Biotech Daily

Thursday March 29, 2012

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: REVA UP 14%, PSIVIDA DOWN 12%**

*** ALLIED TRIALS ADAPT PELVIC FLOOR, HERNIA PATCH IN SHEEP**

*** WEHI: INTERMITTENT TREATMENT CUTS PAEDIATRIC MALARIA 30%**

*** CHINA PATENT FOR USE OF VIRALYTICS COXSACKIE A VIRUSES**

*** AGENIX HEP B CHINA TRIAL 'ON TRACK'; INTEREST IN THROMBOVIEW**

*** CORRECTION: ALLIED HEALTH**

*** PHARMAXIS HIRES ARVATO FOR EURO BRONCHITOL DISTRIBUTION**

*** HEALTHLINX JOURNAL DATA BACKS PROSPECTIVE OVPLEX TRIAL**

*** AVITA READY TO TRADE US SHARES ON OTCQX**

*** CELLMID LAUNCHES ÉVOLIS HAIR GROWTH PRODUCTS**

MARKET REPORT

The Australian stock market edged back 0.13 percent on Thursday March 29, 2012, with the S&P ASX 200 down 5.6 points to 4,337.9 points. Nineteen of the Biotech Daily Top 40 stocks were up, nine fell, eight traded unchanged and four were untraded.

Reva was the best, up 8.5 cents or 13.7 percent to 70.5 cents with 1.6 million shares traded.

Cellmid and Viralytics both climbed 8.3 percent; Biota and Phylogica were up seven percent or more; Tissue Therapies rose 4.8 percent; Allied, CSL and Prana were up more than three percent; Alchemia, Anteo, Avita, Circadian, Cochlear, Nanosonics, Phosphagenics, Starpharma and Sunshine Heart rose two percent or more; QRX was up 1.2 percent; with Sirtex and Universal Biosensors up by less than one percent.

Yesterday's best, Psivida led the falls, down 25 cents or 11.6 percent to $1.90 with 19,000 shares traded.

Antisense, Benitec and Ellex fell five percent or more; Impedimed fell four percent; Prima shed two percent; Mesoblast, Pharmaxis and Resmed were down one percent or more; with Acrux down 0.75 percent.

ALLIED HEALTHCARE GROUP

Allied Health says it has implanted its Adapt-treated patch for pelvic floor and hernia reconstruction procedures into 10 sheep at the University of Leuven in Belgium.

Allied Health said a control group of 10 sheep were implanted with existing synthetic patches.

The company said that its tissue engineering and regenerative medicine division Celxcel continued to develop applications for the treated bovine tissue patches and there was a "growing global demand for substitutes in the pelvic floor and abdominal hernia area" and there had been controversial outcomes with the use of synthetic meshes to repair pelvic floor abnormalities or herniated soft tissues.

Allied Health managing director Lee Rodne said the "positive results will open up the opportunities for a supporting clinical trial and commercial discussions with potential partners in these areas".

The company said that gynaecologists from the University of Leuven successfully implanted the Gynecel patch into the pelvic floor area and the surgical product in the abdominal hernia position.

Allied Health said that the implants would be monitored for six months to compare them to existing synthetic implants, with data expected to be released later this year.

Allied Health said that over the past decade, the Adapt-treated patch had been tested in a number of in-vitro and in-vivo models, in both supportive and non-supportive areas, to assess the durability, biocompatibility and calcification potential of the implant.

The company said that previous results, in an experimental hernia model of abdominal wall replacement in a small animal model, showed the potential for Gynecel in the pelvic floor and another of Celxcel's surgical products for abdominal wall hernia applications.

Celxcel chief executive officer Bob Atwill said the company would monitor the sheep over the next six months with the aim of determining how well the Gynecel and surgical patches perform as substitutes for pelvic floor and hernia repair applications.

The company said the pelvic floor reconstructions and the hernia repairs would be assessed in terms of functional support, structural changes of the implants, immunological response towards the implants or remodeling and for any signs of calcification.

