



# Biotech Daily

Monday August 11, 2014

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: BIOTRON UP 8%, ELLEX DOWN 4%**
- \* **PHOSPHAGENICS DR ESRA OGRU DECEPTION CONSPIRACY TRIAL**
- \* **ORTHOCELL RAISES \$8m TO LIST ON ASX TOMORROW**
- \* **AGENIX SELLS AGX-1009 FOR HEP B TO CHINA'S CINKATE FOR \$2m**
- \* **PHOSPHAGENICS TPM-OXYMORPHONE PHARMACO-KINETIC STUDY**
- \* **ALLAN GRAY TAKES 12% OF NANOSONICS**

## MARKET REPORT

The Australian stock market rose 0.4 percent on Monday August 11, 2014 with the S&P ASX 200 up 21.7 points to 5,457.0 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, six traded unchanged and seven were untraded.

Biotron was the best, up one cent or 8.3 percent to 13 cents with 339,890 shares traded.

Admedus climbed 7.7 percent; Pharmaxis rose 6.9 percent; Universal Biosensors was up 5.9 percent; GI Dynamics rose 2.4 percent; Benitec, Bionomics, Living Cell, Mesoblast, Resmed, Sirtex, Tissue Therapies and Viralytics were up more than one percent; with Clinuvel, CSL, Nanosonics and Starpharma up by less than one percent.

Ellex led the falls, down 1.5 cents or 4.3 percent to 33.5 cents with 35,747 shares traded.

Oncosil and Phosphagenics fell four percent or more; Cellmid, Genetic Technologies and Osprey lost more than three percent; Neuren and Prana shed more than two percent; Impedimed and Medical Developments were down more than one percent; with Acrux, Alchemia and Cochlear down by less than one percent.

## PHOSPHAGENICS

Phosphagenics former chief executive officer Dr Esra Ogru has been bailed to re-appear at the Melbourne Magistrates Court on five charges relating to the theft of about \$6 million. Dr Ogru, 38, is charged with three counts of conspiring to dishonestly obtain property from Vital Health Services Pty Ltd and Phosphagenics Ltd, and two counts of using her position as a company director of Vital Health Service and Phosphagenics to gain an advantage for herself.

Counsel prosecuting on behalf of the Australian Securities and Investments Commission Allan Sharp said that discussions with counsel for Dr Ogru, Dr Martine Marich, had been fruitful and he expected "a straight hand-up brief and plea" at the next hearing.

Magistrate Suzie Cameron extended Dr Orgu's bail to re-appear in court on August 22, 2014.

Phosphagenics fell 0.4 cents or four percent to 9.6 cents with 2.2 million shares traded.

## ORTHOCELL

Orthocell says that following its \$8 million oversubscribed initial public offer it expects to list on the ASX tomorrow August 12, 2014 at 11.30am (AEST) under the code of OCC. Orthocell said it was developing treatments for tendon, cartilage and soft tissue injuries, with treatments including the stem cell Ortho-ATI or autologous tenocyte implantation, using a patient's own cells to repair damaged tendons and ligaments (BD: Apr 16, 2014). The company said that Ortho-ATI was approved by the Australian Therapeutic Goods Administration and had been used in more than 250 patients.

Orthocell said its second product, Celgro, was a collagen-based biodegradable platform scaffold technology providing mechanical strength to facilitate tissue repair and healing in reconstructive surgical applications and was in late stage development.

The company said the funds raised would be used to finalize the development of Celgro and lodge it for regulatory approvals, maintain regulatory approvals for Ortho-ATI and Ortho-ACI, or autologous chondrocyte implants, in Australia; increase marketing of Ortho-ATI in Australia and prepare for regulatory approvals of Ortho-ATI Europe or Japan.

The public offer at 40 cents a share was led by the Sydney-based KTM Capital and the Perth-based Azure Capital with Shaw Stockbroking as co-manager (BD: May 29, 2014).

## AGENIX

Agenix says its wholly-owned China subsidiary has received RMB11,741,864 (\$A2,056,729) from the sale of AGX-1009 to Cinkate Pharmaceutical Intermediates. Agenix said that Cinkate had taken over development of AGX-1009, a tenofovir pro-drug for hepatitis B patented in China and sold by Agenix following completion of preclinical studies.

The company said that four three-party co-operation agreements were also signed by Cinkate, Agenix and its Chinese development partners the Institute of Medicinal Biotechnology, the Institute of Pharmacology and Toxicology of the Academy of Military Medical Sciences, the Institute of Radiation Medicine of the Academy of Military Medical Sciences and Hong Hui Meditech.

Agenix executive chairman Nick Weston said the proceeds from the sale of AGX-1009 "demonstrates our focus on strengthening our balance sheet and exiting all operations in China".

"Agenix will now focus on diagnostics," Mr Weston told Biotech Daily.

Agenix was unchanged at 1.3 cents with 4.1 million shares traded.

## PHOSPHAGENICS

Phosphagenics says it has completed the first of two studies to further characterize its tocopheryl phosphate mixture (TPM) oxymorphone patch (BD: Jul 28, 2014).

Phosphagenics said that study of the TPM-oxymorphone patch on 15 healthy volunteers at the Perth, Western Australia-based Linear Clinical Research facility was in support of an investigational new drug application to the US Food and Drug Administration.

The company said that the study assessed additional pharmacokinetic parameters associated with the safety and elimination profile that were not addressed in the previous multiple dose phase I study and the data generated would be used to help design the phase II study, support the application and inform the eventual product label.

Phosphagenics said that the single dose study “unequivocally reproduced the outstanding results obtained in the previous phase I study, both in terms of the oxymorphone delivery profile from the patch and the oxymorphone blood concentration in subjects”.

The company said that all 15 subjects achieved an oxymorphone blood concentration that was “well above the minimum therapeutic blood level for the drug”.

Phosphagenics said that 27 subjects had been exposed to the TPM-oxymorphone patch with all patients attaining therapeutic oxymorphone blood levels.

Phosphagenics chief scientific officer Dr Paul Gavin said the TPM-oxymorphone patch “demonstrated reproducibility in two independent manufacturing and clinical trial campaigns with all subjects tested demonstrating blood concentrations equivalent to those produced by the commercially available oral dosage form”.

“These studies clearly establish that the TPM-oxymorphone patch has significant potential to be a remarkable product,” Dr Gavin said.

“The latest study also provides new information regarding the elimination phase of oxymorphone after patch removal, an important variable in patient safety that is needed to determine the phase II study design,” Dr Gavin said.

“As with any transdermal system, drug delivery ceased upon patch removal and residual drug in the body was eliminated steadily over time,” Dr Gavin said.

“This represents one of the key safety advantages of a transdermal opioid system compared to the oral dosage form,” Dr Gavin said.

Dr Gavin said that accidental overdose due to the application of multiple simultaneous patches rarely occurred with a transdermal patch because of the ease of intervention, that is the removal of the unintended patches and immediate cessation of delivery.

Phosphagenics said it would begin the second planned study soon, comparing the transdermal absorption of oxymorphone from application of the patch to different parts of the body.

The company said that both characterization studies had been designed to provide valuable information for potential licensees as well as various global regulatory bodies.

Phosphagenics said it expected to begin the US phase II trial by July 2015.

## NANOSONICS

Allan Gray Australia has increased its substantial holding in Nanosonics from 28,384,307 shares (10.85%) to 31,307,520 shares (11.85%).

Allan Gray did not state when it bought the shares or how much it paid for them.

Nanosonics was up half a cent or 1.25 percent to 40.5 cents.