Biotech Daily

Thursday June 5, 2014

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: NEUREN UP 12%, LIVING CELL DOWN 10%**

*** ORTHOCELL $8m IPO FOR STEM CELL TENDON, SOFT TISSUE INJURIES**

*** CALZADA, POLYNOVO TREAT 1st NOVOSORB MAJOR BURNS PATIENT**

*** ALCHEMIA HA-IRINOTECAN TRIAL RESULTS DELAYED 3 MONTHS**

*** FDA WARNING LETTER FOR HEARTWARE'S MIAMI LAKES PLANT**

*** STARPHARMA DOCETAXEL TRIAL UNDERWAY, PHASE III VAGINOSIS**

*** COMPUMEDICS US SUPPLY AGREEMENT WITH MEDASSETS**

*** NUSEP CHANGES SINGAPORE SCRIP PAYMENT TO DEBT**

MARKET REPORT

The Australian stock market slipped 0.15 percent on Thursday June 5, 2014 with the S&P ASX 200 down 7.9 points to 5,436.9 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and two were untraded.

Neuren was the best on no news, up 0.8 cents or 11.9 percent to 7.5 cents with 5.55 million shares traded, followed by Optiscan up 10 percent to 3.3 cents with 30,000 shares traded.

Alchemia and GI Dynamics climbed more than five percent; Uscom was up 4.2 percent; Analytica, Bionomics and Universal Biosensors rose more than two percent; Benitec, Biotron, Phosphagenics and Tissue Therapies were up more than one percent; with Acrux, Nanosonics and Resmed up by less than one percent.

Living Cell led the falls, down 0.5 cents or 10.0 percent to 4.5 cents with 133,170 shares traded.

Circadian lost 6.4 percent; Prana fell 5.4 percent; Anteo, Atcor and Oncosil fell more than four percent; Medical Developments was down 3.1 percent; Impedimed, Mesoblast and Prima shed more than two percent; Pharmaxis lost 1.6 percent; with Cochlear, CSL, Sirtex and Starpharma down less than one percent.

ORTHOCELL

Orthocell says its initial public offer to raise up to $8 million at 40 cents a share to develop treatments for tendon, cartilage and soft tissue injuries has opened.

In April, Orthocell managing director Paul Anderson told Biotech Daily that the company had Australian Therapeutic Goods Administration approval for its autologous, or patient's own, chondrocytes and tenocytes processes and was in the process of applying for TGA approval for the Celgro pig-derived collagen scaffold (BD: Apr 16, 2014).

Mr Anderson said at that time that the funds raised would be primarily for the European and US regulatory processes for its autologous tenocyte implants (Ortho-ATI) and autologous chondocyte implants (Ortho-ACI), as well as to develop its pig-based collagen scaffold for soft tissue reconstruction indications, including pelvic floor reconstruction, vaginal defects, ear drum repair and bladder wall defects.

Today, Orthocell said that the offer, led by KTM Capital and Azure Capital with Shaw Stockbroking as co-manager, opened today and would close on June 27, 2014.

Orthocell said the prospectus was available at www.orthocell.com.au.

CALZADA

Calzada says the first of five patients has been treated and released from the intensive care unit in its trial of Novosorb for major burns.

Last year, Calzada began the trial of wholly-owned subsidiary Polynovo's Novosorb biodegradable temporizing matrix (BTM) in significantly injured burn patients at the Royal Adelaide Hospital assessing Novosorb when implanted in adult patients with deep dermal and full thickness burns to between 20 percent and 50 percent of their body surface area (BD: Jan 19, 2014).

The company said that the goal of the trial was to assess the integration of the matrix in the wound, the ease of removal of the seal prior to skin grafting and the minimization of contraction and scarring.

Calzada said the middle-aged patient sustained flame burns to 75 percent of his total body surface area with full thickness burns affecting 45 percent of his total body surface area.

The trial's principal investigator Dr John Greenwood said the injuries were "a very significant and major burn injury for a patient of this age".

"His clinical course has been exemplary and today, after three weeks, he left the intensive care unit for the burns unit, signifying that his previously critical condition is now stable," Prof Greenwood said.

"We have been closely monitoring the progress of the BTM, which covers approximately 0.4 square metres," Prof Greenwood said.

"To date his treatment, including the use of the BTM, has progressed as planned," Prof Greenwood said.

Calzada said that the study began recruitment on January 1, 2014 had been slow to start, with few significant burns patients admitted in 2014 and those so far had fallen outside the study inclusion criteria.

