Biotech Daily

Wednesday September 26, 2012

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: ALLIED HEALTH UP 24%, PSIVIDA DOWN 6%**

*** LIVING CELL DIABECELL 'REDUCES HBA1C, DIABETES EVENTS'**

*** TGA SPECIAL ACCESS FOR ALLIED HEALTH'S HEART PATCH**

*** CORRECTION: ALCHEMIA**

*** US GROWTH HORMONE RECEPTOR PATENT FOR ANTISENSE ATL1103**

*** BOOTS UK DUMPS PHOSPHAGENICS' ANTI-FAT CREAM**

*** ATCOR AGM FOR 1.4m CEO OPTIONS**

*** ISONEA TAKES CAPITAL RAISING HALT TO SUSPENSION**

*** BLUECHIIP APPOINTS BRETT ROBERTS COMMERCIAL DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.26 percent on Wednesday September 26, 2012 with the S&P ASX 200 down 11.3 points to 4,361.6 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and six were untraded.

Allied Health was the best, up as much as 47.6 percent to 3.1 cents, closing up 0.5 cents or 23.8 percent at 2.6 cents with 13.5 million shares traded, followed by Patrys up 17.9 percent to 3.3 cents, with 1.9 million shares traded and Antisense up 11.1 percent to two cents with 38.2 million shares traded.

Phylogica and Reva climbed more than seven percent; Alchemia and Viralytics were up four percent or more; Impedimed was up 3.3 percent; Acrux, Biota, CSL, Mesoblast, Resmed and Universal Biosensors rose more than one percent; with Clinuvel, Heartware and Starpharma up by less than one percent.

Psivida led the falls, down 11 cents or 6.4 percent to $1.60 with 1,100 shares traded.

Sunshine Heart fell five percent; Prana lost 4.3 percent; Phosphagenics and Tissue Therapies were down more than three percent; Bionomics, Ellex and QRX shed more than two percent; Anteo and Living Cell fell more than one percent; with Cochlear and Sirtex down by less than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says that its Diabecell pig islets of Langerhans reduce unaware hypoglycaemic events in type 1 diabetes, but were non-significant in HbA1c reduction.

Living Cell said its New Zealand phase I/IIa clinical trial saw 14 patients treated with a single implant of Diabecell at doses of 5,000 islet equivalents per kilogram of body weight (IEQ/kg), 10,000 IEQ/kg, 15,000 IEQ/kg and 20,000 IEQ/kg and demonstrated that Diabecell was a safe and effective treatment.

The company said the trial at Auckland's Middlemore Hospital by principal investigators Dr John Baker and Dr David Holland showed a statistically significant reduction in unaware hypoglycaemic events at doses of 5,000 IEQ/kg and 10,000 IEQ/Kg; a trend to reduction in HbA1c; and improvement in patient-reported quality of life.

Living Cell said that a range of safety and efficacy endpoints were assessed and formal statistical analyses were conducted, but due to the small group sizes of two or four patients per treatment group, the ability to show statistically significant effect of treatment was limited.

The company said that the primary endpoint was a reduction in HbA1c2 compared to baseline and at 52 weeks the 5,000 IEQ/kg, 10,000 IEQ/kg and 20,000 IEQ/kg treatment groups levels were lower than baseline and four of 14 patients had HbA1c levels less than or equal to seven at the end of the trial compared to zero of 14 at baseline.

Living Cell said that two patients were treated with 20,000 IEQ/kg, while the other doses were applied to four patients in each group, all patients were monitored for safety and efficacy endpoints for 52 weeks post-transplant, completed the trial and were included in the efficacy and safety evaluations.

The company said that overall, the data was promising with the 5,000 IEQ/kg and 10,000 IEQ/kg groups in particular associated with measures of efficacy.

Living Cell said that the 15,000 IEQ/kg and 20,000 IEQ/ kg treatment appeared less effective and further investigation and refinement of the endpoints and measurements through the Argentinian phase I/IIa would allow a further assessment of the treatment.

The company said there were four serious adverse events related to the transplant, one of which was associated with the surgical procedure.

