Biotech Daily

Monday March 16, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ONCOSIL UP 33%, GENETIC TECHNO DOWN 11%**

*** ONCOSIL EXPANDS INDICATIONS TO LIVER CANCER**

*** REVA IMPLANTS FIRST TWO FANTOM STENT TRIAL PATIENTS**

*** GENETIC SIGNATURES LAUNCHES RESPIRATORY TEST KIT**

*** PHARMAUST RAISES $3m**

*** SIRTEX REQUESTS MAJOR STUDY RESULTS TRADING HALT**

*** ADMEDUS REQUESTS CAPITAL RAISING TRADING HALT**

*** INVION TAKES CAPITAL RAISING HALT TO SUSPENSION**

*** NSW 'WILL BOOST MEDICAL RESEARCH 18% - IF RE-ELECTED'**

*** HYPERION REDUCES BELOW 5% OF COCHLEAR**

*** CB CO, CURRAN SUPER FUND REDUCES TO 11% OF ATCOR**

*** DR CHRISTOPHER HARVEY REPLACES PROGEN DIRECTOR HENG TANG**

MARKET REPORT

The Australian stock market fell 0.29 percent on Monday March 16, 2015 with the S&P ASX 200 down 16.8 points to 5,797.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and five were untraded.

Oncosil was the best, up three cents or 33.3 percent to 12 cents with 26.0 million shares traded, followed by Pharmaxis up 19.05 percent to 12.5 cents with 5.5 million shares traded, IDT up 18.2 percent to 19.5 cents and Anteo up 17.0 percent to 11 cents. Circadian climbed 9.4 percent; Clinuvel was up 7.7 percent; Avita rose three percent; Alchemia, Resmed and Viralytics were up more than one percent; with Osprey and Mesoblast up by less than one percent.

Friday's best, Genetic Technologies led the falls, down 0.5 cents or 10.9 percent to 4.1 cents with 30.1 million shares traded. Phosphagenics lost 8.2 percent; Atcor fell 7.1 percent; Analytica and Universal Biosensors lost more than five percent; Cellmid, Ellex, Neuren and Tissue Therapies fell four percent or more; Acrux, Benitec, Bionomics, GI Dynamics and Starpharma shed three percent or more; Optiscan lost 2.7 percent; Nanosonics was down 1.45 percent; with CSL and Cochlear down less than one percent.

ONCOSIL MEDICAL

Oncosil says it will file an application for Conformité Européenne (CE) mark in both pancreatic and hepatocellular carcinoma, or primary liver cancer, by the end of 2015.

Oncosil said the decision to pursue hepatocellular carcinoma, followed a clinical and regulatory review led by chief executive officer Daniel Kenny and the company would deliver a broader development program, targeting two difficult to treat cancers.

Oncosil said it had previously conducted two pilot clinical studies on the use of its localized radiation therapy treatment in hepatocellular carcinoma.

The company, previously known as Neurodiscovery, acquired the technology from Psivida and renamed the Brachysil technology, invented by executive chairman Dr Roger Aston, Oncosil (BD: Feb 7, Jun 3, 2013).

Oncosil said that the technology was well-tolerated in patients with unresectable hepatocellular carcinoma and indicated that it induced significant reductions in tumor volume in the targeted tumors in the liver.

The company said the pilot study data and the clinical experience in pancreatic cancer demonstrated that the technology platform was capable of use in two solid tumor types.

Oncosil chief executive officer Daniel Kenny said the clinical and regulatory review "highlighted the fact that Oncosil Medical has sufficient clinical data to support a CE mark submission for liver cancer in addition to our original plans for pancreatic cancer".

"Both cancers provide a difficult treatment challenge for oncologists and there is a large unmet medical need for new, viable treatment options in both indications," Mr Kenny said.

"Our goal is to provide a commercially available treatment option for pancreatic and liver cancer patients globally and to explore use of our technology in other solid tumour indications in the future," Mr Kenny said.

Oncosil said that more than 280,000 people would be diagnosed globally with pancreatic cancer this year and treatment was a major unmet medical need with a market potential estimated to exceed $1 billion.

The company said that the median survival after diagnosis with pancreatic cancer was five months and surgery was feasible in 15 percent of patients, with chemotherapeutic treatments working in only one in six patients.

Oncosil said that hepatocellular carcinoma was the sixth most common cancer in the world with 782,000 new cases diagnosed in 2012 and its poor prognosis made it the third leading cause of cancer-related mortality, responsible for about 600,000 deaths a year, with the value of the market expected to triple in size to $1.4 billion by 2019.

The company said that surgery offered the most consistent and significant survival advantage, but fewer than 20 percent of hepatocellular cancer patients were suitable for surgery at time of diagnosis.

