

Biotech Daily

Friday July 19, 2024

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market fell 0.81 percent on Friday July 19, 2024, with the ASX200 down 64.9 points to 7,971.6 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 20 were down, five traded unchanged and one was untraded.

Dimerix was the best, up 3.5 cents or 6.7 percent to 56 cents, with 5.7 million shares traded. Medical Developments climbed 5.3 percent; Mesoblast improved 4.1 percent; Next Science was up 3.6 percent; Clarity, Orthocell and Prescient rose more than two percent; 4D Medical, Alcidion, Clinuvel, Immutep and Imugene were up one percent or more; with CSL, Emvision and Nanosonics up by less than one percent.

Actinogen led the falls, down 0.9 cents or 10.0 percent to 8.1 cents, with 17.4 million shares traded. Proteomics and Syntara lost five percent or more; Amplia and Paradigm fell more than four percent; Avita, Cochlear, Curvebeam, Cyclopharm, Nova Eye and Polynovo shed two percent or more; Impedimed, Medadvisor, Micro-X, Percheron, SDI, Starpharma and Telix were down one percent or more; with Genetic Signatures, Neuren, Pro Medicus and Resmed down by less than one percent.

DR BOREHAM'S CRUCIBLE: COMPUMEDICS

By TIM BOREHAM

ASX code: CMP

Share price: 32 cents; Shares on issue: 183,770,091; Market cap: \$58.8 million

Executive chair: Prof David Burton

Board: Prof Burton, David Lawson, Rod North

Financials (December half 2023): revenue of \$26.4 million (up 38%), earnings before interest tax depreciation and amortization \$2.16 million (\$4.76 million loss previously), net profit \$141,000 (\$7.21 million loss previously), cash of \$3.67 million (down 3.3%), net debt \$3.87 million (up 62%). The company has disclosed unaudited revenue of \$49 million for the year to June 2024, up 16 percent and guided to full-year profitability.

Identifiable major shareholders: D and DJ Burton Holdings (Prof Burton) 53.35%, B&R James Investments 4.03%, Beijing Bestmed Tech 2.67%, Medigas Italia 2.36% (Italian distributor).

Compumedics founder, executive chair and majority shareholder Prof David Burton admits that the company has been too complex for investors to understand and that its market valuation has lagged as a result.

As a rough guide, this week, the company flagged record full-year revenue of \$49 million and a small profit, but its market worth is a mere \$55 million.

For almost four decades, the Melbourne-based Compumedics has perfected diagnostic equipment for interpreting brain and sleep functions.

It's been a slow-burn story, but Prof Burton is undertaking an external review that - in part - will determine whether Compumedics sum-of-the-parts of its four key divisions is worth more than the whole. The process is in its early stages.

"We have been around for a long time and the value hasn't been realized, so we need some independent strategic critique," he says.

Prof Burton cites the experience of the ASX-listed Vision Systems which initiated a similar review. History shows that Danaher Corp of the US acquired the company for \$700 million in a spirited three-way takeover tussle.

"The market was shocked at the multiples generated just in that process," he says.

Prof Burton says the time for a review is ripe because Compumedics has reached numerous "inflexion points" across its four key business. These include the rollout of the home-based subscription sleep diagnosis tool Somfit, which has won leading share of the pharmacy market here and has been selling well in the US since its recent launch there.

A bit of history

With a background in sound recording, Dr Burton was inspired to found Compumedics after visiting a doctor for a sore throat. Que?!

Apart from prescribing antibiotics, the physician asked him if it was possible to invent a sleep monitoring device.

Dr Burton obeyed doctor's orders and founded Compumedics in 1987 - at the tail end of the entrepreneurial era and just before the share market crash. In the same year, the company designed and installed the first fully-computerized Australian sleep clinic, at Melbourne's Epworth Hospital.

Compumedics listed on the ASX in December 20, 2000, having raised \$15 million at 30 cents apiece.

The company claims to be the number one provider of sleep and neurological diagnostics locally and in Japan - and who are we to argue? – and operates via its US-based Neuroscan arm and the German-based DWL Elektronishe GmbH.

Product suite

Compumedics' 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. The aforementioned DWL Elektronishe delivered the company's Doppler transcranial scan capacity (ultrasounds to detect vascular systems within the brain).

The company's flagship product is the Orion Lifespan Curry MEG (magneto-encephalography) a patented double relaxation oscillator super-conducting quantum interference device. Yep - your read that one correctly.

