Biotech Daily

Monday March 7, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: IDT UP 10%, USCOM DOWN 15%**

*** FDA APPROVES CSL'S IDELVION FACTOR IX FOR HAEMOPHILIA B**

*** RESAPP, UNIQUEST COLLABORATION TRIALS PNEUMONIA DIAGNOSTIC**

*** CLARIFICATION: BAXALTA**

*** FDA ALLOWS AVITA RECELL COMPASSIONATE USE FOR 36 PATIENTS**

*** ANTISENSE REQUESTS 'ATL1103 PROGRAM' TRADING HALT**

*** POTENTIAL PARTNER PROMPTS 2nd PROTEOMICS PROMARKERD STUDY**

*** PRIMA BELOW $US1 NASDAQ NON-COMPLIANCE**

*** EGM LOSS TRIGGERS BIONOMICS 'SHAREHOLDER CONSULTATION'**

*** ALCHEMIA APPOINTS KENTGROVE FOUNDER DAVID LAMM DIRECTOR**

*** AUSBIOTECH REMINDER CALL FOR ASIA INVESTMENT PRESENTERS**

MARKET REPORT

The Australian stock market was up 1.04 percent on Monday March 7, 2016 with the ASX200 up 52.8 points to 5,142.8 points. Sixteen of the Biotech Daily Top 40 stocks were up, 14 fell, seven traded unchanged and three were untraded.

IDT was the best, up 2.5 cents or 9.6 percent to 28.5 cents with 145,559 shares traded. Atcor climbed 6.1 percent; Genetic Technologies was up 5.3 percent; Nanosonics was up 3.3 percent; Admedus, Avita, Orthocell, Prima, Pro Medicus and Starpharma rose more than two percent; Actinogen, Bionomics, Biotron, Medical Developments and Opthea were up more than one percent; with Acrux, Cochlear and CSL up by less than one percent.

Uscom led the falls, down 2.5 cents or 15.15 percent to 14 cents with 3,000 shares traded.

Tissue Therapies lost 9.1 percent; Polynovo fell seven percent; Oncosil was down 6.25 percent; Clinuvel and Living Cell were down more than five percent; Compumedics and Neuren fell more than four percent; Mesoblast, Sirtex and Viralytics lost more than three percent; Universal Biosensors shed 2.6 percent; Ellex and Impedimed were down more than one percent; with Resmed down 0.6 percent.

CSL

CSL says that the US Food and Drug Administration has approved Idelvion coagulation factor IX for treatment of haemophilia B.

CSL said that Idelvion, formerly known as CSL654, was a long-acting albumin fusion protein-linking recombinant coagulation factor IX with recombinant albumin.

Last week, the European Committee for Medicinal Products for Human Use recommended marketing authorisation of Idelvion for haemophilia B (BD: Feb 29, 2016).

Today, CSL said that Idelvion was the first and only factor IX therapy to deliver high-level protection with up to 14-day dosing in appropriate patients, while maintaining high levels of factor activity, above five percent over 14 days at 75 international units per kilogram (IU/kg), reducing the monthly number of units needed for prophylaxis therapy.

CSL, chief scientific officer and research and development director Dr Andrew Cuthbertson said that Idelvion had “the potential to significantly impact the treatment of haemophilia B as it maintains factor IX activity levels above five percent over a prolonged period of time”.

“This provides excellent bleeding control,” Dr Cuthbertson said.

“Idelvion is the first product from our innovative recombinant factor development program to receive FDA approval,” Dr Cuthbertson said.

CSL said that Idelvion was indicated in the US for children and adults with haemophilia B for routine prophylaxis to prevent or reduce the frequency of bleeding episodes, on-demand control and prevention of bleeding episodes and the perioperative management of bleeding, that is, around the time of surgery.

The company said Idelvion was expected to be available in the US this month.

CSL said that haemophilia B was a congenital bleeding disorder affects about one in 25,000 primarily male births and was characterized by deficient or defective factor IX.

The company said that people with haemophilia B might experience prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs.

CSL was up 58 cents or 0.6 percent to $103.15 with 917,463 shares traded.

RESAPP HEALTH

Resapp says it has a non-binding agreement with a humanitarian organisation and Uniquest to test its pneumonia diagnostic tool in the developing world.

Resapp said it was restricted from disclosing details of the unnamed organization but said it was “a very large organization with a global presence … in the provision of health services throughout the developing world”.

