



Biotech Daily

Friday August 23, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: IMUGENE UP 9.5%; OPTHEA DOWN 4%**
- * **DR BOREHAM'S CRUCIBLE: SOMNOMED**
- * **MAYNE REVENUE DOWN 1% TO \$525.2m, LOSS UP 111% TO \$283.8m**
- * **SDI REVENUE UP 7% TO \$79.6m, PROFIT UP 30% TO \$7.3m**
- * **NEXT SCIENCE REVENUE UP 222% TO \$3.5m, LOSS UP 10% TO \$9.7m**
- * **TELIX H1 MAIDEN REVENUE OF \$1.8m, LOSS UP 100% TO \$10.4m**
- * **OVENTUS 'OVERSUBSCRIBED' RIGHTS RAISE \$2.3m; TOTAL \$9.3m**
- * **CE MARK FOR RESAPP SMARTPHONE RESPIRATORY DIAGNOSTIC**
- * **W.H.O. NAMES KAZIA GDC-0084 FOR BRAIN CANCER 'PAXALISIB'**
- * **MGC, SWINBURNE TEST MARIJUANA DRIVING**
- * **PAUL COZZI TAKES 10% OF CARDIEX**
- * **BOTANIX, ORTHOCELL DIRECTOR MATTHEW CALLAHAN TAKES LEAVE**

MARKET REPORT

The Australian stock market was up 0.33 percent on Friday August 23, with the ASX200 up 21.3 points to 6,523.1 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and one was untraded.

Imugene was the best, up 0.2 cents or 9.5 percent to 2.3 cents with 6.1 million shares traded. Avita climbed 8.1 percent; Orthocell was up 6.25 percent; Amplia, Patrys and Resonance improved more than four percent; Genetic Signatures, Impedimed, Neuren and Polynovo were up more than three percent; Medical Developments and Universal Biosensors rose more than two percent; Antisense, Clinuvel, Cynata, Ellex and Proteomics were up more than one percent; with Resmed and Volpara up by less than one percent.

Opthea led the falls, down 12 cents or 4.3 percent to \$2.66, with 168,491 shares traded. Cyclopharm and Dimerix lost more than three percent; Kazia, Mesoblast, Next Science, Optiscan, Starpharma and Telix shed more than two percent; Nanosonics, Oncosil and Pro Medicus were down more than one percent; with Cochlear, CSL and Paradigm down by less than one percent.

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

By TIM BOREHAM

ASX code: SOM

Share price: \$2.00

Shares on issue: 62,804,168

Market cap: \$125.6 million

Chief executive officer: Neil Verdal-Austin

Board: Dr Peter Neustadt (chairman), Lee Ausburn, Robert Scherini, Hamish Corlett

Financials: (Year to June 30, 2019): revenue \$58.9 million (up 12%), earnings before interest, tax, depreciation and amortization \$3.4 million (down 13%), net loss after tax \$15.8 million (previously a loss of \$6.9 million), cash of \$7.7 million (down 42.5%)

Identifiable major holders: TDM Asset Management and associates 19.97%, Australian Ethical 10.48%, Dottie Investments (Peter Howarth) 8.23%, FMR LLC (Fidelity) 5.24%, Belgove Pty Ltd (Peter Neustadt).

As the head of a company selling mouthguard-like oral devices to combat obstructive sleep apnoea (OSA), Neil Verdal-Austin surprises us by praising the effectiveness of the standard-of-care rival pumps and masks sold by industry leaders Resmed and Respironics.

He says the continuous positive airways pressure (CPAP) units are 100 percent effective - when worn that is.

The trouble is, the devices are renowned for being uncomfortable and the compliance rate is extremely low at 30 to 50 percent.

At the same time, most OSA sufferers are recommended CPAP devices, even though oral devices could be suitable for two-thirds of users (patients with mild to moderate snoring).

"It's like prescribing someone a wheelchair before crutches and that doesn't make sense to me," he says.

