Biotech Daily

Friday May 5, 2023

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.37 percent on Friday May 5, 2023, with the ASX200 up 26.9 points to 7,220.0 points. Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, nine traded unchanged and two were untraded.

Paradigm was the best, up 6.5 cents or 6.5 percent to $1.06, with 663,459 shares traded. Compumedics improved 3.2 percent; Atomo and Opthea rose more than two percent; Alcidion, Antisense, Neuren and Polynovo were up more than one percent; with CSL, Cyclopharm, Nanosonics and Pro Medicus up by less than one percent.

Pharmaxis led the falls, down 0.5 cents or 8.2 percent to 5.6 cents, with 1.3 million shares traded.

Patrys lost 7.7 percent; Dimerix and Kazia were down more than five percent; Actinogen and Avita fell more than four percent; Micro-X, Next Science and Nova Eye were down three percent or more; Impedimed shed 2.8 percent; Immutep, Medical Developments, Mesoblast, Resmed and Starpharma were down more than one percent; with Clinuvel, Emvision, Telix and Volpara down by less than one percent.

DR BOREHAM'S CRUCIBLE: IMPEDIMED

By TIM BOREHAM

ASX code: IPD

Share price: 17.5 cents; **Shares on issue:** 1,787,664,914; **Market cap:** $312.8 million

Chief executive officer: Richard Valencia

Board: Donald Williams (chair), Mr Valencia, David Anderson (executive director), Prof Robert Graham, Amit Patel, Jan West

Financials (March quarter 2023): revenue $2.7 million, receipts $3.21 million, net cash outflows $2.79 million, cash of $21.3 million, quarters of available funding: eight

Major shareholders: Paradice Investment Management 8.4%, Australian Ethical 7.1%, (founding CEO) Greg Brown 2.0%.

In team sports, the time-honoured way of lifting performance is to replace the coach - a ploy that tends to work about as often as it doesn't.

With investors laser-focused on commercial results rather than vague promises, a number of ASX biotechnology companies have taken the same approach of supplanting long-serving CEOs with those perceived to be more financially-oriented.

Coincidentally, the companies that have done so tend to be US-focussed, such as Avita Medical, Volpara Health Technologies, Lumos and Impedimed.

In the case of Impedimed, Rick Valencia replaced long-serving Richard Carreon in the top job with a clear change agenda.

"When I came to the business, I observed a company that was not functioning at the level it needed to in order to succeed," says the California-based Mr Valencia. "I was hired to identify the company's focus, get it commercialized and get to cash break-even."

Mr Valencia also has a more personal motivation for furthering sales of Impedimed's Sozo devices for detecting lymphoedema, caused by the removal of armpit lymph nodes leading to limb-swelling in breast cancer survivors (because of excess fluid).

"My wife is a cancer survivor and she experienced a lot of the issues we address," he says.

Finally, Impedimed's 20-year history of setbacks has taken a dramatic turn for the better.

In a "transformative moment" for Impedimed, on March 24, the US National Comprehensive Cancer Network (NCCN) designated bio-impedance spectroscopy (BIS) as the standard-of-care for monitoring all cancer patients susceptible to lymphoedema.

Surprisingly, the guidelines included not just breast cancer but other cancers that might result in lymphoedema, such as skin, gastric and genital cancers.

The relevance is that health insurers will stump up for BIS tests and - get this! - Sozo currently is the only BIS lymphoedema test.

About Impedimed

Bio-impedance spectroscopy (the BIS) non-invasively measures, monitors and manages the fluid patient's fluid status.

BIS is all about passing low-frequency currents through the cells (whether they be fluid, fat, bone or muscle). The Sozo gathers data from 256 bodily sources.

The company was founded by biotech doyen Dr Mel Bridges in 1999 and listed in October 2007 at 72 cents apiece - poor timing given the global financial crisis was about to erupt.

Impedimed is based in Pinkemba, Queensland but most of the activity takes place at its Carlsbad, California digs.

Mr Valencia has 30 years in the healthcare sector, having been the interim chairman and CEO of glucose monitoring device maker Waveform Diabetes.

Before that he was on the board of Tandem Diabetes Care and a senior vice-president at Qualcomm Incorporated. Both these companies are Nasdaq-listed.

Mr Carreon had been CEO for more than a decade.

Sozo measures up better

Somewhat laughably, the standard-of-care for lymphoedema has been before-and-after tape measurements of the swollen limbs. Under current care guidelines, clinicians have not been obliged to monitor the condition at all.

Initially, Impedimed introduced the L-Dex U400, which assessed breast cancer patients for lymphoedema. The trouble is, the test took about 30 minutes and required the use of gel-backed electrodes on a prostrate patient.