The company said that with the organization and the University of Queensland’s main commercialisation company Uniquest, it would to secure one or more field sites in the developing world and subject to local ethics approval those sites were expected to be established “in mid-2016”.

Resapp said that pneumonia killed more than 950,000 children under five every year, the vast majority in South Asia and sub-Saharan Africa, with many of the deaths caused by delays in diagnosis due to the lack of high quality medical care.

Resapp chief executive officer Dr Tony Keating said his company was “very excited to collaborate with a global leader in the provision of health services throughout the developing world”.

“Not only will we perform a field trial to gather additional clinical evidence, but we will also develop an in-depth understanding of the difficult environments in which their personnel operate and refine our application to suit,” Dr Keating said.

Resapp was up half a cent or 2.9 percent to 18 cents with 12.5 million shares traded.

BAXALTA AUSTRALIA NEW ZEALAND

Last week Baxalta Australia New Zealand medical affairs director Dr Sabina Furber said that there were 5,385 patients on the Australian Bleeding Disorders Registry in 2013-'14, but only 1,487 patients received treatment and most were treated at specialist centres that provided "comprehensive care" (BD: Mar 3, 2016).

Today, a spokesperson for Baxalta said that access to treatment was available to all Australian bleeding disorder patients, but treatment for haemophilia was "dependent on the severity of the disease and not all patients need treatment at all times".

No sub-editors were hurt in making this clarification.

AVITA MEDICAL

Avita says that the US Food and Drug Administration has provided a second expansion of its Recell compassionate use program from 24 to 36 patients.

Avita said that under the compassionate use investigational device exemption Recell could be used for patients with insufficient healthy skin available for standard skin grafting of their injury.

The company said that the exemption allowed the use of Recell beyond burns to larger, more serious defects than those studied in the US pivotal trial.

In 2014, the FDA gave Avita permission for the compassionate use of Recell for 12 patients, which it increased last year to 24 patients (BD: Apr 10, 2014 Oct 5, 2015).

Avita chief executive officer Adam Kelliher said that second approval from the FDA to expand the number of compassionate use cases was "another mark of validation for the technology, particularly as we continue our pivotal US trial for Recell in burns, for which we recently completed enrolment".

"This expansion allows for the opportunity to treat even more patients who have no other alternative treatment options with Recell for a catalyzed, effective regenerative healing effect that may lead to potentially life-saving outcomes," Mr Kelliher said.

Avita said that to date, 23 patients had been enrolled in the investigational device exemption program and treated with Recell.

Avita was up 0.2 cents or two percent to 10 cents.

ANTISENSE

Antisense has requested a trading halt "pending an announcement in relation to the ATL1103 program".

Last year, Antisense licenced ATL1103 to the then Trevose, Pennsylvania-based Cortendo AB, now known as Strongbridge, for an upfront fee of $6.2 million and up to $131 million for the rights to ATL1103 for endocrinology applications, including acromegaly (BD: May 15, 2015).

Antisense managing director Mark Diamond told Biotech Daily at that time that Cortendo would pay for all further development of ATL1103 for endocrine applications, while Antisense would retain the rights for all other indications as well as the commercialization rights of ATL1103 for endocrine applications in Australia and New Zealand.

Antisense has previously investigated ATL1103 for diabetic retinopathy, nephropathy and some forms of cancer (BD: Oct 12, 2009; Apr 11, 2011).

Trading will resume on March 9, 2016 or on an earlier announcement.

Antisense last traded at 5.5 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says that partnering discussions have led to a 500-patient study of its proteomics-derived predictive test for the diagnosis of diabetic kidney disease.
Proteomics said that last year's study of 576 patients showed that Promarkerd could predict which diabetic patients would progress to a significant decline in kidney function better than any other measure and which people with apparently healthy kidney function as measured by conventional tests were at risk of kidney problems (BD: Jun 9, 2015).
Today, Proteomics said that it was in discussions with a number of diagnostic and pharmaceutical companies in the US, Europe, Japan and Latin America for the commercialization of Promarkerd and one health care company and potential partner requested follow-up validation studies to confirm the initial results.
The company said that the aim of the study on an independent cohort of 500 patients with diabetes was to apply its predictive algorithm to further validate the Promarkerd, and in parallel, advance its application as a laboratory developed test.
Proteomics said that both studies used patients from the Fremantle Diabetes Study in Western Australia, "one of the largest on-going diabetes studies globally".
The company said that it would undertake a cross-centre analysis on the samples, using an independent third-party laboratory and different types of instrumentation.
Proteomics said that the potential partner was "in the process of providing an additional international patient study cohort, with the aim of demonstrating the robustness of Promarkerd across different geographical regions".
The company said that it would begin its own development pathway for Promarkerd with aim of developing a commercial-ready clinical pathology in-vitro diagnostic test kit and it had begun to source antibodies needed for a multiplex enzyme-linked immunosorbent assay (Elisa), the precursor to an in-vitro diagnostic test.
Proteomics said that it had multiple, commercialisation pathways for Promarkerd as a laboratory developed test, in-vitro diagnostic and companion diagnostic.
Proteomics was unchanged at 25 cents.

