

Biotech Daily

Friday March 19, 2021

Daily news on ASX-listed biotechnology companies

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- * DR BOREHAM'S CRUCIBLE: COMPUMEDICS
- * REDHILL REVENUE UP 923% TO \$83m, LOSS UP 80% TO \$98.5m
- * MEDLAB RAISES \$15m, APPOINTS CHERYL MALEY DIRECTOR
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- * NOXOPHARM BEGINS VEYONDA, NIVOLUMAB CANCER STUDY
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- * IDT: FEDERAL ASSESSMENT FOR COVID-19 VACCINE PRODUCTION
- * CRESO LAUNCHES MARIJUANA 'RITUAL STICKS', \$73k FIRST ORDER
- * MEDIBIO TO SUPPLY ILUMEN TO 1000 UK COMPASS EMPLOYEES
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- * ECOFIBRE TO RELEASE 192m ASX ESCROW SHARES
- * MERCHANT FUNDS TAKES 13% OF AUSCANN

MARKET REPORT

The Australian stock market was down 0.56 percent on Friday March 19, 2021, with the ASX200 down 37.7 points to 6,708.2 points. Seventeen of the Biotech Daily Top 40 stocks were up, 18 fell and five traded unchanged. All three Big Caps were down.

Resonance was the best, up one cent or 5.4 percent to 19.5 cents, with 340,012 shares traded. Impedimed, Optiscan and Starpharma improved more than four percent; Clinuvel, Patrys and Uscom were up more than three percent; Antisense, Compumedics, Kazia, Neuren, Next Science, Orthocell and Polynovo rose more than two percent; Nanosonics and Volpara were up one percent or more; with Mesoblast up 0.4 percent.

LBT led the falls, down 0.5 cents or 5.05 percent to 9.4 cents, with 4,000 shares traded. Imugene, Osprey and Prescient fell four percent or more; Actinogen, Avita, Dimerix and Medical Developments were down more than three percent; Alterity and Universal Biosensors shed more than two percent; Cyclopharm, Cynata, Immutep, Oncosil, Proteomics and Resmed were down more than one percent; with Cochlear, CSL, Opthea, Paradigm and Telix down by less than one percent.

DR BOREHAM'S CRUCIBLE: COMPUMEDICS

By TIM BOREHAM

ASX code: CMP

Share price: 42 cents; Market cap: \$74.4 million Shares on issue: 177,162,948

Executive chair: Dr David Burton

Board: Dr Burton, David Lawson, Tucson Dunn

Financials (December half 2021): revenue of \$18 million (down 1%), earnings before interest tax depreciation and amortization \$1.9 million (up 58%), net profit \$1.3 million (up 717%), cash of \$5.6 million (up 65.9%), debt of \$3.7 million

Identifiable major shareholders: D and DJ Burton Holdings (David Burton) 54.2%, Beijing Bestmed Tech 2.77%, Medigas Italia 2.45% (Italian distributor).

The founder of any business needs to think big - in a disciplined manner of course - and for Compumedics chief David Burton it's all about the home-grown neurological imaging emulating the success of magnetic resonance imaging (MRI) devices.

Magnetic resonance imaging is the standard of care for bodily scans - while Compumedics' contender is its brain scanning gizmo called MEG (as in magnetoencephalography, not Margaret). Dr Burton notes there were fewer than 100 MRIs in the 1980s; today there's a global installed base of 32,000 with about 3,400 new ones sold each year.

"I see no reason why there wouldn't be at least more or equal demand for MEG as MRI, because of the importance of brain disorders with mental health and the like," Dr Burton says.

The MEG units sell for \$5 million to \$7 million, which implies a global market of at least \$160 million compared with Compumedics market value of circa \$70 million.

About Compumedics

Dr Burton founded the company back in the mid-1980s – an era when we drove around in our new Commodores and played Tetris on our Commodore 64s, and in 1987, Dr Burton installed Australia's first computerized sleep clinic, at Melbourne's Epworth Hospital.

Compumedics listed in 2000 - late enough to miss the excesses of the tech boom – and core products range across sleep diagnosis, clinical electro-encephalogram (EEG) scans, brain monitoring and ultrasonic blood-flow systems.

