Biotech Daily

Monday May 19, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: UNIVERSAL BIO UP 33%, COMPUMEDICS DOWN 9%**

*** BIONOMICS: 'BNC105P SAFE WITH GEMCITABINE, CARBOPLATIN'**

*** CLINUVEL ON SCENESSE DELAY, ORPHAN STATUS FOR HAILEY-HAILEY**

*** US INSTITUTE BACKS NANOSONICS TROPHON EPR PROBE-CLEANER**

*** GENERA NOTES RAISE $345k, $500k PLACEMENT, Q-SAND SPIN-OUT**

*** ROYAL ADELAIDE APPROVES PHARMAUST PPL-1 CANCER TRIAL**

*** AGENIX TO SELL CHINA AGX-1009 HEP B PROJECT TO US CINKATE**

*** BLUECHIIP $12k SALES, $97k FEDERAL EXPORT GRANT**

*** USCOM APPOINTS UK, IRELAND DISTRIBUTORS FOR BP+**

*** ACORN REDUCES TO 9% OF STARPHARMA**

*** CIRCADIAN APPOINTS MICHAEL TONROE CFO, CO SEC**

MARKET REPORT

The Australian stock market fell 1.28 percent on Monday May 19, 2014 with the S&P ASX 200 down 70.0 points to 5,409.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, nine traded unchanged and two were untraded.

Universal Biosensors was the best, up 4.5 cents or 33.3 percent to 18 cents with 4.5 million shares traded. Benitec climbed 9.7 percent; Analytica and Antisense were up more than seven percent; Tissue Therapies was up 6.35 percent; Impedimed, Nanosonics and Prana rose more than two percent; Alchemia and Medical Developments were up more than one percent; with Osprey, Resmed and Starpharma up by less that one percent.

Compumedics led the falls, down one cent or 9.1 percent to 10 cents with 107,159 shares traded. Circadian and Oncosil fell more than eight percent; Anteo fell 7.1 percent; Ellex and Optiscan were down more than six percent; Acrux and Psivida fell more than four percent; Admedus and Cellmid were down more than three percent; Pharmaxis and Sirtex shed more than two percent; Bionomics, Living Cell, Neuren and Viralytics were down more than one percent; with Cochlear, CSL and Mesoblast down less than one percent.

BIONOMICS

Bionomics says a phase I study shows BNC105P with gemcitabine and carboplatin is safe and tolerable in patients with potentially platinum sensitive recurrent ovarian cancer.
Bionomics said the 15-patient data would be in a poster presentation at the American Society for Clinical Oncology meeting on June 2, 2014 in Chicago.
Entitled 'A phase I study of the vascular-disrupting agent BNC105P in combination with gemcitabine-carboplatin in platinum-sensitive ovarian cancer patients in first or second relapse' concluded the combination was "safe and tolerable in patients with potentially platinum sensitive recurrent ovarian cancer".
"The data supports continued development of BNC105P in this setting," concluded the poster, co-authored by Bionomics and Peter MacCallum Cancer Centre researchers.
The poster abstract is at: http://abstracts.asco.org/144/AbstView_144_130216.html.
The poster said that 15 patients were enrolled in the study and adverse events were most commonly of haematological origin.
The poster said that dose limiting toxicities occurred in one patient on dose level 1 and two patients on dose level 2a and consisted of thrombocytopenia and neutropenia.
The poster said that the recommended dose was gemcitabine 1,000 mg/m2, carboplatin AUC 4 and BNC105P 12 mg/m2.
The poster said that 10 patients achieved a response and increases in blood levels of ferritin, interleukin-8, interleukin-16 and macrophage inflammatory protein-1beta post 12 mg/m2 BNC105P were consistent with a pharmacodynamic response.
Bionomics said the poster would be presented by the Peter MacCallum Cancer Institute Dr Danny Rischin.
The company said that the study was being conducted by the Australian and New Zealand Gynaecological Oncology Group working with the National Health and Medical Research Council Clinical Trials Centre in Australia and the Hoosier Oncology Group in the US.
Bionomics fell half a cent or 1.2 percent to 42 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says the European Medicines Agency review of Scenesse (afamelanotide 16mg) erythropoietic protoporphyria is expected to be completed by October 2014.
Clinuvel said that, yet further reviews by the Agency were possible.
Clinuvel said it had received questions from patients, shareholders and the biotechnology community regarding the company's program and the progress being made towards regulatory approval by the European Medicines Agency.
Biotech Daily understands that the review which formally began in 2012 is believed to be one of the longest reviews by the Agency (BD: Feb 7, 2012; Oct 1, 2012; Apr 5, 2013).
Clinuvel said the review process was taking "so long" for a number of reasons including a complex dossier, that no other melanocortin had been submitted to European regulatory bodies, that erythropoietic protoporphyria (EPP) was a complex disorder and the "overwhelming demand for Scenesse, from experts and patients, needs to be assessed by the EMA and weighed in their final outcome".
The company said that the final decision would be taken by the entire Committee for Human Medicinal Products representing all members of the European Community.
Clinuvel said that an EMA approval would trigger a new drug application to the US Food and Drug Administration.
Separately, the company said the EMA had approved orphan designation for Scenessefor the rare Hailey-Hailey disease, or familial benign chronic pemphigus.
Clinuvel was unchanged at $1.42.