"All the animals in the study recovered fully from the surgical procedures without any adverse effects during or after surgery," Mr Atwill said.

Allied Health said that the Gynecel patch material and the surgical product have previously been successfully used to reconstruct the posterior wall of the vagina and to repair a surgically created abdominal wall hernia respectively.

Allied Health said that the study was in addition to recent results in cardiovascular repair with Cardiocel.

The company said that Cardiocel, Gynecel and surgical products uses the Adapt Tissue Engineering Process, using animal-derived tissues to produce products that are compatible with the human body.

Allied Health said that the Adapt process produced tissue that more closely mimiced human tissue and was expected to open up the potential for medical professionals to replace synthetic products currently used in soft tissue repair.

The company said that along with cardiovascular, pelvic floor reconstructions and hernia repair applications, Celxcel was evaluating how the process could be used in orthopaedics and as a biological scaffold to grow and deliver stem cells.

Allied Health was up 0.1 cents or 3.45 percent to three cents.

WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that a three year trial has shown that intermittent combination drug treatment can cut paediatric malaria by 30 percent.

WEHI said the Papua New Guinea trial showed that paediatric malaria infections could be cut by up to 30 percent when drugs were given intermittently over 12 months.

The Institute said that the drug regime was effective against both Plasmodium falciparum and Plasmodium vivax malaria, the first time anti-malarial drugs had been shown to prevent infections by both species of malaria.

WEHI said that the treatment regime, known as intermittent preventive treatment (IPT), protected the infants against malaria for at least six weeks after treatment, showing an ongoing protective effect and did not hinder the development of natural immunity.

The Institute said the treatment used sporadic, short courses of combined anti-malarial drugs to provide protection against malaria infection.

WEHI said the study was led by its Prof Ivo Mueller with the Papua New Guinea Institute of Medical Research's Dr Patricia Rarau and Dr Nicolas Senn.

Prof Mueller said the findings could lead to trials of IPT in other regions, including South-East Asia and South America, where malaria was a major health problem.

WEHI said that the treatment method had been used in sub-Saharan Africa, where more than 80 percent of all deaths from malaria were in children under the age of five.

"Plasmodium vivax is the main cause of clinical malaria in infants outside of Africa," Prof Mueller said. "What this study has shown is that IPT can be useful in regions other than sub-Saharan Africa, that it can be an effective tool against [Plasmodium] vivax and reaffirms that we need to effectively tailor preventive drugs to different malaria species in different regions."

"IPT is a cheap and easy way to decrease the burden of malaria in those most susceptible clinical illness, such as young infants and pregnant women," Prof Mueller said.

WEHI said that infants aged three to 15 months were treated with a long-lasting anti-malarial drug combination at three, six, nine and 12 months.

Prof Mueller said the most effective drug combination in the trial was the long-lasting anti-malarials sulfadoxine pyrimethamine and amodiaquine (SP-AQ), which acted against the two most lethal species of malaria parasite, Plasmodium falciparum and Plasmodium vivax.

WEHI said that SP-AQ treatment decreased infant infections by 35 percent for Plasmodium falciparum and 23 percent for Plasmodium vivax.

"These are quite remarkable figures," Prof Mueller said.

"Different treatment strategies are required for different regions, depending on the dynamics of disease," Prof Mueller said.

"The drug combination that was most effective in PNG was very different to the drugs you would use to treat malaria in Africa and also different to the drugs currently recommended for treating malaria in PNG," Prof Mueller said.

Papua New Guinea Institute of Medical Research director Prof Peter Siba said that a key factor in the effectiveness of the treatment was running it in parallel with existing vaccination and healthcare programs.

"In the trials, IPT was given at the same time as regular vaccinations and check-ups, using existing health care frameworks to deliver the treatment, so we saw a much higher adherence than with continuous treatment regimes," Prof Siba said.

