars.

So, there's a fair bit of margin in the whole treatment chain that Somnomed doesn't receive. Despite this, the cost is still well below that of CPAP treatment.

## **Finances and performance**

Somnomed's full-year performance was a tale of two halves, in that the first (December) half turnover declined seven percent because of pandemic lockdowns, especially in the US.

But second (June) half revenue rebounded 33 percent, with the June quarter in particular boding well for the current year.

Europe and Australasia revenues rose 20 percent and 17 percent respectively.

Underlying earnings declined to \$2.7 million from \$4.7 million in the previous year, with a reported net loss of \$1.2 million.

Management is now confident enough to predict a 15 percent revenue uptick for the current year, "assuming that Covid does not get worse in any of the 28 markets in which we trade."

Underlying earnings will be flat, reflecting an expected \$8 million spend on the new tech platform.

Over the last year Somnomed shares have ranged between a somnolent \$1.65 (early March 2021) and \$2.58 (early October last year).

The shares hit a historic high of \$4.86 in October 2004.

## **Rivals ride the COAT tails of Somnomed**

Somnomed reckons it accounts for 40 to 55 percent of the COAT market globally, with a 60 to 65 percent share in Europe.

In the US the company accounts for 20 to 25 percent of the market while in Australia it's more like 40 to 45 percent.

In the US, Somnomed competes directly with ProSomnus Sleep Technologies: "a formidable competitor who we watch very carefully".

In Australia, the competitors are more like independent laboratories that make devices for dentists who distribute directly.

We also must mention the ASX-listed Oventus, which sells a device with a vent (duckbill) to enable mouth breathing when the nose is blocked.

Somnomed argues these nasal blockages should be addressed as part of the treatment.

Who nose which philosophy is right, but we merely note that Oventus last year recorded modest revenue of \$1.1 million, albeit 160 percent higher.

About eight years ago Resmed dabbled in the COAT sector by buying a French outfit called Narval, which had 90 percent of the Gallic market.

Resmed expanded Narval into the US and Canada, but eventually surrendered.

Mr Verdal-Austin says the foray was like a train company deciding to become an airline because it was in the transportation business.

But no submarine-building analogies, fortunately ...

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

Your columnist last got his teeth into Somnomed in the halcyon pre-Covid days of August 2019.

At the time, the shares traded at \$2 and the company was valued at \$125 million, with full-year revenue of \$59 million.

On that basis the company has merely marked time, although back then it reported a \$15.8 million loss.

Some 1.36 billion people suffer from obstructive sleep apnoea, 900 million mildly and 400 million moderately to severely. But it's hard to know because they don't exactly stay awake to hear themselves snoring - and increasingly don't share their bed with anyone but a dog to alert them to their rumblings.

Of the mild sufferers - of most interest to Somnomed - 54 million are in the US.

Snoring is also endemic in kranski-munching Germany (26 million), beef bourguignon - loving France (23 million) and even the leaner denizens of Japan (22 million).

Evidently something is amiss when seven out of 10 CPAP patients do not use the prescribed product obtained at great expense.

Mind you, Resmed is a hugely successful global company with turnover of \$US3.2 billion and Somnomed bears a \$150 million market valuation.

But like China in the 1970s, the sleeping giant could be about to wake as COAT increasingly proves its credentials over CPAP.

"Our message is that you cannot ignore compliance and that aspect will start to move the dial for oral appliances," Mr Verdal-Austin says.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. As far as he knows he doesn't suffer from obstructive sleep apnoea but has been known to bore people to snores in waking hours.***

## CYNATA THERAPEUTICS

Cynata says the data safety monitoring board says the trial of its Cymerus mesenchymal stem cells for Covid-19-related respiratory failure should continue as planned.

Cynata said the Australian 'Mend' trials were open labelled, randomized, controlled clinical trials to investigate early efficacy of Cymerus Mesenchymal stem cells in 24 adult patients admitted to intensive care with respiratory failure.

In May, the company said it enrolled the first of 24-patients for its 'Mend' Cymerus mesenchymal stem cells trial for adult Covid-19 and respiratory failure patients in intensive care (BD: May 24, 2021).

Today, Cynata said the primary efficacy endpoint was the trajectory of the measure of hypoxemia, or the low level of oxygen in the blood, caused by compromised lung function by day-7, as well as safety and tolerability up to day-28.