The company said that the burns trial and the first patient treatment was "an important step in the development of the [matrix] using the Novosorb technology to treat burns".

Calzada said that knowledge and data from the trial would be used in designing the protocol for a European burn trial.

Polynovo chief executive officer Laurent Fossaert said Polynovo and Dr Greenwood's team had collaborated for nearly 10 years and they hoped the first patient and the trial would pave the way for better treatment for burns victims.

Calzada was unchanged at 11.5 cents.

ALCHEMIA

Alchemia says its phase III trial of hyaluronic acid irinotecan (HA-irinotecan) for metastatic colorectal cancer has been delayed by a further three months.

Last year, Alchemia said it expected the trial results by July 2014 but today revised that to by October 2014 (BD: Nov 28, 2013).

In 2012, Alchemia said the trial would take about 12 months to recruit then expected 390 patients with the primary endpoint reached when 350 patients experienced disease progression; expected by October 2013 (BD: Jan 22, 2012).

Alchemia chief executive officer Thomas Liquard said that “based on the number of events accumulated to date and the progress the team is making on preparing the data for database lock, we expect to announce the phase III top line results before the end of [September] 2014”.

“We are excited to be approaching the period when the primary endpoint analysis will be conducted on our HA-irinotecan phase III trial, and we look forward to communicating the results of this pivotal trial to the community at the earliest opportunity,” Mr Liquard said.

Alchemia said that the 415-patient trial randomized the first patient in December 2011 and recruited the last patient in February 2013 and had completed four safety reviews by the data safety monitoring board.

The company said that colorectal cancer was one of the most common cancers, with more than 1.2 million new cases diagnosed annually and was the second leading cause of cancer deaths in the US, claiming more than 50,000 lives each year.

Alchemia said that more than $7.5 billion was spent annually on colorectal cancer drug treatments across the major markets.

The company said that “assuming a positive outcome of the primary endpoint analysis” US and European regulatory submissions were expected to be filed by July 2015, instead of the previously advised April 2015.

Alchemia said that the change to filing timelines was “driven primarily by the need to accommodate the drug-product stability data package needed for submission”.

Alchemia was up 2.5 cents or 5.15 percent to 51 cents.

HEARTWARE INTERNATIONAL

Heartware says the US Food and Drug Administration has issued a warning letter following an inspection of its Miami Lakes, Florida heart pump facility.

Heartware said that the operations, development and manufacturing facility was inspected in January 2014 and the FDA letter cited four categories for the company to address including procedures for validating device design, including device labeling; procedures for implementing corrective and preventive action; maintaining records related to investigations; and validation of computer software used as part of production or quality systems.

The company said the FDA letter did not require any action by physicians or patients and did not restrict use of Heartware's left ventricular assist devices.

Heartware said it took the matter seriously and would respond to the FDA letter within the required 15 days.

The company said it expected to implement new and enhanced systems and procedures, and would perform additional actions as may be required to resolve the issues raised.

Heartware chief executive officer Doug Godshall said that the company was dedicating the resources necessary to address the items discussed in the letter”.

Last night on the Nasdaq, Heartware fell $US1.07 ($A1.15) or 1.19 percent to $US 88.84 ($A95.75) with 152,676 shares traded.

STARPHARMA

Starpharma says the first patient group in its 30-patient, phase I dose-escalation trial of dendrimer-docetaxel for solid tumors has received one or more cycles of treatment.

Starpharma said that along with the Nucleus Network at Melbourne's Alfred Hospital, Melbourne's Austin Health and the Royal Brisbane and Women's Hospital had received ethics approval and were due to commence enrolment (BD: Jan 23, 2014).

The company said that so far dendrimer docetaxel had shown "very good tolerability ... with no evidence of neutropenia" or low white blood cell count.

Starpharma chief executive officer Dr Jackie Fairley said that while it was early in the trial "it is very encouraging to see that the patients treated so far have shown no signs of neutropenia, one of the most important, dose-limiting side effects of docetaxel and other forms of chemotherapy".

Starpharma said that about 25 to 30 patients with solid tumors would be enrolled in the trial, with the primary objective of establishing the maximum tolerated dose, as determined by the occurrence of dose limiting toxicities of dendrimer enhanced docetaxel or DEP-docetaxel given intravenously, once every three weeks, with the secondary objectives to characterize the safety, pharmacokinetic and tolerability profiles of DEP-docetaxel in patients with advanced cancer.

