Biotech Daily

Wednesday May 17, 2017

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: GENETIC SIGS UP 7.5%, NEUREN DOWN 6%**

*** REVA POSTS POSITIVE 12-MONTH FANTOM STENT DATA**

*** CARDIOLOGIST HITINDER GURM: 'OSPREY DIVERT REDUCES DYE 40%'**

*** PARADIGM PPS EQUALS HAY FEVER STEROIDS WITHOUT SIDE-EFFECTS**

*** CHINA ORDERS $3m COMPUMEDICS SLEEP, NEURO SYSTEMS**

*** SIRTEX REQUESTS 'META-STUDY, SIRVENIB RESULTS TRADING HALT'**

*** AUSCANN, TASMANIAN ALKALOIDS $15m JOINT MARIJUANA OPIATE HALT**

*** PHARMAUST PATENT FOR MONEPANTEL NON-CANCER USE**

*** MEDIBIO, VITAL CONVERSATIONS 2nd 'MENTAL HEALTH CHECK-IN'**

*** RESPIRI SWAPS LEON L'HUILLIER OPTIONS, COMPANY SECRETARIES**

*** REGAL FUNDS INCREASE, DILUTED TO 10% OF ONCOSIL**

MARKET REPORT

The Australian stock market fell 1.1 percent on Wednesday May 17, 2017 with the ASX200 down 64.5 points to 5,786.0 points. Fourteen Biotech Daily Top 40 stocks were up, 12 fell, 12 traded unchanged, including Reva trading one solitary share, and two companies were untraded. All three Big Caps fell.

Genetic Signatures was the best, up three cents or 7.5 percent to 43 cents with 23,254 shares traded. Actinogen climbed 5.3 percent; Benitec was up 3.2 percent; Mesoblast and Viralytics rose more than two percent; Avita, Compumedics, Factor Therapeutics, Psivida and Sirtex were up more than one percent; with Ellex, ITL, Medical Developments and Pro Medicus up by less than one percent.

Neuren led the falls, down 0.4 cents or 5.9 percent to 6.4 cents with 1.3 million shares traded. Uscom lost five percent; Living Cell fell four percent; Admedus, Impedimed and Pharmaxis were down more than three percent; Bionomics, Cochlear and Orthocell shed more than two percent; Atcor, Clinuvel, CSL, Nanosonics and Osprey were down more than one percent; with Resmed down 0.65 percent.

REVA MEDICAL

Reva says that 12-month data from its 240-patient Fantom stent trial shows “a very low … rate of major adverse cardiac events” and late lumen loss “in the desired range”.

Last year, Reva published six-month data on the Fantom bio-resorbable, drug-eluting coronary stent showing a 2.1 percent major adverse cardiac events rate and a final in-scaffold late lumen loss - the difference between the vessel diameter at stenting and at follow-up - for the 117 patients in cohort A of 0.25mm (±0.40 mm), which compared favorably to the rates of commercially available competitive bio-resorbable scaffolds and drug-eluting stents (BD: Nov 1, 2016).

Today, Reva said that data presented at the Paris Course on Revascularization by the Sao Paulo, Brazil-based Institute Dante Pazzanese of Cardiology’s Dr Alexandre Abizaid, showed “a very low 4.2 percent rate of major adverse cardiac events through 12 months, [with] no reported cases of late or very late scaffold thrombosis to date”.

The company said that subset angiograms showed a final in-segment late loss of 0.17mm (±0.34mm) at six months and 0.29mm (±0.41mm) at nine months, which was in the desired range of 0.20mm to 0.40mm, which corresponded with positive long-term outcomes for stents and scaffolds.

Reva said that nine-month optical coherence tomography results on a subset of patients showed continued vessel patency and sustained healing with greater than 99 percent strut coverage at nine months.

“These results, sustained through an extended timeframe, provide additional confidence about the future outlook for this next-generation bio-resorbable scaffold,” Dr Abizaid said.