Somnomed markets continuous open airway therapy, or COAT. Somnomed's Somnodent mouthguard is a mandibular advancement splint that moves the lower jaw slightly forward, keeping the airway open at all times.

Somnomed sells in 28 countries and has treated 500,000 patients, including a failed CPAP cohort and previously untreated users.

Based on “patient feedback”, the company claims that 91 percent of users have a better night’s sleep, with 88 percent using the device regularly. What’s more, all of the patients continued using the device to treat their condition over the longer term.

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.

US strategy put to sleep

Despite its steady growth, Somnomed has undergone several strategy pivots, notably a hasty and costly retreat from its headline strategy of setting up a chain of direct-to-patient US sleep diagnostic centres, Renew Sleep Centres (RSS).

“We have been through different strategic and board changes as we work out what we are, and who we are best at treating,” Mr Verdal-Austin says.

Somnomed opened its first RSS centre in December 2016 but abandoned the strategy in December 2018, having opened 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 - sound familiar? - and reduced reimbursement rates for Somnomed.

While the chain received 60,000 inquiries, patient conversions were not strong enough.

“Whilst we believe there may be a future for a direct-to-patient approach in the US ... it would require more time, more money and a lot of good management to turn RSS into the business we were originally expected to have,” chairman Peter Neustadt said at the time.

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. In those roles, Mr Verdal-Austin was integral to all of the company’s major decisions, including establishing a manufacturing facility in the Philippines and - presumably - the RSS strategy.

“We went a little bit too quickly,” he says of the US misstep. “The RSS concept was borne out of the fact that the process of sleep specialists referring sleep-study patients to dentists was really slow.”

Somnodent Avant

While Somnodent continues to sell okay, no device company can stand still and Somnomed is working on its next iteration: the digitally manufactured Somnodent Avant.

Avant avails of computerized design and manufacturing techniques to produce the mouthguards cheaper and more quickly. It's also promised to be more comfortable for the user - a key driver of compliance - and highly durable.

Avant will enable dentists to form mouth impressions with intra-oral scanners, rather than gunk. "We can manufacture our device in our Philippines facility within minutes," Mr Verdal-Austin says.

"It's a new manufacturing process for us. While others have done this, I believe we have done this right."

Somnomed also tackles the nocturnal blight of bruxism - teeth grinding that can wear down the pearly whites. Bruxism can also be an indicator of OSA.

A cheaper COAT is sometimes better

As always with medical devices, cost is a key factor in the CPAP versus COAT equation.

The Avants sell for around \$500 - or the equivalent 500 units in other major currencies (unfortunately for snorers in Indonesia, they don't sell for 500 rupiahs, or about five cents).

Because the devices have to be fitted by a dentist - who fiddle around with the mandible - the total cost comes in at \$1,500 to \$2,000.

CPAP treatments cost in the thousands, but in some countries the devices can be rented.

Putting the bite on dentists

In theory, Somnomed's target market should be the dentists, given they're the ones fitting the devices.

But typically snorers won't go to a dentist with an OSA problem: they'll go to a general practitioner and be referred to a sleep specialist, with the dentists then getting the mandate to fit the devices (by law, only dentists are allowed to).

Having said that, Mr Verdal-Austin describes dentists as "partners" of the company, which seeks alignment with the large dental groups. Over the last four years Somnomed has built a network of 20,000 to 25,000 dentists.

"Whether you have one dentist or a roll-up, our job is the same: train and educate them to treat obstructive sleep apnoea effectively with an oral appliance," Mr Verdal-Austin says.

Of the 28 countries in which Somnomed currently sells, the company distributes directly in 27 (the exception being a Singapore-based third party deal).

Surveying the competitive landscape

Mr Verdal-Austin estimates that oral devices account for about 10 percent of the sleep apnoea market, but it's not as if the company has the market to itself.

