Biotech Daily

Friday September 20, 2024

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.21 percent on Friday September 20, 2024, with the ASX200 up 17.6 points to 8,209.5 points. Twenty-one of the Biotech Daily Top 40 companies were up, 15 fell and four traded unchanged.

Amplia was the best (see below), up three cents or 28.6 percent to 13.5 cents, with 1.4 million shares traded. Cynata climbed 13.2 percent; Clarity was up 12.2 percent; Telix improved 8.3 percent; 4D and Universal Biosensors were up seven percent or more; Curvebeam, Impedimed and Mesoblast improved six percent or more; Neuren was up 4.8 percent; Syntara climbed 3.1 percent; Opthea and Percheron rose two percent or more; Immutep, Medadvisor and SDI were up more than one percent; with Emvision, Genetic Signatures, Nanosonics, Pro Medicus, Proteomics and Resmed up less than one percent.

Nova Eye led the falls, down 1.5 cents or 8.1 percent to 17 cents, with 963,285 shares traded. Imugene lost 7.7 percent; Actinogen, Compumedics and Paradigm shed more than six percent; Dimerix and Micro-X were down more than five percent; Cyclopharm and Resonance fell four percent or more; Aroa, Clinuvel and Prescient shed two percent or more; Avita, Medical Developments and Orthocell were down more than one percent; with Cochlear and CSL down by less than one percent.

DR BOREHAM'S CRUCIBLE: IMPEDIMED

By TIM BOREHAM

ASX code: IPD

Share price: 5.3 cents; **Shares on issue:** 2,023,093,918; **Market cap:** $107.2 million

Chief executive officer: Dr Parmjot Bains

Board: Christine Emmanuel-Donnelly (chair), Dr Bains (M-D), McGregor Grant (CFO), Andrew Grant, Janelle Delaney, Fiona Bones.

Financials (Year to June 30, 2024): revenue $10.3 million (down 9.0%), net loss $19.8 million ($20.6 million loss previously), cash of $24.6 million (down 46%).

Major shareholders: Paradice Investment Management 7.1%, Australian Ethical 6%

When we last covered Impedimed in May last year, we opined that the time-honored way of lifting team performance was to replace the coach - a ploy that works about as often as it doesn't.

Back then, Rick Valencia had just replaced the long-serving Richard Carreon as CEO in the top job, with a clear agenda to jazz up the joint.

But all was not oranges, or apples, for Mr Valencia and in November he departed after a boardroom coup that also saw four directors exiting (including subsequent interim CEO David Anderson).

Former Nanosonics CFO, McGregor Grant was appointed interim chair followed by new CEO, Dr Parmjot Bains.

Mr Grant said the changes were made because some shareholders were concerned about corporate costs, the timing of a March 2023 capital raising and the perception the company was not capitalizing on favorable US conditions.

History doesn't repeat, but it sure rhymes.

"When we came into the business, we had a good hard look at that and made a few changes," Mr Grant said. "We found there was just not enough in the [sales] pipeline.

"We have adjusted the cost base of the business and focused resources on the sales end and we believe we are seeing the results of that work coming through."

Impedimed's Sozo, by the way, is an accurate and non-invasive means of detecting and measuring lymphoedema, caused by the removal of armpit lymph nodes leading to limb-swelling in breast cancer survivors (because of excess fluid), along with the detection of other bodily fluid build-ups.

About Impedimed

Impedimed 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.

Initially, Impedimed introduced the L-Dex U400, which assessed breast cancer patients for lymphoedema.

Before then, the standard-of-care for lymphoedema was before-and-after tape measurements of the swollen limbs which – needless to say – is totally inadequate.

The trouble is, the L-Dex 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.

Last September's board spill saw four incumbents replaced with Mr Grant, the former-long standing CFO of fellow device house Nanosonics, the unrelated Andrew Grant and non-executive directors Christine Emmanuel-Donnelly and Janelle Delaney.

In June 2024, their ranks were bolstered with the appointment of Fiona Bones.

McGregor Grant is also the company's CFO, having replacing long-term numbers man Tim Cruickshank.

Dr Parmjot Bains was anointed interim CEO after the boardroom blitz and was made permanent chief on July 22 this year.

A medical doctor, Dr Bains was joint CEO of Neuren Pharmaceuticals and the unlisted New York based hair-loss house Perseus Therapeutics.

Dr Bains has also held commercial roles at Pfizer and the management consultancy McKinsey.

The board spill motion was passed on fairly slim majorities of 55 to 60 percent, depending on the director subject to appointment or removal. Two directors not subject to the removal petition, Janet West and Dr Michael Seiden, resigned in October and November respectively.

The incumbents argued that removing them would be unnecessarily disruptive and that the agitators lacked the requisite skills.