Oncosil said that radiation therapy could be used, but had systemic side effects in an already sick patient population, while localized radiation therapy could offer a potential treatment option without systemic side effects.

The company said that its technology was an implantable device that emitted radiation directly into a specific targeted tumor, delivering radiation therapy locally for up to three months and was classed by regulators as a class III medical device, not a drug.

Oncosil said that as a medical device, development studies were undertaken as pilot and pivotal or registration studies and "typically require less clinical trial work for approval, less funding and have a faster time to approval when compared to drug development".

Mr Kenny told Biotech Daily the company expected to file an investigational device exemption to the US Food and Drug Administration for pancreatic cancer by the end of this year.

Oncosil was up three cents or 33.3 percent to 12 cents with 26.0 million shares traded.

REVA MEDICAL

Reva says it has implanted the first two patients in its up to 110-patient Fantom II clinical trial of its Fantom sirolimus-eluting bioresorbable scaffold, cardiac strent.

Reva said that the scaffold was made from its polymer and was designed to allow the restoration of blood flow in patients being treated for coronary artery disease, then resorb from the body over time.

The company said that the trial would enrol patients at multiple sites in eight countries and the data was intended to be used in a Conformité Européenne (CE) mark application by mid-2016.

Reva said that the co-principal investigator at the Sao Paulo, Brazil-based Instituto Dante Pazzanese de Cardiologia Dr Alexandre Abizaid and his team performed the first two implants, one of which was broadcast during a live video satellite transmission at the American College of Cardiology's scientific session and exposition in San Diego, California on March 14 to 16, 2015.

The company said that the live implant involved a patient that had a 70 percent blockage of the left anterior descending artery of the heart and the Fantom scaffold was clearly visible during the procedure, easily delivered to the location of the blockage and expanded to its intended diameter in a standard clinical procedure to restore blood flow.

Reva head of clinical and regulatory affairs Jeffrey Anderson said that Fantom's visibility was "a valuable tool in precisely placing the scaffold and physicians appreciate the ability to deploy the scaffold directly to the desired size without the need for intermediate inflation steps".

Reva was up one cent or 1.9 percent to 53 cents.

GENETIC SIGNATURES

Genetic Signatures says it has launched its Easyscreen respiratory virus detection kit that identifies 15 of the most common respiratory infections.

Genetic Signatures said it had recorded the first sales of the Easyscreen respiratory virus detection kit, which detected multiple viral gene targets, allowing rapid screening of a large number of viral pathogens.

The company said that the multiplex assay was initially available in research use form.

Genetic Signatures chief executive officer Dr John Melki said the kit provided "an efficient and comprehensive system for the daily screening of patient samples".

Dr Melki said that the Easyscreen respiratory virus detection kit could be integrated into existing Easyscreen workflows already in place in pathology laboratories in Australia.

"The introduction of this product will contribute to ongoing growth of our strong domestic base, as we continue expansion into European and US markets," Dr Melki said.

"Our 3-base technology continues to support the goal of accurately screening for a wide array of infectious pathogens, thereby saving time, money and lives," Dr Melki said.

Genetic Signatures said that respiratory viral infections killed an estimated 3.9 million people a year and were one of the top five causes of mortality worldwide particularly in children, the elderly and immuno-compromised persons.

The company said that in addition to increasing the risk of secondary bacterial infections, respiratory viruses cause an enormous burden to health systems through direct medical expenses and indirect productivity losses.

Genetic Signatures said rapid identification of viral respiratory infections is critical in initiating antiviral treatment and limiting the spread of the infection.

Genetic Signatures is a public unlisted company currently undertaking an initial public offer, which has been extended until March 20, 2015 (BD: Nov 20, 2014).

PHARMAUST

Pharmaust says it has raised $3.14 million through an over-subscribed placement of 400 million shares at 0.785 a share to sophisticated and professional investors.
Pharmaust said the initial placement would be under its existing placement capacity with the remainder to be placed, pending shareholder approval.
The company said that the funds were to accelerate its phase I/II PPL-1 cancer trial at the Royal Adelaide Hospital and initiate a phase II trial to investigate PPL-1 in conjunction with chemotherapy standard-of-care in patients with cancer.
Pharmaust said that its wholly-owned subsidiary Epichem had identified a suitable building at Technology Park next to the Perth, Western Australia-based Curtin University which could be fitted out with a laboratory of sufficient size to enable significant growth.
The company said that the proposed facility would remove the existing capacity constraints and enable significant growth in revenues and profitability.
Pharmaust said that the lead manager was Blue Ocean Equities.
Pharmaust was unchanged at 0.9 cents with 10.0 million shares traded.

