



Biotech Daily

Wednesday November 4, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH EVEN: AVITA UP 10%, ANTISENSE DOWN 8%**
- * **ADMEDUS LAUNCHES CARDIOCEL IN MALAYSIA**
- * **ANTISENSE, STRONGBRIDGE ATL1103 REDUCES ACROMEGALY GHBP**
- * **BIONOMICS: 'BNC105, TH302 RENAL, BREAST CANCER SYNERGY IN-VIVO'**
- * **PROTEOMICS SIGNS CHINA PROMARKERD KIDNEY TEST DEAL**
- * **USCOM ESTABLISHES LONDON OFFICE**
- * **ELLEX'S ABIC FOR GLAUCOMA AT US OPHTHALMOLOGY MEETING**
- * **EUROPE GRANTS BLUECHIIP PATENT**
- * **MMJ CANADA MARIJUANA PLANT READY FOR INSPECTION**
- * **GORDAGEN APPOINTS NE1-HEART US DISTRIBUTOR**
- * **ALLEGRA 'OUTSOURCES' ACTIVE KNEE MANUFACTURE TO SIGNATURE**
- * **LAGODA, FATIMA DICKEY, RICHARD BAYLES TAKE 7% OF CLINUVEL**

MARKET REPORT

The Australian stock market edged up 0.06 percent on Wednesday November 4, 2015 with the ASX200 up 3.1 points to 5,242.3 points. Fifteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and five were untraded. All Big Caps fell.

Avita was the best, up one cent or 10 percent to 11 cents with 186,890 shares traded. Ellex, Impedimed and Uscom climbed five percent or more; Anteo and Cellmid were up more than three percent; Atcor, Benitec, Living Cell, Oncosil and Optiscan rose more than two percent; Medical Developments, Pro Medicus and Sirtex were up more than one percent; with Viralytics up 0.9 percent.

Antisense led the falls, down 0.7 cents or 8.2 percent to 7.8 cents with 156,000 shares traded. IDT lost 6.2 percent; Genetic Technologies fell five percent; Compumedics shed 4.4 percent; Orthocell, Osprey, Polynovo and Prima were down more than three percent; Actinogen, Bionomics, Biotron and Starpharma were down one percent or more; with Acrux, Cochlear, CSL, Nanosonics and Resmed down by less than one percent.

ADMEDUS

Admedus says that its Cardiocel Adept-treated bovine cardiac tissue repair scaffold has been launched in Malaysia.

Admedus said that Cardiocel was used to repair and treat cardiovascular defects including reconstructing and repairing heart valves.

The company said that Malaysia had more than 30 million people and serviced the regional patient needs in treating cardiovascular disease.

Admedus said that Malaysia had “a strong record in the region for cardio-thoracic surgery” and was an important strategic market.

The company said that Cardiocel was sold in Europe, the US, Canada, Hong Kong, Singapore and Malaysia and was accessed in Australia through early access programs.

Admedus said it was working with its partner Genpharm in the Middle East and Northern Africa for additional regulatory approvals as well as exploring new markets in Asia.

Admedus chief executive officer Lee Rodne said that the Malaysia launch was “another important step in building our global Cardiocel franchise, the lead product from our regenerative tissue portfolio”.

“Having launched in a number of markets including the US and EU, we are delighted now to be working with key Malaysian heart centres and heart surgeons in introducing Cardiocel to the region with the prospect of improving patient lives,” Mr Rodne said.

Admedus said it was undertaking a post-market clinical study to show improved patient outcomes in reconstructing the aortic heart valve with Cardiocel compared to the available replacement bio-prosthetic valves.

Admedus was unchanged at 6.4 cents with 2.3 million shares traded.

ANTISENSE THERAPEUTICS

Antisense says that Strongbridge Biopharma has presented data showing that ATL1103 reduces growth hormone-binding protein in a dose dependent manner.

Antisense said the Trevose, Pennsylvania-based Strongbridge, formerly Cortendo, had licenced ATL1103 for acromegaly, renamed it COR-004, and the data was from a secondary analysis of the 26 patient phase II trial (BD: Sep 3, 2014; May 15, 2015).

The company said that the data, entitled ‘In patients with acromegaly antisense oligomer therapy directed at the GH receptor is associated with reduction in circulating GHBP levels’ would be presented at the Society for Endocrinology conference in Edinburgh, Scotland November 2-4, 2015.