Established products include Grael and Siesta for sleep, Neuron for neurology and Synamps RT and Curry for brain research. CHECK!!!!!!

Compumedics owns the US-based Neuroscan and Germany's DWL Elektronishe (which delivered the company's Doppler transcranial scan capacity: that is, ultrasounds to detect vascular systems within the brain).

Half of Australia's hospitals use Compumedics neuro-diagnostics and EEG products, while the company has also tied up the majority of sleep clinics.

The MEG story to date

Apart from being able to spell magneto-encephalography, Compumedics reports progress on other fronts with its MEG ambitions.

The company's flagship product is the Orion Lifespan Curry MEG, a patented double relaxation oscillator super-conducting quantum interference device. (And no, we haven't been watching too many old Dr Who episodes.)

Dubbed the "MRI of the brain", MEGs measure the electrical speed of the brain's thinking and processes. Compumedics licenced the MEGs hardware from the (South) Korean Research Institute of Standards and Science (KRISS), their equivalent of the CSIRO.

In 2017, the company won the first contract with Arizona's Barrow Neurological Institute, "the number one training centre and world leader in neurosurgical practices".

As home to the Muhammed Ali Parkinson Centre, Barrow can claim to "the greatest", at least in terms of neurology training and neurological vascular surgery.

"Many Australian neurologists have trained there," Dr Burton says. "We were quite conscious that was going to be the important battle and we won that deal."

... and how it's unfolding

In February this year, the company won US Food and Drug Administration assent for a socalled dual-helmet dewar Orion Lifespan MEG, a version that's been designed for both children and adults.

After Covid-related delays, the unit is due to be installed at the Barrow this year.

In Dr Burton's user-friendly vernacular, the dewar units look like "Marj Simpson hairdryers".

If a child's head is placed in an adult sized dewar, the strength of the signal is reduced because of the distance from the sensors to the brain synapses.

"It makes an awfully big difference," Dr Burton says.

"With this tech you need to put the child's head against one side of the (unit) and scan it and then against the other side and join the hemispheres in the software. Then you have the inaccuracies resulting from merging the two digital images." Dr Burton adds the Orion MEG units use virtually no helium, which prevents downtime created by the noisy phase when the gas is recycled.

"You can use ours day and night and for twice the population," he says.

No napping in the sleep diagnosis market

Another growth foray revolves around Somfit, an internet cloud sleep diagnostics tool based on a single-use disposable sensor and reusable monitor. Somfit is designed for home use.

In effect, Compumedics is entering the 'wearable' device sector, leveraging its 30 years of the sleep experience.

The company expects Somfit to be available for less than \$200, or by monthly subscription. Currently, the company is mulling its commercialization route, which should involve partners such as pharmacies.

"We won't be opening up a lot of corner shops but we will be working with a lot of strategic healthcare deliverers," Dr Burton says.

He adds, by way of a hint: "We are open minded and welcome approaches as we are open for business."

In the meantime, Compumedics' professional version, Nexus360 is experiencing substantial growth. This "clinic in the cloud" is deployed across 46 sites, covering 270 beds.

"The new era has allowed us to expand that side of the business," chief financial officer David Lawson says. "Everyone is talking telemedicine and e-health."

Finances and performance

Despite the site restrictions posed by Covid, the company had a 'good' pandemic, as evidenced by its reported 717 percent net profit surge for the first (December) half, to \$1.3 million.

Revenue dipped one percent to \$18 million because of Covid constraints, but turnover was a tale of disparate geographies. While European sales surged 46 percent and Australian sales jumped 15 percent, US and Asian sales retreated 17 percent and 20 percent, respectively.

"The American business has been a bit soggy throughout the pandemic," chief finance officer Mr Lawson says. "But we do have a strong pipeline heading into March."

Management expects full-year performance to be "at or better than" 2020, partly because delayed shipments will trickle to the revenue line in the current quarter. New sales orders were 13 percent higher, at \$20.3 million.

"From my perspective the core business has weathered the storm much better than we thought," Mr Lawson says. "I'm quietly confident we will bounce back to growth in the second half."