SIRTEX MEDICAL

Sirtex has requested a trading halt “pending an announcement regarding the company’s Sirflox study”.
Trading will resume on March 18, 2015 or on an earlier announcement.
Last year, Sirtex said it had completed the 500-patient trial comparing its SIR-Spheres with standard-of-care to standard-of-care alone and expects to publish results in June 2015 (BD: Oct 9, 2014).
Sirtex previously said that the trial compared oxaliplatin, leucovorin and 5- fluorouracil (Folfox) against oxaliplatin, leucovorin and 5- fluorouracil with the administration of Sirtex Yttrium-active microspheres in patients with inoperable liver metastases from primary colorectal cancer, or bowel cancer.
The company previously said the primary endpoint was progression-free survival, with secondary endpoints including overall survival, tumor response rate, quality of life and surgical resection rate.
Sirtex last traded at $39.00.

ADMEDUS

Admedus has requested a trading halt “pending an announcement regarding a capital raising”.
Trading will resume on March 18, 2015 or on an earlier announcement.
Admedus last traded at 9.8 cents.

INVION

Invion has requested a voluntary suspension to follow the trading halt requested on March 12, “pending an announcement regarding a proposed capital raising” (BD: Mar 12, 2015).
Invion last traded at 3.9 cents.

NEW SOUTH WALES GOVERNMENT

The New South Wales Liberal Government says that if re-elected on March 28, 2015 it will increase medical research funding by $159 million or 17.7 percent over four years.

A media release from the Minister for Health and Medical Research Jillian Skinner said that “a re-elected Baird Government will break through the billion dollar barrier in medical research over the next four years”.

Ms Skinner said the New South Wales Government invested $900 million in medical research in its first four-year term and if re-elected, it would be increased by $159 million over the next four years.

“Under Labor, medical research was disconnected from the health system, it was an afterthought, but the Baird Government understands medical research is at the very heart of a modern health system,” Ms Skinner said. “Medical research unlocks the secrets of disease, offers hope, delivers cures, keeps people well and out of hospital and profoundly impacts lives for the better.”

Ms Skinner said the additional $159 million would include $70 million in grants for medical research infrastructure; an extra $20 million for the Medical Research Support Program, which provides infrastructure support to independent institutes; a new $40 million Health Services Research Support Program to support research by frontline health clinicians; an extra $19 million to help more locally-developed medical devices reach the market and remain New South Wales-based; $10 million for scholarships for up to 66 doctorate of philosophy and post-doctorate fellowships to support and retain early and mid-career researchers.

“I am passionate about research, especially translational research, which takes ideas from the laboratory bench top to the patient’s bedside,” Ms Skinner said.

COCHLEAR

Hyperion Asset Management says it has ceased its substantial holding in Cochlear, falling below to five percent threshold.

Hyperion said it bought and sold shares between September 8, 2014, and March 9, 2015 reducing its holding by 691,044 shares.

An executive of the company told Biotech Daily that Hyperion held 4.98 percent of Cochlear.

The Brisbane-based Hyperion said it traded the shares on behalf of a large number of holders including superannuation funds and the University of Queensland.

Cochlear fell 34 cents or 0.38 percent to $89.36 with 169,574 shares traded.

ATCOR MEDICAL

CB Co Pty Ltd for the Curran Superannuation Fund says it has reduced its substantial shareholding in Atcor from 22,332,347 shares (14.18%) to 17,800,000 shares (11.31%).

Last September, CB Co said it had reduced its holding in Atcor from 22,332,347 shares (14.18%) to 20,632,347 shares (12.97%) (BD: Sep 13, 2014).

No one from CB Co was available to explain the discrepancy.

The substantial shareholder notice said that the shares were sold on-market with the largest transaction 1,549,400 shares for $325,374 or 21.0 cents a share on March 10, 2015.

The Sydney-based CB Co said that it acted for the Curran Superannuation Fund, which was associated with Capital Investment director Charles Paul Curran.

Atcor fell 1.5 cents or 7.1 percent to 19.5 cents.

PROGEN PHARMACEUTICALS

Progen says that director Heng Tang has resigned and Dr Christopher Harvey has been appointed as an independent non-executive director.

Progen said that former chief executive officer Mr Tang had resigned as subsidiary Pharmasynth managing director and Progen director “to pursue other business interests”.

The company said it thanked Mr Tang for his contribution to the company over the last few years in his executive and non-executive capacity.

Progen said Dr Harvey was currently the chairman of privately owned Australian companies Global Speciality Chemicals Pty Ltd and Healthguard Corporation Pty Ltd which were engaged in the research and development, manufacture and sales of Healthguard which produces a range of anti-bed bug, anti-dust mite, anti-mosquito, anti-bacterial and anti-fungal treatments.

The company said that Dr Harvey held a Diploma in Art and Design, a Bachelor of Science and a Masters of Philosophy in microbiology from the UK’s Bradford University and a Doctorate of Philosophy in organic chemistry.

Progen was untraded at 14.5 cents.