So Impedimed devised Sozo, a wirelessly connected unit that looks like a cross between scales and an exercise bicycle. Sozo doesn't require electrodes and can accurately measure fluid in 30 seconds.

Impedimed's clinical piece-de-resistance was its Prevent trial, which measured lymphoedema in 1,200 breast cancer patients over three years, across 10 mainly US sites.

The trial met its primary endpoints and was statistically significant, showing 92 percent of early detection patients did not progress to chronic lymphoedema.

Sozo is approved for use in the US, Europe and Australia for lymphoedema, as well as other indications including heart failure and protein calorie malnutrition.

But Mr Valencia has made it clear that while the company is interested in these non-cancer markets, it will focus on the US lymphoedema opportunities.

Becoming the standard-of-care

Consisting of 33 of the top US cancer centres, the National Comprehensive Cancer Network (NCCN) holds powerful sway when it sets its clinical guidelines, because they become the standard-of-care for the whole market.

“You don’t want to be the insurer not paying for what is considered standard-of-care,” Mr Valencia says.

Nonetheless, the company was surprised at the swift manner in which the insurers agreed to review their policies to cover BIS testing.

While there are around 1,000 US health insurers, most are subsidiaries of 63 companies accounting for 80 percent of the market. At last count, 47 of these had agreed to review their policies. All but two have made this decision ‘out of cycle’, which means they won’t wait for their regular review meetings.

“This is unusual and means they have taken it very seriously,” Mr Valencia says. “The NCCN guidelines are very powerful and that has caused them to react very quickly.”

Sizing up the market

The company estimates the size of the US lymphoedema treatment market at $US10 billion ($A15 billion) - a cost borne by insurers or the health system.

“Lymphoedema is a horrible disease, but you can stop it in its tracks before it becomes a lifelong chronic disease, simply by wearing compression garments and doing some exercises,” Mr Valencia says.

The company estimates the size of the lymphoedema prevention market at $US1 billion for breast cancer, rising to $US2 billion when the other cancers are included.

Impedimed’s selling point to the insurers is that spending $US2 billion makes sense if it means avoiding outlaying $US10 billion over time. Hmm - makes sense.

Currently, Impedimed charges a subscription of around $A1,500 a month per client, for each of the 500 machines currently used in the US. Post reimbursement, the company expects to be able to charge $2,500 per month, rising to $4,000 per month for all four relevant cancers.

Elsewhere there are also about 500 machines - notably in Australia - but they yield much less because the deals tend to be on a ‘capital sale’ basis: the clinics buy the machine rather than a subscription.

Under the ‘all you can eat’ subscription model the clinics can do any number of tests and receive a current US Medicare/Medicaid rebate of $US140 per measurement. With private reimbursement, this is expected to rise to $US200 to $US220 per test.

The clinics pocket this payment, but as a general rule, the vendors (such as Impedimed) enjoy an economic benefit of 30 to 50 percent of the reimbursed amount.

Testing volumes currently are a modest 50,000 per quarter (for high-risk patients).

Mr Valencia says it’s possible the company could introduce a cap on testing under the subscription model, but it doesn’t want to deter testing, not just because of the obvious patient benefit, but because more testing means more data accrual to support other uses for Sozo.

Finances and performance

In the March 2023 (third) quarter Impedimed posted revenue of $2.7 million, flat on the year previously and five percent down on the December 2022 quarter.

The company also claimed record receipts of $3.2 million.

Net cash outflows of $2.79 million compared with a deficit of $6.5 million in the December quarter. Annual recurring revenue (ARR) was $8.7 million, up 28 percent. ARR is the amount of revenue reasonably expected to be booked in the next 12 months, based on existing contracts.

Based on built-in price escalators pertaining to the 500 US units, this ARR is expected to rise to $10.2 million in the 2023-’24 financial year (and eventually to $13 million).

During the quarter, new contracts with a total value of $3.2 million were inked, 44 percent higher than previously.

Meanwhile, customer churn was less than two percent.

The company’s cash balance stood at $23 million,12 percent down year-on-year. But management is confident of achieving cash-flow break even with its existing capital, which is based on 300 more machines being sold in the US.

Broker Morgans estimates the company will be profitable in the 2024-’25 year, to the tune of $2.7 million.

Over the last year Impedimed shares have traded between 19 cents on April 26, 2023 and five cents (July 2022). They peaked at an all-time high of $1.68 in mid-2016 and bottomed at four cents in May 2020.

What's next?

Impedimed had been carrying out trials in relation to end-stage renal failure and heart failure. These programs remain of interest but have been "semi parked" in favor of commercializing the oncology tests.

