Biotech Daily

Wednesday March 6, 2019

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: UNIVERSAL BIO UP 14%; PRESCIENT DOWN 8%**

*** OSPREY: 'BREAKEVEN BY 2022'**

*** PRANA: BOSTON LIFE BIOSCIENCES CONTROL, NAME CHANGE EGM**

*** IMMUTEP: '9 OF 24 RESPOND TO IMP321, KEYTRUDA'**

*** ORTHOCELL TO COMPLETE ORTHO-ATI RECRUITMENT BY JULY**

*** REVA FURTHER EXTENDS CAPITAL RAISING SUSPENSION**

*** ZELDA CANNABIDIOL BREAST CANCER BIOMARKER PATENT**

*** CARDIEX BAYER SPHYGMOCOR CONTRACT UP $494k**

*** TELIX TO RELEASE 814k VOLUNTARY ESCROW SHARES**

*** PINNACLE (HYPERION) TAKES 5% OF COCHLEAR**

*** CVC TAKES 13.5% OF UNIVERSAL BIOSENSORS**

MARKET REPORT

The Australian stock market was up 0.75 percent on Wednesday March 6, 2019, with the ASX200 up 46.3 points to 6,245.6 points. Thirteen of the Biotech Daily Top 40 stocks were up, 13 fell, 13 traded unchanged and one was untraded. All three Big Caps were up.

Universal Biosensors was the best, up three cents or 14.3 percent to 24 cents, with 268,753 shares traded.

Imugene and Paradigm climbed more than five percent; Actinogen, Benitec, Clinuvel and Genetic Signatures were up more than three percent; Cochlear, Compumedics, Immutep, Nanosonics and Volpara rose more than two percent; Starpharma was up 1.4 percent; with CSL, Pro Medicus and Resmed up by less than one percent.

Prescient led the falls, down half a cent or 7.9 percent to 5.8 cents with 542,688 shares traded, followed by Orthocell down 7.1 percent to 13 cents with 826,326 shares traded.

LBT fell 4.5 percent; Medical Developments, Opthea and Proteomics lost more than three percent; Airxpanders, Oncosil and Polynovo shed two percent or more, Telix was down 1.4 percent; with Cynata, Kazia and Neuren down by less than one percent.

OSPREY MEDICAL

Osprey chief executive officer Mike McCormick is confident the company's new sales strategy will lead to cash flow breakeven by early 2022.

In Melbourne and Sydney for a non-deal roadshow, Mr McCormick told Biotech Daily that the company had moved from trying to convince individual doctors at individual hospitals of the benefit of the company's Dyevert cardiac dye reduction system to engaging with group purchasing organizations (GPOs) which had multiple hospitals on their books.

Mr McCormick said the largest GPO in the US was Premier and the company understood the cost benefit of both dye reduction as well as the reduction in contrast induced acute kidney injuries (AKIs).

Mr McCormick said that cardiac dye which had the potential to injure kidneys or exacerbate already damaged kidneys was used in all angiography procedures including diagnostic imaging and coronary stent operations.

He said that in the US there were six million procedures a year, of which 1.3 million patients had "a bad kidney".

Mr McCormick said that data from Premier showed that acute kidney injuries had increased in incidence from 18 percent of patients in 2012 to 28 percent in 2017 and was costing the US healthcare system $US1.67 billion a year.

He said that Premier had "the world's largest data base of costs and procedures" and was able to determine which technologies reduced costs.

Mr McCormick said that the change of strategy meant that instead of having to contact each cardiac surgeon to convince them of the utility of the Dyevert system, the group purchasing organizations would mandate the use of the system to reduce firstly the costs of the wasted dye and then the cost of further injury to the patient.

Mr McCormick said that the company had signed 12 new hospitals in the six months to December 31, 2018, of which five were with Premier, five with a second group purchasing organization and two were hospitals separate from group purchasing organizations and had taken 55 percent, 47 percent and four percent of market share, respectively.

Mr McCormick said that with the hospital administration mandating the use of Dyevert, nurses were able to raise the issue with cardiologists and recommend the use of Dyevert.

Mr McCormick said that Premier had 4,000 member hospitals in the US with a $US50 billion supply chain spend and 1,200 suppliers.

He said that each year, Premier provided 30 'breakthrough technology awards' recognizing leaders across a range of hospital departments and Osprey won the sole award in the cardiac division.

Mr McCormick said that revenue for the year to December 31, 2018 was up 54 percent to $3.5 million and the 22 percent increased loss to $24.5 million primarily related to expenditure on sales and marketing.

He said that he expected Osprey to be cash flow breakeven by late 2021 or early 2022.

Mr McCormick said that with a $10 million investment from Allan Gray Australia, Osprey had $US25 million ($A36 million) in cash and at 11 cents a share, the company had a market capitalization of $48 million.