"Over the last 10 years we have attracted more and more competitors as we have gone along," he says.

Rivals tend to operate in only certain regions: in the US, it competes with ProSomnus Sleep Technologies and TAP (as in Thornton Adjustable Positioner).

"We're competitors on one side, but also industry leaders trying to grow the size of the prize."

Resmed also has an oral device called Narva, a business acquired seven years ago: "but they haven't done much with it".

Then there's Oventus, which listed on the ASX in 2015. Founded by entrepreneurial dentist Dr Chris Hart with some heavy-hitting backing, Oventus sells mouthguard devices called O2Vents, with a pipe forcing air to the back of the throat.

Finances and performance

Somnomed this week reported a net loss of \$15.76 million for the year to June 30 2019, compared with a \$6.93 million deficit previously. Earnings before interest, tax, depreciation and amortization fell 13 percent to \$3.39 million.

Revenue climbed 12 percent to \$58.89 million.

Management also reports 'core earnings before interest, taxation, depreciation and amortization' (Ebitda) of \$4.94 million, up 27 percent (this number excludes some inconvenient one-off expenses, such as the former CEO's severance payment).

The reported loss mainly was the result of \$16.39 million of expenses and write downs pertaining to the RSS closure. "As far as I can legally say, we have provided all the future costs [of the closure] we could possibly experience," Mr Verdal-Austin says.

Somnomed ended the year with cash of \$7.69 million. On the debt side, the company has an overdraft facility of \$5 million, \$3 million of which has been drawn.

Mr Verdal-Austin says the company has recovered 95 percent of the US clients that were lost during the RSS closure, with a turnaround evident in the fourth (June) quarter. He is especially chuffed that direct dentist revenue in North America improved by 31 percent.

Management has guided to revenue of \$67 million to \$69 million for the current year, up 14 to 17 percent. Ebitda - the reported version rather than the core one -- is expected to climb by 26 percent to 34 percent, to \$6.3 million to \$6.7 million.

“We are very excited about the turnaround we are going to have in the business,” Mr Verdal-Austin says.

Investors weren't so convinced, knocking 15 cents, or 7.5 percent off the share price on the day. Two days later, they changed their mind and added 25c, or 13 percent to the valuation.

The gyrations continue the topsy-turvy ride of Somnomed shares, which slumped to a record low of \$1.45 in late June and then climbed a 12-month peak of \$2.34 in late July.

The shares hit an all-time zenith of \$4.00 in October 2016.

Dr Boreham's diagnosis:

Given that roughly four-fifths of obstructive sleep apnoea cases are undiagnosed and thus untreated, Somnomed has plenty of room to grow.

The company estimates the global sleep apnoea market at \$US7billion to \$US8 billion, growing at six to eight percent a year.

In the key markets where Somnomed operates, the share of continuous open airway therapy (COAT) treatments as a proportion of the total OSA market ranges from four percent (Italy) to 52 percent (Sweden).

In Australia, 15 percent of mild snorers treated use mouthguard devices. Sleep Health Foundation Australia claims that more than 1.5 million Australians have a sleep disorders, more than half for obstructive sleep apnoea.

Mr Verdal-Austin estimates 2.5 million new continuous positive airways pressure (CPAP) machines are sold in the US each year, which implies plenty of disaffected users that can be wooed over to the Somnodents.

As always, Somnomed's success will come down to the cost and efficacy of the devices and the availability of reimbursement.

The use of artificial intelligence also means the company will be able to share accrued patient data with physicians and dentists, thus allowing them to predict suitable COAT candidates.

Somnomed looks to be on the right track, despite the somewhat blah full-year numbers. Management's work has only just begun. “We have a long way to go to persuade sleep experts to try COAT,” Mr Verdal-Austin says.

Disclosure: Dr Boreham is not a qualified medical practitioner, does not possess a doctorate of any sort and does not snore – in his waking hours at least.