In the renal sphere, the dialysis blood-cleansing process involves fluid being removed and this has to be done using an accurate baseline.

The current measurement is by "clinical estimate" - also known as a rough guess. If the machine removes too much liquid, the patient can dehydrate. Too much fluid can cause heart failure.

Today, the company said the FDA had approved its tweaked Sozo Pro device under the so-called special 510(k) pathway.

Sozo Pro includes a medical-grade weight-scale of up-to 220 kilograms and has extra features to improve patient workflows and data collection.

Dr Boreham's diagnosis:

Mr Valencia says the company's long-standing (or long suffering?) shareholders might wonder what comes next, but he dubs the NCCN edict as a "once in a lifetime opportunity".

He says the "endless possibilities" for Sozo have been both a blessing and a curse, given that the multiple development programs have detracted from the company's focus.

While newbie 'coaches' usually enjoy a honeymoon period, Mr Valencia acknowledges he has no excuses, given the company's commercial tailwinds in the US.

"This a market that is ours to win or lose," he says. "We are the only company that can execute into the NCCN guidelines."

One could say there's no impediment to success now …

Mr Valencia says the company will be "very intentional" with its market pronouncements and "lead with the facts" - which sounds like one of your columnist's grumpy former editors.

The fact is, Impedimed's fortunes always rested on the willingness of US public and private payors to stump up for the tests.

Now that's happening, Team Impedimed is poised to shrug off its past setbacks and prevail in the premiership quarter.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. This column contains nothing but facts, albeit some people occasionally try to tell us alternative ones.

IMPEDIMED

Impedimed says the US Food and Drug Administration has issued Special 510(k) clearance for its 'next generation Sozo Pro bioimpedance spectroscopy monitor.
Impedimed said the Special 510(k) clearance covered Sozo Pro for lymphoedema and protein calorie malnutrition indications.
The company said that the clearance was a "milestone" which allowing it to submit a traditional 510(k) application to the FDA for the heart failure indication, including the removal of the contra-indication for patients with pacemakers and implantable cardioverter-defibrilators, allowing these patients to use Sozo Pro.
Impedimed said that the Sozo Pro had "a new, integrated weight scale, a higher standing weight capacity and an updated stand design allowing for easier transition between the standing and seated measurement positions".
The company said that the changes would improve clinical workflow, allowing for greater scalability of the Sozo digital health platform.
Impedimed said its immediate focus was expansion of insurance reimbursement coverage of Sozo testing for breast cancer-related lymphoedema.
The company said it expected to launch Sozo Pro in the year from July 1, 2023, and once launched, it would further help accelerate expansion in oncology and, with removal of the contra-indication for pacemakers and implantable cardioverter-defibrilators would be "crucial to additional markets such as heart failure".
Impedimed chief executive officer Richard Valencia said the Sozo Pro FDA clearance was "an important milestone in our product development and regulatory strategy".
Impedimed fell half a cent or 2.8 percent to 17.5 cents with 13.7 million shares traded.

KINOXIS THERAPEUTICS

Kinoxis says it will work with the Ingelheim, Germany-based Boehringer Ingelheim to develop its oxytocin receptor-targeting molecules for mental health disorders.
Kinoxis said Boehringer would pay it up to $US181 million ($A271.2 million) upfront, and that it would also receive royalties from future Boehringer Ingelheim products.
The company said it would work with Boehringer to develop "first-in-class oxytocin-targeting, precision psychiatry treatments" that would use small molecules to target the brain oxytocin system to treat social behavior disrupted by psychiatric disorders.
Kinoxis said it would receive an upfront payment and research support payments and be eligible for research, pre-clinical, clinical, regulatory, and commercial milestones of up-to $US181 million, in addition to royalties on future Boehringer Ingelheim product sales.
Kinoxis is a private company.

BLUECHIIP

Bluechiip says it has raised $2.2 million through a placement at 2.5 cents a share and hopes to raise an additional $300,000 through a share purchase plan.
Bluechiip said its chair Iain Kirkwood had subscribed for $100,000 worth of shares, with the rest bought by institutional, sophisticated and professional investors.
The company said the non-underwritten share plan had a record date of May 4 would open on May 12 and close on May 25, 2023.
Bluechiip said it would use the funds for continued production scaling and sales expansion, especially in North America, and working capital.
The company said MST Financial Services was the lead manager to the placement.
Bluechiip fell 0.3 cents or 10.3 percent to 2.6 cents.

4D MEDICAL

4D Medical says it will begin a commercial pilot program of its x-ray velocimetry (XV) lung imaging technology with the US Department of Defense Military Health System.