Mr McCormick said that Osprey was extending its coverage to the whole of the US having started with the Southern States from Texas across to Florida and would then focus on introducing the Dyevert system to Europe.

Mr McCormick said that the company had applied to the UK National Institute of Health and Care Excellence (NICE) and a recommendation would make Dyevert available at all UK National Health Service hospitals.

He said the applications process was likely to take about 12 months.

Osprey was unchanged at 11 cents.

PRANA BIOTECHNOLOGY

Prana says shareholders will vote on resolutions to approve Life Biosciences investing up to $41.8 million for 63 percent of the company and a change of company name.

In its notice of meeting Prana included the independent expert report from FTI Consulting (Australia), which said the potential US takeover was “not fair but is reasonable”.

The notice of meeting said that the Boston-based Life Biosciences LLC proposed to take a 63 percent hold in the company, appoint its co-founders Dr David Sinclair and Tristan Edwards as directors and change the name to Alterity Therapeutics.

The company said that while diluting existing shareholders, the takeover would provide funding for its programs, primarily PBT434, which was in an up-to 48-patient, phase I trial for Parkinson’s disease (BD: Jul 4, 2018).

In late December, Prana said that Life Biosciences agreed to invest up to $US29.4 million ($A41.8 million) (BD: Dec 28, 2018).

Prana said at that time that Life Biosciences would initially invest $US7.5 million ($A10.6 million) at 3.9 cents a share, with two free attaching warrants for each share, after which Prana would raise an additional US$2 million from other investors and a further up to $US21.9 million ($A31.1 million) would be invested by Life Biosciences and other investors on the exercise of the short-term warrants.

Prana chief executive officer Geoffrey Kempler said the funds would “potentially allow us to accelerate our drug development programs”.

Today, Mr Kempler told Biotech Daily that the warrants were exercisable at 4.5 cents each by the end of this year.

“To get the amount of money we need for PBT434 it was clear that we couldn’t raise it locally, nor through traditional capital markets,” Mr Kempler said.

Mr Kempler said that his company knew about Life Biosciences as both founders, Dr Sinclair and Mr Edwards, were Australians.

“We were given an introduction to [Life Biosciences] by one of our directors and they were very interested - primarily in PBT434,” Mr Kempler said.

“So, this has taken six months to December, and since then we have been dealing with compliance and regulatory issues to get to this stage,” Mr Kempler said.

“I think it is a fantastic opportunity for shareholders, for the drug and for Parkinson’s patients, otherwise we wouldn’t have done it,” Mr Kempler said.

The notice of meeting said the first four resolutions were interdependent and if any were not passed by a 50 percent majority, all would be withdrawn, as would the fifth resolution to change the company’s name to Alterity, which would require a 75 percent majority.

Prana said the first four resolutions sought approval for Life Biosciences to take up to 63 percent of Prana; for Life Biosciences to acquire an interest in itself of up to 64 percent; elect Dr Sinclair as a director and elect Mr Edwards as a director.

The company said the sixth resolution sought approval for a prior issue of 17,701,800 shares at 4.67 cents a share to an unrelated party and the seventh and last resolution proposed the approval of up to $US1,421,000 in shares at 3.9 Australian cents a share along with two warrants for every share exercisable at 4.5 cents a share by December 19, 2019.

Prana said that if Life Biosciences appointed a third director and Brian Meltzer resigned, the US company would control the board, with executive chairman Mr Kempler continuing as a director along with Peter Marks and Lawrence Gozlan, while Dr George Mihaly and Pro Ira Shoulson would resign on completing the deal.

The meeting will be held at Level 3, 62 Lygon Street, Carlton, Victoria on April 5, 2019 at 11am (AEDT).

Prana was unchanged at 3.8 cents.

IMMUTEP

Immutep says that nine of 24 patients in its Tactimel phase I trial of IMP321 or eftilagimod alpha with Keytruda for metastatic melanoma had an overall response.
Immutep that one of the 24 patients had a complete response.
The company said data presented at the World Immunotherapy Congress in San Diego on March 5, 2019 showed that six of 18 patients in the dose escalation part A of the trial had an overall response, meaning a reduction in tumor size, with 12 of 18 having a reduction of tumor size or "stable disease".
Immutep said that three of six patients in the second part of the trial had a reduction in tumor size and four had either a reduction or stable disease.
The company said it assessed four cohorts of six patients at doses of 1mg, 6mg and 30mg of IMP321 in combination with Merck Inc's anti-programmed cell death-1 (PD-1) therapy Keytruda, or pembrolizumab.
Immutep said in part A, three cohorts of patients were dosed with Keytruda and IMP321 at three different dose levels in the fifth cycle for six months, and in part B, six patients were dosed with 30mg of IMP321 with Keytruda, starting at cycle 1, day 1 for twelve months.
Last year, Immutep said after three months of IMP321 with Keytruda, three of six patients in part B of the trial had a partial response, and it had shown safety from 18 patients in part A and six patients in part B (BD: Nov 12, Nov 28, 2018).
Today, the company said it showed a disease control rate of 66 percent in both part A and part B of the trial, and showed an overall response rate of 33 percent in part A and 50 percent in part B.
Immutep said IMP321 had a "very favorable" safety profile in doses up to 30mg every two weeks and had no dose-limiting toxicities or new safety signals.
The company said treatment was ongoing in part B for four patients.
Immutep was up 0.1 cents or 2.9 percent to 3.5 cents with eight million shares traded.

