



Biotech Daily

Friday April 12, 2019

Daily news on ASX-listed biotechnology companies

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MARKET REPORT

The Australian stock market was up 0.85 percent on Friday April 12, 2019, with the ASX200 up 52.6 points to 6,251.3 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and five were untraded.

Yesterday's 10.3 percent worst, Osprey, was today's best, up two cents or 15.4 percent to 15 cents, with 55,324 shares traded. Antisense, Pharmaxis and Telix climbed more than seven percent; Kazia was up 5.6 percent; Opthea improved 4.5 percent; Ellex and Starpharma were up more than three percent; Alterity (Prana), LBT, Mesoblast, Nanosonics and Polynovo rose more than two percent; with Clinuvel, Pro Medicus and Resmed up by less than one percent.

Uscom led the falls, down 1.5 cents or 9.1 percent to 15 cents, with 121,912 shares traded. Avita lost 8.9 percent; Volpara fell 5.2 percent; Benitec and Proteomics were down more than three percent; Cochlear, Genetic Signatures, Impedimed, Optiscan and Prescient shed more than two percent; Medical Developments was down 1.3 percent; with CSL, Cynata and Neuren down by less than one percent.

[DR BOREHAM'S CRUCIBLE: OSPREY MEDICAL](#)

By TIM BOREHAM

ASX code: OSP

Share price: 14 cents

Shares on issue: 431,797,370 Chess depository instruments (CDIs)

Market cap: \$64.8 million

Chief executive officer: Mike McCormick

Board: John Erb (chairman), Mike McCormick, Andy Jane, Neville Mitchell, Dr Chris Nave, Sandra Lesenfans

Financials (2018 calendar year): revenue \$3.5 million (up 54%), net loss \$24.5 million (up 22.2%), cash \$35.4 million (down 21.4%)

Major shareholders: Brandon Capital Partners 26.9%, Allan Gray 17.1%, Australian Super 7.9%, CM Capital 7.9%, Kinetic Investment Partners 5.9%

Having invented a device to reduce the usage of contrast dye used in x-rays, Osprey is heading to the GPO to spread the message that it's well and truly open for business.

But we're not talking about the General Post Office. For the Minnesota-based Osprey, GPO is an acronym for group purchasing organization - powerful hospital-based procurement bodies that give the healing institutions greater buying power and help them to navigate reimbursement protocols.

In a breakthrough for Osprey's US distribution, the company's Dyevert products are being listed by four GPOs with coverage of half of all US hospitals.

These GPOs include the biggest, Premier, which has 4,000 member hospitals and channels \$US50 billion of annual supply spend.

The Premier tie-up is a shift in focus for Osprey, which to date had been targeting heart specialists and hospitals one by one - a time consuming way of doing things.

Be kind to kidneys

The reason for Osprey's existence is that contrast dyes used in procedures such as stents and angiograms are toxic and thus hazardous to patients with vulnerable kidneys.

So much so, that the dyes induce a specific condition, contrast-induced acute kidney injury (AKI).

About 25 percent of patients are considered vulnerable because they have poor kidney function in the first place.

A catheter-like device, Dyevert recovers a portion of the dye once it has done its job of guiding the cardiac surgeons.

Osprey then followed up with Dyevert Plus, an Ipad-sized screen that monitors the amount of dye going into the patients and measures whether they have exceeded the recommended 'dose'.

Under a printer and cartridge type revenue model, the 'Plus' components are virtually given away: Osprey makes its dough from the \$US350 (\$A491) a pop, single-use Dyevert.

Dyevert/Dyevert Plus is approved by both US and European regulators. In the US, the Food and Drug Administration recognizes Dyevert as the only product that can reduce dye usage.

The mail on the GPO strategy

Osprey has been selling directly in the US since 2015, starting with a sole sales rep in San Antonio but expanding to 27 operatives across 18 sales territories.

Each territory covers 30 to 40 hospitals responsible for 35,000 to 50,000 heart procedures a year.

But it's a hard slog winning doctor advocacy and then persuading the hospital to approve usage (which will only be for the specific surgeon initially).

The GPOs influence hospitals where it counts the most: the bottom line. In the case of Dyevert, that means reducing the cost of readmissions caused by patients contracting acute kidney injury.

Under US healthcare's "patient outcome" based mantra - yes, we hate the term, too - hospitals are not reimbursed for ailments contracted as a result of the hospital visit.

In terms of the hard evidence, Premier kindly did much of the work for Osprey, by analyzing the results of 2.8 million patients who underwent angiographs at 749 member hospitals between 2012 and 2017.