Cynata fell one cent or 1.6 percent to 61.5 cents.

## LUMOS DIAGNOSTICS

Lumos says it has agreed with the ASX to retract Wednesday's article saying Febridx could save the US healthcare system \$2.5 billion a year.

On Wednesday, Lumos said that using its Febridx to guide antibiotic treatment for patients with acute respiratory infections could save the US healthcare system \$2.5 billion a year (BD: Oct 6, 2021).

The company said the study estimated the healthcare costs with current antibiotic prescribing, including the cost associated with treating antibiotic-related adverse events, and compared them with an estimate of the costs when Febridx was used.

Today, Lumos said it contracted Avalon Health Economics to undertake the study but was "not involved in the modelling nor aware of the conclusions of the study until the publication was released this week".

Lumos said Wednesday's announcement was not intended to constitute a financial forecast of the potential market for the use of its Febridx test and investors should not rely on the announcement for making any investment decisions relating to Lumos shares.

Lumos was up 2.5 cents or 2.75 percent to 93.5 cents.

## LBT INNOVATIONS

LBT says the South Australian Government has deferred its loan repayment of \$512,000 by six months to November 22, 2022.

LBT said the final loan repayment date on its \$4 million loan facility, to support development of its automated plate assessment system (APAS), had been extended by six months from May 2024 to November 2024.

In 2018, LBT said the South Australian Government had approved a \$4 million low-cost loan as part of a jobs and innovation initiative (BD: Aug 28, 2018).

LBT said the funding was designed to help extend its platform technology by recruiting 16 full time Adelaide-based staff in areas artificial intelligence, science, and software engineering over the next two years.

Today, the company said the deferral of the next two quarterly principal and interest repayments would support its with Thermo Fisher Scientific Inc as exclusive APAS Independence distributor for the US and "in recognition of the ongoing impact of Covid-19 on clinical microbiology markets globally".

LBT fell half a cent or 4.35 percent to 11 cents.



## STARPHARMA

Starpharma says it has a sales and distribution agreement with Bologna's Admenta Italia Group for its Viraleze nasal spray for Covid-19 and other viruses.

Starpharma said Viraleze inactivated more than 99.9 percent of the Delta variant of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).

Earlier this year, the company said Viraleze had been registered for sale in Europe, the UK and India and contained SPL7013, or astodimer sodium, the active ingredient in its condom coatings and Vivagel for bacterial vaginosis (BD: Feb 23, Jun 11, 2021).

Today, Starpharma said Viraleze was not registered for sale or supply in Australia.

Starpharma was up 2.5 cents or 2.1 percent to \$1.22.

## ADHERIUM

Adherium says it made a submission to the US Centers for Medicare and Medicaid Services on proposed current procedural terminology for remote therapeutic monitoring. Adherium said the US Centers for Medicare and Medicaid Services (CMS) proposed five new current procedural terminology codes for remote therapeutic monitoring of non-physiologic patient data such as respiratory system status, medication-based therapy adherence, and medication-based therapy response.

The company said the CMS requested public input to the proposed rules and current procedural terminology (CPT) codes and responded with a detailed submission.

Adherium chief executive officer Rick Legleiter said the proposed changes were a "potentially important development for our business as the CMS fee schedule is critical to driving market adoption of technological innovation in digital health, and would be complementary to our existing route to enabling reimbursement under remote physiologic monitoring codes through incorporating physiological measures into our Hailie sensors".

"Healthcare is at a global tipping point for smart medicine," Mr Legleiter said

"As such it is important that Adherium assert thought leadership with US policy makers on remote monitoring and [electronic] health," Mr Legleiter said.

Mr Legleiter said the final rule was expected by early-December with the policy expected to be effective on January 1, 2022.

Adherium was unchanged at 1.6 cents with 1.6 million shares traded.

## IMMURON

Immuron says its cow colostrum-based oral IMM124E shows anti-viral T-cell immunity in human cell cultures and mice, and it has filed a patent application.

Immuron said the research, titled 'Augmented antiviral T cell immunity by oral administration of IMM124E in preclinical models and a phase I/IIa clinical trial: A method for the prevention and treatment of Covid-19' was published in the journal Drug Development Research and was available at: <https://doi.org/10.1002/ddr.21890>.

The company said the study at Jerusalem's Hadassah Medical Centre examined IMM-124E's ability to promote antiviral interferon- $\gamma$  in mice and in a five-volunteer phase I/IIa clinical study.

