Biotech Daily

Friday October 16, 2020

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: AMPLIA, PATRYS UP 10%; USCOM DOWN 10%**

*** DR BOREHAM'S CRUCIBLE: IMPEDIMED**

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*** ALTERITY RAISES $35m**

*** CANN GLOBAL SHORTFALL $859k; TOTAL $2m OF HOPED-FOR $4.7m**

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*** PYC REQUESTS 'CAPITAL RAISING' TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.54 percent on Friday October 16, 2020, with the ASX200 down 33.5 points to 6,176.8 points. Eighteen of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and one was untraded.

Amplia and Patrys were equal best, up 10.0 percent to 22 and 2.2 cents, respectively, with 972,130 shares and six million shares traded, respectively. Osprey climbed 7.4 percent; Actinogen improved 4.2 percent; Antisense, Nova, Oncosil, Prescient and Proteomics rose more than three percent; Dimerix, Impedimed, Imugene, Medical Developments, Resmed and Volpara were up one percent or more; with Genetic Signatures, Nanosonics, Neuren and Next Science up by less than one percent.

Uscom led the falls, down two cents or 10.3 percent to 17.5 cents, with 1.1 million shares traded. Both Alterity and Paradigm fell four percent; Mesoblast, Orthocell and Pro Medicus lost more than three percent; Clinuvel, Cynata, Polynovo and Starpharma shed two percent or more; Cochlear, Compumedics, Cyclopharm and Telix were down more than one percent; with Avita and CSL down by less than one percent.

DR BOREHAM'S CRUCIBLE: IMPEDIMED

By TIM BOREHAM

ASX code: IPD

Share price: 8.1 cents; **Market cap:** $87.0 million; **Shares on issue:** 1,073,636,393

Chief executive officer: Richard Carreon

Board: Scott Ward (chairman), Mr Carreon, David Anderson, Prof Robert Graham, Judith Downes, Donald Williams, Amit Patel

Financials (year to June 30 2020): revenue $5.7 million (up 38.1%), loss of $21.4 million (previous $24.1 million deficit), cash of $19.7 million*****

***** the company expects to bank approximately $15 million more, via the conversion of in-the money options

Identifiable major shareholders: Allan Gray Australia 8.92%, Paradise Investment Management 6.58%, Australian Ethical 5.98%.

In the medical device development milieu, few products evolve in a neat linear manner and investors can expect a misstep or two.

Impedimed has been no different in its two decades' long quest to devise a machine that accurately measures fluid in the body - especially where it should not be.

Initially, Impedimed introduced the L-Dex U400, which assessed breast cancer patients for lymphoedema (fluid in the limbs, caused by the removal of suspect lymph nodes).

But like most U-boats the U400 eventually sank, for two key reasons. Firstly, the test took about 30 minutes and, secondly, it required the use of gel-backed electrodes on a prostrate patient. We can add a third reason: the company went about pursuing an all-important US reimbursement code the wrong way.

Learning from its mistakes, Impedimed devised Sozo, a wirelessly connected unit that looks like a cross between scales and an exercise device. Crucially, Sozo doesn't require electrodes and can accurately measure fluid in 30 seconds.

"When I arrived eight years ago, we took a blank piece of paper, stopped all development work and asked 'how do we change the business model'," says Richard Carreon, the company's San Diego, California based chief executive.

"We took a great technology with a business model that was struggling."

While Impedimed's business is US-centric, the company remains Brisbane based, having been founded by biotech doyen Mel Bridges in 1999. The company listed in September 2007, having raised $18 million at 72 cents apiece.

Impediments to success

Even with the ‘right’ device, Impedimed has had a hard slog selling Sozo to US hospitals and clinics. One reason is that lymphoedema did not have its own reimbursement code, even though one in three cancer patients are afflicted. There’s also a reluctance to ‘own’ the disease, with the oncologists passing the buck to the radiologists (and vice versa).

The company now has public US Medicare funding, covering just under half of the lymphoedema patients. But the private insurers want clinical proof, even though there’s plenty of ‘real world evidence’ from 152,000 tests carried out to date.

While lymphoedema remains a key focus, the company is expanding the use of Sozo for heart failure and renal disorders - both of which involve fluid retention.

Last month, the company received a boost when drug house Astra Zeneca ordered 175 Sozo units to measure for fluid levels in patients enrolled for the trial of a combined heart and renal failure drug. The drug giant will lease the machines for 18 months, delivering $2 million in revenue to Impedimed.