In the last six months the company has launched new products for the home sleep testing market: Somfit and a variant called Falcon.

Following US Food and Drug Administration approval of Somfit on December 4, 2023, the company started sales in the US with first revenue invoiced in the June quarter. In June this year the company appointed a US based head of sales for home sleep testing and the company plans to hire six dedicated US sales staff.

One of Compumedics' most important products is the magneto-encephalo-graphy MEG device - the neurological equivalent of the common magnetic resonance imaging (MRI) devices. Compumedics licenced the MEG hardware from the (South) Korean Research Institute of Standards and Science (KRISS), that country's equivalent of the CSIRO.

In 2017, the company won the first contract with Arizona's Barrow Neurological Institute, home to the Muhammed Ali Parkinson Centre.

'Hairdryers' for kids

To date, the company has sold two MEGs - to China's Tsinghua and Tianjin Universities for around \$14 million. The company reports two additional MEG sales in China worth \$9.2 million and due for delivery in 2025.

In February 2021, the company won FDA assent for a so called dual-helmet "dewar" Orion Lifespan MEG, a version that's been designed for both children and adults.

The problem with the full dewars - the "Marj Simpson hairdryers" - is that the strength of the signal is reduced because the smaller head of a child creates a bigger gap between sensors.

An added advantage is that the Orion MEGs use virtually no helium, which prevents downtime created by the noisy phase when the gas is recycled.

In March 2023, the company won FDA approval for Okti, "the world's first high-density ambulatory EEG amplifier", under the 510k route. Okti pertains to epilepsy and general neurological monitoring.

The company cites a \$US400 million market for Okti, growing at a compound annual rate of 9.0 percent. The company targets a one to two percent share of this market "in the midterm".

Not a sleeper

Consisting of a single-use disposable sensor and reusable monitor, Somfit has captured about 75 percent of the local pharmacy-based home sleep apnoea testing market.

This is courtesy of its relationship with Philips Pharmacy Sleep Services, which has a tieup with the Amcal chemist chain.

Following FDA approval of Somfit in December last year, the company started selling in the land of the free and snoozy.

"This relatively new and growing consumer-accessible sleep health monitoring sector will underpin future growth in similar or adjacent areas," Prof Burton says.

Somfit captures eight physiological data points, compared with 32 for a full diagnosis at an overnight sleep clinic. Released in late 2023, a variant called Falcon has 12 data points and in chief financial officer David Lawson's words is "going gangbusters".

Compumedics also has a professional version, Nexus 360, used by clinics.

"Somfit is important because the health software-as-a-service businesses are attracting valuations of multiples of annual sales," Prof Burton says.

In the US, Compumedics sniffs an opportunity with the retreat of Philips arm Respironics from the sleep lab market, following well-reported product recalls.

Phillips had a 40 percent share of this market and Compumedics estimates a replacement value of \$US55 million to \$US70 million.

Prof Burton is buoyed by the experience of key rival Itamar Medical, which was taken over for by Zoll Medical Corporation for \$US538 million three years ago.

"Over time we think we can carve out \$6 million to \$7 million of software-as-a-service revenues in Australia, while in the US we are looking at \$US25 million to \$US30 million, if we execute correctly."

... but this one is

In Compumedics' infancy in the 1980s, artificial intelligence referred to an enthralling manversus-machine Pacman duel.

Now, the company is embracing the vogue technology by way of its German arm, DWL, which has devised a robotic artificial intelligence tool to check for brain trauma after an accident.

The prototype device – TCD - is the first to measure the "doppler transcranial characteristics" or blood through the brain.

Prof Burton says the current treatment involves transporting the patient to hospital for an MRI or other scan, within a window of about one hour. A hole in the skull may be required to alleviate blood pressure.

TCD consists of a motor-controlled robotic server that zeroes into the vessels with far more accuracy than an ultrasound probe held by an intern on their 60th hour of overtime and 60th coffee.

Finances and performance

In this week's trading update, management pre-announced record revenue of \$48 million for the year to June 2024, up 16 percent.

The sales order book surged 22 percent to \$52 million.

The company said it would "build on" first half underlying earnings (Ebitda) of \$2.2 million, but expected to fall shy of the previous guidance of about \$5 million.

This was due to continuing investment in the US business and the "positive resumption" of the company's DWL China's business taking longer than expected.

