Biotech Daily

Thursday May 14, 2015

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: SIRTEX UP 35%, RESMED DOWN 18%**

*** MELBOURNE UNI HOPE FOR SINGLE LIFETIME 'FLU VACCINATION.**

*** RIDGEBACK INVESTS $15m IN PRIMA, $5m SHARE PLAN**

*** SIRTEX: 'ABSTRACT BACKS SIR-SPHERES LIVER TUMOR REDUCTION'**

*** RESMED FALLS 19% ON SLEEP APNOEA DEVICE-RELATED DEATHS**

*** PHOSPHAGENICS 'MORE WORK NEEDED FOR OXYMORPHONE PATCH'**

*** ITL'S MYHEALTHTEST WINS $1m FEDERAL COMMERCIALISATION GRANT**

*** SIEMENS LAUNCHES UNIVERSAL BIOSENSORS XPRECIA ANALYZER**

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*** ANTISENSE REQUESTS 'ATL1103 LICENCING' TRADING HALT**

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*** EDINBURGH UNI DILUTED TO 8% OF ACTINOGEN**

*** DAVID DOLBY, DAGMAR DOLBY TRUST DILUTED TO 18.5% OF COGSTATE**

MARKET REPORT

The Australian stock market fell 0.32 percent on Thursday May 14, 2015 with the S&P ASX 200 down 18.5 points to 5,696.6 points. Nineteen of the Biotech Daily Top 40 stocks were up, seven fell, 12 traded unchanged and two were untraded.

Sirtex was the best, up $7.02 or 35.1 percent to $27.00 with 3.1 million shares traded, followed by Patrys up 18.2 percent to 1.3 cents with 1.2 million shares traded. Oncosil climbed 10 percent; both Analytica and Circadian rose 6.25 percent; Pharmaxis was up 5.7 percent; Cellmid and Prima were up four percent or more; Starpharma and Universal Biosensors were up more than three percent; Actinogen, Clinuvel, Neuren and Optiscan rose two percent or more; Admedus and Bionomics were up more than one percent; with Cochlear, Medical Developments, Mesoblast and Nanosonics up less than one percent.

Resmed led the falls, falling as much as 18.9 percent to $6.69 before closing down $1.52 or 18.4 percent to $6.73 with 57.9 million shares traded. Viralytics lost 10 percent; IDT was down 8.9 percent; Psivida fell four percent; Atcor shed 2.3 percent; Acrux, Benitec and Impedimed were down more than one percent; with CSL down half a percent.

THE UNIVERSITY OF MELBOURNE

The University of Melbourne says its researchers have understood how influenza-killing immunity cells memorize distinct strains, which could lead to a single lifetime vaccination.
The University said that the understanding of how killer CD8+ T-cells retain memories of virus strains they encounter could lead to novel cellular memory-implant technologies and hence a single vaccination for a range of influenza strains.
The research, led by the University with China and US collaborators, is entitled 'Recovery from severe H7N9 disease is associated with diverse response mechanisms dominated by CD8+T cells' and was published in the Nature Communications and an abstract is at: http://www.nature.com/ncomms/2015/150513/ncomms7833/abs/ncomms7833.html.
University of Melbourne's Prof Katherine Kedzierska said the Australia-Sino collaboration began during the first outbreak of the avian-derived H7N9 virus in China in 2013, in which 99 percent of people infected were hospitalized, with a 30 percent mortality rate.
The University said that the first patient was an elderly man who caught the virus from a chicken his wife asked him to buy at the local live bird market.
"We'd never seen anything like H7N9," Prof Kedzierska said. "The virus was infecting more people rapidly and nobody had immunity."
Prof Kedzierska said the virus was contained but "we had come face-to-face with a potential pandemic that could kill millions of people around the world".
She said that having collected infected patient samples "we found that people who couldn't make these T-cell 'flu assassins were dying" which led to the potential of moving from vaccines for specific influenza strains to developing a protection based on T-cells.
"From the 30 percent mortality rate in China we knew the clock was ticking on the situation," Prof Kedzierska said. "Had the contagion spread ... we're talking about a history-altering event on the Spanish 'flu scale."
Prof Kedzierska said that boosting the T cell adaptive memory capacity was the way to stop the virus and the breakthrough "could lead to the development of a vaccine component that can protect against all new influenza viruses, with the potential for future development of a one-off universal 'flu vaccine shot."