"Premier has the world's biggest data base of costs and complications and can compare hospitalizations," Mr McCormick says.

Shockingly, AKI in the subset of acute patients adjudged to have bad kidneys increased from 18 percent in 2012 to 28 percent in 2017.

Premier assessed the financial burden at \$US1.67 billion.

“They were stunned and we were stunned too,” Mr McCormick says. “That’s why we got a contract with Premier. They understood our value proposition because they looked at their own data.”

The reason for the increased kidney disease rate is rising global obesity and diabetes rates. Another is that angioplasty tools such as stents and wires are improving all the time, so more of these procedures are being carried out relative to bypass surgery.

McCormick says the GPOs don’t handle the goods themselves, but negotiate a contract price with a supplier.

These supply terms are then sent to the hospitals, who continue to deal directly with the supplier.

“It’s not like Costco, the GPOs don’t stock and ship the supplies,” he says.

The Osprey guarantee

Strictly speaking, Osprey lacks formal clinical evidence of Dyevert’s efficacy, after a 2015 trial showed no reduced incidence of kidney disease. But the trial did show 15 percent reduction in dye usage, with no reduction in x-ray image quality.

Along with adequate hydration via a drip and proper screening in the first place, the white coat brigade acknowledges reduced dye usage as a key factor in reducing kidney damage during a procedure.

To win over any doubters, Osprey is offering a money-back guarantee if the devices do not result in at least a cost neutral outcome for the hospitals.

Mr McCormick reckons he’s on safe ground: with each AKI event costing \$US12,000, Dyevert only needs to reduce one such event in every 30 patients for the hospital to be ahead.

That adds up because using Premier’s negotiated discounted Dyevert price of \$US333, the tool would cost just under \$US10,000 for these 30 patients.

So far, Osprey has supplied 13,600 Dyevert units and has never had to repay a hospital.

Mr McCormick says hospitals normally hate buying cutting-edge technology because the promised cost savings rarely materialize. And as the old maxim goes, no one gets sacked for choosing IBM (the proven safe provider).

“With Dyevert it’s easy to track the savings because the data is all there,” Mr McCormick says.

Financials and performance

Osprey posted a calendar 2018 loss of \$US17.5 million (\$A24.5 million) up 22 percent, despite revenue increasing 54 percent to \$US2.5 million (\$A3.5 million).

Sales of Dyevert units increased 57 percent to 7,201.

Osprey sits on cash of \$US25.25 million at December 31, having bolstered its depleting coffers with a November 2018 capital raising that brought in \$14.3 million.

This included a \$10 million placement to Allan Gray, which has emerged as a 14.9 percent shareholder.

Osprey aims to be cash flow positive in late 2021 or early 2022, with the company focusing on the US business despite having the product approvals elsewhere.

“I don’t want to divert money into Europe right now,” he says.

However, Osprey is working on gaining approval from the UK National Institute of Health and Care Excellence, or NICE.

It’s not an easy task. But consent from NICE, which has access to similar acute kidney injury data to Premier, would open the way for Dyevert devices being available in UK National Health Service hospitals.

As for Australia, Osprey plans some pilot programs here, but it’s a hard market to justify given the Boston and New England market alone is bigger.

Since last July, Osprey has signed up 12 new US hospitals, 10 of them via the GPO process.

Osprey shares (Chess depositary instruments) listed in May 2012 at 40 cents. They were as high as 76 cents in August 2015 and are currently trading at record lows, around 13 cents.

Mr McCormick says that given Osprey’s revenues doubled in 2017, investors may have assumed turnover would double again in 2018.

“That was disappointing for me and disappointing for the business,” he says. “I think it (the 57 percent increase) should have been more robust.”

Dr Boreham’s diagnosis:

The Osprey board should expect a torrid time in relation to at least one agenda item at the company’s scheduled AGM in Melbourne on May 8.

That's not because the board isn't doing its best to grow the company per se, but is lowering the performance incentive bar to the last stages of a limbo contest.

Just to explain: three directors were subject to several million performance options with a strike price of 30c, which is now in Darryl Kerrigan "you're dreamin'" territory.

The solution? Re-issue the paper at Osprey's current market valuation. "The board believes that the outstanding out-of-the-money options are no longer effective as performance and retention incentives because they provide little or no value to option holders," the company states in the notice of meeting.

