Biotech Daily

Wednesday September 23, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: USCOM UP 8%; LIVING CELL DOWN 5%**

*** ADMEDUS STARTS AORTIC VALVE REPAIR TRIAL**

*** WEHI, ACRF CANCER LAB OPENS**

*** SINGAPORE APPROVES MEDICAL DEVELOPMENTS PENTHROX**

*** OPTISCAN TAKES COLLABORATION HALT TO SUSPENSION**

*** PHARMAUST AGM VOTES ON 20-1 CONSOLIDATION, DR BEST OPTIONS**

*** BIOTA LOSES DR JIM FOX, GAINS ARMANDO ANIDO, DR MICHAEL DUNNE**

*** SOLAGRAN LOSES ACE AIM, SALIM GROUP DIRECTOR ANDI SOLAIMAN**

MARKET REPORT

The Australian stock market lost 2.07 percent on Wednesday September 23, 2015 with the ASX200 down 105.5 points to 4,998.1 points.

Ten of the Biotech Daily Top 40 stocks were up, 18 fell, nine traded unchanged and three were untraded. All three Big Caps fell.

Uscom was the best, up one cent or 7.7 percent to 14 cents, with 10,000 shares traded.

Actinogen climbed 6.5 percent; Compumedics was up 5.6 percent; Ellex and Polynovo were up more than four percent; Orthocell was up 3.15 percent; Mesoblast and Pharmaxis rose more than two percent; with Admedus and Neuren up by less than one percent.

Living Cell led the falls, down 0.2 cents or 5.4 percent to 3.5 cents with 40,000 shares traded, followed by IDT down 5.1 percent to 37 cents with 141,681 shares traded.

Clinuvel fell 4.7 percent; Benitec, Cellmid and Oncosil lost more than three percent; Acrux, Anteo, Avita, Bionomics, Cochlear, CSL, Impedimed, Nanosonics, Prima, Sirtex and Starpharma were down more than one percent; with Medical Developments, Osprey, Resmed and Viralytics down by less than one percent.

ADMEDUS

Admedus says it has begun an 80-patient, European and US clinical study of its Cardiocel bovine scaffold for aortic tri-leaflet heart valve reconstructions.

Admedus said the study hoped to show the utility and benefits of Cardiocel in aortic valve reconstruction over valve replacements for aortic valvular disease such as aortic stenosis.

The company said that Cardiocel was available in North America, Europe and Asia and the study would support its use in heart valve repair and reconstructions.

Admedus said that the study followed the completion of the first animal study, in sheep, using Cardiocel for aortic stenosis, or narrowing, in conjunction with Leuven, Belgium-based Katholieke Universiteit Leuven University.

Admedus chief executive officer Lee Rodne said that following the "very successful pre-clinical study, we have now commenced a clinical study to provide further data to use Cardiocel for complete aortic valve reconstructions".

"This is an important study in aortic valve reconstruction, which has never been done before with a bio-prosthetic tissue like Cardiocel," Mr Rodne said.

"We believe the results will highlight the patient benefits of completely reconstructing the aortic valve with Cardiocel compared to the current industry need of replacing it multiple times throughout a patient's life," Mr Rodney said.

Admedus said that surgeons would use Cardiocel to reconstruct the three leaflets of the aortic valve as an alternative to replacing it with a bio-prosthetic valve.

The company said that the procedure provided "an opportunity for autologous repair and the potential for patients to have a 'native' valve with better haemodynamic outcomes and overall improved health benefits compared to a replacement valve".

Admedus said that aortic stenosis was the most common valvular heart disease in developed countries, with the incidence rate of around 25 percent in people over the age of 65 years and prevalence increasing with age.

The company said that in 2014, there were 165,000 aortic valve replacement surgeries in the US alone and the market size for valve reconstruction would be larger once the benefits of treating patients earlier and more effectively was recognised.

Admedus said that the primary safety endpoint for the clinical study was to ensure same rates of in-hospital survival, while also looking for superior long-term benefits for patients, better haemodynamic outcomes, cell infiltration, regrowth of native tissue and long-term durability without calcification.

The Munich, Germany-based Deutsches Herzzentrum München surgeon and clinical study lead Dr Domenico Mazzitelli said that surgeon "often [asked] …are we really repairing the valve or are we just delaying the next heart valve operation or replacement".