“This endorsement of our technology is timely as the company begins the launch of Sozo into the cardiology market,” Mr Carreon said.

How Sozo measures up

Impedimed contends that while fluid monitoring is crucial for all three conditions, current methods are “inaccurate, invasive and expensive”. Somewhat laughably, the standard of care for lymphoedema is before-and-after tape measurements of the swollen limbs.

Heart patients are often monitored by permanent electrodes inserted into the aorta, but the method is obviously invasive and extremely expensive.

Sozo deploys bioimpedance spectroscopy (BIS), which is all about passing low-frequency currents around cells and low frequency pulses through the cells (whether they be fluid, fat, bone or muscle).

The company has US Food and Drug Administration and European consent for lymphoedema and heart disease and also a condition called protein calorie nutrition (PCN) which is synonymous with kidney disease. The company has approvals for end stage renal disease in Europe - but it’s yet to attack that market.

Where’s the evidence?

While Impedimed boasts a swelling body (sorry) of real-world lymphoedema evidence, it’s sweating on the final results of a major seven-year trial comparing bio-impedance spectroscopy with the tape measure. Dubbed Prevent, the trial enrolled 1,100 breast cancer patients across 10 oncology sites: nine in the US and New South Wales’ Macquarie University Cancer Institute.

The patients were measured twice in the first six months and then every six months over a total of three years.

Published in the journal Cancer Medicine in June, the data from the first 508 patients showed a “statistically significant” linkage between the Sozo readings and post-surgery lymphoedema. Put another way, the results showed a 95 percent reduction in the progression of lymphoedema because of interventions inspired by the Sozo measurement. The final results are due in the March quarter next year.

Monitoring heart patients ...

At the heart of the coronary stuff - sorry again - Sozo is all about monitoring patients so they don’t get to the point where excess fluid results in them returning to hospital. This is via an add-on function called HF-Dex.

Between 20 and 25 percent of chronic heart disease patients in the US are readmitted, at an average cost of $US14,000 each.

“Heart failure readmissions put a substantial cost burden on both public and private payers,” Mr Carreon says. “We believe our technology can reduce costs associated with managing heart failure patients and (improving) their quality of life.”

In early October, Impedimed fronted the Heart Failure Society of America - remotely of course - with an outline of its heart monitoring results to date. These pertain to two studies, one of them for home testing.

The gist is HF-Dex could ascertain that patients with high fluid ratios were more likely to need another hospital visit - and not to see a glowing mum in the maternity ward.

On average, readmitted patients scored 52.1 percent (the proportion of extracellular fluid relative to total body water), compared with 49 percent for non-admitted patients and 44.8 percent for a healthy sample.

Rather like two-party preferred political opinion polls, there’s obviously a big difference between 52 percent and 49 percent. Let’s just hope the Sozo measures are more reliable than the polls leading up to the last Federal election, the last US presidential poll and the Brexit ballot. [Editor’s note: the polls were accurate; the interpretation was wrong.] [Author’s note: that’s what I meant.]

... and dodgy kidneys

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

The sums become compelling because 450,000 Americans are on dialysis, equating to 44 million expected treatments in 2021. These patients account for one percent of the populace, but a whopping seven percent of Medicare costs.

The US dialysis market is dominated by Fresenius and DaVita, which have about 2,500 clinics each and treat 85 percent of all patients. This means that Impedimed only has to knock on two doors to find two mega customers, although we guess it's a bummer if they're not interested.

Finances and performance

Impedimed doubled its Sozo revenue in the year to June 2020, to $4.7 million, with recurring subscriptions of $3.4 million and contracted revenue of $10.9 million.

Having reported a $21 million loss in the 2019-'20 and a $24 million deficit the previous year, Impedimed has been burning through more cash than a drunken sailor - or a sober Coronavirus-hit government.

But in the Covid-19 era, the company has implemented a cost-cutting program. In April, the company also embarked on a $24.9 million capital raising, by way of a placement and 13-for-10 rights offer at 3.75 cents a share, a 24 percent discount. In the end the company raised $18.2 million, $10 million via the placement.

Post raising Impedimed has just under $20 million in the kitty and can confidently expect to pocket $15 million more from in-the-money options that expire in March this year.

As of the June 30 balance date, 560 Sozo units were in the market, compared with 401 previously. About two-thirds of these machines are in the US and one-third in Australia.

In the US Impedimed deploys a hybrid subscription model, based on $US5,000 for the machine itself and a monthly fee of several thousand dollars (the heart and renal functions are software add-ons at an additional cost).