NANOSONICS

Nanosonics says the American Institute of Ultrasound in Medicine has included the Trophon EPR in new guidelines for high level disinfection of ultrasound probes.
Nanosonics chief executive officer Michael Kavanagh said that “having Trophon EPR mentioned in the AIUM guidelines, which are recognized and respected internationally, is excellent news for Nanosonics”.
“This is a further step towards achieving our goal of establishing Trophon globally as the new standard of care for ultrasound probe disinfection,” Mr Kavanagh said.
Nanosonics said that the reference to Trophon followed inclusion of a recommendation from the US Centers for Disease Control for environmental infection control in the case of Clostridium difficile, which caused infectious, antibiotic-resistant enteritis including abdominal pain, diarrhoea and fever, which could cause serious problems for healthcare facilities.
The company said that the Trophon EPR had proven disinfection efficacy against Clostridium difficile spores, which were highly resistant to disinfection.
“The reference is highly positive for Nanosonics’ market positioning of trophon EPR,” Mr Kavanagh said.
“We expect to see further movements with regulations and guidelines, and a trend towards stricter controls for high level disinfection,” Mr Kavanagh said.
Nanosonics was up two cents or 2.6 percent to 80 cents.

GENERA BIOSYSTEMS

Genera says it has placed the final tranche of 3,442 unlisted convertible notes with major shareholders to raise about $345,000 and will raise a further $500,000 (BD: Jul 17, 2013).
Genera said that a total of 10,000 notes with an aggregate face value of $1,000,000 had been issued.
The company said that it was finalizing a placement of shares to raise $500,000 at a discount to the 20 five-day volume weighted average price.
Genera said that the funds were for general working capital and to complete the process being undertaken by its corporate advisor together with providing the company with adequate funding through the execution phase of any resulting transaction.
The company said that with its advisor, it was working through a number of options with the decision to be made by the end of June 2014.
Genera said it could enter into a partnering agreement incorporating an associated capital injection including but not limited to a material change in the current composition of Genera’s share register or otherwise potentially a change of control event.
Genera said it was also finalizing the spin-out of its Q-Sand, possibly to the US, involving an in-specie distribution to shareholders.
The company said that Q-Sand was its ultra-sensitive testing platform targeting the point-of-care testing market assets was “a truly disruptive nanotechnology”.
Genera said that Q-Sand could “revolutionise the traditional approach to [medical diagnostics] using quantum dots encased in an outer shell of a silica microsphere measuring the spectral shifts in wavelengths to provide a unique method for analyte detection”.
The company said that Q-Sand could incorporate few operating handling steps, ease of design and administration requiring extremely small volumes of sample with no fluorescence or radioactive tagging of samples while providing unparalleled multiplexing capability.
Genera fell half a cent or 2.6 percent to 18.5 cents.

