Biotech Daily

Monday February 10, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: USCOM UP 28%, PRANA DOWN 16.5%**

*** FDA CLEARS ADMEDUS CARDIOCEL FOR US MARKET**

*** CYNATA HIRES WAISMAN FOR STEM CELL MANUFACTURE**

*** CLINUVEL STARTS PHASE II SCENESSE HAILEY-HAILEY DISEASE TRIAL**

*** USCOM WINS 4-STAR CENTRAL BLOOD PRESSURE RATING**

*** PSIVIDA H1 REVENUE UP 4.5% TO $1.3m, LOSS UP 39% TO $8m**

*** US PATENT FOR CELLMID FOR PREVENTING SURGICAL ADHESIONS**

MARKET REPORT

The Australian stock market was up 1.08 percent on Monday February 10, 2014 with the S&P ASX 200 up 55.6 points to 5,222.1 points.

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

Uscom was the best, up four cents or 27.6 percent to 18.5 cents with 97,000 shares traded, followed by Psivida up 50 cents or 10.4 percent to $5.30 with 4,700 shares traded.

Admedus climbed 9.4 percent; Osprey was up 4.6 percent; QRX was up 3.0 percent, Benitec, Cochlear, Resmed, Reva and Universal Biosensors rose more than two percent; with CSL, Ellex, Medical Developments, Mesoblast and Tissue Therapies up more than one percent.

Prana led the falls, down 19.5 cents or 16.5 percent to 99 cents, with 4.5 million shares traded.

Both Prima and Optiscan fell 7.4 percent; Cellmid lost 5.4 percent; Avita and Phosphagenics fell four percent or more; Anteo, Atcor, Oncosil and Pharmaxis were down more than three percent; Patrys and Starpharma shed more than two percent; Neuren and Viralytics were down more than one percent; with Acrux, Alchemia, Bionomics and Nanosonics down by less than one percent.

ADMEDUS

Admedus says the US Food and Drug Administration has cleared its bovine cardiac repair tissue Cardiocel for the US market.

Admedus said that Cardiocel was its lead regenerative tissue product to repair and treat a range of cardiovascular and vascular defects.

The company said it would complement its existing product launch in Europe with preparation for initial sales in the US, expected by July 2014.

Admedus said that in the US, Cardiocel was intended for pericardial closure and for the repair of cardiac and vascular defects in both adults and children.

Admedus chief executive officer Lee Rodne said the approval was “a significant milestone … as we expand into global markets and further develop our range of regenerative tissue products for commercialization and sale”.

“Cardiocel is an important addition to the surgeon’s armory in the treatment of congenital heart disease, as well as for the repair of heart valves and other cardiac defects,” Mr Rodne said.

Admedus said that with approvals in both Europe and the US it would pursue market approvals for Cardiocel in Asia and other jurisdictions.

“Admedus is looking forward to an exciting 2014-‘15 as we launch Cardiocel globally and continue to grow our sales revenue and cardiovascular teams in these regions,” Mr Rodne said.

The company said that Cardiocel used its Adapt tissue engineering process to create a durable, pure collagen scaffold that avoided calcification, supported native cell infiltration, growth and differentiation and promoted a regenerative healing process.

Admedus said that the a ready-to-use, off-the-shelf Cardiocel had shown benefits over existing products by not calcifying like other tissues and facilitated autologous tissue regeneration once surgically implanted, while retaining strength and natural elasticity.

The company said that the Cardiocel program was supported with a grant from Commercialisation Australia, funded by the Australian Federal Government.

Admedus was up 1.5 cents or 9.4 percent to 17.5 cents with 43.8 million shares traded.

CYNATA THERAPEUTICS

Cynata says the Madison, Wisconsin-based Waisman Biomanufacturing will manufacture its Cymerus off-the-shelf stem cells.

Cynata said that Waisman would undertake the manufacturing process development, scale-up and clinical-grade manufacture of the Cymerus stem cells to take the stem cell technology to clinical trials and commercial transactions.

Cynata chief executive officer Dr Ross Macdonald said that Waisman had extensive experience in manufacturing process development and the production of biologic products for human clinical trials.

“Our pre-clinical studies have shown great promise for bringing the Cymerus technology into the clinic and eventually to the market,” Dr Macdonald said.

“The next step is the establishment of this relationship to demonstrate the commercial scalability of Cymerus to address substantial market opportunities,” Dr Macdonald said.