"IPT is also preferable to long-term, continued use of anti-malarial drugs, as it allows some natural immunity to develop while decreasing the number and severity of malaria infections," Prof Siba said.

WEHI said the study was supported by the Bill & Melinda Gates Foundation.

VIRALYTICS

Viralytics says that China has granted a patent for the use of a panel of Coxsackie A viruses including Cavatak in the treatment of the blood cancer, multiple myeloma.
Viralytics said that the application covered the use of Coxsackieviruses A13, A15, A18 and A21 (Cavatak) in the manufacture of a medication for treating multiple myeloma.
The company said that the application covered the use of the Coxsackie A viruses in the laboratory removal of malignant multiple myeloma cells within auto grafts prior to autologous stem cell transplantation.
Viralytics said that multiple myeloma was a cancer that began in the white blood cells that produced antibodies and about 22,000 new cases and 11,000 deaths were expected from multiple myeloma in the US in 2012.
Viraytics said that Cavatak was being evaluated in a US phase II clinical trial in late stage melanoma patients.
Viralytics was up three cents or 8.3 percent to 39 cents.

AGENIX

Agenix says that subject to China regulatory clearance, it expects to begin its phase I trial of prodrug AGX- 1009 for hepatitis B in China in 2013.
In a media release, Agenix executive chairman Nick Weston said he had discussed the company's program at the inaugural Ausbiotech Brokers Meet Biotech investment event in Melbourne.
Benetic and Biotron also presented at the event.
Mr Weston told Biotech Daily after the meeting that that he discussed potential partners for the phase III study of the blood clot diagnostic technology, Thromboview and progress on the phase I trial of AGX-1009 in China.
Mr Weston said the company had a funding strategy in place to address its short term and long terms capital needs.
Agenix has a three year $5 million drawdown equity facility with Fortrend Securities, which runs until March 2013 (BD: Mar 25, 2010).
In the media release, Mr Weston said that with the Institute of Medicinal Biotechnology of the Chinese Academy of Medical Sciences in Beijing, Agenix was on track to submit a clinical trial application to China's State Food and Drug Administration this year.
Mr Weston said the costs and risks of developing the new drug in China were reduced by AGX-1009 being based on the same proven active compound in Gilead's blockbuster drug Viread, a version of tenofovir, to treat chronic hepatitis B in the US and Europe.
Mr Weston said there was "strong interest" in the results of the successful phase II Thromboview trial (BD: Jul 7, 2011).
Mr Weston said the diagnostic agent promised to improve the way hospitals scanned and detected deadly blood clots and subsequent pulmonary embolism, the leading cause of preventable deaths in hospitals.
Agenix fell 0.1 cents or 7.1 percent to 1.3 cents with 2.2 million shares traded.

ALLIED HEALTHCARE GROUP

Last night's edition incorrectly reported that the Metal Group, Avexa and McRae Technology had changed their substantial shareholdings in Avexa, which should have read 'Allied Health'.
The mistake was made by the sub-editor who is better suited to reporting on mining companies, preferably in another country.

PHARMAXIS

Pharmaxis says it has finalized a logistics and distribution services agreement for the supply of Bronchitol across Europe.
Pharmaxis said it expected to launch Bronchitol for cystic fibrosis in Europe by July 2012 and had signed a three-year agreement with the Gütersloh Germany-based Arvato Healthcare, a member of the Bertelsmann AG group of companies.
Pharmaxis chief executive officer Dr Alan Robertson said the agreement completed the infrastructure to make Bronchitol available throughout Europe.
"Launch stock of Bronchitol is in the final stages of manufacture and our Pharmaxis and Quintiles sales teams are introducing Pharmaxis to cystic fibrosis centres in the United Kingdom and Germany," Dr Robertson said.
"The customer services and logistics are now also in place," Dr Robertson said.
Pharmaxis fell two cents or 1.45 percent to $1.36.