PRIMA BIOMED

Prima says the US-based Ridgeback Capital Investments will invest $15 million primarily to fund the start of two new clinical trials of IMP321 and provide working capital.
Prima said that Ridgeback was a specialist healthcare investor run by Wayne Holman and the two part investment would see immediate placement of 72,206,500 shares at 1.73 cents each raising about $1.25 million and pending shareholder approval, the investment of about $13.75 million for 10-year 3.0 percent per annum convertible notes converting at 2.0 cents a share, along with 8,475,995 10-year warrants exercisable at 2.5 cents a share and 371,445,231 five-year warrants exercisable at 2.37 cents a share.
The company said the funds would support a phase IIb chemo-immunotherapy trial of IMP321 in combination with paclitaxel to treat metastatic breast cancer in patients not eligible to receive trastuzumab (Herceptin) and a phase I trial of IMP321 in combination with an immune checkpoint inhibitor.
Prima said that the Ridgeback funds would allow for the current Bergen funding facility to be terminated by mutual consent.
The company said that it would offer a share purchase plan to raise up to $5 million.
Prima said that Ridgeback had the right to name a new director and it would issue $US500,000 ($A$630,000) in shares to the new director.
Prima was up 0.1 cents or 4.55 percent to 2.3 cents with 7.7 million shares traded.

SIRTEX MEDICAL

Sirtex says that a Sirflox study abstract published by the American Society for Clinical Oncology shows median progression-free survival in the liver was significantly extended.

The abstract, entitled 'SIRFLOX: Randomized phase III trial comparing first-line mFOLFOX6 ± bevacizumab (bev) versus mFOLFOX6 + selective internal radiation therapy ± bev in patients with metastatic colorectal cancer', is available at: http://abstracts.asco.org/156/AbstView_156_145884.html.

In March, Sirtex fell as much as 62.05 percent to $14.80 on news that SIR-Spheres with chemotherapy "does not result in a statistically significant improvement in the overall progression-free survival" (BD: Mar 17, 2015).

Sirtex said at that time that the 500-patient trial compared its SIR-Spheres with the current standard-of-care, oxaliplatin, leucovorin and 5- fluorouracil (Folfox) to standard-of-care alone for non-resectable metastatic colorectal cancer, with the primary endpoint progression-free survival and secondary endpoints including overall survival, tumor response rate, quality of life and surgical resection rate.

Today, Sirtex said that there was an additional 7.9 months (20.5 months vs 12.6 months; p = 0.002), or a 62.7 percent improvement in median progression-free survival in the liver for patients whose treatment included SIR-Spheres Y-90 resin microspheres and patients whose treatment included SIR-Spheres had a 31 percent lower risk of the tumors in their liver progressing during the time they were on the Sirflox study.

The company said that median overall progression-free survival was 10.7 months in the SIR-Spheres arm compared to 10.2 months for the standard-of-care (p = 0.428) and overall tumor response rate was 76.4 percent in the SIR-Spheres arm compared to 68.0 percent in the Folfox arm (p = 0.113).

Sirtex said the hepatic response rate was 78.7 percent in the SIR-Spheres arm compared to 68.8 percent in the Folfox arm (p = 0.042), with the complete response rate in the liver 6.0 percent for the SIR-Spheres arm compared to 1.9% in the Folfox arm (p = 0.02), indicating that patients receiving SIR-Spheres had a threefold higher rate of complete disappearance of tumors in their liver, compared to those who did not.

The abstract said that of the 530 patients in the trial, 212 or 40 percent had extra-hepatic cancer, implying that 60 percent or 318 patients had metastatic colorectal cancer solely in the liver at randomization, but the abstract did not detail that sub-group's overall survival or progression-free survival.

A spokesman for Sirtex said that while the authors might know that detail, the company did not.

Sirtex said that overall survival data from the study needed to be combined with the Foxfire and Foxfire Global studies to provide sufficient statistical power to detect a clinical significant difference in overall survival between SIR-Spheres and the control arms, which was expected by July 2017.

Sirtex chief executive officer Gilman Wong said the reduction in the risk of tumor progression in the liver was encouraging.

Sirtex said that Royal Melbourne Hospital principal investigator Prof Peter Gibbs would present the Sirflox findings in the Gastrointestinal (colorectal) Cancer Oral Abstract Session at the American Society for Clinical Oncology meeting on May 30, 2015, with "important new information" expected to arise from the Session facilitating "a greater understanding of the implications and impact of the Sirflox study for SIR-Spheres Y-90 resin microspheres in first-line [metastatic colorectal cancer], and how this may apply to clinical practice".