Immuron said that in the clinical study, healthy volunteers received 600mg of IMM-124E a day for four consecutive days and 1200mg for an additional day.

The company said the preliminary clinical data suggested a similar effect was observed in humans in augmenting anti-viral responses against severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) and hepatitis B.

Immuron was up 2.5 cents or 19.2 percent to 15.5 cents with four million shares traded.

## ACTINOGEN MEDICAL

Actinogen says its annual general meeting will vote to issue 48,362,300 shares to chief executive officer Dr Steven Gourlay and 4,500,000 loan shares to directors.

In March, Actinogen said it appointed Dr Gourlay chief executive officer on a base salary of \$400,000, a short-term incentive bonus up-to 35 percent of the annual salary, along with interest free loan shares as a long-term incentive, including 24,181,150 shares at 3.5 cents a share, and 24,181,150 shares at 4.5 cents a share (BD: Mar 15, 2021).

Today, the company said Dr Gourlay's shares would vest over three years, with 6,045,288 shares vesting on the 12-month anniversary of commencement, and the remainder to vest in equal monthly increments over the following two years.

The company said shareholders would vote to issue 11,900,000 loan shares to employees and issue 2,500,000 loan shares to chair Dr Geoffrey Brooke and 1,000,000 shares each to directors Dr George Morstyn and Malcolm McComas.

Actinogen said the loan was repayable five years after the loan advancement date or a month after the employee's resignation.

The company said shareholders will also vote on the remuneration report, the re-election of chair Dr Brooke, the approval of the employee share plan and the placement capacity. The meeting will be held virtually on November 10, 2021 at 11am (AEDT).

Actinogen was up half a cent or 4.8 percent to 11 cents with 4.4 million shares traded.

## CLINUVEL PHARMACEUTICALS

The Clinuvel annual general meeting will vote on the remuneration report and a potential second-strike board spill.

Last year, Clinuvel said its annual meeting passed all resolutions, but with 35.35 percent of votes against the remuneration report, earning a first strike (BD: Nov 20, 2020).

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. If the spill vote fails, the trigger is reset to no opposition.

Today, Clinuvel said shareholders would vote on the re-election of directors, Dr Karen Agersborg and Mr Sue Smith.

The meeting will be held virtually on November 10, 2021 at 6pm (AEDT).

Clinuvel fell \$1.48 or 3.5 percent to \$40.72 with 206,704 shares traded.

## MACH7 TECHNOLOGIES

Mach7 says its annual general meeting will vote to issue 402,185 performance rights to managing-director Michael Lampron and 335,000 options to four directors.

Mach7 said Mr Lampron's performance shares would vest from when it reached the 50th to the 75th percentile of the S&P ASX All Technology Index total shareholder value.

The company said shareholders would vote to issue 250,000 options to director Phillippe Houssiau, 35,000 options to chair David Chambers and 25,000 options each to directors Dr Elliot Siegel and Robert Bazzani, with the options exercisable at \$1.38, vesting in three equal tranches and expiring on the fifth anniversary of the grant date.

Mach7 said shareholders would vote on the remuneration report, the re-election of directors Mr Houssiau and Mr Chambers and the 10 percent placement capacity.

The meeting will be held virtually on November 11, 2021 at 10am (AEDT).

Mach7 fell two cents or two percent to 97 cents.

## OSTEOPORE

Osteopore says accountant Daniel Ow will replace directors Stuart Carmichael and Geoff Pocock.

Osteopore said Mr Carmichael and Mr Pocock resigned as non-executive directors effective on October 7, 2021.

The company said Mr Ow had more than 20 years' experience and was currently Perth Airport's manager of financial business partners.

Osteopore fell three cents or 9.7 percent to 28 cents.

## RESMED

Resmed says Rajwant Sodhi has ceased his position as head of software as a service business on August 25 and full-time employment effective on September 1, 2021.

Resmed said in a filing to the US Securities and Exchange Commission that Mr Sodhi would receive \$US603,500 (\$A825,994), representing 12 months base pay and additional payments totalling \$US100,191 (\$A137,134).

The company said Mr Sodhi would continue as advisor to the chief executive officer on technology and strategic opportunities until November 20, 2022.

Resmed fell 11 cents or 0.3 percent to \$35.22 with 845,401 shares traded.