MAYNE PHARMA GROUP

Mayne says revenue for the year to June 30, 2019 fell 1.0 percent to \$525,208,000, with net loss after tax up 111.3 percent to \$283,751,000.

Mayne said generics revenue fell 16.8 percent to \$320.8 million, specialty brands revenue was up 104.9 percent to \$91.6 million, metrics contract services revenue was up 14.4 percent to \$72.2 million and Mayne Pharma International revenue was up 10.6 percent to \$40.7 million.

The company said expenditure on research and development was up \$1.8 million to \$50.3 million, with marketing and distribution expenses up \$13.9 million to \$76.7 million, finance costs of \$17.5 million and impairments of \$351.7 million following a review of the company's intangible assets.

Mayne said that net tangible asset backing per share rose 25 percent to 15 cents, with diluted loss per share of 19.04 cents at June 30, 2019, up 107.9 percent, and cash and cash equivalents of \$89,004,000 at June 30, 2019 compared to \$87,312,000 at June 30, 2018.

Mayne fell five cents or 10.5 percent to 52.5 cents with 18.3 million shares traded.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says revenue for the year to June 30, 2019 was up 6.8 percent to \$79,598,000, with net profit after tax up 29.5 percent to \$7,329,000.

SDI said sales revenue from its aesthetics, amalgam and whitening products was up 13.8 percent in the Asia Pacific to \$14.7 million, up 35.5 percent to \$8.7 million in the Middle East and Africa, up 6.3 percent to \$19.2 million in North America, up 1.6 percent to \$9.4 million in South America and down 1.3 percent to \$27.6 million in Europe.

The company said the final fully-franked dividend was up 7.1 percent to 1.5 cents to paid on September 20, for a record date of September 6, 2019, with an interim dividend of 1.2 cents and special dividend of 1.0 cents.

SDI said net tangible asset backing per share was up 5.6 percent to 40.79 cents, diluted earnings per share was up 29.6 percent to 6.17 cents and it had cash and cash equivalents of \$6,481,000 at June 30, 2019 compared to \$8,246,000 at June 30, 2018. SDI was up one cent or 1.3 percent to 79 cents.

NEXT SCIENCE

Next Science says revenue for the six months to June 30, 2019 was up 222 percent to \$US2,345,170 (\$A3,470,265), with net loss after tax up 10 percent to \$US6,579,284 (\$A9,735,696).

In April, Next Science said it raised \$35 million in its initial public offer at \$1.00 a share to list on the ASX and commercialise its Xbio anti-bacterial technology (BD: Apr 17, 2019). Today, the company said revenue was from US sales of its Blast X and Bactisure products through its partnerships with 3M and Zimmer Biomet.

Next Science said its loss was up due to an increase in sales and marketing expenses, general and administration expenses, consulting and regulatory expenses and research and development expenses.

The company said net tangible asset backing per share rose 19.14 US cents from negative 6.45 US cents to 12.69 US cents at June 30, 2019, diluted loss per share fell 15.6 percent to 4.32 US cents and it had cash and cash equivalents of \$22,980,128 at June 30, 2019 compared to \$7,211,102 at December 31, 2018.

Next Science fell seven cents or 2.5 percent to \$2.77.

TELEX PHARMACEUTICALS

Telex says it has maiden revenue for the six months to June 30, 2019 of \$1,817,502, with net loss after tax up 99.6 percent to \$10,360,431.

Telex said revenue was from global sales of its Ilumet positron emission tomography (PET) prostate imaging kit, which it launched in December 2018.

The company said the loss was due to \$7,839,708 in research and development costs, \$1,977,342 in administration and corporate costs, \$2,323,342 in depreciation and amortization, \$5,132,855 in employment costs and \$1,064,919 in finance costs, offset by other income.