Living Cell said that quality-of-life questionnaires showed a positive impact of treatment; there was no evidence of xenogeneic infection of patient, partners or persons in close contact with the transplant recipients; a statistically significant improvement in hypoglycaemic events was observed in the 10,000 IEQ/kg treatment group; a statistically significant reduction in the number of unaware hypoglycaemic events was also observed in both the 5,000 IEQ/kg and 10,000 IEQ/kg treatment groups; reductions in insulin use was evident in all treatment groups and group means show marked reductions in the 5,000 IEQ/kg and 10,000 IEQ/kg groups; and daily insulin dose calculated as a four week average was significantly reduced in the early stages post transplant in the 10,000 IEQ/kg group.

Living Cell said that while the Argentinean phase I/IIa trial was on-going, preliminary data confirmed the New Zealand findings with a reduction in HbA1c, insulin dose and unaware hypoglycaemia following two implants at a dose of 5,000 IEQ/Kg each implant; and a reduction in HbA1c, insulin dose and unaware hypoglycaemia following a single implant at a dose of 10,000 IEQ/kg.

The company said the Argentinean data would be reported by the end of 2012.

Living Cell chief executive officer Dr Andrea Grant said the company was "readying for the pivotal trial phase and remain on track to meet our goal of completing the clinical trials of Diabecell by 2015".

Living Cell fell 0.1 cents or 1.9 percent to 5.2 cents with two million shares traded.

ALLIED HEALTHCARE GROUP

Allied Health says the Australian Therapeutic Goods Administration has authorized the use of its Cardiocel, bovine tissue patch under an authorized prescriber scheme.

The approval is effectively the first commercial use of the treated bovine cardiac patch and competitor products are believed to sell for about $750 each.

Allied said that the authorized prescriber scheme allowed cardiothoracic surgeons to apply to use Cardiocel for reconstruction and repair of congenital heart defects in patients prior to marketing approval under a special access program once the product had been reviewed by the hospital.

The company said that Brisbane's Mater Hospital had reviewed the product and Prof Tom Karl was able to use Cardiocel to repair and reconstruct congenital heart defects.

Allied said that congenital heart defects were a major cause of infant death, worldwide.

Allied managing director Lee Rodne said that TGA-authorized prescriber status demonstrated the support the company was receiving from key surgeons.

"Crucially it brings our Adapt treated tissue to a major patient group in need in Australia," Mr Rodne said.

Allied regenerative medicine chief executive officer Bob Atwill said his team was "very excited about pre-approval authorization for use".

"A number of other key cardiothoracic surgeons are also in [the] process of making similar applications to the TGA as a result of Cardiocel's preclinical and clinical data showing its effectiveness in treating congenital heart defects," Mr Atwill said.

Allied said that its Adapt technology had shown significant anti-cytotoxic and anti-calcification properties in preclinical studies and a phase II clinical study.

The company said those properties helped prevent cell damage and the hardening of tissue after surgery, demonstrating Cardiocel's "significant benefits over existing tissues".

Allied said that the use of Cardiocel was expected to reduce or eliminate the need for repeat surgeries in paediatric patients, potentially a significant impact on patients' lives.

The company said that the use of Cardiocel in congenital heart defect patients filled a high unmet clinical need and it was expecting additional hospitals to be successful in their authorized prescriber applications to the TGA in the coming months.

Allied said that the Adapt platform technology, used in the production of Cardiocel, had the potential to have a major impact on global markets for many soft tissue repair and reconstruction surgical procedures.

The company said that in addition to the cardiovascular suite of products, it was evaluating other applications for its Adapt tissue engineering platform technology, such as pelvic floor reconstructions, hernia repairs, orthopaedics and as a biological scaffold to grow and deliver stem cells.

Allied Health was up 0.5 cents or 23.8 percent to 2.6 cents with 13.5 million shares traded.

ALCHEMIA

Last night's edition reported that there had been no unexpected toxicities among Alchemia's first 82 patients to receive 10 cycles or more of treatment in its randomized pivotal phase III trial of HA-irinotecan for metastatic colorectal cancer.

Alchemia has told Biotech Daily more than 215 patients had been recruited to the trial and were in a range of stages of treatment from one cycle to more than 10 cycles and there had been no unexpected toxicities among any of the treated patients.

The mistake was made by the Collins Class sub-editor who was very expensive and could not perform her primary function. She has been retired from active service.

Alchemia was up two cents or four percent to 51.5 cents.