In an attached media release, Strongbridge said the phase II trial was a randomized, open-label, parallel group clinical trial of the safety, tolerability, pharmacokinetics and efficacy of two subcutaneous regimens of COR-004 in patients treated over 13 weeks. Strongbridge said the trial met its key efficacy endpoint with a significant reduction in the serum insulin-like growth factor 1 (IGF-1) levels the higher dose group, COR-004 was safe and well tolerated, with the main adverse event mild to moderate injection site reactions.

Strongbridge said that one of the secondary endpoints, the level of growth hormone-binding protein (GHBP) as a marker of growth hormone receptor expression was evaluated and with the larger dose, a continuous decrease in GHBP reached statistical significance at the end of the study, coinciding with a significant reduction in IGF-1.

The company said the data provided further evidence for the efficacy of COR-004 and its ability to inhibit growth hormone receptor expression and data from future trials would help evaluate the relationship between COR-004 dose, growth hormone levels, GHBP levels and IGF-1 changes with treatment.

Antisense fell 0.7 cents or 8.2 percent to 7.8 cents.

BIONOMICS

Bionomics says that mouse studies of BNC105 in combination with the pro-drug evofosfamide shows “encouraging synergistic activity in renal and breast cancer”. Bionomics said the combination treatment with the San Francisco, California-based Threshold Pharmaceuticals’ evofosfamide, previously known as TH-302, showed enhanced tumor growth inhibition compared to monotherapy and in work completed after abstract submission but included in the poster, the combination of BNC105 and evofosfamide also demonstrated additive activity in a model of soft tissue sarcoma. The company said that the pre-clinical data from on-going studies the vascular disrupting agent BNC105 would be presented at the Conference on Molecular Targets and Cancer Therapeutics in Boston, Massachusetts on November 7, 2015.

Bionomics said that the posters were entitled ‘Complementary activity of the vascular disruption agent BNC105 and the hypoxia-activated prodrug evofosfamide (TH-302) in suppressing the growth of preclinical renal and breast solid tumors’ and ‘Tubulin-targeting agent BNC105 potentiates the efficacy of Immune checkpoint inhibitors in preclinical models of colorectal cancer’.

The company said evofosfamide was being evaluated in two phase III trials for locally advanced unresectable or metastatic soft tissue sarcoma and locally advanced unresectable or metastatic pancreatic cancer by Threshold and the Darmstadt, Germany-based Merck KGaA.

Bionomics said that it, Threshold and Merck KGaA collaborated on the pre-clinical evaluations of BNC105 and evofosfamide.

The company said BNC105 was also studied in mice, in combination with antibodies targeting PD-1 or CTLA4 in colorectal cancer and the data showed a synergistic relationship for the combination therapy when looking at inhibition of tumor growth.

Bionomics fell half a cent or one percent to 51.5 cents.

PROTEOMICS INTERNATIONAL

Proteomics says that the Shanghai, China-based Newsummit Biopharma will commercialize its Promarkerd test for diabetic kidney disease in China.

Proteomics said that managing director Dr Richard Lipscombe formally signed the agreement, made in February prior to listing on the ASX, last week in Shanghai.

The company said it was the first commercial agreement for Promarkerd and the first proteomics-derived in-vitro diagnostic to enter the Chinese market.

Proteomics said that diabetes had increased in Asia with chronic kidney disease a major complications and 120 million Chinese had diabetes and were at risk of kidney disease.

Proteomics climbed 3.5 cents or 8.6 percent to 44 cents.

USCOM

Uscom says it has established Uscom Medical as wholly owned London-based subsidiary.

Uscom said that the UK entity was the next step in its global expansion “and extends its strategic reach into the European and US markets in response to increased global demand” following the acquisition of the Budapest, Hungary-based Thor Laboratories, re-named Uscom Budapest (BD: Sep 1, 2015).

Uscom said that the London office would be the regional hub for Uscom Budapest manufactured goods and ensure delivery of Uscom products and service to the regional US and European markets.

Uscom was up one cent or 5.6 percent to 19 cents.

ELLEX MEDICAL LASERS

Ellex says that featuring its ab interno canaloplasty in the American Academy of Ophthalmology's scientific program is "a critical milestone in ... market acceptance". Last month, Ellex said its Itrack canaloplasty micro-catheter could reduce surgery for glaucoma to a five-minute procedure, through the use of its new ab-interno, or within the colored part of the eye, canaloplasty surgical procedure (BD: Oct 1, 2015).

Today, the company said that American Academy of Ophthalmology conference, to be held in Las Vegas, Nevada, November 14-17, 2015 was "the pre-eminent ophthalmic conference" attracting about 10,000 ophthalmologists.