Somfit revenues rose twenty-fold to \$2.1 million, while total software-as-a-service revenues (Somfit and the laboratory management software Nexus 360) gained 140 percent, to \$4.2 million.

In the 2022-'23 year, Asia, Europe and the US each contributed about 25 percent of revenue, with Australia accounting for 10 to 15 percent.

"We are an exporter at heart," Mr Lawson says. "The Australian market is not big enough for what we do, but we do have a revamped sales team in Melbourne carving out a big market."

The company recently raised \$1.9 million in a placement at 28 cents apiece, pitched at supporting the US rollout of the home sleep testing product.

As at December's end Compumedics held cash of \$\$3.67 million, with net debt of \$3.87 million.

Over the last year, Compumedics shares have traded between 43 cents in mid-January this year and 16 cents in late October last year. The stock peaked at 85 cents in December 2019.

Dr Boreham's diagnosis:

When we last covered Compumedics in March 2021, Prof Burton compared the company with a slowly ageing wine that was yet to reach its peak. Should we be popping the corks - or twisting the Stelvins screw cap - now?

While the company has issued more false upbeat signals than a drunken semaphore operator over the years, a step-change in its prospects appears imminent.

"The time has come to speed things up," Prof Burton says.

This could be by way of a demerger or asset sales - perhaps a 'Megsit' of the researchstage MEGs business. Mind you, if the company achieved anything like the penetration of MRIs - 40,000 to 50,000 machines currently - it would be in more clover than a Gippsland cow.

But investors should be dreaming of sleep therapies - especially in the insomniac US market. As Mr Lawson notes, there are 65 million to 80 million Americans with sleep problems and only 25,000 sleep beds "which is just not enough to make a dint into that number".

Prof Burton adds that more than half of people with depression, anxiety and bipolar disorders have sleep problems

"Sleep is a recovery period for the body and the brain," he says. "Functions such as generating insulin production rely on deep sleep, as does the restoration of the brain to flush out the toxins."

Compumedics holders can sleep - perchance to dream - of prosperous times ahead.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He's feeling very sleepy and is off to bed.

IMRICOR MEDICAL SYSTEMS

Imricor says it has raised \$35 million in an institutional placement of Chess depository interests (CDIs) and US shares at 52.0 cents per security.

Imricor said the issue price was an 11.9 percent discount to the last closing price on July 16, 2024 of 59.0 cents and a 10.0 percent discount to 10-day volume weighted average price of 57.8 cents.

The company said the funds would support the completion of its US Food and Drug Administration trial, expand treatments in its Visabl-ventricular tachycardia (VT) trial and its commercialization activities, including opening sites in Europe and the Middle East and expanding to Australia and New Zealand.

Imricor said the funds raised, with its existing cash reserves, would "specifically be applied towards sales and marketing, research and development, clinical trials and regulatory compliance, general working capital and costs of the offer".

Imricor managing-director Steve Wedan said the "the work that took place at Imricor in 2023 allowed us to start 2024 with great momentum, and we have entered the current quarter on the cusp of several major milestones for the company".

"With the support of our existing and new investors, we can now realize these catalysts with a strong balance sheet," Mr Wedan said.

The company said the placement would issue a first tranche of 49,514,682 CDIs under its existing placement capacity, with 17,793,243 shares to be issued in a second tranche, subject to shareholder approval.

Imricor said Canaccord Genuity (Australia) and Morgans Corporate were the joint lead managers to the placement.

Imricor was up three cents or 5.1 percent to 62 cents.

NEUREN PHARMACEUTICALS

Neuren says the US Food and Drug Administration has granted NNZ-2591 rare paediatric disease designation for Phelan-McDermid syndrome.

Last year, Neuren said that an 18-child, phase II trial of NNZ-2591 for Phelan-McDermid syndrome showed a statistically significant improvement for multiple efficacy measures (BD: Dec 18, 2023).

At that time, the company said overall, two of the 18 children were described as "very much improved", eight were "much improved", six were "minimally improved", with two observed as "no change".

Neuren said that there were "no approved treatments for [Phelan-McDermid syndrome] despite its severely debilitating impact".

Today, the company said the designation meant it "may qualify for a priority review voucher that can be redeemed to receive priority review for a different product or sold to another sponsor".

Neuren said that the rare paediatric disease priority review voucher program aimed "to incentivize drug development for serious rare paediatric diseases".