For the first time, the company has broken down the performance of the established core device business and the research division. Without the \$800,000 loss recorded by the latter, the company would have reported a \$2.4 million net profit.

Compumedics shares have traded as high as \$1 (January 2001) and as low as 8 cents (June 2013).

End of the jet-set era?

The company's improved earnings were partly achieved by an eight percent reduction in expenses, reflecting the near absence of travel costs during the pandemic.

Pre-Covid, the company spent \$80,000 to \$90,000 a month on travel. And if that seems steep, bear in mind that the company derives only 15 percent of revenue from our shores.

As with so many other companies, don't expect things to snap back to Prime Minister's Scott Morrison hoped-for "normality".

"If we are able to make more money by not travelling, you can bet there will be more scrutiny," Dr Burton says. "I expect we will get better margins out of the company because we will bring better processes and methods to double check whether we do need to travel."

Given so many other companies will be adopting the same stance, we suggest investors lighten up on Qantas and any exposure to the Las Vegas convention industry.

Save your nuts for a rainy day

A quirk of Compumedics is that despite the company's long history, it has only raised equity twice: at the 2000 initial public offer and in 2016 (\$6.5 million).

"Our biggest shareholder is a squirrel at the best of times," Mr Lawson says.

That's a cheeky reference to the 'other' David, 54 percent shareholder Dr David Burton.

The company has \$4.3 million of cash, but if needs be, the bank will help out with nondilutive debt funding.

Dr Burton adds that he would "assist" with a sell down of his stake if a major opportunity arose.

"That's when the squirrel will unload a few nuts and create a bit more liquidity," he says. "But as we get older it takes a bit more to get you excited and you should keep your nuts for a rainy day."

What happens from here?

Management alludes to developing two new major product platforms for home sleep testing, "as well as a new range of laboratory and portable neurodiagnostic and devices for epilepsy and general monitoring".

Dr Burton notes the company has a captive customer base, given the widespread use of its Curry analytics software.

But with this product selling for tens of thousands – rather than millions – of dollars, the trick is to capture more value with offerings such as the Orion MEG.

"We will tap into that as the best customers are your current customers and we need to look after them first," he says. "We have a well-seeded position going back 20 to 30 years - and that gives us a head start."

Dr Boreham's diagnosis:

Compumedics already claims to be the number one provider of sleep and neurological diagnostics, locally and in Japan.

But with the global sleep diagnostics market worth valued at \$US250 million and the neuro-diagnostics market at \$US1.3 billion, there are bigger prizes to seize.

MEG is considered a high-growth sector given the prevalence of Alzheimer's disease and other dementia conditions, not to mention autism, Huntington's disease and epilepsy.

One key criticism of Compumedics is that it's been around since Adam was whelped, but is still a modest concern.

The stock has treaded water: when we last looked at them in early April 2020 the stock traded at 47 cents; and before then (in July 2017) at 45 cents.

Dr Burton says with deep-pocketed potential partners knocking on the company's door, momentum should be felt in 2022.

He adds that all good things take time.

"We have a foundational track record with real leading technology, but we haven't yet executed the step-out from the diagnostics [capital equipment] to the major breakout [products]," he says.

"That was our strategy and still is. Yes, it's been a long time but your best wines have been there for a while too."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Sadly, he didn't wait to see if his best wines improved with age but his nuts are safely stored away.

REDHILL BIOPHARMA

Redhill says revenue for the year to December 31, 2020 rose 923.0 percent to \$US64,359,000 (\$A83,196,533) with net loss after tax up 80.1 percent to \$US76,173,000 (\$A98,497,915).

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picocona (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2019).

Today, the company said revenue came from sales of Talicia, formerly Heliconda, for Helicobacter pylori, Aemcolo for traveller's diarrhoea and Movantik for opioid-induced constipation which it acquired from Astrazeneca (BD: Feb 26, 2020).

Redhill did not disclose the amount of revenue from each drug.

Redhill chief executive officer Dror Ben-Asher said the company had "delivered broad commercial growth culminating in a very strong end to 2020 for both Movantik and Talicia".

