Biotech Daily

Tuesday July 7, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRIMA UP 44%; POLYNOVO DOWN 5%**

*** AVITA DONATES RECELL, STAFF TO TAIWAN BURNS VICTIMS**

*** ACRUX, LILLY SUE LUPIN OVER AXIRON PATENTS**

*** PRIMA: 'EMA ENDORSES IMP321 PHASE IIb BREAST CANCER TRIAL'**

*** SANDON WITHDRAWS ALCHEMIA BOARD SPILL EGM**

*** USCOM SIGNS 8 DISTRIBUTION AGREEMENTS**

*** PETER MEURS TAKES 19.96% OF SUN**

*** RAFF GROUP TRANSFERS 7.6% OF GENERA**

*** CELLMID APPOINTS DR BRYCE VISSEL ADVISORY BOARD CHAIR**

MARKET REPORT

The Australian stock market climbed 1.94 percent on Tuesday July 7, 2015 with the ASX200 up 106.4 points to 5,581.4 points.

Seventeen of the Biotech Daily Top 40 stocks were up, nine fell, nine traded unchanged and five were untraded. All three Big Caps were up.

Prima was the best, up 2.6 cents or 44.1 percent to 8.5 cents with 82.7 million shares traded, followed by Optiscan up 11.1 percent to six cents with 355,350 shares traded.

Admedus, Cellmid and Ellex climbed more than six percent; Antisense and Mesoblast rose more than four percent; Prana and Universal Biosensors were up more than three percent; Benitec, Clinuvel, CSL, Oncosil, Resmed, Sirtex, Starpharma and Viralytics rose more than two percent; Psivida and Compumedics were up more than one percent; with Cochlear up 0.8 percent.

Polynovo led the falls, down half a cent or five percent to 9.5 cents with 87,000 shares traded.

Biotron, IDT and Osprey fell more than four percent; Actinogen and Tissue Therapies both shed 2.8 percent; Impedimed and Neuren were down more than one percent; with Medical Developments down 0.7 cents.

AVITA MEDICAL

Avita says it has donated 30 Recell wound repair devices and sent experienced burn treatment staff to Taiwan to treat Formosa Fun Coast water park burns victims.

Avita said that an explosion during a party on June 27, 2015 at the water park near the capital Taipei was set off when colored powder being sprayed over the crowd ignited, injuring close to 500 people, most of them in their teens and twenties.

The company said that two people had died from their injuries and about 270 people remained in intensive care units.

Avita chief executive officer Adam Kelliher said that the company "believed a rapid response was necessary when we heard about the magnitude of this disaster and the disturbing accounts of the types of burns that the victims had suffered".

"We have done this purely on an humanitarian basis and are now on-hand and ready to support the medical personnel in any capacity that they may require, particularly now that significant skin graft operations are underway," Mr Kelliher said.

Avita said that Asia Pacific general-manager Lorraine Glover and Perth staff member Phil de Dubois had arrived in Taipei and both had extensive experience in training medics in an operating theatre environment.

The company said that the two staff had taken 30 Recell units as donated devices and more could be shipped if required.

Avita said that Recell was approved in Taiwan in 2010 where Avita is represented locally by Shawhan Biomedical Co.

Avita said that the Recell device originated in Australia to treat victims of the 2002 bombing in Bali, Indonesia and had been used about 6,000 times.

"We will follow the guidance of medics and officials in Taiwan and we are committed to helping them achieve the best outcome for their many patients," Ms Glover said.

"Recell can be of great benefit for supporting the healing of burns patients and we know that it can help reduce scarring, which will of course be a real consideration for so many young people," Ms Glover said.

Avita was unchanged at 8.4 cents.

ACRUX

Acrux says that Eli Lilly and Co, Eli Lilly Export SA and Acrux DDS have filed a lawsuit against Lupin Pharmaceuticals for infringement of US patents that cover Axiron.

Acrux said that the patents were owned by wholly-owned subsidiary Acrux DDS and were exclusively licenced to Lilly.

The company said that the lawsuit was filed in the US District Court for the Southern District of Indiana in response to a notice letter sent by the Baltimore, Maryland-based Lupin regarding its filing to the US Food and Drug Administration of an abbreviated new drug application for a "testosterone metered dose transdermal solution".

The company said that the Lupin letter stated that the application contained Paragraph IV certifications with respect to five US Patents, which were expected to expire between 2026 and 2030, and included claims relating to the application of testosterone formulations to the underarm and to the applicator used to apply Axiron.

Acrux said that Paragraph IV certification alleged invalidity, unenforceability and/or non-infringement of a patent and with Lilly it was "committed to asserting their intellectual property rights for Axiron".