The company said it was preparing for an end-of-phase II meeting with the FDA, which it expected before October, to discuss "the development program for NNZ-2591 in Phelan-McDermid syndrome".

This year, Neuren said Health Canada had granted its new drug submission to market trofinetide for Rett syndrome "priority review" (BD: Apr 23, 2024).

Biotech Daily is aware that reported purchase prices of priority review vouchers to third parties on the open market had averaged about \$US100 million (\$A149 million).

Neuren fell 10 cents or 0.5 percent to \$20.68 with 307,097 shares traded.

MEMPHASYS

Memphasys says it will prioritize development of its oxidative stress management technology following a "detailed evaluation" of all its research technologies. Earlier this year, Memphasys said it appointed Michael Cameron and Rod Wellstead to assist the company "in evaluating ... its animal products", including its artificial insemination (AI)-Port media, Roxsta and/or Felix devices (BD: May 30, 2024). Today, the company said that following an evaluation by research director Prof John Aitken and Klean Gene it "became evident that the oxidative stress measurement system be advanced as a priority given its innovative nature and its ability to offer true product differentiation".

Memphasys said oxidative stress resulted from low levels of anti-oxidant protection, was linked to infertility in animals and humans and to DNA damage in both sperm and eggs. The company said its measurement system provided rapid, point-of-care assessment that could identify and monitor animals requiring anti-oxidant supplementation and improving reproductive performance.

Memphasys said it believed the technology could have applications in the reproductive animal industry, including dairy and beef cattle, as well as other industries; and the system held "substantial commercial merit due to its ability to differentiate itself in the market with unique features and applications that address significant needs in the industry". Memphasys said it would conduct a study to establish "a baseline and thresholds for oxidative stress likely to be associated with ... events in reproductive performance". The company said the study of its "early-stage oxidative stress measurement prototype" was designed to include both longitudinal and retrospective analyses to identify oxidative stress thresholds in bovines and potential correlations with productive performance. Previously, Memphasys said it was working on its Felix sperm separator for in-vitro fertilization in humans and an 'AI-Port' system to store and transport animal sperm without the effects of freezing sperm used in standard procedures (BD: Jan 25, May 20, 2024). Memphasys fell 0.1 cents or 12.5 percent to 0.7 cents.

MEDADVISOR

Medadvisor says it will release 28,559,245 shares from voluntary escrow on July 27, 2024, and following their release will have 550,543,912 shares available for trading. Medadvisor said the voluntary escrow shares were issued as part of its payment to Guild Group Holdings for acquisition of Guildlink Pty (BD: Jul 25, 2022). Medadvisor fell one cent or 1.8 percent to 54 cents.

NEUREN PHARMACEUTICALS

The Auckland, New Zealand-based Milford Asset Management Ltd says it has ceased its substantial shareholding in Neuren.

Milford said that between December 2, 2022 and July 17, 2024 it bought 8,499,600 shares for \$132,031,318, or \$15.53 a share and sold 9,003,256 shares for \$131,556,267, or \$14.61 a share.

In 2022, Milford said it had reduced its Neuren holding to 6,771,157 shares (5.174%) and a week later, said it had ceased its substantial holding, selling 321,225 shares for \$2,571,228, or an average of \$8.00 a share (BD: Nov 23, Dec 2, 2022).

According to its most recent filing, Neuren had 127,815,676 shares on issue, meaning that Milford's remaining 5,946,276 shares amounted to about 4.65 percent.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra director Dr Nicholas Hartnell says he has increased his substantial holding in the company from 71,967,146 shares (60.17%) to 75,555,842 shares (63.17%).

In May, Allegra said Dr Hartnell would pay 0.4 cents a share in a cash bid, valuing it at \$478,444; and later, filed his bidder's statement (BD: May 27, Jun 20, 2024).

Today, the Bowral, New South Wales-based Dr Hartnell said that with Robinwood and Allegra Innovations he acquired the shares "as a result of acceptances of takeover offers made by [Allegra Innovations] dated June 20, 2024".

Allegra was in a suspension and last traded at 2.9 cents.

ISLAND PHARMACEUTICALS

Island says joint company secretary Stephanie Vipond has stepped down "whilst she takes maternity leave", effective from July 19, 2024.

Island said Cameron Jones would remain as sole company secretary. Island was untraded at 6.6 cents.