Cynata said that Waisman was close to centres of stem cell discovery and research in Madison, including the laboratories of Cynata co-founder Prof Igor Slukvin.

Cynata said that the Cymerus technology included proprietary methods of manufacture of stem cell therapeutic products that were believed to provide advantages over the current generation of multi-donor dependent manufacturing methods.

Cynata was unchanged at 40 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says that a physician-led 10-patient phase II study of Scenesse for Hailey-Hailey disease has begun in Italy, with recruitment expected to be completed by March 2014.
In 2013 Clinuvel said that a physician-led two-patient pilot study in Rome showed that Scenesse (afamelanotide 16mg implant) could offer long term remission from Hailey-Hailey disease (BD: Oct 28, 2013).
Today, Clinuvel said the 10 patients would be treated with 12 doses of Scenesse over 12 months, with a three month clinical follow up period and results by the end of 2015.
The company said that in 2012, the proof-of-concept pilot study of afamelanotide in Hailey-Hailey disease was carried out in two female patients, aged 53 and 61 years, who had existing skin lesions and ulcerations which had been present since their adolescence.
The company said that following afamelanotide treatment, the lesions began to decrease in size and totally disappeared by day 60.
Clinuvel said that the clinical remission was also reflected by an improved quality-of-life survey, with no adverse reactions reported.
The company said that both patients experienced moderate skin tanning, as expected on the basis of the secondary pharmacology of Scenesse.
Clinuvel said that disease recurrence was seen eight months after completion of the treatment and by comparison, only few complete or partial remissions are reported in the literature.
The company said that afamelanotide was an analogue of alpha-melanocyte stimulating hormone (alpha-MSH) and has been shown to be an effective photo-protective agent in a range of skin disorders other than Hailey-Hailey disease.
Clinuvel said that several preclinical studies had provided evidence that natural alpha-MSH had potent protective and anti-oxidative effects in cutaneous cells.
The company said that alpha-MSH affected various pathways implicated in the regulation of inflammation and cytoprotection and in particular alpha-MSH had been shown to increase expression of nuclear respiratory factor 2, a key transcription factor involved in the expression of anti-oxidative enzymes in keratinocytes.
Clinuvel said that it was plausible that Scenesse as a potent alpha-MSH analogue could mimic its physiological antioxidant properties.
Clinuvel said that Hailey-Hailey disease, also known as familial benign pemphigus, was a rare, chronic, inherited disorder where epidermal skin cells, or keratinocytes, do not adhere correctly, causing periodic eruption of plaque-like lesions and blisters on areas where skin folds, often on the neck, armpits or groin.
The company said that Hailey-Hailey disease could be very distressing for patients, with outbreaks on the legs and groin leading to immobilization due to the pain of friction and a high risk of skin infection.
Clinuvel said that current treatments, including topical corticosteroids and antibiotics, could manage minor outbreaks, but were seen as ineffective in severe cases and there was no professional consensus on a first-line therapy as no remission had been achieved.
The company said prevalence was one in 50,000 and there were reports that Hailey-Hailey disease patients were predisposed to skin cancer.
Clinuvel chief executive officer Dr Philippe Wolgen said that “from a clinical viewpoint, we have learned during the past decade that the potential of Scenesse to treat severe skin disorders may be quite substantial”.
“We are gradually beginning to understand the positive impact Scenesse can have on disorders where suprabasal skin cell separation is manifest,” Dr Wolgen said.
Clinuvel was untraded at $1.45.