The lymphoedema tests attract a $US140 Medicare rebate. The heart tests - which can be carried at as frequently as every day - are rebatable at $US40 a test by both public and private insurers.

Impedimed shares have given investors a wild ride, with the stock trading between 19.8 cents (mid-November 2019) and 3.4 cents (mid-April this year).

In mid-May the stock surged from 4.2 cents to 8.5 cents over four trading days. Impedimed hit an all-time high of $1.68 in August 2016.

Mandatory Covid-19 commentary

Not surprisingly, Impedimed saw a "dramatic fall" in patient testing at the start of the pandemic. Because of the company's skew to subscription revenue, turnover did not suffer.

Impedimed's business recovered to pre-coronavirus levels in the June quarter and in the month of June the Sozos carried out a record 8,600 tests.

Mr Carreon says while no hospital was accepting face-to-face calls, it was easy enough to ship out the units and instruct users how to set them up with a five-minute online tutorial.

Even at the height of Covid-19, all 14 major hospitals up for contract renewals agreed to re-sign – and at a higher price.

The company also claims a low churn rate of one percent over the last three years.

Dr Boreham's diagnosis:

Impedimed and the Sozos, in essence, are about measuring a disorder correctly in the first place, so that the doctors can intervene and prevent the dire knock-on effects.

Impedimed's pursuit of cancer, heart and kidney disease indications makes sense because they are inter-related.

For breast cancer patients aged over 50, heart disease is more likely to kill them than the tumors, because the treatments are toxic to the ticker.

Cardiovascular disease is also the most common form of death for dialysis patients.

"We are not a one-trick pony like we used to be," Mr Carreon says.

The Prevent trial results loom as a key event in persuading the private payers to stump up; and encouraging hospital take-up generally across all the indications.

The home testing market is also promising because individual patients add up to far more units than the hospitals themselves.

Balancing all of this promise, Impedimed still faces a long slog to achieve profitability and may still have to tap patient investors for more funds.

Hopefully the September quarter numbers due out on Tuesday week will show the promising Sozo take-up trends have not gone to water.

"We have a great investor base that has stuck with us through thick and thin," Mr Carreon says.

"Those who have hung in there will appreciate we are on the precipice of some great things."

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He may also be on the precipice of great things, but the situation is fluid.

KAZIA THERAPEUTICS

Kazia says it will pay $US5 million ($A7.1 million) to the Global Coalition for Adaptive Research to include Paxalisib in an up-to 200-patient trial for glioblastoma.
Last year, Kazia said Paxalisib, formerly GDC-0084, would join the phase II/III multi-drug glioblastoma adaptive, innovative learning environment trial (BD: Dec 11, 2019).
Today, the company said it had an agreement the Global Coalition for Adaptive Research (GCAR) to include Paxalisib in the 'GBM Agile' trial for the initial payment, plus milestone payments throughout the study.
Kazia said the trial would "serve as the pivotal study for registration of Paxalisib in key markets".
The company said it expected to enrol between 50 and 200 newly diagnosed glioblastoma patients for the Paxalisib arm of the trial, the same population of patients in Kazia's ongoing 30-patient, phase II trial (BD: Mar 6, Apr 7, Jun 22, 2020).
Kazia said the data would be compared against several hundred patients in a shared control arm, allowing for considerable operational efficiency, it would enrol patients in early 2021 and expected the study to take 30 to 36 months, plus follow up.
The company said the GBM Agile trial would recruit recurrent patients to the Paxalisib arm and the drug might "ultimately be considered efficacious in either or both of these patient groups".
Kazia chief executive officer Dr James Garner said the company was "very gratified" to move into the operational phase of the study".
"This is a faster, more cost effective, and higher quality study than any company of our size could mount independently, and we are confident that it will provide the best possible opportunity for Paxalisib to demonstrate its potential in this very challenging disease."
Kazia was unchanged at 79.5 cents.

RECCE PHARMACEUTICALS

Recce says it has approval to start its up-to 30-patient, 14-day, phase I/II trial of Recce-327 for infected burn wounds at Perth's Fiona Stanley hospital.
Recce said that 10 patients would receive Recce-327 treatment daily and 20 patients would receive Recce-327 three times a week.
Recce said that a spray formulation of Recce-327 would be compared with a parallel phase I trial of Recce-327 with intravenous administration (BD: Sep 10, 2020).
Recce chair Dr John Prendergast said ethics approval was "another milestone" for Recce and clinicians seeking effective treatments to combat antibiotic resistant bacteria.
Recce was up one cent or 0.9 percent to $1.07 with 1.4 million shares traded.

ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Alterity says it has "binding commitments" to raise $35 million in a two-tranche placement at 3.7 cents a share.
Alterity said the share price was a 25.7 percent discount to the 30-day volume weighted average price to the last closing price.
The company said it would issue investors one free option for each new share, subject to shareholder approval, exercisable at seven cents within three years.
Alterity said the funds would be used for two studies of its ATH434 for multiple system atrophy and for general working capital.
The company said the capital raising was managed by Sydney's MST Financial.
Alterity fell 0.2 cents or four percent to 4.8 cents with 6.2 million shares traded.

CANN GLOBAL

Cann Global says its entitlement offer shortfall at 0.5 cents a share has raised $859,363 of a hoped-for $2,036,744, taking the total raised to $3,060,111.
In July, Cann Global said its one-for-four renounceable entitlement offer had raised $2,200,748 of a hoped-for $4,661,235 and planned to place the remaining $2,036,744 shortfall by October 23, 2020 (BD: Jul 29, 2020).
Today, the company said the shortfall had closed and had been placed by the directors to existing shareholders and new investors.
Cann Global fell 0.2 cents or 25 percent to 0.6 cents with 141.8 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has appointed Medical Horizons to distribute its Promarkerd immunoassay predictive blood test for diabetic kidney disease in Italy.
Proteomics said it would receive an undisclosed payment for every Promarkerd kit sold by the Florence-based Medical Horizons, with the further details of the two-year licence agreement remaining confidential.
The company said it expected distribution to begin to in one month, once Medical Horizons registered Promarkerd with the Italian Ministry of Health.
Proteomics managing-director Dr Richard Lipscombe said the partnership “marked the first distribution licencing deal for the immunoassay version of the Promarkerd test”.
Medical Horizons chief executive officer Guido Osto said that with the Promarkerd “used as an annual test, doctors will be able to identify at-risk patients for early intervention, … minimize the effects of diabetic kidney disease, and potentially save the healthcare system billions of Euros,” Mr Osto said.
Proteomics was up two cents or 3.7 percent to 56.5 cents.

RHYTHM BIOSCIENCES

Rhythm says it has received $1,108,507 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Rhythm said the rebate related to research and development expenditure for the year to June 30, 2020.
Rhythm was unchanged at 23.5 cents.

ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS)

Anteris says it has extended the maturity date of its $1.3 million loan facility with New York hedge fund SIO Partners from November 2020 to December 15, 2021.
Last year, the then Admedus said it a $1 million, 18-month loan from SIO Partners at 12 percent compounding monthly and carrying a $125,000 “facility fee” to fund general working capital and operational costs (BD: May 9, 2019).
Today, the company said the loan had a current outstanding balance of $1.3 million and no changes had been made to the interest rate.
Anteris said SIO Partners could seek repayment of the outstanding balance if the company had a capital raising or finalized a transaction generation more than $5 million.
Anteris was unchanged at $4.04.

GENETIC SIGNATURES

Genetic Signatures says it will vote to issue 250,000 options to chief executive officer Dr John Melki and increase the directors' fee pool by 80 percent to $450,000 a year.
Genetic Signatures said Dr Melki's proposed options would be exercisable at $2.30 each, the 30-day volume weighted average price to September 8, 2020, within 15 years, vesting in four equal tranches over four years.
The company said the meeting would vote to increase the directors' fee pool from $250,000 to $450,000 a year due to the growth of the company resulting "in increased demands on current non-executive directors' time".
Genetic Signatures said the meeting would vote to adopt the remuneration report, re-elect chair Dr Nick Samaras, and approve the change of auditor.
The meeting will be held online on November 20, 2020 at 10am (AEDT).
Genetic Signatures was up 1.5 cents or 0.8 percent to $1.95.

OPTHEA

Opthea has requested a trading halt pending "an announcement in relation to the outcome of its US initial public offering of new American depositary shares".
Earlier this week, Opthea said it hoped to raise $US160 million ($A221.4 million) in American depository shares to list on the Nasdaq Global Select Market under the code OPT (BD: Oct 12, 2020).
Trading will resume on October 20, 2020, or on an earlier announcement.
Opthea last traded at $2.78.

PYC THERAPEUTICS

PYC has requested a trading halt pending "an announcement regarding a proposed capital raising that is material to the company".
Trading will resume on October 22, 2020 or on an earlier announcement.
PYC last traded at 18.5 cents.