Biotech Daily

Monday March 9, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ATCOR UP 14%, GENETIC TECHNO DOWN 16%**

*** DEATHS TAKE SUNSHINE HEART TO 'TEMPORARY ENROLMENT PAUSE'**

*** GENETIC TECHNOLOGIES RAISES $18.6m**

*** MAYO CLINIC JOINS IMPEDIMED L-DEX STUDY**

*** ORTHOCELL READY FOR PILOT DENTAL BONE REPAIR TRIAL**

*** REGENEUS APPLIES FOR HUMAN PROGENZA OSTEOARTHRITIS TRIAL**

*** CORRECTION: SIRTEX**

MARKET REPORT

The Australian stock market fell 1.32 percent on Monday March 9, 2015 with the S&P ASX 200 down 77.6 points to 5,821.3 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 20 fell, four traded unchanged and two were untraded.

Atcor was the best, up 1.5 cents or 13.6 percent to 12.5 cents with 513,209 shares traded.

Optiscan climbed 9.1 percent; Biotron rose 7.7 percent; Circadian and GI Dynamics were up more than six percent; Medical Developments was up 4.3 percent; IDT and Prana were up more than three percent; Clinuvel, Prima and Uscom rose more than two percent; Mesoblast, Osprey and Tissue Therapies were up more than one percent; with Resmed up 0.9 percent.

Genetic Technologies led the falls, down 0.8 cents or 16.0 percent to 4.2 cents with 16.2 million shares traded.

Compumedics, Oncosil and Universal Biosensors lost more than seven percent; Phosphagenics fell 6.15 percent; Benitec, Impedimed, Neuren and Viralytics fell more than four percent; Alchemia, Anteo, Antisense, Living Cell, Nanosonics and Sirtex were down three percent or more; Admedus and Starpharma shed two percent or more; Acrux, Cochlear, CSL and Pharmaxis were down more than one percent; with Bionomics down 0.9 percent.

SUNSHINE HEART

Sunshine Heart says it is “taking a temporary pause from enrolment” of its C-Pulse aorta cuff pump trial, following four patient deaths which it says appear non-device related.
Sunshine Heart said that the ‘Counter HF’ pivotal US trial was a prospective, randomized, multi-center, controlled study evaluating the safety and efficacy of the C-Pulse system for the treatment of New York Heart Association class III and ambulatory class IV heart failure, expected to randomize 388 patients in up to 40 clinical sites.
The company said that the number of patients considering enrolment increased from seven in the three months to March 31, 2014 to approaching 100 for the three months to March 31, 2015.
Sunshine Heart said that the enrolment “pause” was in accordance with the study protocol where in the event more than three of the first 20 subjects died for any reason, including non-device related deaths, it would work with the US Food and Drug Administration to discuss a plan to resume enrolment.
The company said that of the four reported patient deaths two had been adjudicated by an independent clinical events committee as non-device related.
Sunshine Heart said it had received study documentation from the sites that reported the most recent two deaths that these were also non-device related, and patients in the trial would continue follow-up according to the protocol.
Sunshine Heart said the FDA had advised it to file an investigational device exemption supplement discussing the reasons for the suspension and a plan for resumption.
The company said that a supplement carried up to a 30-day review period by the FDA and it expected to submit the document by March 16, 2015.
Sunshine Heart chief executive officer Dave Rosa said the company was “confident this matter will be resolved in a very short timeframe”.
“While the current data suggest these incidents are non-device related, we have decided that in the absolute interest of patient safety, having a temporary pause in enrolment is the right course of action while we work with the FDA to discuss the findings,” Mr Rosa said.
“We remain excited by the increasing number of patients who are being presented for study review and are pleased that the screening process for enrolment will continue while we resolve this matter,” Mr Rosa said.
On the Nasdaq on Friday, Sunshine Heart fell $US1.32 or 24.67 percent to $US4.03 ($A5.23 equivalent to 2.7 cents prior to departing the ASX) with 2,910,449 shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has raised about $18.6 million at a weighted average issue price of 3.72 cents a share from US-based professional and sophisticated investors.
Genetic Technologies said it was selling the securities directly to the US investors and retained Maxim Group LLC as its placement agent.
The company said that offer of 499,999,950 Australian shares was equal to 3,333,333 American depositary shares (ADS) with each ADS representing 150 Australian shares.
Genetic Technologies said the funds would support the refocused US molecular diagnostics market and commercialization of the Brevagenplus breast cancer risk test.
Genetic Technologies chief executive officer Eutillio Buccilli said the company was “extremely pleased by both the approval by shareholders of all resolutions at the extraordinary general meeting this morning and our successful securing of commitments for approximately $18.6 million further capital”.
Genetic Technologies fell 0.8 cents or 16.0 percent to 4.2 cents with 16.2 million shares traded.