"Where most patients with symptomatic aortic valve disease will be delayed to surgery, this study could prove that Cardiocel could offer earlier intervention, with possible life-long benefits," Dr Mazzitelli said.

Admedus said the 80 adult patients would be enrolled at two European and two US sites, with initial cases already enrolled.

The company said that the patients would be reviewed at six months, 12 months and 24 months post-surgery to evaluate safety data and primary and secondary endpoints.

The company said that it had ethics approval at the Katholieke Universiteit and Deutsches Herzzentrum, with US ethics approval expected in the coming months.

"While a majority of current aortic valve procedures follow the replacement strategy, we hope to show that reconstructing the valve with Cardiocel is superior to replacing the valve and provides patients with long-term health benefits," Mr Rodne said.

Admedus was up 0.1 cents or 1.5 percent to 6.7 cents with 2.6 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says the $2.5 million Australian Cancer Research Foundation Breakthrough Technologies Laboratory opened today.

WEHI said that its partnership with the Foundation led to the establishment of Australia's first facility to research and develop new treatments for cancer and the laboratory was Australia's first dedicated cancer laboratory to use 'clustered regularly interspaced short palindromic repeats using the Cas9 protein' (CRISPR/Cas9) technology to target and directly manipulate genes in cancer cells.

The Institute said that the CRISPR/Cas9 technology would be used with researcher partners at the Victorian Comprehensive Cancer Centre to enhance and accelerate research into many of Australia's most common and deadly cancers including cancers of the blood, such as leukaemia and lymphoma, breast, ovary, lung and bowel.

WEHI director Prof Doug Hilton said the Laboratory would provide "an enormous boost to Australia's cancer research efforts".

"It has become clear that technologies such as CRISPR/Cas9 can accelerate new breakthroughs in understanding cancer and developing new treatments," Prof Hilton said.

"The generosity of ACRF and its donors has allowed us to equip our research teams with precisely the tools they need to advance their research," Prof Hilton said.

Victorian Comprehensive Cancer Centre executive director Prof Jim Bishop said the Laboratory was "a critical addition to the Victoria's cancer research capabilities".

"The facility provides our researchers with unparalleled access to world-leading technology," Prof Bishop said.

"The strength of the VCCC lies in the close ties it fosters between the laboratory-based, clinical and other researchers in its partner organisations," Prof Bishop said.

"This means that discoveries made in the ACRF Breakthrough Technologies Laboratory will be translated into new treatments for cancer as rapidly in Melbourne as anywhere in the world," Professor Bishop said.

WEHI said that the Victorian Comprehensive Cancer Centre was an alliance of 10 organizations committed to cancer care including the Peter MacCallum Cancer Centre, Melbourne Health and the Royal Melbourne Hospital, the University of Melbourne, the Royal Women's Hospital, the Royal Children's Hospital, Western Health, St Vincent's Hospital, Austin Health and the Murdoch Children's Research Institute.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says Singapore has approved its Penthox inhaled analgesic for trauma and associated pain, as well as pain in surgical procedures in adults.

Medical Developments said that Singapore partner Link Healthcare Singapore Pte would be able to sell Penthrox immediately.

The company said that as part of the Singapore approval process it used the results of a head-to-head clinical trial comparison of its methoxyflurane Penthrox against Tramadol conducted by Singapore Ambulance, to show that Penthrox was preferred in the emergency medicine.

Medical Developments chief executive officer John Sharman said that Singapore was "an important market in the Asian region and has a population of 5.2 million people".

"This approval is another important step in establishing a global footprint for Penthrox," Mr Sharman said.

He said that the company was "hopeful that further country approvals to sell Penthrox will be achieved in the coming months".

Medical Developments fell one cent or 0.3 percent to $3.11.

OPTISCAN

Optiscan has requested a voluntary suspension to follow the trading halt requested on September 21, pending an announcement “concerning the re-negotiation of some aspects of a significant development collaboration” (BD: Sep 21, 2015).

Optiscan said that “one particular matter has required reference to an overseas corporate office and a response has not yet been received due to both time differences and availability of executives who themselves are travelling in different time zones”.

“It is difficult to forecast when this will resolve, but our best estimate is that it may require a further 48 hours,” Optiscan said.

Optiscan last traded at 4.4 cents.

PHARMAUST

Pharmaust shareholders will vote on a 20-to-one share consolidation and the issue of 5,000,000 pre-consolidation options to Dr Wayne Best.