4D Medical said the Military Health System provided military personnel with health services at 45 hospitals and inpatient facilities in the US.

The company said it would perform an agreed number of scans on full commercial terms, with the potential to expand.

4D Medical managing-director Prof Andreas Fouras said he was “incredibly excited to share our success in winning a commercial pilot [program] with the US Department of Defense”.

“In particular, this major development, side by side with our growing momentum at the [Department of Veterans Affairs] allows us to contemplate a vision where 4D Medical is a core part of lung health for all US military personnel, both past and present,” Prof Fouras said.

Earlier this week, 4D Medical said it had completed its first commercial x-ray velocimetry lung ventilation analysis software (XV LVAS) scan with the US Department of Veterans Affairs (BD: May 1, 2023).

4D Medical was in a trading halt and last traded at $1.135.

CRESO PHARMA

Creso says two patients in Halucenex Life Science’s 20-patient trial of psilocybin have shown “total remission” from depression and post-traumatic stress disorder (PTSD).

Creso said data from the phase II trial showed two psilocybin doses, one micro and one macro dose, administered one-week apart lead to a “marked decrease” of symptoms in patients with treatment resistant post-traumatic stress disorder.

The company said early results from the two patients included improvements in total sleep time, reduced cravings for tetrahydrocannabinol (THC) and “junk food”, blood pressure was reduced from hyper-tensive to normal, and they had better interpersonal relationships.

Creso said it had amended the trial to allow for a larger window for pre-screening, as well as spread each patient’s seventh visit over one to three days, and let Halucenex’s chief science officer prepare doses without the need for a pharmacist.

The company said that all patients who completed three months of assessments to date “reported a 95 percent reduction in symptoms at month one and a 75 percent reduction in symptoms by month three, with one patient experiencing a total remission of PTSD by month three”.

Creso did not disclose the number of patients who had completed three-month assessments, but said that “of the 20 trial participants, only two patients to-date have received an initial dosing, which took place in December 2022”.

The company said that after the initial low 10mg dose, there was a “nearly 40 percent reduction in PTSD symptoms”.

Creso said that the 25mg macro dose given one week later resulted in an “immediate decrease in symptoms associated with PTSD” with both participants endorsing zero symptoms of PTSD at one-month post-macro dose, indicating a drop of 51 points on the CAPS-5”.

Creso was up 0.1 cents or 10 percent to 1.1 cents with 12.6 million shares traded.

INCANNEX HEALTHCARE

Incannex says subsidiary Clarion Clinics Group has leased a premises in Abbottsford, Melbourne to provide psychedelic-assisted therapy, but did not disclose the cost.
Incannex said the fit out and commissioning of the premises would begin “shortly” and was expected to be completed in August 2023.
The company said the clinic had capacity to treat more than 600 patients a year and was designed as a prototype that could be scaled and replicated at other locations.
Incannex said it had ordered an initial supply of psilocybin and 3,4 methylene-dioxy-meth-amphetamine (MDMA).
Incannex chief executive officer Joel Latham said “Clarion Clinics will be the first dedicated psychedelic-assisted psychotherapy business in Australia”.
“We’re delighted to be at the forefront of an industry that has the potential to change the lives of thousands of people who have been living with conditions for which there have been no adequate treatment options,” Mr Latham said.
Incannex was up one cent or 9.5 percent to 11.5 cents with 4.5 million shares traded.

GLOBAL KINETICS CORP

Global Kinetics says it has appointed Zach Henderson as chief executive officer and a director, and Dr David Atkins as a director, effective from May 4, 2023.
Melbourne’s Global Kinetics said Mr Henderson had more than 25 years’ experience with healthcare software and data, and was previously Glooko’s chief commercial officer, where he worked with life science and healthcare businesses.
The company said Mr Henderson had held management roles with public and private equity-backed healthcare companies.
Global Kinetic said Dr Atkins’ experience in operational and investor roles, including in digital health, would be valuable to the business.
Global Kinetics is a private company.

BIO-MELBOURNE NETWORK

Bio-Melbourne Network says it will host workshops with higher education and research consultants Marlow Hampshire on leading and managing technical and scientific staff.
The Network said the workshops, titled ‘Industry Program - Leading and Managing: The People Side of Technology and Manufacturing Teams in Biosciences’ twice, with the first program running from June 16 to July 27 and the second from October 26 to November 30, 2023.
The industry organization said the event would provide participants with tools, techniques and tips that could be applied in the workplace.
The Network said that the courses emphasized learning by doing and included group problem solving and skills development elements.
To register, go to: https://bit.ly/3LQ4eIF.