Biotech Daily

Wednesday June 17, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ANALYTICA UP 10%, LIVING CELL DOWN 13%**

*** WEHI GENE DISCOVERY HOPE FOR MUSCULAR DYSTROPHY**

*** CSL TO PRESENT RAFT OF DATA ON HAEMATOLOGY PORTFOLIO**

*** ATCOR RAISES $2.2m, 1-FOR-10 RIGHTS ISSUE FOR $3.2m MORE**

*** PHARMAUST TAKES PPL-1 DOG CANCER TRIAL TO COMBINATION DOSE**

*** USPTO ALLOWS AVITA COMPOSITION OF MATTER PATENT**

*** MEDIBIO 'VALIDATES HEART RATE STRESS TEST'**

*** CHAIRMAN DAVID WILLIAMS BUYS 2m POLYNOVO SHARES**

*** BIO-MELBOURNE 'THINK GLOBAL' BIO-BREAKFAST**

*** RACI DINNER - DR PAUL MACLEMAN: LIFECYCLE OF A MOLECULE**

MARKET REPORT

The Australian stock market climbed 1.08 percent on Wednesday June 17, 2015 with the S&P ASX 200 up 59.6 points to 5,595.4 points.

Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and four were untraded. All three Big Caps fell.

Analytica was the best, up 0.1 cents or 10 percent to 1.1 cents with 1.2 million shares traded. Antisense and Cellmid climbed four percent or more; Bionomics and Starpharma were up more than three percent; Genetic Technologies, Nanosonics, Optiscan and Pharmaxis rose two percent or more; Admedus was up 1.5 percent; with Osprey and Mesoblast up by less than one percent.

Living Cell led the falls for the second trading day in a row, down 0.8 cents or 13.3 percent to 5.2 cents with 1.7 million shares traded.

Compumedics and Viralytics lost more than 10 percent; Patrys fell 7.7 percent; Atcor and Prana were down five percent or more; Oncosil and Prima fell four percent or more; Impedimed and Psivida were down more than three percent; Acrux and Ellex shed more than two percent; Actinogen, Anteo, Benitec, Clinuvel, CSL and Neuren lost more than one percent; with Cochlear, Resmed and Sirtex down by less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says a discovery about a gene involved in muscular dystrophy that could lead to future therapies for the untreatable disease.

The Institute said that facio-scapulo-humeral muscular dystrophy (FSHD) was a progressive wasting disease that affected the face, arms and shoulders, most commonly diagnosed in teenage or early adults.

WEHI said that the genetic disease was rarely fatal but was “very debilitating” and affected one in 8,000 children with no treatments or cures currently available.

The Institute said that a single change to one molecule that made up the DNA of patients could affect the ability of the gene, known as structural maintenance of chromosomes flexible hinge domain containing-1 (Smchd1), to reach and bind to the DNA properly, and it was no longer able to function, potentially leading to a treatment for FSHD.

The research, entitled, ‘Genome-wide binding and mechanistic analyses of Smchd1-mediated epigenetic regulation’ was published in the US journal Proceedings of the National Academy of Sciences.

WEHI said the research was led by Dr Marnie Blewitt, Dr James Murphy and Kelan Chen who investigated the Smchd1 gene, which was dysfunctional in people with a form of the disease called FSHD2.

Ms Chan said that the researchers duplicated the genetic changes found in some patients with FSHD2 to understand how the mutation led to disease.

“Our colleagues at the University of Leiden in the Netherlands work with patients who have FSHD2 and have been studying the genetic changes in these families,” Ms Chan said. “We reproduced in the lab the genetic change to Smchd1 found in one of the families to better understand how this mutation alters Smchd1 and its ability to function in the cell,” Ms Chan said.

“We discovered that just a single change to one molecule that makes up the DNA can affect the ability of Smchd1 to reach and bind to the DNA properly, and it is no longer able to do its job,” Ms Chan said.