But a hurdle price equivalent to the current lowly valuation? As Eildon's most famous resident Darryl Kerrigan (at least before the fugitive Tony Mokbel) might say: "Fair suck of the sav, cobber." (Translators note: to eat ones' portion of a hot-dog type sausage – colloquial for the John McEnroe "You gotta be kiddin'". An expression of disbelief.)

At last year's Osprey jamboree, around 19 percent of attending holders and 12 percent of the total register opposed a similar motion to refresh the option arrangements for Mr Erb and Ms Lesenfants.

As students of Australian corporate law would know, a 5.0 percent holding is enough to call an EGM and initiate a board spill motion.

But let's not get too Dyeverted by this dubious adjustment of the performance goal posts.

The heartening aspect of the Premier deal for Osprey is that GPOs usually only deal with healthcare giants such as, say, Johnson & Johnson for billions of dollars of hip replacement parts.

A company with a \$US3 million revenue run-rate would normally be told: "There's the door and don't let it hit you on the arse." (Tr: US "ass".)

Even though Osprey's share price hasn't exactly soared like its namesake bird of prey, Mr McCormick says the company is happy to remain exclusively ASX-listed.

"We've found the Australian market to be outstanding and we've never tried to raise funds in the US," he says. "The knowledge of Australian investors about medical devices is very high and it's been a good supportive capital market for Osprey."

We're confident that like 'our' GPO, Osprey will deliver. But like a household awaiting a second-class mail delivery, patience is required.

Mr McCormick cites the experience of ASX-listed devices darling Nanosonics, which took seven years to get from first revenues to breakeven and is now valued at \$1.23 billion.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He's learnt that GPO also stands for Good for Parts Only, which pretty much sums up your columnist.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it has appointed Dr Julie-Anne White as its chief executive officer, effective from May 13, 2019.

The Network said Dr White had translational research and commercialization experience and most recently acted as Deloitte's private business advisor for the Federal Government Entrepreneurs Program for pharmacology, biotechnology and medical technology.

The Bio-Melbourne Network said that previously Dr White worked for Wyeth Pharmaceuticals, Merck, Sharpe and Dohme and Cerebrus.

The Network said that Dr White had been the chief executive officer at Avipep, Salus Technologies and Zingo TX and deputy chief executive officer of the Notting Hill, Victoria-based Cooperative Research Centre (CRC) for Polymers.

The Bio-Melbourne Network said Dr White held a Bachelor of Science from the University of Adelaide, a Master of Science and a Doctor of Philosophy from Kings College London.

NUHEARA

Nuheara says it has launched a direct-to-customer, internet-based, self-care hearing platform.

Nuheara said its online hearing assessments would categorize a person's level of hearing and determine what hearing support was needed, to enable customers to self-assess their hearing needs.

Nuheara chief executive officer Justin Miller said that "people who may be concerned about their hearing had no self-assessment avenue with which to measure it and subsequently, no affordable products to then support themselves".

"This is a wrap-around self-care platform, enabling us to build a direct relationship at the moment in time our customers begin to engage in their hearing health journey," Mr Miller said. "Until now, people who are becoming hearing challenged either had the time-consuming option of visiting a hearing specialist to be tested and fitted for an expensive hearing aid or more frustratingly, simply putting up with the problem."

"According to the Hearing Loss Association of America, this is the major reason people wait 10 years before they seek help once they have noticed hearing loss," Mr Miller said.

"One in six people worldwide are hearing challenged, and most of those fit into the mild-to-moderate category ... [and] until recently, this massive consumer group has been completely underserved by unaffordable and inaccessible products," Mr Miller said.

"For people needing mild to moderate hearing support, traditional hearing aids are prosthetically over engineered for their needs, they are non-functional as lifestyle headsets and cost an average of \$6,000 which then require set-up, tuning and maintenance from an audiologist," Mr Miller said.

"These barriers have demonstrated it's overkill for the category and as a result, most people who need help with their hearing wait too long to get it," Mr Miller said.

"Critically, Nuheara's uptake data [for its hearing and sound filtering ear buds] has proven that we are now supporting hearing customers on average 20 years sooner than the average hearing aid wearer," Mr Miller said.

"With our new program, we're out to remove the barriers to better hearing health: to reach people where they live, with products and technology they can afford, and transform their lives for the better at a much earlier age," he said.

"In a similar way that we assess our hearing customers in our retail partner stores with Iqconnect, we can now do the same consultative assessment process online," Mr Miller said.

Nuheara fell two cents or 2.5 percent to 7.7 cents with four million shares traded.