Telex said net tangible asset backing per share was down 86.4 percent to 3.0 cents compared to the previous corresponding period, but prior to a \$45 million capital raising, diluted loss per share was up 81.3 percent to 4.75 cents and it had cash and cash equivalents of \$10,145,304 at June 30, 2019 compared to \$26,374,835 at June 30, 2018. Telex fell 3.5 cents or 2.4 percent to \$1.40 with 965,905 shares traded.

OVENTUS MEDICAL

Oventus says its "oversubscribed", fully-underwritten, one-for-20 rights issue at 38 cents a share has raised \$2.3 million, taking the total raised to \$9.3 million.

Last month, Oventus said it had completed a "heavily oversubscribed" two-tranche placement for \$7 million at 38 cents a share (BD: Jul 26, 2019).

The company said unallocated applications for shortfall shares would be refunded and shares would be issued on August 28, 2019.

Oventus was up three cents or seven percent to 46 cents.

RESAPP HEALTH

Resapp says its Resappdx-EU diagnostic for acute paediatric respiratory disease has Conformité Européenne (CE) mark certification as a class IIa medical device.

Resapp said its Resappdx-EU smartphone test was a mobile application used by clinicians to analyze cough sounds to diagnose lower respiratory tract disease, croup, pneumonia, asthma or reactive airway disease and bronchiolitis in infants and children.

Resapp chief executive officer Dr Tony Keating said the company was "very excited about receiving our first regulatory approval for Resappdx-EU, our flagship acute diagnostic product".

"This is our biggest achievement yet and results from many years of hard work by our dedicated team," Dr Keating said.

"For the first time clinicians in Europe will have access to a rapid and accurate diagnostic test for the most commonly seen acute respiratory conditions in children," Dr Keating said.

Resapp was up five cents or 33.3 percent to 20 cents with 11.3 million shares traded.

KAZIA THERAPEUTICS

Kazia says the World Health Organisation has given its drug GDC-0084 for brain cancer its international non-proprietary name, "paxalisib".

Kazia said the name was a necessary step before commercial registration and it would begin using its international non-proprietary name (INN), paxalisib, in all documentation and communications on completion of the World Health Organisation (WHO)'s confirmation procedure.

Kazia fell one cent or 2.7 percent to 36 cents.

MGC PHARMACEUTICALS

MGC says it has approval for a 30-subject trial of Cannepil's impact on driving performance with Melbourne's Swinburne University of Technology and Cannvalate. MGC said Cannepil had a 20-to-one ratio of cannabidiol (CBD) to tetrahydrocannabinol (THC) and was a treatment for drug resistant epilepsy.

The company said 15 men and 15 women between 21 and 60 years of age would receive either Cannepil or a placebo and would be tested over 14 days using a driving simulator at Swinburne University.

MGC said the trial would compare safety and the impact of Cannepil on driving by identifying changes in "the standard deviation of the lateral position" or driving performance.

The company said it hoped to provide evidence to change driving legislation for Cannepil patients and would begin recruitment in October 2019.

MGC fell 0.4 cents or 8.2 percent to 4.5 cents with 3.7 million shares traded.

CARDIEX

Paul Cozzi says he has increased his substantial shareholding in Cardix from 57,904,160 shares (8.33%) to 67,303,574 shares (9.68%).

The Sydney-based Mr Cozzi said that between July 24 and August 16, 2019, he acquired 9,399,414 shares for \$247,009 or 2.6 cents a share.

Cardix was up 0.3 cents or 13 percent to 2.6 cents with 1.6 million shares traded.

BOTANIX, PHARMACEUTICALS ORTHOCELL

Botanix and Orthocell say that Botanix executive director and Orthocell director Matthew Callahan is taking temporary leave "for personal reasons".

Botanix and Orthocell said Mr Callahan would continue to consult with both companies and would re-join after his leave of absence.

Botanix fell one cent or 4.65 percent to 20.5 cents with 3.75 million shares traded.

Orthocell was up 2.5 cents or 6.25 percent to 42.5 cents with 1.2 million shares traded.