Dr Blewitt said that the fundamental understanding of how Smchd1 functioned would help researchers to develop future treatments for FSHD.

“FSHD is a progressive disease, and we don’t begin to see symptoms until the affected person is in their teens or early twenties,” Dr Blewitt said.

“By understanding the function of Smchd1 and how mutations affect its function, we could in the long term develop drugs that would substitute for its activity and prevent the debilitating muscle wasting which occurs in FSHD,” Dr Blewitt said.

Dr Blewitt said the Smchd1 gene encoded an epigenetic factor that switched genes off to suppress their function.

“Epigenetic factors are like the punctuation marks on the DNA that enables the cell to read and comprehend it correctly for the functioning of the cell,” Dr Blewitt said.

“We knew that Smchd1 was an epigenetic suppressor, a factor that switches off genes that are unnecessary for that particular cells’ function, but we were in the dark about where and how it was acting on the DNA,” Dr Blewitt said.

The Institute said that Smchd1 was unusual in its interactions with the genome and that as a massive ‘Goliath’ molecule Dr Blewitt expected it would be greedy and crude, spreading out across the DNA to exert its power, the the opposite was true.

“Smchd1 … very delicately squeezes itself into a tiny seat on the DNA [and] binds at just a few discrete sites on the DNA, then draws these pieces together to shield them from being activated.”

CSL

CSL says that CSL Behring will present more than 20 abstracts, from its haematology portfolio of investigational and branded products.

CSL said that the abstracts including five oral presentations would be presented at the International Society on Thrombosis and Haemostasis meeting in Toronto, June 20 to 25 2015 and included pivotal trial data for two of its late-stage recombinant products recombinant factor VIII singlechain (rVIII-singlechain) compound for haemophilia A and its long-acting recombinant factor IX albumin fusion protein (rIX-FP) for haemophilia B.

CSL said that haemophilia was an inherited bleeding disorder caused by missing or defective proteins that prevented the blood from clotting normally and affected more than 175,000 people worldwide, the majority of whom have haemophilia A.

CSL chief scientific officer and research and development director Dr Andrew Cuthbertson said the company was “proud to be sharing a significant amount of new scientific and clinical research at [the] conference”.

“I am particularly excited that data from our phase III pivotal studies, for both rVIII-singlechain and rIX-FP, will be presented publically for the first time,” Dr Cuthbertson said.

“These product candidates hold great promise and potential and could offer patients strong and sustained efficacy and improved convenience with less frequent dosing, two key areas of unmet need,” Dr Cuthbertson said.

“These data, along with abstracts for other [research and development] candidates and products in our coagulation franchise, reinforce the depth and breadth of CSL Behring’s knowledge and commitment to advancing the care of patients with serious medical conditions and confirms that we remain on track with our development timelines for rVIII-singlechain and rIX-FP that we announced at our most recent research and development briefing,” Dr Cuthbertson said (BD: Dec 3, 2014).

CSL said that rVIII-singlec was a novel recombinant single-chain factor VIII construct specifically designed for greater molecular stability and used a strong covalent bond that formed one structural entity, a single chain, to improve the stability and half-life of factor VIII.

The company said that the phase III trial was an open-label, non-randomized, multi-center study evaluating the efficacy, safety and pharmacokinetics of rVIII-singlechain.

CSL said it had engineered rIX-FP to extend the half-life of recombinant factor IX through genetic fusion with recombinant albumin.

CSL fell $1.00 or 1.1 percent to $87.20 with 2.5 million shares traded.

ATCOR MEDICAL

Atcor says it has raised $2.2 million from sophisticated and institutional investors at 18 cents a share and hopes to raise a further $3.2 million in an underwritten rights issue.

Atcor said that the one-for-10 non-renounceable rights was fully underwritten by Taylor Collison.

The company said that securing a US current procedural terminology 1 (CPT1) code covering its Sphygmocor non-invasive central blood pressure test was :a seminal event” and the capital raised would help ensure it was fully prepared for January 1, 2016 when the code came into effect.

