Biotech Daily

Wednesday April 22, 2015

Daily news on ASX-listed biotechnology companies

* **ASX, BIOTECH DOWN: ANALYTICA UP 9.5%, BIOTRON DOWN 11%**

*** USCOM: 'MONITOR DETECTS PRE-ECLAMPSIA AT 5 WEEKS'**

*** INVION RIGHTS ISSUE RAISES $5.4m, TAKES TOTAL TO $6.3m**

*** REGENEUS PHASE I PROGENZA OSTEOARTHRITIS ETHICS APPROVAL**

*** ACTINOGEN REQUESTS ALZHEIMER'S TRIAL CAPITAL RAISING HALT**

*** US ORPHAN STATUS FOR NOVOGEN CANTRIXIL FOR OVARIAN CANCER**

*** ADMEDUS APPOINTS GENPHARM FOR MID-EAST, NORTH AFRICA SALES**

*** NUSEP SETTLES $132k LAWLER PARTNERS AUDITOR DEBT**

*** HUNTER HALL TAKES 12% OF GI DYNAMICS**

*** AUSTRALIAN ETHICAL TAKES PROFIT ON PHARMAXIS TO 6%**

*** DIRECTOR JOHN DUNLOP TAKES 10.5% OF PROTEOMICS**

*** SUDA APPOINTS ANTHONY FOX, ROGER CADY MIGRAINE ADVISERS**

MARKET REPORT

The Australian stock market fell 0.59 percent on Wednesday April 22, 2015 with the S&P ASX 200 down 34.8 points to 5,837.5 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and three were untraded. All three Big Caps fell.

Analytica was the best, up 0.2 cents or 9.5 percent to 2.3 cents with 1.0 million shares traded. Nanosonics climbed 7.1 percent; both Circadian and GI Dynamics were up 6.7 percent; Antisense and Cellmid rose four percent or more; Ellex, IDT, Prana and Universal Biosensors were up more than three percent; Viralytics rose 2.3 percent; with Clinuvel and Mesoblast up more than one percent.

Biotron led the falls, down 1.5 cents or 11.1 percent to 12 cents with 910,198 shares traded. Genetic Technologies lost 7.1 percent; Psivida shed 6.7 percent; Pharmaxis fell 5.6 percent; Neuren and Tissue Therapies fell more than four percent; Anteo, Osprey and Sirtex were down more than three percent; Admedus, Atcor, Medical Developments and Starpharma shed two percent or more; Benitec, Bionomics, Living Cell and Resmed were down more than one percent; with Acrux, Cochlear and CSL down less than one percent.

USCOM

Uscom says the Uscom 1A can detect pre-eclampsia in otherwise normal pregnant women as early as five weeks into pregnancy and screening may improve outcomes.

Uscom said that a study using its entitled 'Assessment of total vascular resistance and total body water in normotensive women during the first trimester of pregnancy. A key for the prevention of preeclampsia', published in the Journal of Pregnancy Hypertension found the Uscom 1A detected pre-eclampsia as early as five weeks into pregnancy, while conventional blood pressure measures detect it after 20 weeks.

The company said the study concluded that early pregnancy Uscom 1A screening for pre-eclampsia might allow more appropriate and earlier intervention and improved outcomes.

An abstract is at: http://www.sciencedirect.com/science/article/pii/S2210778915000197.

The journal article said that all haemodynamic measurements were acquired with the Uscom 1A which had been validated against invasive gold standards and flow probes and had proof of effectiveness in pre-eclampsia.

Uscom executive chairman Prof Rob Phillips told Biotech Daily that there was no other diagnostic that could detect pre-eclampsia changes at five weeks with blood pressure measurements not detecting changes until 20 weeks.

Prof Phillips said that the measure of "total vascular resistance" (TVR) used in the study was an Uscom-developed measure.

The study concluded that "high TVR during the first weeks of gestation may be an early marker of cardiovascular maladaptation".

Uscom said that pre-eclampsia, or high blood pressure in pregnancy, was a common complication which increased mortality and morbidity for pregnant mothers and their unborn babies, with an estimated 10 million pregnant women developing pre-eclampsia every year, but early detection and treatment improved outcomes for mothers and babies

The company said that pre-eclampsia was responsible for about 76,000 maternal and 500,000 fetal and neonatal deaths each year.