Influential proxy advisers CGI Glass Lewis and ISS also endorsed the status quo, but ultimately (unless you're Donald Trump) you can't argue with the numbers.

About Sozo

Sozo is the only US Food and Drug Administration-cleared device for managing breast cancer-related lymphoedema using bio-impedance spectroscopy (BIS).

Seeing you asked, BIS works by passing low-frequency currents through the cells (whether they be fluid, fat, bone or muscle). Sozo gathers data from 256 bodily sources.

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.

In May last year, the FDA cleared Sozo Pro, an enhanced version with an updated seat design, a more integrated weight scale and an increased standing weight capacity from 170 kilograms to 220 kilos.

Sozo's efficacy was supported by a 1,200 global clinical trial called Prevent, which assessed the patients' fluid levels over three years. The study showed only 7.9 percent of patients progressed to chronic lymphoedema, compared to 19.2 percent of those assessed with a tape measure.

Since then, Impedimed has cited 'real world' evidence, including supportive research from the New South Wales Health Lymphoedema Program. Of the 1,800 patients assessed, only 75 (4.2%) progressed to chronic lymphoedema compared with 480 (26.7%) with the standard-of-care.

In March 2024, the influential US National Comprehensive Cancer Network (NCCN) designated BIS as the standard-of-care for monitoring all cancer patients susceptible to lymphoedema.

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

Consisting of 33 of the top US cancer centres, the NCCN holds powerful sway in determining a product to be the standard-of-care.

The ruling means health insurers will stump up for BIS tests - which is handy given Sozo currently is the only BIS lymphoedema test.

As at the end of June 2024, 66,000 Sozo tests had been carried out, a three-year compound annual growth rate of 21 percent.

It's the economics, stupid

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.

The company also estimates the size of the lymphoedema prevention market at $US1 billion for breast cancer, rising to $US2 billion when non-breast 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.

About 20 percent of breast cancer patients will develop lymphoedema, incurring an average out-of-pocket cost of $US2,306.

In the US, Impedimed's clinical customers usually pay a monthly licence fee of around $US1,300 to $US1,400.

In other markets (including Australia) the clients usually buy the hardware up front, at a cost of around $A20,000.

The US pricing model is far more attractive: while the rest of the world accounts for about half of the installed Sozo base, it only contributes about 10 percent of revenue.

Mr Grant said the company "went a little hard" on US pricing with a stepped arrangement by which the fee was structured to rise to $US2,500 by year three.

Not surprisingly, customers queried why they should pay more in what amounted to a reverse loyalty discount.

The structure now has been "flattened", with more flexibility based on examination volumes and to state-by-state reimbursement.

The US Medicare/Medicaid system reimburses clinicians to the tune of $US145 per measurement, while private insurers pay anywhere between $US150 to $US400.

Impedimed takes 30 to 50 percent of the spoils, but clinics don't need to do too many tests to break even on their investment.

Economically speaking, the company could restrict the number of tests, but more testing means more data to support future extensions and it doesn't want to deprive patients.

Finances and performance

In the year to June 2024 Impedimed chalked up revenue of $10.391 million, down 9.0 percent, with a loss of $19.79 million compared with a $20.57 million deficit previously.

McGregor Grant says the company has a two-year target for free cash-flow break even "all things being equal".

The company has targeted a 10 percent reduction in cash burn, mainly from reducing headcount.

Impedimed reports that 38 more Sozos were installed in the June quarter - 23 in the US - taking its global base to 1,083 compared with 997 a year previously. Of these, the US accounts for around 570 units and Australia (around 400 units) accounts for most of the remainder. The churn rate was a low three percent.

The company cites a Texan oncology clinic that ordered another two machines, taking its complement to eight and a national breast surgery group which expanded its take-up from three to eight.

June quarter annual recurring revenue (ARR) was $11 million, up 10 percent on the March quarter. ARR is the amount of revenue reasonably expected to be booked in the next 12 months, based on existing contracts.

Dr Bains notes that renewal pricing has increased by an average 38 percent, with about one-third of contracts up for renegotiation each year.

At the end of June, Impedimed had cash of $24.6 million, having raised $30 million last year in a $20 million placement and $10 million in an oversubscribed share plan.

Over the last 12 months, Impedimed shares have ranged between 22 cents (early August last year) and a low of six cents (July 19 this year). Over the company's listed life, the shares peaked at an all-time high of $1.68 in mid-2016 and bottomed at four cents in May 2020.

Dr Boreham's diagnosis:

Like the Chinese Communist Party, every company needs a decent manifesto. In the case of Impedimed, management has outlined five goals to be achieved over the next two years.

In oncology, this includes expanding reach into leg lymphoedemic pain, and pelvic melanoma and gynaecological cancers at risk of lymphoedema.