Redhill chief financial officer Micha Ben Chorin said the company was "delivering on a clear strategy designed to enable us to achieve fast growth and increased profit margin ... and we expect to achieve commercial operational breakeven by the end of this year". The company said it had cash and cash equivalents of \$US29,295,000 at December 31, 2020 compared to \$US29,023,000 at December 31, 2019.

On the Nasdaq, Redhill was down 49 US cents or 6.2 percent to \$US7.43 (\$A9.61) with 647,342 shares traded.

MEDLAB CLINICAL

Medlab says it has raised \$15 million in a placement at 24 cents a share and has appointed Cheryl Maley as a director, effective from March 19, 2021.

Medlab said the placement share price was an 18.6 percent discount to the last closing price and a 24.3 percent discount to the 15-day volume weighted average price. The company said it would use the funds for phase III clinical trials in the US, UK and Australia, development of its Nanocelle delivery technology and working capital. Medlab said Acova Capital, Morgans Corporate and Blue Ocean Equities were the joint lead managers to the placement with Sydney's MST Financial as co-manager. Separately, the company said Ms Maley had more than 20 years' experience in the pharmaceutical industry and was currently the managing-director of oncology for Novartis Australia and New Zealand.

Medlab fell 3.5 cents or 11.9 percent to 26 cents with two million shares traded.

PHARMAXIS

Pharmaxis says its distributor, the Parma, Italy-based Cheisi, has launched its Bronchitol dry powder inhaled mannitol for cystic fibrosis in the US.

Last year, Pharmaxis said the US Food and Drug Administration approved Bronchitol as "add-on maintenance therapy" for adult cystic fibrosis patients, triggering a milestone payment from the Chiesi Farmaceutici SpA (BD: Nov 2, 2020; Jan 17, 2021).

Today, Pharmaxis chief executive officer Gary Phillips said the company expected "Bronchitol sales in the US to contribute strongly to the product's global sales and profit growth, making the Pharmaxis mannitol respiratory business cash flow positive from [the year to June 30, 2021]," Mr Phillips said.

Pharmaxis was unchanged at 8.5 cents.

RACE ONCOLOGY

Race said it will collaborate with the University of Newcastle to study the use of Bisantrene as a combination drug for melanoma using cellular and mouse models.

Race said the research at the Central New South Wales University of Newcastle, led by Prof Xu Dong Zhang and Prof Lei Jin, aimed to identify drug combinations with Bisantrene that improved melanoma treatment, with a focus on treatment-resistant cancer patients. The company said Bisantrene had been identified as a potent targeted inhibitor of the fat mass and obesity associated protein (FTO), which was over-produced in about 50 percent of metastatic melanoma cancers.

Race said that the inhibition of FTO could overcome programmed cell death protein-1 (PD-1) immune checkpoint resistance in mouse models of melanoma.

The company said that results from the collaborative research would be reported in "the coming 12 months" and would inform phase II human trials of Bisantrene for melanoma, planned to begin "in early 2022".

Race chief scientific officer Dr Daniel Tillett said that "recent scientific developments have identified Bisantrene as a potent targeted agent of FTO which offers the possibility of novel treatment options for patients with drug-resistant melanomas that can rapidly be translated into the clinic."

Race fell seven cents or 1.75 percent to \$3.93 with 756,353 shares traded.

NOXOPHARM

Noxopharm says will begin recruitment of its 30-patient study of Veyonda combined with Bristol Myers Squibb's nivolumab for resistant cancers.

Last year, Noxopharm said the phase Ib trial would assess whether Veyonda, or NOX66, could overcome tumor resistance to immune checkpoint inhibitors such as nivolumab in patients with breast, ovarian, prostate and sarcoma cancers (BD: Nov 9, 2020).

Today, the company said it would begin recruitment of patients in two trial cohorts immediately.

Noxopharm said one cohort would comprise cancer patients who were previously ineligible for nivolumab and the other cohort would recruit patients whose cancers displayed resistance to nivolumab.

The company said the trial endpoints were the safety and tolerability of the drug combination, efficacy and the effect on various blood biomarkers.

The trial principal investigator Prof Paul De Souza that "if we're able to enhance the effect of [Bristol Myers Squibb's] nivolumab with Veyonda, this will bring some truly life-changing treatment to cancer patients' lives and will change the way that cancer is treated worldwide".