Uscom said that the University of Rome Tor Vergata's Prof Herbert Valensise and his team had been working on the project for more than three years and conducted a prospective observational trial of normal healthy pregnant women with normal blood pressure, finding that the Uscom 1A detected the circulatory changes of pre-eclampsia as early as five weeks, while the current standard of care, conventional blood pressure monitoring, detected pre-eclampsia after 20 weeks, thus significantly delaying diagnosis and treatment.

Prof Phillips said the study "provides evidence supporting Uscom 1A screening in early pregnancy".

"The study suggests Uscom 1A screening will significantly improve pregnancy outcomes and contribute to the saving of lives of mothers and babies world wide," Prof Phillips said.

"This is the first study to prove that Uscom 1A measurements detect changes in cardiovascular function long before they are detected by simple blood pressure monitors," Prof Phillips said.

"This potentially revolutionizes the way we approach hypertension and all cardiovascular disease and opens the door to markets worth hundreds of millions of dollars annually to Uscom," Prof Phillips said.

Uscom said that maternal health was an emerging Uscom 1A application with a number of centres researching pre-eclampsia using the Uscom 1A.

The company said that the publication would accelerate the research and supported the appointment of specialized distributors into maternal health centres, thus creating a new revenue stream for Uscom.

Uscom was untraded at 21 cents.

INVION

Invion says its two-for-seven, non-renounceable rights offer at 2.5 cents a share was over-subscribed raising $5,391,801 taking the total raised to $6,286,801 (BD: Mar 20, 2015).
Invion said the fully-underwritten entitlement offer for 163,213,389 shares was fully subscribed and a placement to sophisticated and professional investors of 52,458,650 shares raised a further $1.3 million reducing the scale-back for the top-up facility.
Invion chief executive officer Dr Greg Collier said the board was "very pleased with the response to the capital raise, and in particular the response by existing shareholders to take up new shares under the entitlement offer".
Dr Collier said the funds were for the phase II clinical trial of INV102 for smoking cessation and production of phase I clinical supplies of inhaled INV102, selection of the formulation and device for inhaled INV104 and partnering the program as well as the receipt of data from the phase II trial of INV103, formerly known as XToll or chaperonin 10, for lupus.
The company said that the entitlement offer was underwritten by Morgans and Patersons Securities.
Invion was unchanged at three cents with 2.2 million shares traded.

REGENEUS

Regeneus says it has ethics approval for a 20-patient, phase I trial of its fat-derived Progenza off-the-shelf allogeneic stem cell treatment for patients with knee osteoarthritis.
Regeneus said that the phase I, randomized, double-blind, placebo-controlled, single ascending dose Step study would evaluate the safety, tolerability and preliminary efficacy of intra-articular Progenza in adults with symptomatic knee osteoarthritis.
The company said that the trial was expected to begin recruitment by July 2015, with Sydney-based sports medicine specialist Dr Donald Kuah as the principal investigator.
Regeneus said that patients would receive ultrasound-guided injections of Progenza or placebo directly into their arthritic knee joint.
The company said that the primary objective was to evaluate the safety and tolerability of Progenza and secondary objectives were to investigate the effect of Progenza on knee pain and function; quality of life; knee joint structures using magnetic resonance imaging; and osteoarthritis biomarkers.
Regeneus said that patients would be monitored for 12 months with an interim safety review at one month following treatment.
The company said the Progenza mesenchymal stem cells were expanded through the company's scalable manufacturing process capable of producing millions of therapeutic doses from one donor and when injected into a patient's osteoarthritic joint, the Progenza cells had "the potential to reduce pain and inflammation and slow the progression of disease".
Regeneus said that the trial would be registered on the Australian New Zealand Clinical Trials Registry and notified to the Australian Therapeutic Goods Administration through the clinical trials notification scheme.
Regeneus was up 0.5 cents or 3.7 percent to 14 cents.

ACTINOGEN

Actinogen has requested a trading halt "pending an announcement regarding a capital raising for a phase II study in Alzheimer's dementia".
Trading will resume on April 24, 2015 or on an earlier announcement.
Actinogen last traded at 15 cents.

NOVOGEN

Novogen says the US Food and Drug Administration has granted Cantrixil orphan drug designation for ovarian cancer.

Novogen said that its Yale University joint venture company Cantx was developing Cantrixil and orphan drug designation provided subsidization for clinical research, tax incentives, extended patent protection and enhanced marketing rights.