Pharmaust said that it had 1,840,069,106 shares and 8,500,000 options on issue and the consolidation would “result in a more appropriate and effective capital structure … and a share price potentially more appealing to a wider range of investors”.

The company said that Dr Best was a director of Pharmaust and the managing-director of its revenue positive wholly-owned Epichem synthetic and medicinal chemistry subsidiary and the options would be exercisable at a pre-consolidation price of 0.8 cents each by September 3, 2018.

Pharmaust said that other resolutions included the re-election of director Sam Wright, the approval of an additional 10 percent placement capacity and the remuneration report.

The meeting will be held at Epichem, Suite 5, 3 Brodie-Hall Drive, Bentley, Perth, Western Australia, on October 27, 2015 at 12pm (AWST).

Pharmaust fell 0.1 cents or 14.3 percent to 0.6 cents with 3.95 million shares traded.

SOLAGRAN

Solagran says that director Andi Solaiman has resigned as a non-executive director, effective immediately.

Solagran said that Mr Solaiman represented the Salim Group of companies, which was “a significant investor in Solagran”, indicated that conflicting commitments meant he was no longer able to fulfil his duties.

The company said that the Salim Group was considering a suitable replacement.

Mr Soliman’s Appendix 3X initial director’s interest statement in July 2009 said he held no shares in Solagran, as did today’s Appendix 3Z final director’s interest statement.

In 2009, Mr Solaiman as a director of the Singapore-based Ace Aim Pte Ltd said that Ace Aim and the Salim Group held 36,916,918 Solagran shares (13.04%) acquired at 15 cents a share.

Solagran had been attempting to commercialize Ropren and its range of Bioeffectives derived from pine needles since listing on the ASX in December 2002 and described itself as a “healthcare and wellness company” based in South Melbourne, developing a treatment for liver cancer, Alzheimer’s disease and a raft of other indications based on Ropren and the Bioeffectives (BD: Feb 25, 2009; Feb 5, 2010).

Despite claiming large contracts and building a Siberian manufacturing plant, Solagran was twice suspended by the ASX for failing to lodge accounts and remains in a suspension (BD: Mar 1, 2011; Mar 9, 2012).

Solagran remained suspended at 3.9 cents.

BIOTA PHARMACEUTICALS

Biota says that Dr James Fox will not stand for re-election as a director at its November 2015 annual general meeting.

Dr Fox was appointed chairman of Biota in 2009, replacing John Grant who oversaw a number of controversial decisions (BD: Oct 24, 2008 Mar 2, 2009).

Dr Fox was the company's chairman when it decided to merge with Nabi Pharmaceuticals for its $US54 million in cash, later settling for $US27 million and relocating to the US to be close to regulators and funders in Washington DC, before moving to Alpharetta, near Atlanta, Georgia.

Biota said that "there was no disagreement between Dr Fox and the company on any matter relating to the company's operations, policies or practices relative to his decision not stand for re-election".

The company said that Armando Anido and Dr Michael Dunne had been appointed as directors, effective immediately, and each was granted an option to purchase 30,000 shares under the company's omnibus equity incentive plan, vesting on the first, second and third anniversary of the date of grant.

Biota said that Mr Anido had been served the chairman and chief executive officer of Zynerba Pharmaceuticals since October 2014 and previously was the chief executive officer and a director of Nupathe from 2012 to its acquisition by Teva Pharmaceuticals in 2014, during which time he led the company through US Food and Drug Administration approval of its Zecuity transdermal patch for migraine.

The company said that Mr Anido had been an executive with Glaxo Wellcome and held a Bachelor of Science and a Masters of Business Administration from West Virginia University.

Biota said that Dr Dunne was currently Iterum Pharmaceuticals chief science officer and previously was the head of research and development at Actavis, now Allergan, and was Durata Therapeutics chief medical officer, prior to Durata's acquisition by Actavis in 2014.

The company said that Dr Dunne worked at Pfizer for 17 years, leading the clinical development of a number of infectious diseases products.

Biota said that Dr Dunne held a Medical Degree from the State University of New York and a Bachelor of Arts in economics from the Chicago, Illinois-based Northwestern University.

Last night on the Nasdaq, Biota was up six US cents or 3.08 percent to $US2.01 ($A2.85 equivalent to 35.7 cents prior to the Nabi merger, when it was trading around $A1.00) with 146,229 shares traded.