Sirtex said it would host an investor call following Prof Peter Gibbs ASCO presentation.

Sirtex climbed $7.02 or 35.1 percent to $27.00 with 3.1 million shares traded.

RESMED

Resmed fell as much as 18.9 percent on news that its Serve-HF trial showed an increased risk of cardiovascular mortality for patients using its adaptive servo-ventilation therapy.
Resmed said the trial studied adaptive servo-ventilation (ASV) therapy in patients with symptomatic chronic heart failure and predominant central sleep apnoea.
The company said that the study did not show a statistically significant difference between patients treated with ASV therapy and those in the control group, in the primary endpoint of “time to all-cause mortality or unplanned hospitalization for worsening heart failure.”
Resmed said that a preliminary analysis of the data identified a statistically significant 2.5 percent absolute increased risk of cardiovascular mortality for those patients in the trial who received ASV therapy per year compared to those in the control group.
The company said that based on the data, it was working with regulatory authorities to proactively revise the labels and instructions for use for Resmed ASV devices to include a contra-indication for people with symptomatic chronic heart failure with reduced left ventricular ejection fraction below 45 percent.
Resmed said that revenue from the ASV flow generators for the 12 months to March 31, 2015, was “less than seven percent of our total revenue” with about 25 percent of the ASV flow generators prescribed for patients with symptomatic chronic heart failure with reduced left ventricular ejection fraction.
The company said that ASV devices were “less than two percent” of flow generator devices shipped to customers so about 98 percent of the flow generator field population would not include this contraindication.
Resmed said it expected to incur costs associated with the field safety notification in the three months to June 30, 2015.
Resmed closed down $1.52 or 18.4 percent to $6.73 with 57.9 million shares traded.

PHOSPHAGENICS

Phosphagenics says “additional specialized formulation work” will needed for its tocopheryl phosphate mixture (TPM) oxymorphone patch can be progressed in the clinic.
Phosphagenics said that external consultants had reviewed its patch development program and following clinical trials showing that the TPM-oxymorphone patch could deliver blood levels of oxymorphone corresponding to the therapeutic levels seen with oral dosing, a further three critical path non-clinical studies had been completed, assessing the development and commercial readiness of the patches made during the recently completed technical transfer process.
The company said that the review of the non-clinical trials concluded that additional specialized formulation work would need to be completed before the patch could be progressed further in the clinic.
Phosphagenics said that it would engage an external group with expertise in patch development for this process and the reformulation was expected to delay lodging an investigational new drug application and phase II trial planned for the US by more than 12 months.
In 2010, Phosphagenics hired the Minnesota-based 3M to develop its oxycodone patch, in 2011 said it was ready for trials, in 2012 said the adhesive caused crystallization and took it to Germany’s Labtech GmbH (BD: Nov 16, 2010; Sep 19, 2011; May 23, Jun 5, 2012).
Today, the company said that its topical oxycodone patch was in phase II trials, the number of patients dosed was increasing each month and the trial was on-track to be completed by the end of 2015.
Phosphagenics fell 0.7 cents or 25 percent to 2.1 cents with 20.1 million shares traded.