Novogen and Cantx chief executive officer Dr Graham Kelly, said the designation was "one more step in our objective of bringing Cantrixil to market as a drug that we hope will provide meaningful clinical benefit to patients with ovarian cancer and deliver that long-sought breakthrough for patients with a cancer that has shown only slight improvement in five-year survival rates over the last 30 years".

Novogen said that Cantrixil pre-clinical data was presented at the American Association of Cancer Research meeting two days ago showing a greater than 95 percent tumor reduction in mice (BD: Nov 7, 2014).

The company said that Cantrixil was "on-track to enter the clinic in Australia in late-2015, early-2016 in patients with the condition, malignant ascites, a terminal condition associated with cancers such as ovarian cancer and for which no effective long-term therapies exist.

Novogen was up 7.5 cents or 25.9 percent to 36.5 cents with 50.3 million shares traded.

ADMEDUS

Admedus says it has appointed the Dubai, United Arab Emirates-based Genpharm as its Cardiocel marketing and sales partner in the Middle East and North Africa

Admedus said that the Middle East and North Africa was "a fast-growing region and its eight largest countries have a combined population of over 120 million people".

The company said that the agreement expanded the number of centres using its Cardiocel bovine cardiac tissue product for heart defects.

Admedus said there were currently 31 centres in Europe and 31 centres in the US using Cardiocel, along with recent approvals for use in Canada and Hong Kong.

Admedus fell 0.2 cents or 2.5 percent to 7.9 cents with 7.9 million shares traded.

NUSEP HOLDINGS

Nusep says it has reached a settlement with previous auditors Lawler Partners to pay $131,800 plus GST by instalments over six months beginning in May 2015.

Nusep said it had provided $30,300 in the balance sheet for the payments which relate to the periods ended June 30, 2012 and December 31, 2012.

Nusep was untraded at three cents.

GI DYNAMICS

Hunter Hall Investment Management says it has increased its substantial shareholding in GI Dynamics from 52,693,955 shares (11.12%) to 58,793,955 shares (12.40%).

The Sydney-based Hunter Hall said that on April 15 and 17, 2015 it bought 6,100,000 shares for $733,098, or an average price of 12.02 cents a share.

GI Dynamics was up one cent or 6.7 percent to 16 cents.

PHARMAXIS

Australian Ethical Smaller Companies Trust has reduced its substantial shareholding in Pharmaxis from 22,289,718 shares (7.22%) to 19,207,764 shares (6.16%).
Australian Ethical's substantial shareholder notice said that between January 5 and April 17, 2015 it sold 2,253,321 shares for $345,534 or 15.33 cents a share.
Australian Ethical did not disclose the price of the remaining 828,633 shares sold.
Australian Ethical last increased its holding in Pharmaxis in 2013 when it acquired 3,491,976 shares for $473,326 or 13.55 cents a share (BD: Oct 23, 2013).
Pharmaxis fell one cents or 5.6 percent to 17 cents with 1.3 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Director John Sutherland Richardon Dunlop says he has become a substantial shareholder in Proteomics with 5,305,188 shares (10.49%).
Proteomics listed last week following an initial public offer at 20 cents a share which raised $3.05 million (BD: Apr 17, 2015).
Proteomics was up one cent or 5.1 percent to 20.5 cents.

SUDA

Suda says it has appointed headache specialists Prof Anthony Fox and Dr Roger Cady to a clinical advisory board for its SUD-001 oral spray of sumatriptan for migraine headache.
Suda said that Prof Fox and Dr Cady would provide advice and guidance on the pivotal development plan, to be presented to the US Food and Drug Administration.
The company said that Prof Fox was a physician with more than 25 years' experience in the pharmaceutical industry with both large and small companies, including Glaxo Inc in North Carolina, where he led the US clinical development of oral, intranasal and subcutaneous sumatriptan for migraine and cluster headache.
Suda said that Prof Fox was currently a visiting professor at King's College London and an adjunct associate clinical professor at the University of California, San Diego and had published research papers on migraine therapies and pharmacokinetics.
The company said that Dr Cady was a graduate of the Mayo Medical School, held board certification in headache medicine by the United Council for Neurologic Subspecialties and founded the US-based Headache Care Centre.
Suda said that Dr Cady had authored or co-authored more than 250 peer-reviewed articles, was the lead author on a paper that first described the therapeutic properties of sumatriptan, and co-edited 'Treating the Headache Patient', authored by Prof Fox.
Suda fell 0.2 cents or five percent to 3.8 cents.