ORTHOCELL

Orthocell says it has ethics approval for a 15-patient pilot study examining the safety and effectiveness of its Celgro collagen scaffold to repair bone loss around dental implants.
Orthocell said that the Subiaco, Western Australia-based St John of God Hospital approved the trial to begin by July 2015, to be carried out by oral and maxillofacial surgeon Dr Brent Allan in collaboration with the University of Western Australia.
Orthocell managing director Paul Anderson said the study was “an important step in the development of Celgro and further demonstrates that Celgro is a very valuable product in the large and growing regenerative medicine market”.
The company said that guided bone regeneration was the standard-of-care to support new bone formation at dental implant sites, with a barrier membrane placed over the bone defect to allow the in-growth of bone without competition from gum tissue.
Orthocell said that Celgro was different from other membrane barriers and was “completely pure and free from cells and reactive DNA and [had] been shown to promote tissue in-growth and repair”.
The company said that the Celgro scaffold had been developed for use in surgical applications such as tendon repair, dental applications and restructuring of damaged soft tissue in the body.
Orthocell said that there were more than three million dental implant procedures carried out in US every year and that number was growing by 500,000 a year, which was a significant potential market opportunity for Celgro.
Orthocell was up one cent or 2.9 percent to 36 cents.

REGENEUS

Regeneus says it has completed a study in rabbits of its Progenza stem cell product for osteoarthritis and will apply for ethics approval for a first-in-human safety study.
Regeneus said the ethics application would be for a clinical trial to assess safety and preliminary efficacy of the fat-derived, allogeneic, off-the-shelf Progenza in patients with osteoarthritis of the knee.
Regeneus clinical research director Janet Wilson said the study was “an important milestone in taking Progenza through the regulatory approval process”.
The company said that the study showed no Progenza-related safety or toxicity issues, “even at doses well in excess of the intended human dose”.
Regeneus said that Progenza-treated knees showed no deterioration from the time of injection, in contrast to the vehicle control group, which continued to deteriorate over the seven week study.
“The planned trial is a single centre study and will include patients with symptomatic knee [osteoarthritis],” Ms Wilson said.
Ms Wilson said that Progenza would be injected once into the knee and along with safety monitoring, assessments for preliminary efficacy, such as magnetic resonance imaging before and after treatment would be included.
Regeneus said that using donor adipose, or fat, tissue the stem cells were expanded and was in contrast with autologous stem cell therapy where a patient’s own stem cells were used as the therapeutic product.
The company said that stem cells, such as Progenza, “work by homing to the site of injury and damage, exerting action through the production and release of various growth factors and anti-inflammatory proteins to stop cell death and promote healing and normal growth”.
Regeneus was up one cent or 6.45 percent to 16.5 cents.

IMPEDIMED

Impedimed says the Jacksonville, Florida-based Mayo Clinic has joined the L-Dex lymphoedema post-approval clinical trial.

Impedimed said that Mayo Clinic's Dr Sarah McLaughlin was named as the site's principal investigator.

Last year, Impedimed said that the randomized controlled trial would enrol 1,100 patients and was led by the Nashville Tennessee-based Vanderbilt University School of Nursing's Prof Sheila Ridner as principal investigator, would be completed in about two years and conducted in at least five sites in the US and Australia. (BD: Jun 26, 2014).

The company said that other sites participating in the trial were Macquarie University and the MD Anderson Cancer Center.

Impedimed fell 3.5 cents or 4.2 percent to 80.5 cents.

SIRTEX MEDICAL

Last Friday's edition headlined the article on Hunter Hall being forced by its investment rules to sell down in Sirtex as it had sold down to $7, which should have been 7%.

The mistake was made by the Friday sub-editor who has been reprimanded, but in recognition of both the Victoria Labor Day Moomba public holiday and International Women's Day has not had her pay reduced, any further.

Sirtex fell $1.25 or 3.5 percent to $34.54 with 229,622 shares traded.