HEALTHLINX

Healthlinx says data from its trial of the Ovplex test for ovarian cancer has been published in the Journal of Translational Medicine confirming advantages over CA125 alone.
Healthlinx said the study confirmed in an independent sample set that the Ovplex assay had significant clinical advantages over CA125 for distinguishing symptomatic women with borderline and malignant ovarian cancer from controls or those with benign disease.
The company's Ovplex test includes CA-125 along with other biomarkers.
The article, entitled 'Performance of a multianalyte test as an aid for the diagnosis of ovarian cancer in symptomatic women' was co-authored by Healthlinx chairman Prof Greg Rice and chief scientific officer Dr Dominic Autelitano.
An abstract is at http://www.translational-medicine.com/content/10/1/45/abstract.
The journal article said that the study cohort comprised plasma (blood) samples from 244 healthy controls, 223 women with benign gynecological conditions, 53 borderline ovarian cancer cases and 222 women with malignant epithelial ovarian cancer.
The article concluded that "in an independent sample set that a blood-based multianalyte assay has significant advantages over CA125 for distinguishing symptomatic women with borderline and malignant ovarian cancer from controls or those with benign disease".
Healthlinx said the interim result had prompted a follow-up pivotal trial which would determine the efficacy of the Ovplex test in a prospective setting.
The company said its collaboration with Queensland's Mater Health Services and Prof Lewis Perrin would be extended to oversee the design and implementation of the prospective trial.
Healthlinx said the study would be a 12 month study, with nine months for recruitment of patients and three months for data analysis.
Healthlinx managing director Nick Gatsios said the trial would be "a pivotal test of the efficacy of the Ovplex diagnostic test in a clinical setting".
Prof Perrin said the diagnosis of a pelvic mass "can cause severe anxiety for any patient and her family".
"This test has the potential to identify patients who would be best managed by a gynaecological oncologist," Prof Perrin said. "We hope with further validation that we could begin to incorporate this test into clinical practice in the next year."
Healthlinx said the collaboration would expand the immuno-histochemistry study to obtain data on a novel biomarker that presents as a prognostic biomarker for patient survival.
The company said it had filed for a provisional patent to cover the novel invention.
Healthlinx was unchanged at 0.9 cents with 1.4 million shares traded.

AVITA MEDICAL

Avita Medical says it has initiated trading of its American Depositary Receipts (ADRs) on the Nasdaq Over The Counter Quality Exchange (OTCQX).
Avita said the ADRs would be traded under the symbol AVMXY, with each ADR equivalent to 20 Australian shares.
Last night, under the previous Nasdaq code of AVMXF, Avita fell one US cent or 3.8 percent to 25.5 US cents with 322,051, with no trades recorded under the AVMXY code.
On the ASX today, Avita was up half a cent or 2.1 percent to 24 cents with 2.4 million shares traded.

CELLMID

Cellmid says it has launched its Évolis hair growth products in Sydney.
Cellmid said it received Australian Therapeutic Goods Administration approval for the products in February and expected completion of the good manufacturing practice and commercial launch in May 2012.
The company said the timetable had been brought forward and commercial sale of the products through pharmacies was likely to begin in the middle of the calendar year, three months earlier than previously planned.
Cellmid said that Évolis for Men and Évolis for Women products had “important TGA approved claims of ‘promotes hair growth’, ‘helps prevent hair loss and thinning’ and ‘restores the natural hair growth cycle’”.
The company said that the Évolis products would not require a prescription and would be sold as over-the-counter medicines in individual pharmacies as well as pharmacy chains at the recommended retail price of $89 for each 50ml bottle.
Cellmid said it was targeting a minimum of 400 pharmacies nationally within the first 12 months and estimated that 40 percent of women and 50 percent of men in Western countries were affected by hair loss at some stage in their life, but existing hair growth products either had serious side effects or lacked evidence of efficacy.
The company said its Évolis range had safety combined with efficacy and represented a significant market opportunity.
Cellmid was up 0.1 cents or 8.3 percent to 1.3 cents with 12.9 million shares traded.