USCOM

Uscom says a study identifies central blood pressure as a new clinical standard for hypertension and its BP+ as a leading device for measuring central blood pressure.
Uscom said the independent study of 10 devices was authored by researchers from England's Cambridge University, the Wales Heart Institute in Cardiff, New York's Weill Cornell Medical College and the University of California, Irvine.
The company said that the study reviewed evidence supporting adoption of central blood pressure over conventional blood pressure measurement and ranked the devices, awarding the Uscom BP+ and the Centron device a four-star rating.
Atcor's Sphygmocor XCel received a three-star rating with two other Atcor devices a one-star rating.
Biotech Daily has seen the article which focused on the utility of central blood pressure and the comparison was made in one table and without clear explanation of the star rating, which was described as a "personal view based on experience, operator-dependency, need for computer/software interface, with [one-star] indicating limited applicability to routine clinical practice and [four stars] indicating high applicability".
The article, entitled 'Central blood pressure: current evidence and clinical importance' was published in the European Heart Journal and an abstract is available at: http://eurheartj.oxfordjournals.org/content/early/2014/01/22/eurheartj.eht565.abstract.
Uscom said that the study concluded that central blood pressure better predicted cardiovascular risk than conventional arm cuff blood pressure measurements and that treatment based on central blood pressure was likely to improve diagnosis and management of hypertension.
Uscom said that the blood pressure device market was estimated at about $US2 billion and growing at 11.5 percent a year.
The company said that its BP+ was "a break-through" technology based on patent protected supra-systolic oscillometry, which had US Food and Drug Administration clearance and had completed the Conformité Européenne (CE) mark process for Europe.
Uscom executive chairman Rob Phillips said the review of the current science by the world's leading hypertension experts "comes at a great time for us as we negotiate global distribution and licensing agreements for BP+".
"The study confirms that [central blood pressure] is the new gold standard measurement for hypertension, and that the Uscom BP+ is the gold standard … technology," Mr Phillips said.
Mr Phillips said that Uscom was preparing to manufacture the device to meet this demand as the world began the upgrade from conventional blood pressure to central blood pressure technology.
Uscom was up four cents or 27.6 percent to 18.5 cents.

PSIVIDA

Psivida says that revenue for the six months to December 31, 2013, was up 4.5 percent to $US1,189,000 ($A1,331,410) with net loss after tax up 38.6 percent to $US7,259,000.
Psivida said an increase in collaborative research and development revenue compensated for a fall in royalty income.
The company said that diluted loss per share was up 17.4 percent to 27 US cents.
The company said that it had cash and cash equivalents of $US15,721,000 at December 31, 2013 compared to $US10,273,000 at June 30, 2013.
Psivida was up 50 cents or 10.4 percent to $5.30.

CELLMID

Cellmid says the US Patent and Trademark Office has allowed a patent entitled 'Preventative for Adhesion Following Abdominal Surgery'.

Cellmid said that the patent protected the use of midkine-specific DNA and RNA antisense molecules that disrupted midkine expression and prevented the formation of surgical adhesions, complementing a granted patent entitled 'Agents for Preventing Post-Laparotomy Adhesions, covering the use of anti-midkine antibodies (BD: April 18, 2012).

The company said that other patents in the family had been granted in Japan, were under examination in Europe and its portfolio included more than 80 patents in 19 patent families covering the use of midkine and anti-midkine agents for diseases including cancer, inflammatory conditions and autoimmune diseases, as well as patents for midkine as a diagnostic marker in cancer and other disorders.

Cellmid said the adhesion patents made up one of the five key families which provided a dominant patent position over treatment of inflammatory diseases by targeting midkine.

Cellmid said that adhesion was the build-up of internal scarring following surgery and adhesions frequently occurred between different organs or between organs and the abdominal wall, causing pain and sometimes infertility in women.

The company said that adhesions occurred in more than 95 percent of abdominal operations, were under-recognized and accounted for six percent of all readmissions following surgery, costing about $US3 billion in the US and $US5 billion globally, with no drugs available for preventing adhesions.

The company said that surgical adhesion was most frequently treated by further surgery to sever the adhesions and about 85 percent of those resulted in more adhesions.

Cellmid said that the leading method for preventing abdominal surgical adhesions was insertion of bio-absorbable barriers during surgery, but this practice was often ineffective, extended operating time and associated costs, with increased risks.

The company said that nucleotide-based drugs had been difficult to deliver so that they achieved pharmacokinetic levels that allow for a therapeutic effect.

Cellmid said that an anti-midkine drug could be administered directly to the site of surgery negating the requirement for a delivery agent so that a nucleotide-based drug, such as an anti-midkine antisense, DNA or RNA interference drug covered by this patent, could be a feasible and effective therapy for adhesions and it was preparing its anti-midkine antibody program for first-in-class clinical trials.

Cellmid said that one of the objectives of the trial was to demonstrate that midkine could be a safe therapeutic target.

The company said that evidence of safety of an anti-midkine agent could open up opportunities for a number of pipeline products "due to the strong intellectual property position Cellmid holds around this novel disease target".

Cellmid fell 0.2 cents or 5.4 percent to 3.5 cents with 19.8 million shares traded.