Atcor said the funds would allow investment in additional sales and support personnel, consulting services and other activities.

The company said that the record date for the rights issue was June 30, the offer would open on July 6 and would close on July 23, 2015.

Atcor fell one cent or five percent to 19 cents.

PHARMAUST

Pharmaust says that its trial of PPL-1 for cancer in dogs will move to a combination trial with existing chemotherapy drugs.

Pharmaust said that PPL-1 had “significantly suppressed a key cancer marker in two dogs evaluated” and was safe and well tolerated by all 11 dogs treated so far.

The company said that with the Homebush, Sydney-based Veterinary Oncology Consultants it would make use of the synergy discovery, which showed that PPL-1 had the potential to significantly enhance the anti-cancer activity of conventional chemotherapeutics without simultaneously enhancing the associated side-effect profile (BD: Feb 17, 2014).

Pharmaust executive chairman Dr Roger Aston said that the chemotherapy drugs being investigated included the platinum compounds and gemcitabine.

Ina media release, Pharmaust said the dogs would be treated with a combination of standard-of-care chemotherapy and PPL-1 and two dogs had received the combination therapy and were being monitored for the effects of the treatment on regression of their cancers.

Veterinary Oncology Consultants dog cancer specialist and principal investigator Dr Angela Frimberger said “we now know that not only is PPL-1 both safe and has biological activity in dogs, but also that it has the potential to improve the performance of chemotherapeutic drugs”.

“This allows us to offer a new treatment option for dogs with resistant cancers,” Dr Frimberger said.

“The dogs currently being treated have late stage cancers that are resistant to chemotherapy alone and we will be measuring the effects of the combination on regression of their cancers; but we will also be evaluating first-line combination treatment,” Dr Frimberger said.

Dr Aston said that PPL-1 was “already approved for veterinary use by Pharmaust’s partner, a major global corporation in the animal health industry [and] we believe that if successful in this trial, PPL-1 will be able to be approved quickly for the treatment of dog cancers following a further pivotal study”.

Pharmaust also has a phase I/II dose escalation trial of PPL-1 in humans underway (BD: Apr 15, May 11, 2015).

Pharmaust fell 0.1 cents or 10 percent to 0.9 cents with 1.6 million shares traded.

AVITA MEDICAL

Avita says that the US Patent and Trademark Office has allowed a composition of matter patent relating to its Recell, Renovacell and Regenercell wound treatments.

Avita said that the patent was for the novel composition of matter in the form of an epithelial cell suspension and provided broad protection for the autologous, non-cultured cell suspension prepared peri-operatively and directly applied to the patient.

Avita chief executive officer Adam Kelliher said that a strong intellectual property platform was “a crucial part of our strategy as we work towards US regulatory approval”.

The company said that Recell, Renovacell and Regenercell were protected by a family of patents and applications covering the composition of an epithelial suspension, method of production, device and automation for generating the epithelial suspension and pending worldwide patents and applications would expire from 2022 to 2034.

Avita said that additional filings with a later expiration date would be made as it continued to invent in the regenerative medicine field.

Avita was untraded at 7.8 cents.

MEDIBIO

Medibio says it has produced and validated the first objective test to measure the level of stress and its impact on health and well-being.

Medibio said the test using its circadian heart rate technology was “a global breakthrough in the diagnosis and treatment of stress”.

The company said that there was “no gold standard for the measurement of stress and no available test to objectively assess the impact of stress on health and well-being”.

Medibio said that chronic stress was “one of the largest issues in healthcare today with research showing that stress contributes to the development of major illnesses such as heart disease, depression and obesity”.

The company said that the ability to assess accurately the impact of stress via a simple test had the potential to save the workplace and the healthcare system globally billions of dollars and said that in Australia workplace stress alone cost employers an estimated $10.1 billion a year.

Medibio said it would focus initially on the workplace stress market following discussions with potential corporate customers.