PHARMAUST

Pharmaust says it has Royal Adelaide Hospital Governance Committee approval for its phase I/II trial of PPL-1 for cancer.

In April, Pharmaust said the Hospital's research ethics committee approved the trial of up to 15 patients with a variety of late stage cancers, who had failed standard-of-care and had been without treatment for at least two weeks. (BD: Apr 15, 2014).

Today, the company said governance committee approval was the final approval and it expected to start screening patients in the coming weeks.

Pharmaust was unchanged at 1.1 cents with four million shares traded.

AGENIX

Agenix says it has a binding agreement to sell its AGX-1009 hepatitis B China project to Cinkate Pharmaceutical Intermediates Co for $US2.0 million ($A2.1 million).

Agenix said that Oak Park, Illionois-based Cinkate would take over development of AGX-1009, a tenofovir prodrug for hepatitis B, patented in China, with four three-party agreements signed by Cinkate, Agenix and its Chinese development partners.

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

The company said that the sale was expected to settle by the end of 2014.

Last year, Agenix said that an unnamed Chinese pharmaceutical company agreed to buy its AGX-1009 hepatitis B drug for $US2 million and it had a binding term sheet with the payment expected to be completed by December 31, 2013 (BD: Oct 31, 2013).

Agenix was unchanged at 1.4 cents with two million shares traded.

BLUECHIIP

Bluechiip says it has its first follow-on commercial sales order to a US hospital and its first European sales order to an Italian bio-bank, totaling about $12,000.

Bluechiip chief executive officer Jason Chaffey said the sales were "further validation of the company's success in implementing our new commercialization strategy".

The company said it that a $97,000 Federal Government Export Market Development Grant had been approved with the first tranche of $60,000 within the next two weeks and the balance by the end of July, 2014.

Bluechiip was untraded at 5.5 cents.

USCOM

Uscom says it has appointed three new distributors for the Uscom BP+ supra-systolic oscillometric blood pressure monitor in the UK and Ireland.

Uscom said that Medimax Global and Healthwatchers had been appointed in England and Castleblack Health in Ireland.

The company said that the BP+ central blood pressure diagnostic received Conformité Européenne (CE) mark in February 2014.

Uscom executive chairman Rob Phillips said the appointment of the three distributors would "shift our profile and deliver our technology into the hands of new users".

"We are currently preparing to manufacture the Uscom BP+ and these distributors are a vital link in a new network of global BP+ distribution planned to come online in the next 12 months as manufacture increases to meet growing distributor demand," Mr Phillips said.

Uscom was untraded at 25 cents.

STARPHARMA

Melbourne's Acorn Capital has again reduced its substantial holding in Starpharma from 29,110,336 shares (10.23%) to 26,357,951 shares (9.26%).
Acorn reduced its holding from 36,614,463 shares (13.05%) to 33,092,814 shares (11.66%) and again in January 2014 from 33,092,814 shares (11.66%) to 29,110,336 shares (10.23%) (Aug 19, 2013).
Acorn said that between January 14 and May 16, 2014 it sold 2,752,385 shares for $2,205,761 or an average price of 80.1 cents a share.
Starpharma was up half a cent or 0.8 percent to 66.5 cents

CIRCADIAN TECHNOLOGIES

Circadian says it has appointed Michael Tonroe as chief financial officer and company secretary, effective from today, May 19, 2014.
Circadian said that Mr Tonroe had more than 20 years experience in finance and company secretarial roles and was most recently the chief financial officer of the Australian Synchrotron Co.
The company said that Mr Tonroe had previous roles in financial analysis, forecasting, implementing growth plans, fund-raising, board and shareholder reporting.
Circadian said that Mr Tonroe held a Graduate Degree in Business Studies from Buckingham University.
Circadian fell two cents or 8.5 percent to 21.5 cents.