Reva was unchanged at 91 cents.

OSPREY MEDICAL

Independent University of Michigan hospital cardiologist Dr Hitinder Gurm says that one month after adopting Osprey’s divert he has reduced dye use by about 40 percent.

In Melbourne with Osprey chief executive officer Mike McCormick for tomorrow’s annual general meeting, Dr Gurm told a stockbrokers lunch that he did not adopt the first generation Osprey Avert because it didn’t complement his workflow.

Dr Gurm said that something as simple as an extra cable or tube was sufficient to get in the way of stenting a patient, but he adopted the Osprey Divert system one month ago to reduce cardiac dye when stenting patients.

“Divert does not interfere with the workload,” Dr Gurm said. “There is no downside and we are seeing about 40 percent dye reduction, which is clinically meaningful.”

Dr Gurm said that contrast-induced acute kidney injury (CI-AKI) was a growing problem with “more older patients, more diabetes patients, more hypertension patients and more sicker patients” and while severe kidney injury leading to dialysis was rare but when it occurred it was “catastrophic” so reducing contrast-induced kidney injury was critical.

Mr McCormick said that the company was rolling-out the Dyvert cardiac dye reduction system and its Dyvert Plus monitoring system throughout the US and planned to begin sales in Europe by the end of the year, starting with Germany.

Mr McCormick said that the Dyvert machine was provided free to hospitals but the disposable materials for individual patient use cost about $US355 ($A478) each, with the Divert Plus disposables costing a similar amount.

Mr McCormick said that there were 1.3 million chronic kidney disease procedures in the US and Western Europe each year, of which about 20 percent had contrast-induced acute kidney injury, providing a target market worth up to $621.4 million a year for Dyvert alone.

Osprey fell half a cent or 1.2 percent to 41 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says its Rhinosul pentosan polysulfate sodium (PPS) nasal spray is equal to steroid treatment for allergic rhinitis, or hay fever, in guinea pigs, without the side effects.
Paradigm chief executive officer Paul Rennie told Biotech Daily that results published in the journal 'Immunity, Inflammation and Disease' showed that PPS was equal in effect on hay fever to the leading treatment, the intra-nasal cortico-steroid, budesonide.
Mr Rennie said that cortico-steroids nasal sprays could cause thinning of the nasal mucosa leading to bleeding and the formation of nasal polyps with earlier treatments being absorbed systemically causing bone thinning and other unwanted side-effects.
He said that pentosan polysulfate sodium had been shown to be safe and well-tolerated without such side-effects.
Mr Rennie said it was the first time PPS had been shown to be equal to cortico-steroids in efficacy (BD: Sep 16, 2016).
The study, entitled 'Broad Th2 neutralization and anti-inflammatory action of pentosan polysulfate sodium in experimental allergic rhinitis' was authored by researchers at Sweden's Lund University, led by Prof Jonas Erjefalt, and the article is available at: http://paradigmbiopharma.com/investors/peer-reviewed-publications.
Tables in the study showed that PPS and budesonide reduced allergen-induced influx of nasal lumen leukocytes and plasma extravasation equally.
The study concluded that PPS was "a potent Th2 cytokine-binding molecule with biological neutralization capacity and broad anti-inflammatory effects in-vivo".
"As such PPS fulfils the role as a potential candidate molecule for the treatment of [hay fever] and further studies of clinical efficacy seems highly warranted," the study concluded.
Last year, Prof Erjefalt said the data "showed that the anti-inflammatory properties of PPS were as effective as well-known intra-nasal corticosteroid-based treatments".
In March, Paradigm completed treatment in its 80-patient, phase IIa trial of Rhinosul for allergic rhinitis in Sweden, with results expected by late June 2017 (BD: Mar 23, 2017).
Paradigm was unchanged at 62.5 cents.