ITL

ITL says the Department of Industry and Science has awarded investee company Myhealthtest Pty Ltd an Accelerating Commercialisation grant of up to $1 million.
ITL is in the process of acquiring Myhealthtest and in April said it expected to acquire the related-party consumer pathology test provider, for up to $3,350,000 through a series of milestone-based call options (BD: Apr 29, 2015).
ITL said at that time that chairman Bill Mobbs owned 67 percent of Myhealthtest.
Today, ITL said the grant was for the commercialization of dry blood spot pathology testing and the funds were 40 percent of the approved budget for the project.
The company said that Myhealthtest was “one of the first entrants into the direct to consumer pathology testing market” and the grant would drive and underpin its growth.
ITL said that customers would order a home test kit online, receive it by post or collect it from a local pharmacy or general practitioner, return the sample and they and their doctor would receive the test results through a secure online portal.
The company said that Myhealthtest would serve chronic health conditions that require regular blood testing such as diabetes and cardiovascular disease.
ITL said it would launch an HbA1c blood glucose test to diagnose and manage diabetes and the grant would enable it to accelerate the launch of its tests for thyroid and prostate conditions and help establish advanced laboratory test processing facilities.
“[Myhealthtest] is already poised to launch its first test in the diabetes sector which we are now even more confident will provide the springboard for its expansion into testing for other chronic diseases in 2016,” Mr Mobbs said.
ITL was up 1.5 cents or 6.5 percent to 24.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says that Siemens Healthcare Diagnostics has launched the co-developed Xprecia Stride Coagulation Analyzer.
Universal Biosensors said the commercial launch followed the limited European release and the system would be marketed through Siemens sales and distribution network, excluding the US which required US Food and Drug Administration 510(k) clearance.
The company said that the Xprecia Stride Coagulation Analyzer had won the Red Dot Award for Product Design for 2015.
Universal Biosensors said the Xprecia Stride Coagulation Analyzer delivered hand-held prothrombin time, international normalized ratio (PT-INR) testing for point-of-care monitoring and management of the oral anticoagulation therapy Warfarin.
The company said that the Analyzer was designed to meet the demand for fast and reliable PT/INR results in physician offices and walk-in clinics to help healthcare professionals make informed decisions about patient care.
Universal Biosensors said it would manufacture the PT/INR strips for Siemens at its plant in Rowville, Victoria.
Universal Biosensors chief executive officer Paul Wright said the company was “thrilled that the limited release has gone well and that Siemens will now be rolling out the Xprecia Stride Coagulation Analyzer”.
Mr Wright told Biotech Daily that his company had received a $US1,000,000 milestone payment from Siemens for the European launch, there were several more milestone payments expected from the Siemens relationship and the company would receive a volume-related payment in the range of 50 US cents to $US1.50 per strip.
Universal Biosensors was up one cent or 3.6 percent to 29 cents with 1.1 million shares traded.

REVA MEDICAL

Reva says it has begun a search for a chief executive officer with expertise in bringing medical device products to market and leading a publicly traded company.

Reva said that the search was to support its transition from a clinical-stage organization to a company preparing for commercialization, as well as a Nasdaq or other securities exchange listing at an appropriate time.

The company said that co-founder, chairman and chief executive officer Robert Stockman would continue as chief executive officer until his successor had been chosen and following the appointment Mr Stockman would remain chairman and help oversee the transition.

Mr Stockman told Biotech Daily he co-founded the company 17 years ago and had been chief executive officer for five years, but he had no experience in commercial sales of cardiac medical technologies.

Mr Stockman said that while large cardiac companies might be interested in acquiring Reva, the company needed to prepare for entering the stent market in its own right.

“We are preparing to be a stand alone commercial entity to market the Fantom scaffold and to develop our pipeline of products for future uses,” Mr Stockman said.

In a media release, Mr Stockman said that “to ensure we are positioned for success, Reva requires a leader with expertise in overseeing regulatory approvals in Europe and the United States and building a world-class commercial organization”.

I view this as a natural evolution and believe it reflects the quality and progress of our technology and the market opportunity that awaits Reva,” Mr Stockman said.

Reva said it was currently evaluating the Fantom sirolimus-eluting bioresorbable scaffold in the Fantom II clinical trial, which began enrolling patients in March, and was underway in multiple countries (BD: Mar 16, 2015).

Reva was unchanged at 51 cents.

ANTISENSE

Antisense has requested a trading halt “pending an announcement in relation to the out-licencing of ATL1103” (BD: Dec 9, 2014).

Trading will resume on May 18, 2015 or on an earlier announcement.

Antisense last traded at 15 cents.

RHINOMED

Rhinomed has requested a trading halt pending an announcement “in relation [to] European sales of its Mute product”.

Trading will resume on May 18, 2015 or on an earlier announcement.

Rhinomed last traded at 2.7 cents.

ACTINOGEN

The University of Edinburgh says its Edinburgh Technology Fund’s 48,147,864 shareholding in Actinogen has been diluted from 10.76 percent to 8.06 percent.

Last year, the University said that it received the shares in consideration for 6,265 shares in Corticrine on November 28, 2014 (BD: Dec 8, 2014).

Last month, Actinogen raised $10 million at 9.5 cents a share, with a share plan for a further $1.0 million due to close today, May 14, 2015 (BD: Apr 24, 2015).

Actinogen was up 0.2 cents or 2.4 percent to 8.6 cents with 1.6 million shares traded.

COGSTATE

The Dagmar Dolby Trust a related entity of director David Dolby, has had its 19,776,389 share holding reduced from 19.98 percent to 18.47 percent in this week's placement.
On May 12, 2015, companies associated with newly-appointed director Dr Alan Finkel bought 8,000,000 shares at 25 cents a share raising $2 million (BD: May 12, 2015).
Cogstate fell two cents or 7.4 percent to 25 cents.