Noxopharm fell two cents or 2.9 percent to 66.5 cents with 1.7 million shares traded.

PALLA PHARMA

Palla says it has received the first order for its 30mg codeine phosphate-500mg paracetamol tablet and caplet combination from an unnamed UK customer.

Last month, Palla said the UK Medicines and Healthcare products Regulatory Agency had approved its Norway production facility and had granted marketing authorization for the codeine phosphate tablets and caplets (BD: Feb 1, 18, 2021).

Today, the company said the first shipments of tablets and caplets were expected to leave the Norway facility in April, but did not disclose the value of the order.

Palla was up half a cent or one percent to 50.5 cents.

IDT AUSTRALIA

IDT says the Federal Government Department of Health has requested a feasibility assessment of its sterile manufacturing facility for the production Covid-19 vaccines. IDT was up 10 cents or 54.05 percent to 28.5 cents with 30.4 million shares traded.

CRESO PHARMA

Creso says it has launched its pre-rolled marijuana Ritual Sticks in Canada, with the first purchase order from Nova Scotia Liquor Corp for \$C70,560 (\$A72,890).

Creso said the order was made through its Canadian subsidiary, Mernova Medicinal Inc, and was received alongside \$C106,562 worth of orders for its Ritual Green branded marijuana products.

The company said Ritual Sticks, or pre-rolled marijuana cigarettes, used "indoor grown, hand-trimmed, hang-dried, cured, artisanal, craft cannabis" and would be "sold at a lower price point" than the Ritual Green products.

A spokesperson for Creso told Biotech Daily the Ritual Sticks would retail at \$C22.99 (\$A23.76) each.

The company said Ritual Sticks would address a market of "people that do not know how to roll their own joints, or simply want to avoid the inconvenience of rolling joints themselves".

Creso fell one cent or 4.35 percent to 22 cents with 34.4 million shares traded.

MEDIBIO

Medibio says will supply its Ilumen heart-rate mental health assessment platform to 1,000 employees of the UK Compass Group for a minimum of 12 months.

Last year, Medibio said it had an initial three-year licence and services agreement with the Chertsey, West London-based Compass which allowed Compass to licence Ilumen to its clients and contract food and support services companies (BD: Nov 23, 2020).

Today, the company said the statement of works agreement with Compass marked the roll-out of Ilumen to Compass employees.

Medibio did not disclose financial details of the agreement.

Medibio was up 0.1 cents or 11.1 percent to one cent with 126.8 million shares traded.

<u>RESPIRI</u>

Respiri has requested a trading halt pending "the results of an application to the US Food and Drug Administration for market clearance of Wheezo".

Respiri, previously known as Karmelsonix and Isonea, has been developing the Wheezo asthma monitor since 2006 (BD: Nov 24, 2006).

Trading will resume on March 23, 2021 or on an earlier announcement.

Respiri last traded up half a cent or three percent to 17 cents with 2.3 million shares traded.

ECOFIBRE

Ecofibre says it will release 191,907,744 shares from ASX escrow on March 29, 2021. According to Ecofibre's most recent Appendix 2A new share issue, following the release from escrow, the company will have 339,369,861 shares available for trade on the ASX. Ecofibre fell eight cents or 5.9 percent to \$1.27.

AUSCANN GROUP HOLDINGS

Merchant Funds Management says it has increased its substantial shareholding in Auscann from 42,570,578 shares (13.43%) 72,223,727 shares (16.39%).

The Perth-based Merchant said that between November 2019 and March 18 2021 it bought and sold shares with the single largest purchase 7,500,000 shares for \$1,128,712 or 15 cents a share.

Merchant said that on March 18, 2021 it acquired 41,159,196 shares for \$1,658,209 or 4.0 cents a share under the scheme of arrangement for Auscann's acquisition of Cannpal. Yesterday, Auscann said it had completed its acquisition of Cannpal, paying 1.3 Auscann shares for every one Cannpal share (BD: Nov 16, 2020; Mar 18, 2021).

Auscann fell half a cent or 3.45 percent to 15 cents with 2.5 million shares traded.