COMPUMEDICS

Compumedics says it has received purchase orders for sleep and neuro diagnostic systems worth about $3 million from two of its distributors in China.
Compumedics said that between $1 million and $2 million of the orders would be partially shipped by June 30, 2017.
The company said it had more than 1,700 sleep and neuro diagnostic systems installed in China at 535 hospitals and 333 universities, with seven of the top 10 hospitals in China having its equipment.
Compumedics said the new orders included its Grael LT long term electro-encephalogram monitoring and Sleep low-cost systems, opening up the smaller and private practice market in China.
The company said that with orders from its Germany subsidiary DWL gave it an average growth rate in China over the last five years of about 15 percent per year, giving it a "dominant position in China", with more than 2,000 of DWL's trans-cranial doppler systems installed at more than 600 hospitals and 333 universities across China.
Compumedics executive chairman Dr David Burton said the purchase orders "not only generate a minimum of $3 million in new revenue for Compumedics, but confirms China as equally as important a market to the success of the company as the US".
Compumedics was up 0.75 cents or 1.9 percent to 39.75 cents.

SIRTEX MEDICAL

Sirtex has requested a trading halt pending the presentation of four sets of trial results at the American Society of Clinical Oncology meeting in Chicago, tonight.

Sirtex said the halt was required “to provide the company sufficient time to review and assess the implications on the business of the soon-to-be-released clinical data relating to the Sirflox/Foxfire/Foxfire Global and Sirvenib clinical studies”.

The company previously released progression-free survival data from the Sirflox study and said it would combine the Sirflox data with the Foxfire and 360-patient Foxfire Global studies comparing SIR-Spheres with chemotherapy for metastatic colorectal cancer to chemotherapy alone, providing 1,100 patient meta-data on overall survival (Mar 17,2015).

Sirtex said that the Singapore-based Sirvenib trial for hepatocellular carcinoma was the same as the French sorafenib versus radio-embolization in advanced hepatocellular carcinoma (Sarah) trial, except in an Asian population.

Last month, Sirtex said that the 459-patient French Sarah trial failed to meet its primary endpoint of overall survival, but showed that safety, tolerability and quality of life were significantly better for the SIR-Spheres group than the sorafenib chemotherapy cohort (BD: Apr 21, 24, 2017).

Trading will resume on May 19, 2017 or on an earlier announcement.

Sirtex last traded up 16 cents or 1.1 percent at $15.00 with 171,310 shares traded.

AUSCANN GROUP HOLDINGS

Auscann says it has requested a trading halt for a capital raising of up to $15 million for a strategic partnership with opiate producer Tasmanian Alkaloids Pty Ltd.

Auscann chairman Harry Karelis told Biotech Daily that the company expected to raise a minimum of $10 million but hoped for up to $15 million for the collaboration.

The company said that Tasmanian Alkaloids was owned by the New York-based SK Capital Partners and was “one of the world’s largest manufacturers of controlled substances” producing alkaloid raw material for opium poppies grown in Tasmania, producing about 40 percent of the world’s alkaloid raw material crop.

Auscann said it would work with Tasmanian Alkaloids to establish cultivation, manufacturing and distribution operations for medicinal cannabis in Australia and overseas and jointly, the two companies would secure a licence to cultivate and manufacture medicinal cannabis in Tasmania, in addition to its medical cannabis cultivation licence granted last week by the Federal Office of Drug Control.

The company said it would continue to import product from its partner the Smiths Falls, Ontario-based Canopy Growth Corporation (BD: May 19, 2016).

Auscann said that “the inclusion of medicinal cannabis into existing pain management regimes involving opiates resulted in an improvement in pain management and quality of life outcomes, and less adverse side effects” with cannabinoids and opioids sharing several pharmacologic properties and potentially acting synergistically in pain treatment.

Auscann managing-director Elaine Darby said the partnership with Tasmanian Alkaloids “significantly builds on our position within the Australian market as a leading medicinal cannabis company that intends to cultivate, manufacture and supply the Australian market with access to high quality medicinal cannabis products”.