Starpharma said that in characterizing the safety profile of DEP-docetaxel, the study would investigate the impact of the improved dendrimer formulation on problematic side effects seen with Taxotere, such as neutropenia, which was markedly reduced with the dendrimer formulation in pre-clinical studies, as well as anaphylaxis and hair loss.

Starpharma said that docetaxel was marketed by Sanofi Aventis under the trade name Taxotere to treat solid tumors including breast, lung and prostate and generated sales of more than $US3 billion in 2010.

Starpharma said that it had reached agreement with US and European regulators for the trial design of its phase III trial of Vivagel for the prevention of recurrent bacterial vaginosis and preparations were underway "for the imminent commencement of two pivotal phase III clinical trials ... in North America, Europe and Asia".

The company said that Quintiles had been appointed for the trials and about 600 women would be recruited to each trial with the primary efficacy endpoint of recurrence of bacterial vaginosis over a 16-week treatment period.

Starpharma said that the previous phase II trial for prevention of recurrent bacterial vaginosis was a double-blind exploratory study in 205 US women comparing one-percent Vivagel with placebo, which showed that Vivagel reduced recurrent bacterial vaginosis and delayed time to first recurrence.

Last year, Starpharma reported that the trial failed to meet its primary endpoint with a "clinically" but not statistically significant difference between Vivagel and placebo with a significance of p = 0.0588 (BD: Apr 3,4, 2013).

In 2012, Starpharma reported that Vivagel failed to meet its phase III trial primary endpoint of "clinical cure [of bacterial vaginosis] at two to three weeks after the cessation of treatment" (BD: Nov 28, 29, 2012).

"Starpharma has an opportunity to be first in class with a therapeutic to prevent the recurrence of [bacterial vaginosis, which occurs in a large number of women, and we are looking forward to the commencement of enrolment," Dr Fairley said today.

Starpharma said that in addition to the prevention of recurrence indication for Vivagel it was pursuing regulatory approval in multiple geographies for Vivagel with a claim of symptomatic relief, with the first submissions for the symptomatic relief product expected by the end of 2014.

Starpharma fell half a cent or 0.8 percent to 59.5 cents.

COMPUMEDICS

Compumedics says it has three year agreement with Medassets Purchasing Group for the purchase of its sleep diagnostic and neuro-monitoring systems.

Compumedics said that the Alpharetta, Georgia-based Medassets would provide its 2,800 hospitals and 90,000 acute healthcare facilities with access to buy Compumedics range of sleep diagnostic and neuro-monitoring systems.

The company said it was one of two vendors that had been given preferred vendor status for sleep diagnostic and neuro-monitoring systems to the Medassets Group.

Compumedics executive chairman Dr David Burton said the company was “delighted to announce another substantial contract win for Compumedics”.

“Medassets Purchasing Group is one of the major member networks for hospitals in the US market and to sign a three year agreement with them, giving access to 2,800 hospitals is a significant milestone achievement for our company”.

“Together with the recent announcement of a similar contract win with the HealthTrust Purchasing Group it provides a solid basis for the US business to grow and prosper,” Dr Burton said.

Compumedics was unchanged at 11 cents.

NUSEP HOLDINGS

Nusep says it has renegotiated payment terms for its Singapore facility from a 10 percent holding to a debt facility of $S4,034,000 ($A3,456,590).

Nusep said that the Singapore facility was required for producing human grade pharmaceutical products and would be used by subsidiary, Prime Biologics Pte Ltd to produce protein products, including albumin and immunoglobulins, from blood plasma fractionation and had been independently valued at more than $S9 million.

Nusep said the debt was at an interest rate of five percent a year, repayable in four tranches from March 2016.

The company said that the revised terms meant its share of Prime was maximized.

Nusep said the Prime was valued at $S27 million.

The company said that non-executive director Andrew Goodall had offered to guarantee the debt and documentation was expected to be finalized within seven days.

Nusep said the guarantee would be subject to shareholder approval and provide a guarantee fee of 3.5 percent of the debt, with the ability to be converted to equity

The company said that Mr Goodall’s obligations would be secured by a share charge over up to 20 percent of the shares held by Nusep in Prime

Nusep said that Mr Goodall would be issued a converting note by Nusep and would be granted a call option with respect to up to 20 percent of the equity in Prime held by Nusep

Nusep fell 0.1 cents or 1.5 percent to 6.5 cents.