Acrux said that, as with prior notices, the conduct of the lawsuit would not have a material impact on its operating expenditure.

Acrux was unchanged at 85.5 cents.

PRIMA BIOMED

Prima says the European Medicines Agency has “confirmed in writing its endorsement of the development program of IMP321 in metastatic breast cancer”.

Prima said that the 200 patient phase IIb trial was “considered well-designed by the Agency” and was expected to begin in Europe by the end of 2015.

The company said that the multi-center, randomized, double blind, placebo-controlled clinical trial in HER-2 negative metastatic breast cancer patients receiving IMP321 or placebo as adjunctive to the standard-of-care chemotherapy drug paclitaxel would be known as the active immunotherapy paclitaxel, or Aipac, trial

Prima said that the “Agency’s communication has suggested that the achievement of certain clinical endpoints may lead to marketing authorization in the EU based on this one pivotal study”.

The company said that after a smaller safety run-in phase that would extend into 2016 and yield safety, pharmaco-kinetic and pharmaco-dynamic data, the trial would recruit about 200 patients randomizing them to either paclitaxel plus placebo or paclitaxel plus IMP321.

Prima said that the primary endpoint was progression-free survival, with overall survival among the secondary endpoints and the study was powered to show a four-month progression-free survival advantage for the treatment group.

The company said the trial was expected to take about three years.

Prima chief scientific and medical officer Prof Frédéric Triebel said the EMA advice was “a significant step forward in terms of IMP321 clinical development in Europe”.

“We now have the opportunity to introduce active immunotherapy to metastatic breast cancer patients, a promising novel strategy that we believe has the potential to fulfil an unmet medical need,” Dr Triebel said.

Prima said that a phase IIa trial showed IMP321 was able to increase the response rate at six months from the 25 percent expected of paclitaxel to 50 percent for IMP321 with paclitaxel.

Prima was up 2.6 cents or 44.1 percent to 8.5 cents with 82.7 million shares traded.

ALCHEMIA

Alchemia says that Sandon Capital Investments has withdrawn its requisition for an extraordinary general meeting to spill the board.

Last month Sandon requested a meeting to replace directors Tim Hughes and Dr Tracie Ramsdale with Dinimus Capital principal Ken Poutakidis and Sandon Capital founder and managing director Gabriel Radzyminski (BD: Jun 18, 2015).

One week later, the company appointed Mr Poutakidis as a director (BD: Jun 26, 2015).

Today, Alchemia said that no meeting in relation to the resolutions would be called.

Alchemia fell 0.1 cents or 2.9 percent to 3.4 cents.

USCOM

Uscom says it has executed eight new distribution agreements for its Uscom 1A cardiac output monitor and BP+ central blood pressure monitor.

Uscom said the five distribution agreements for five for Uscom 1A and three for the Uscom BP+, covered India, the Middle East, Europe and Australia.

Uscom executive chairman Prof Rob Phillips said the distribution agreements were “in-line with our stated management strategy to grow distribution to increase sales and achieve our milestone revenue goals”.

Uscom was untraded at 16 cents.

SUN BIOMEDICAL

The South Melbourne-based Peter Meurs says he has become a substantial shareholder in Sun with 264,236,879 shares or 19.96 percent of the company.
Mr Meurs did not state a consideration for the share acquisition.
Sun recently acquired Dimerix (BD: May 13; Jul 3, 2015).
Sun was unchanged at one cent with 1.4 million shares traded.

GENERA BIOSYSTEMS

The Raff Family Fund has transferred its 7,559,524 shares (7.6%) in Genera to JPS Distribution as trustee for the Raff Superannuation Fund.
Former chief executive officer of Starpharma and the former chairman of the Bio-Melbourne Network, Dr John Raff told Biotech Daily that the group had converted notes and transferred the shares.
The substantial shareholder notice said that the shares were transferred for $2,570,238 or 34 cents each.
The previous substantial shareholder notice said that the Raff group held 5,962,370 shares (7.19%), with 2,175,581 shares bought for $228,436 or 10.5 cents a share in a placement (BD: Jan 20, 2013).
Genera was untraded at 33 cents.

CELLMID

Cellmid says it has appointed Dr Bryce Vissel as chairman of its scientific advisory board.
Cellmid said that Dr Vissel was currently the Garvan Institute of Medical Research head of neurodegenerative diseases research group as well as a University of New South Wales senior lecturer in medicine.
The company said that Dr Vissel was previously at the La Jolla, California-based Salk Institute and was recruited by the Garvan to establish and lead research in brain and spinal cord disorders and repair.
Cellmid said that Dr Vissel had published more than 50 peer-reviewed papers.
Cellmid climbed 0.2 cents or 6.7 percent to 3.2 cents with 3.7 million shares traded.