“Tasmanian Alkaloids are the perfect partner and strategic fit for Auscann given their expertise in the cultivation, manufacture and distribution of therapeutic pain products within Australia,” Ms Darby said.

Trading will resume on May 19, 2017 or on an earlier announcement.

Auscann last traded at 58 cents.

PHARMAUST

Pharmaust says that IP (intellectual property) Australia has granted a patent covering monepantel (PPL-1) for non-cancer applications.
Pharmaust said that the patent, entitled 'Compounds For The Treatment Of mTOR Pathway Related Diseases', related to the use of amino-acetonitrile derivatives for the treatment of mTOR pathway-related diseases, including neurodegenerative diseases, diabetes and age-related disorders, until 2033.
The company said that amino-acetonitrile derivatives included the Novartis Animal Health compound Monepantel originally used for roundworm in sheep but trialled by Pharmaust for cancers in dogs and humans (BD: Mar 8, Sep 19, 2016).
Pharaust chief executive officer Dr Richard Hopkins said that in addition to granted patents covering amino-acetonitrile derivatives for cancer the company had "secured a strong [intellectual property] position for these compounds for treatment of non-cancer indications such as neurodegenerative diseases, diabetes and age-related disorders".
"There is increasing evidence that the mTOR pathway plays a major role in these diseases," Dr Hopkins said.
Pharmaust fell 0.2 cents or 2.8 percent to seven cents.

MEDIBIO

Medibio says that with the Perth, Western Australia-based Vital Conversations it would launch the second 'Australia's Biggest Mental Health Check-in'.
Medibio said the Check-in would combine Vital Conversations online assessment of mental health with its "mental wellness diagnostics", previously described as a cardiac rate algorithm for diagnosing major depressive illness.
The company said the partnership was focussed on reducing the $11 billion a year cost to Australian workplaces.
Medibio said that Australia's Biggest Mental Health Check-in aimed to deliver a large scale health initiative using wearable technology and online psychological health software.
The company said that the Check-in would be launched to large corporate customers with a pool of more than 45,000 employees, a four-fold increase in volume on the 2016 Check-in, making it the world's largest scale corporate health initiative using wearable technology and online psychological health software.
Medibio chief executive officer Jack Cosentino said the program "validates our technology's ability to serve an increasing mental health population".
The company said that Broadspectrum, Price Waterhouse Coopers and St John of God Health Care were among investors in the program.
Medibio was up 1.5 cents or 4.6 percent to 34 cents.

RESPIRI (FORMERLY ISONEA, KARMELSONIX)

Respiri says it has proposed to replace executive chairman Leon L'Huillier options exercisable at 28.5 cents with options exercisable at 7.5 cents and 10 cents.
Respiri said it proposed that Mr L'Huillier's 4,000,000 options exercisable at 28.5 cents by November 30, 2019 be replaced with 10 million options exercisable at 7.5 cents by December 31, 2018 and 10,000,000 options exercisable at 10 cents by June 30, 2021, pending shareholder approval at the 2017 AGM.
The company said that FAL Lawyers' Jenni Lightowlers had been appointed company secretary following the resignation of the CFO Solution's Peter Vaughan and Phillip Hains.
Respiri was untraded at five cents.

ONCOSIL

Regal Funds Management says it has increased its holding in Oncosil but has been diluted from 45,454,546 shares (10.98%) to 47,707,780 shares (7.97%).

The Sydney-based Regal Funds substantial shareholder notice said that between February 11, 2016 and February 7, 2017 it bought 6,535,502 shares at prices ranging from nine to 19 cents and sold 4,282,268 shares at prices from nine to 11 cents.

Regal said it was diluted "due to the exercise of options that were issued to [former deputy chairman] Martin Rogers".

The company said the shares were held by UBS AG Australia, and Merrill Lynch International.

Last week, Mr Rogers has exercised 19,000,000 options at five cents each or $950,000 (BD: May 12, 2017).

Oncosil was unchanged at 11.5 cents with 1.4 million shares traded.