PRIMA BIOMED

Prima says it has been notified by the Nasdaq that it is non-compliant with the rule that listed securities maintain a minimum bid price of $US1.00 per share.
Prima said that notification had no effect at this time on the listing of its American depositary shares (ADSs) which would continue to trade under the symbol PBMD.
The company said that its ASX shares were in compliance with ASX listing requirements and were completely independent of the Nasdaq listing.
Prima said it would "actively monitor the bid price for its ADSs and will consider all available options to regain compliance with the … minimum bid price requirement".
The company said it had 180 days, until August 29, 2016, to regain compliance with the minimum bid price requirement and if its closing bid was at least $US1.00 for at least 10 consecutive business days, Nasdaq would provide the company a written confirmation of compliance and the matter would be closed.
Prima said that in the event that it did not regain compliance, it might be eligible for an additional 180 calendar days' extension to regain compliance.
Prima said that if the Nasdaq concluded that it would not be able to cure the deficiency or if the company was otherwise not eligible, the ADSs would be subject to delisting.
Prima was up 0.1 cents or 2.5 percent to 4.1 cents with 1.3 million shares traded.

BIONOMICS

Bionomics says it has begun “a consultation process to consider the views of shareholders as to the governance arrangements and future direction of the company”.
Last week, Bionomics extraordinary general meeting defeated four resolutions offering 16,082,988 options over shares to CVI Investments, Empery Asset Master, Sabby Healthcare and Biotechnology Value Fund, exercisable at 59.38 cents a share within five years of issue (BD: Mar 3, 2016).
Last year, Bionomics raised $US12 million ($A16.4 million) through the issue of 40,207,472 shares at 40.8 cents a share in a private placement to four US institutional investors when the company had been trading around 48 to 50 cents (BD: Dec 8, 2015).
Today, Bionomics said it was “working to bring additional skills to the board through an on-going recruitment process” and it had appointed the New York-based Greenhill & Co to assist the consultation and the findings would take about one month.
Bionomics was up half a cent or 1.7 percent to 30.5 cents.

ALCHEMIA

Alchemia says that Kentgrove Capital founder and managing director David Lamm as a non-executive director.
Last week, Kentgrove became a substantial shareholder in Alchemia with 64,619,996 shares or 19.9 percent (BD: Mar 4, 2016).
Today, Alchemia said that Kentgrove was an investment management firm with a focus on small and micro-cap Australian stocks.
The company said that Mr Lamm was currently the executive chairman of New Guinea Energy and previously was portfolio manager at the Melbourne-based Alter Family Office.
Alchemia said that Mr Lamm had a background in investment banking and management consulting with roles at Credit Suisse and Bain & Co.
Alchemia appointed Simon Gennari as chairman last week (BD: Feb 29, 2015).
Alchemia was unchanged at 0.8 cents with 3.7 million shares traded.

AUSBIOTECH

Ausbiotech’s says its 2016 Asian investment series begins in Singapore on May 3, with the Asia Biotech Invest meeting in Hong Kong on May 5 and 6, 2016.
Ausbiotech said that it was expecting more than 350 delegates from the global investment industry across both events, as well as biotechnology industry professionals and potential joint ventures partners.
The industry organization said that presentation places were available at both events, including a few places on day one in Hong Kong.
Ausbiotech said that as a company presenter in Hong Kong a company would have a table within the conference exhibition area to set up meetings with potential investors through the online business partnering system.
For further information or to secure a place as a company presenter, contact investment events coordinator Amelia Lundstrom by email: alundstrom@ausbiotech.org or telephone: +61 3 9828 1435.