ANTISENSE THERAPEUTICS

Antisense says the US Patent Office has allowed a patent entitled 'Modulation of Growth Hormone Receptor Expression and Insulin-like Growth Factor 1 Expression'.

Antisense said that the US patent covered the application of ATL1103 "to the human growth hormone receptor (GHr) and other effective and useful antisense oligonucleotide therapeutics to the human growth hormone receptor (GHr) capable of reducing serum insulin like growth factor 1 (sIGF-1) for the treatment acromegaly and other diseases that would benefit from sIGF-1 reduction".

The company said the patent was expected to be granted in the coming months and would protect these inventions until December 2024.

Antisense said that ATL1103 was a second generation antisense drug that targeted the human growth hormone receptor and had been shown in animal studies and in a phase I study in normal volunteers to reduce growth hormone receptor expression and serum insulin like growth factor 1.

The company said that normalization of sIGF-1 was the therapeutic endpoint in the treatment of acromegaly and reduction of sIGF-1 had a potential role in the treatment of certain cancers and diabetic complications.

Antisense said it was in advanced preparations for a phase II clinical trial of ATL1103 in patients with acromegaly.

Antisense drug discovery and patents director Dr George Tachas said the company was "delighted to have this important US patent application allowed for grant as it provides expanded protection beyond that already in place for ATL1103".

"Importantly it provides additional protection for ATL1103 by blocking the development of other gene-silencing or RNA targeting approaches that would result in sIGF-1 reduction," Dr Tachas said.

Antisense was up 0.2 cents or 11.1 percent to two cents with 38.2 million shares traded.

PHOSPHAGENICS

Phosphagenics says the Boots retail chain will no longer stock its Bodyshaper anti-fat cream, launched in the United Kingdom on June 1, 2012.

In May, Phosphagenics said the Bodyshaper UK launch would be supported by a comprehensive marketing and local public relations campaign (BD: May 21, 2012).

Today, Phosphagenics said on the sixth page of a 10-page 'September 2012 Newsletter' that "Boots have completed the Latest Finds promotion that included the sale of Bioelixia's Bodyshaper product in the UK. Boots will not continue to stock the product but we believe the exposure will assist us in appointing other stockists in Europe in 2013".

The May 21 announcement to the ASX was tagged by the company as market sensitive, while today's newsletter was not.

In May, Phosphagenics chief executive officer Dr Esra Ogru said that launching the company's "top selling Bodyshaper product, which is part of our Bioelixia range, to a global retailer like Boots is a coup for our company".

Bodyshaper includes AOP9604 (then known as AOD9604) which Phosphagenics licenced from Calzada (BD: Sep 22, 2010).

No one from Phosphagenics was available to speak with Biotech Daily at the time of publication.

Phosphagenics fell half a cent or 3.7 percent to 13 cents.

ATCOR MEDICAL

Atcor shareholders will vote to issue chief executive officer Duncan Ross 1,400,000 options exercisable at 8.4 cent or 10 percent more than the five-day volume weighted average price.
Atcor said the options would be issued under the employee share option plan and would vest in three tranches, exercisable within three years of issue.
The company said shareholders would vote on the re-election of directors Prof Michael O'Rourke and Dr David Brookes.
The meeting will be held at the Dibbs Barker, Level 8, Angel Place, 123 Pitt Street, Sydney on October 26, 2012 at 11am (AEDT).
Atcor was untraded at six cents.

ISONEA

Isonea has requested a voluntary suspension to follow the trading halt it requested on September 24, pending a capital raising (BD: Sep 24, 2012).
Isonea last traded at 5.4 cents.

BLUECHIIP

Bluechiip says it has appointed Brett Roberts as commercial director to drive sales of its sample tracking system.
Bluechiip said Mr Roberts would plan, control and manage its sales, marketing and business development activities.
Bluechiip chief executive officer Brett Schwarz said the appointment was important as the company made the transition from research and development to a commercial entity with sales.
The company said that Mr Roberts was the founder of Melbourne sales consultancy Critical Moments and previously held senior sales positions with the Athletes Foot, Pfizer Australia, Hi-Fert (now Impact Fertiliser) and cord blood bank Cell Care Australia.
Bluechiip was unchanged at 25 cents.