But five-year visions are one thing and near-term performance is another. Biotech history shows that when new boards and management promise sweeping changes, the share price does not move in lock-step and Impedimed shares remain off the pace.

To be fair, the company has been gaining sales traction in that crucial US market - but it is still happening too slowly for some pundits.

A little over a year ago, Mr Valencia said the market was "ours to win or lose" given the supporting reimbursement in the US.

Riffing on the theme of her predecessor, Dr Bains says "both revenue and costs are heading in the right direction".

But the clear message is that like building an underperforming footy team, the change process is a marathon rather than a sprint.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He has witnessed too many games where it was 'theirs to lose' for his hapless football team - and indeed it did.

EBR SYSTEMS

EBR says it raised $45.8 million in a placement and institutional rights offer at 82 cents per Chess depository instrument (CDI), with a retail offer to raise a further $4.2 million.
EBR said it has raised $37.4 million in the placement and $8.5 million through the institutional rights offer (BD: Sep 18, 2024).
The company said Bell Potter securities underwrote the placement with Bell Potter, Morgans Corporate, E&P Capital Pty Ltd and Wilsons Corporate joint lead managers.
EBR fell 8.5 cents or 8.7 percent to 89 cents with 3.3 million shares traded.

CONTROL BIONICS

Control Bionics says it hopes to raise $2,092,868 through a non-renounceable, one-for-seven rights issue at 7.0 cents a share, and a further $1 million in a placement.
Control Bionics said that in the rights offer, investors would receive one option for every two shares purchased, exercisable at 10 cents within two years.
The company said that the 7.0 cents issue price was a 20 percent discount to the 19-day volume weighted average price.
Control Bionics said that it intended to place $1 million pending shareholder approval.
Control Bionics chief executive officer Jeremy Steele told Biotech Daily that the placement was concurrent with the rights offer and on the same terms.
The company said the rights offer was underwritten for $850,000, with Nightingale Partners underwriting $604,680 and North Star Impact Fund underwriting $150,000.
Control Bionics said that chief executive officer Jeremy Steele and directors Roger Hawke, Prof Rob Heard and Damian Lismore had collectively committed a total of $92,000, including an underwritten amount of $33,000.
Control Bionics said the rights offer was for shareholders on the record date of September 25, would open on September 26 and close on October 9, 2024.
The company said proceeds would go towards development, testing, design and trial of its Neurostrip technology, strategic investments and working capital.
Control Bionics was untraded at 7.6 cents.

LUMOS DIAGNOSTICS HOLDINGS

Lumos says Hologic Inc has paid $US300,000 ($A440,779) for the first milestone of phase two of their development agreement for its foetal fibronectin test.
Lumos said that increased levels of the foetal fibronectin protein could “indicate that a woman is at higher risk of pre-term delivery”.
In January, Lumos said the Marlborough, Massachusetts’ Hologic Inc would pay it $US10 million to improve their women’s health products and adapt them for use with its platform (BD: Jan 21, 2024).
In May, the company said it would receive $US400,000 from Hologic in milestones for the first phase of development for its foetal fibronectin test (BD: May 6, 2024).
Today, Lumos said the total milestones payments were worth $US4.7 million, with phase two covering work demonstrating that the assay could detect the biomarker, for a total of $US600,000 in milestone payments, with this first milestone being for defining the parameters for the product and establishing a project plan.
Lumos chief executive officer Doug Ward said “we are proud to receive this milestone payment, which demonstrates the strong progress the Lumos and Hologic are making in developing a new foetal fibronectin test”.
Lumos was unchanged at 3.3 cents with 7.2 million shares traded.

AMPLIA THERAPEUTICS

Amplia says the US Food and Drug Administration has granted its focal adhesion kinase inhibitor narmafotinib, or AMP945, 'fast track designation' for pancreatic cancer.
Amplia said fast track designation was for drugs that provided an advantage over current therapies for treating serious conditions, allowing them access to more frequent meetings and written communication with the FDA, with AMP945 possibly eligible for accelerated approval and priority review in the future.
The company said it had previously received FDA orphan drug designation for AMP945 for pancreatic cancer and had a trial for advanced pancreatic cancer ongoing in Australia and South Korea.
Amplia chief executive officer Dr Chris Burns said "fast track designation for narmafotinib is a significant milestone for the company".
Amplia was up three cents or 28.6 percent to 13.5 cents with 1.4 million shares traded.