MEDIBIO

Medibio will vote to grant six directors 14,500,000 options in lieu of directors' fees. Medibio said the meeting would vote to issue Peter Carlisle 4,000,000 options, Claude Solitario 3,000,000 options, Patrick Kennedy 2,600,000 options, with Dr Franklyn Prendergast and Michael Phelps to receive 2,200,000 options each and 500,000 options for retired director Andrew Maxwell.

The company said the options, exercisable at the 30-day volume-weighted average price to the grant date within four years.

Medibio said it previously announced cost reductions including the cessation of cash remuneration of non-executive directors and they had not been remunerated since for services from January 1, 2019 (BD: Jan 20, 2019).

The company said shareholders would vote to adopt the employee incentive option plan. The meeting will be held at Chartered Accountants Australia and New Zealand, Level 18, 600 Bourke Street, Melbourne on May 15, 2019 at 11am (AEST).

Medibio was unchanged at 1.5 cents.

VOLPARA HEALTH TECHNOLOGIES

Volpara says 51,482,213 shares will be released from voluntary escrow on April 27, 2019. Last year, Volpara said the shares would be released from ASX escrow on April 27, 2018 but held in voluntary escrow for 12 months (BD: Mar 15, 2018).

The company's most recent Appendix 3B new issue announcement said Volpara had 179,800,158 shares available for trading on the ASX, with no further shares in escrow. Volpara fell 9.5 cents or 5.2 percent to \$1.74 with 1.3 million shares traded.

MGC PHARMACEUTICALS

MGC says it has an import permit for the UK and purchase orders for its medical marijuana product Cannepil in Australia and the UK.

Last year, MGC said that Cannepil had been approved by the Australian Therapeutic Goods Administration for drug-resistant epilepsy in adults (BD: Oct 11, 2018).

Today, the company said its UK Controlled Drug Import Licence permit to import Cannepil would be managed by distribution partner Lenis.

MGC said its first formal purchase orders of Cannepil in the UK and Australia would be fulfilled in April 2019.

The company said it expected to sign formal agreements with licenced distributors in Australia and the UK in the coming weeks.

MGC was up 0.9 cents or 26.5 percent to 4.3 cents with 27.6 million shares traded.

IMMURON

Empery Asset Management says it has reduced its holding in Immuron from 10,271,535 shares (7.17%) to 8,799,105 shares (6.15%).

The New York-based Empery said it disposed of 1,472,430 shares on April 10, 2019 for undisclosed prices.

In the substantial shareholder notice, Empery said the listed holders of shares included Ryan Lane, Marin Hoe, Empery Asset Management, Empery AM GP, Empery Asset Master, Empery Tax Efficient LP and Empery Tax Efficient II LP.

Immuron was up two cents or 10.5 percent to 21 cents.

[VISIONEERING TECHNOLOGIES](#)

Renaissance Smaller Companies says it has increased its share-holding but been diluted in Visioneering from 12,261,908 shares (6.22%) to 12,848,367 shares (5.17%).

The Sydney-based Renaissance Smaller Companies said that between March 29 and April 9, 2019 it acquired 1,666,667 shares for \$300,000 or 18 cents a share and disposed of 1,394,495 shares for \$136,604 or 9.8 cents a share.

Last year, Visioneering raised \$344,399 of a hoped-for \$3.0 million in a share plan at 18 cents per Chess depository instrument (BD: Sep 12, 2018).

Visioneering was up 0.2 cents or 2.6 percent to 7.8 cents with 2.2 million shares traded.

[ELIXINOL GLOBAL](#)

Elixinol says it has appointed “consumer retail specialist” Greg Ellery as a non-executive director, effective from today.

Elixinol said that most recently Mr Ellery was Asahi Premium Beverages’ Asia Pacific chief executive officer and held executive positions at companies including Spectrum Brands, Polaroid Corporation, Fosters Group and New Balance Athletics.

The company said Mr Ellery was currently a fellow of the Australian Institute of Company Directors and previously was a director of the Melbourne Racing Club.

Elixinol fell 10 cents or 1.9 percent to \$5.26 with 362,250 shares traded.

[GENERA BIOSYSTEMS](#)

Genera says it has appointed Dr Guillermo Elias as corporate development director for North America.

Genera said Dr Elias was the San Francisco-based Iperian’s manager of business development, worked for Next Generation Sequencing, Roche Diagnostics, Genentech and most recently was Corvus Pharmaceuticals’ director of business development.

The company said Dr Elias held a Bachelor of Arts from New Jersey’s Rutgers University and a Doctor of Philosophy from the University of California San Francisco.

Genera was in a suspension at 16 cents.