The company said its stress algorithms maintained a diagnostic accuracy of more than 80 percent using data collected during sleep rather than a 24 hour period and the reduction of the time required to assess an individual to less than 10 hours made the test compatible with wearable diagnostics and mobile telephone applications.

Medibio said that current methods of measuring stress included the occurrence of demanding events, how the individual perceived the stressfulness of each event and measuring the biological elements of the stress response, with subjective questionnaires and interviews the main tools, along with biomarkers including salivary cortisol, heart rate, pressure-pain sensitivity and galvanic skin response.

Medibio said that it was “porting the new stress algorithms into a cloud-based environment … in parallel with the completion of its corporate stress product including an [application] based intervention tailored to the assessed level” expected to be completed by October 2015.

Medibio was up two cents or 6.45 percent to 33 cents.

POLYNOVO

Polynovo chairman David Williams has bought 2,000,000 shares in his company “to send a signal to the market that I am more confident than when I arrived”.

Mr Williams previously held an indirect interest in 190,000 shares as a trustee for Saul Williams and 10,000,000 unlisted options held by Moggs Creek Superannuation Fund.

In an Appendix 3Y Change of Director’s Interest Notice, Mr Williams said that between June 11 and June 15, 2015, a related company Lawn Views Pty Ltd acquired 2,000,000 shares for $159,108 or an average price of 7.96 cents a share.

Mr Williams told Biotech Daily that when he became chairman of Polynovo the though it “might be able to be fixed but it was just a well-informed hunch”.

“Now I am convinced the company has something valuable,” Mr Williams said.

“We have cleared the decks so we can focus on our core and we added some critical mass to our staffing and there is more to come as I don’t want [Polynovo] to die by a thousand cuts like most Australian pharmaceutical companies who raise too little and employ too few,” Mr Williams said.

“While there is still a lot of water to go under the bridge, I decided it was time to send a signal to the market that I am more confident than when I arrived,” Mr Williams said.

Polynovo fell 0.3 cents or 3.45 percent to 8.4 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that the July 7 'Think Global' Bio-Breakfast will discuss strategies for international positioning.

The Network said that Blamey Saunders Hears managing director Dr Elaine Saunders and Circadian Technologies chief executive officer Dr Megan Baldwin would discuss their experience with the global supply chain, growing international networks of investors and stakeholders and how to return value to the broader global community.

Bio-Melbourne Network chief executive officer Dr Krystal Evans said that positioning globally in the healthcare market was essential for biotechnology and medical technology success.

The Network also said that Dr Saunders and Dr Baldwin would provide distinct perspectives from different points on the pathway, from early in the positioning process to accessing global markets.

The July 7, 2015 Bio-Breakfast will be held at The Cube, at the Australian Centre for the Moving Image, Federation Square, Melbourne.

Registration is from 7.15am for a networking breakfast from 7.30am and presentation from 8:00am to 9:00am.

To register go to: http://www.biomelbourne.org/events/view/372.

ROYAL AUSTRALIAN CHEMICAL INSTITUTE

The Royal Australian Chemical Institute Bioactive Discovery and Development Group says Dr Paul MacLeman will discuss the lifecycle of a molecule at its July dinner.

IDT managing director Dr MacLeman told Biotech Daily that the commercialization lifecycle of a molecule began with discovery and went through stages from development to generic production.

The Bioactive Discovery and Development Group said its dinners were "excellent opportunities to meet with chemists from the private and public sectors, to engage with our carefully selected after-dinner speakers and enjoy some fine food in relaxed surroundings".

The Group said that the July 7, 2015 dinner would be held at 7pm at the Conservatory Restaurant at the Pumphouse Hotel, 128 Nicholson Street, Fitzroy, Victoria and the entry price included finger food, a two course meal and a complimentary glass of wine and tea/coffee, with a cash bar open through the evening.

To register go to: http://wired.ivvy.com/event/435VBG/.