WOKE PHARMACEUTICALS

Woke says it will work with the University of Western Australia to develop "novel and active analogues of lysergic acid diethylamide (LSD)".
Woke said that LSD was a hallucinogen, used recreationally since 1938, and had "shown to have meaningful benefit for patients with certain mental health disorders".
The company said Prof Scott Stewart and Dr Michael Nutt had discovered 55 compounds including nine that met the potency and selectivity requirements for 5-HT2A over 5-HT2B.
Woke said that 5-HT2A was the serotonin receptor required for psychedelic effects and 5-HT2B was "an important but unwanted off-target cardiac receptor … which with chronic use is associated with life-threatening side effects including heart valve failure".
"This cardiac toxicity liability is currently shared by all classical psychedelics in use, and engineering new compounds without activity at 5HT2B is a top priority for next-generation drugs," the company said.
Woke said the next stage involved in-vitro pharmaco-kinetic research and it had sent five compounds for pharmaco-kinetic testing, with results expected in four to six weeks.
Woke previously said it was trialing two doses of 'magic mushroom' psilocybin for treatment-resistant depression with WP002 containing 25mg psilocybin; and WP001 with 1.0mg psilocybin for moderate depression (BD: Aug 16, 2022; Jun 21, 2024).
Woke is a private company.

PATRYS

Patrys says its contract development manufacturing organization expects specification testing for PAT-DX1 to be complete "in the first half of October 2024".
In 2021, Patrys said Covid-19 delayed PAT-DX1 manufacturing by six months, and in 2022, said purification of the fermentation process resulted in less drug product than expected, delaying the first clinical study to mid-2023 (BD: Aug 3, 2021; Jan 24, 2022).
Last year, the company said the trial had been delayed to 2024 due to issues relating to the cell line used to produce the drug and later said it would have PAT-DX1 in time for its trial by 2025, and in July said manufacturing run testing would be completed by the end of July 2024 one month later than expected (BD: Mar 31; Dec 13, 2023; Jul 1, 2024).
In late July, Patrys said the manufacture had been delayed following "an inconsistency" with one of the processes, and last month, said its manufacturing organization expected testing to be completed in "mid-September 2024" (BD: Jul 29, Aug 29, 2024).
Patrys was up 0.1 cents or 16.7 percent to 0.7 cents.

ANATARA LIFESCIENCES

Anatara says the European Patent Office has granted a patent for its 'Gastrointestinal reprogramming product', or Garp, valid in 19 European counties and the UK.
Anatara said the patent, titled 'GaRP II formulation' would protect its intellectual property until March 2039.
Anatara was up 0.2 cents or 4.35 percent to 4.8 cents.

AUSTCO HEALTHCARE

Austco former executive chair Robert Grey says he has ceased his substantial shareholding in the company.
The Mornington Peninsular, Victoria-based Mr Grey said that on September 18, 2024 he sold 38,874,548 shares for $7,710,099 or 19.8 cents a share.
Earlier this year, Mr Grey said he reduced his shareholding in from 54,504,139 shares (19.18%) to 52,839,950 shares (17.7%) (BD: Mar 13, 2024).
According to its latest filing, Austco had 364,060,863 shares on issue, with Biotech Daily calculating Mr Grey retaining about 3.8 percent of the company.
Austco was up half a cent or two percent to 25.5 cents.

LUMOS DIAGNOSTICS

Sydney's Perennial says it has reduced its substantial shareholding in Lumos from 66,186,221 shares (11.76%) to 59,169,517 shares (10.51%).
Perennial said that between September 13 and 17, 2024 it sold shares, with the single largest sale on September 17 of 1,760,996 shares for $58,336 or 3.3 cents a share.

GENETIC SIGNATURES

Genetic Signatures says Dr Jenny Harry will replace non-executive director Stephane Chatonsky, effective from October 1, 2024.
Genetic Signatures said Dr Harry had more than 25 years' management experience in the biotechnology, diagnostic and pharmaceutical sectors, was a director of Neuren and Aeris Environmental and had been a chief executive officer in companies from start-up to commercialization.
According to Dr Harry's Linkedin page she held a Bachelor of Science, a Diploma of Education and a Doctor of Philosophy from Macquarie University.
Genetic Signatures Mr Chatonsky was resigning to "focus on his other commitments".
Genetic Signatures was up half a cent or 0.7 percent to 69 cents.

CSL

CSL says chief financial officer Joy Linton will replace CSL Behring head Andy Schmeltz as he takes a temporary caregivers leave, effective immediately.
CSL said deputy chief financial officer John Levy would be the interim chief financial officer for the period.
The company said it "fully supports Mr Schmeltz in taking this time away and sends his family our support and best wishes".
CSL fell 84 cents or 0.3 percent to $293.64 with 971,318 shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has formally appointed Michelle Parker as executive director, effective September 20, 2024.

In August, Clarity said it appointed chief clinical officer Michelle Parker as an executive director, with director Rob Thomas resigning, on August 24 (BD: Aug 26, 2024).

Clarity climbed 94 cents or 12.2 percent to $8.64 with 22.4 million shares traded.