ORTHOCELL

Orthocell says it has recruited 17 of 30 patients in its trial of Ortho-ATI for rotator cuff tendinopathy with recruitment to be completed by July 2019.
Orthocell said the randomized, controlled trial would assess the effectiveness of its autologous tenocyte injection (Ortho-ATI) compared to a corticosteroid injection for the tendinopathy, or tear in the shoulder.
Orthocell chief executive officer Paul Anderson said that "demonstrating the efficacy of Ortho-ATI for the treatment of rotator cuff tendinopathy is an important element of our product development and partnering strategy".
"We expect results to show Ortho-ATI is a durable and effective treatment for degenerate shoulder injuries," Mr Anderson said.
Orthocell fell 0.1 cents or 7.1 percent to 13 cents.

REVA MEDICAL

Reva says it has requested a further extension for its voluntary suspension pending an announcement of "an accurate update on its capital raising efforts".
Last week, Reva requested an extension on its voluntary suspension, following its initial request for voluntary suspension and February 18, 2019 capital raising trading halt (BD: Feb 18, Feb 25, 2019).
The company said it expected suspension to last until March 13, 2019.
Reva last traded at 17 cents.

ZELDA THERAPEUTICS

Zelda says it has been granted an Australian patent for its HER2 and CB2R endo-cannabinoid receptor biomarker for breast cancer.
Zelda said the patent, titled 'Prognostic method and kits useful in said method' would protect it until 2038.
The company said the method used a HER2 and CB2 novel receptor complex as a prognostic marker for HER2-positive breast cancer.
Zelda chief executive officer Dr Richard Hopkins said the patent "supports Zelda's strategy of building a world-class intellectual property portfolio and the development of cannabis-based products".
"Prof Sanchez's discovery of a novel prognostic biomarker will complement our ongoing efforts develop to cannabis-based medicines to treat breast cancer," Dr Hopkins said.
Zelda was unchanged at 5.6 cents with 1.7 million shares traded.

CARDIEX

Cardiex says Bayer AG has expanded by $494,000 a contract to supply of its Sphygmocor central blood pressure monitor in a phase IIa trial for congestive heart failure.
Cardiex said its original contract with the Leverkusen, Germany-based Bayer AG included the supply of its Sphygmocor cardiovascular monitoring system in trial sites across Europe.
The company said the expansion would extend the trial to 10 countries and 20 new trial sites, beyond the initial 18 to 24 months and would require an increase in Sphygmocor systems and data management services.
Cardiex fell 0.3 cents or 5.45 percent to 5.2 cents with 13.9 million shares traded.

TELIX PHARMACEUTICALS

Telix says that 814,189 shares will be released from voluntary escrow on March 24, 2019.
Telix said the shares were held under escrow in relation to the acquisition of Advanced Nuclear Medicine Ingredients SA (ANMI) (BD: Jan 20, 2019).
The company said it would release 2,442,565 shares from voluntary escrow on December 24, 2019 and 2,834,051 shares on December 24, 2020.
The company's most recent Appendix 3B new issue announcement said that Telix had 150,973,923 shares available for trading on the ASX, including the voluntary escrow shares, with a further 67,391,913 shares held in ASX mandatory escrow.
Telix fell one cent or 1.4 percent to 69 cents.

COCHLEAR

Pinnacle Investment Management Group says it has become a substantial shareholder in Cochlear with 2,955,885 shares or 5.12 percent of the company.
The Brisbane-based Pinnacle Investment said that it bought the shares between October 31, 2018 and February 28, 2019, with a single largest purchase of 60,736 shares for $10,340,092 or $170.25 a share.
Yesterday, Hyperion Asset Management, owned by Pinnacle, said it became a substantial shareholder with 2,931,961 shares or 5.08 percent of the company (BD: Mar 5, 2019).
Cochlear climbed $4.58 or 2.6 percent to $178.08 with 412,562 shares traded.

UNIVERSAL BIOSENSORS

CVC Limited says it has increased its substantial holding in Universal Biosensors from 21,944,614 shares (12.41%) to 23,820,765 shares (13.455%).

The Sydney-based CVC said that between October 11, 2018 and March 5, 2019 it purchased the 1,876,151 shares on-market for $398,308, or 21.2 cents a share.

Universal Biosensors was up three cents or 14.3 percent to 24 cents.