Ellex said that the minimally invasive glaucoma surgery device, ab interno canaloplasty or ABIC would be showcased during a skills transfer course at the meeting and the course would also address its traditional ab externo canaloplasty procedure.

Ellex chief executive officer Tom Spurling said that ABIC had been developed over the past 12 months and it was "a significant refinement of our traditional canaloplasty procedure that has dramatically reduced the overall procedure time to just five minutes".

"It is also designed as an adjunct to cataract surgery," Mr Spurling said.

The company said that it expected ABIC to be "a key player in the relatively new and fast-growing minimally invasive glaucoma surgery market, which was valued at \$US90 million in 2015 and was expected to grow to \$US686 million by 2020.

Mr Spurling said that including ABIC in the Academy's program was "a critical milestone in ensuring growing market acceptance and physician uptake".

Mr Spurling said that Ellex had a five to six percent share of the growing minimally invasive glaucoma surgery market and the introduction of ABIC would provide an opportunity to significantly increase that share.

Ellex was up three cents or 5.8 percent to 55 cents.

BLUECHIIP

Bluechiip says the European Patent Office has granted one patent and will grant a second for its bio-storage tracking tags.

Bluechiip said European Patent Office had granted the patent, entitled 'Ringup/Ringdown Interrogation of RFID Tags' which described the method of radio frequency communication between a radio frequency identification (RFID) reader and a micro-electromechanical system-based tag, which was "fundamental to the wireless communication and operation of [its] wireless tracking system".

Bluechiip chief executive officer Andrew McLellan told Biotech Daily that the patent provided coverage until September 30, 2029.

The company said that the EPO had indicated its intention to grant the patent application 'RFID Memory Devices' which described a dual identification device where two sets of data were stored in the same circuit but were accessed independently, providing coverage until June 19, 2029.

Mr McLellan said the patent grant and intent to grant were "a significant milestone in advancing Bluechiip's technology leadership in sample tracking for extreme environments".

"The approval continues to strengthen our ability to protect our valuable technology and [intellectual property] in a key high-value market," Mr McLellan said.

Mr McLellan said the company had 13 approved patents and seven patents pending in the areas of micro-electromechanical system identification, RFID tagging, sample storage technologies and temperature monitoring of samples during heating.

Bluechiip was up 0.3 cents or 7.9 percent to 4.1 cents.

MMJ PHYTOTECH

MMJ Phytotech said that it has notified Health Canada that its Duncan British Columbia marijuana plant was ready for inspection and requested an inspection date.

MMJ said that through subsidiary United Greeneries it had received full occupancy at the Duncan facility near Vancouver.

The company said that pre-licencing inspection was the final step to a cultivation licence from Health Canada under the Marijuana for Medical Purposes Regulations.

MMJ was unchanged at 29.5 cents with 2.5 million shares traded.

GORDAGEN PHARMACEUTICALS

Gordagen says it has appointed Nutritional Products International as its US marketing and distribution partner for its NE1-Heart health food additive product.

Gordagen said that NE1-Heart was “an evidence-based nutraceutical for the maintenance of a healthy heart” based on its vitamin E-derived tocotrienol platform and was planned for release in the US by July 2016.

Gordagen chief executive officer Dr Glenn Tong said the appointment of the Boca Raton, Florida-based Nutritional Products was “a major step forward in our entry into the US market”.

Gordagen is a private company.

ALLEGRA ORTHOPAEDICS (ADVANCED SURGERY DESIGN & MANUFACTURE)

Allegra says it will ‘outsource’ the manufacturing activities associated with its Active Knee product range to the Sydney-based Signature Orthopaedics Pty Ltd.

Allegra said that Signature would manufacture its Active Knee product “to the highest possible standard” and relevant equipment was being sold to Signature along with the transfer of personnel.

The company said its strategic plan would enable it to scale its production of Active Knee more effectively as it focused on new opportunities.

Allegra was untraded at 25 cents.

CLINUVEL

Lagoda Investment Manager, Fatima Dickey and Richard Bayles have increased their holding in Clinuvel from 2,717,149 shares (6.10%) to 3,122,221 shares (7.01%).

The substantial shareholder noticed said that the shareholders included “various clients of Lagoda”, Merrill Edge, Oppenheimer, Fiduciary Trust, US Trust, JP Morgan, State Street, Brown Brothers, Northern Trust, Bank of New York Mellon, Wells Fargo and Fidelity.

The Columbus Circle, New York-based Lagoda said it acquired shares on-market between October 6 and November 2, 2015 at prices ranging from \$2.79 to \$3.01.

Clinuvel was unchanged at \$3.00.