Biotech Daily

Tuesday May 12, 2015

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PATRYS, STARPHARMA UP 10%**
- USCOM DOWN 20%

*** MESOBLAST 'RA STEM CELLS CARDIO-VASCULAR IMPACT'**

*** ACTINOGEN XANAMEM SAFE TO 35mg**

*** COGSTATE APPOINTS DR ALAN FINKEL, $2m, MYER DILUTED**

*** BONE QUITS BIOTECH FOR TAKOR GEOSPATIAL IMAGING**

*** MEDICAL DEVELOPMENTS NEGOTIATING GLOBAL DISTRIBUTION DEALS**

*** MEDICAL DEVELOPMENTS DAVID WILLIAMS SELLS 7m SHARES TO 40.5%**

*** MEDLAB IPO FOR UP TO $9m FOR FOOD ADDITIVES, MEDICAL CANNABIS**

*** PHOSPHAGENICS LOSES LAWRENCE GOZLAN, PETER LANKAU CHAIR**

MARKET REPORT

The Australian stock market climbed 0.88 percent on Tuesday May 12, 2015 with the S&P ASX 200 up 49.5 points to 5,674.7 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and five were untraded.

Patrys and Starpharma were the best, both up 10 percent to 1.1 cents and 77 cents, respectively, with 1.2 million shares and 2.3 million shares traded, respectively.

Biotron climbed 8.3 percent; both Antisense and Living Cell rose 7.1 percent; Benitec was up 4.4 percent; Clinuvel, Sirtex and Viralytics were up more than three percent; Acrux, Genetic Technologies and Optiscan rose more than two percent; Impedimed was up 1.8 percent; with Cochlear up half a percent.

Uscom led the falls, down four cents or 20.0 percent to 16 cents with 9,347 shares traded.

Atcor and Compumedics lost more than eight percent; Anteo, Medical Developments and Pharmaxis fell more than five percent; Actinogen, Oncosil and Prima fell more than four percent; IDT lost 3.6 percent; Admedus, Bionomics, Nanosonics and Neuren shed more than two percent; with CSL, Mesoblast, Osprey and Resmed down less than one percent.

MESOBLAST

Mesoblast says that a sheep rheumatoid arthritis trial has shown that its mesenchymal precursor cells can reduce inflammation and reverse abnormal function of blood vessels.

Mesoblast said that the study, entitled 'Effect of Mesenchymal Precursor Cells on the Systemic Inflammatory Response and Endothelial Dysfunction in an Ovine Model of Collagen-Induced Arthritis sheep trial' was published by the Public Library of Science One and is at: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0124144.

The study, co-authored by Mesoblast chief executive Prof Silviu Itescu, concluded that arthritic sheep treated with mesenchymal precursor cells demonstrated "a marked spike" in plasma levels of the anti-inflammatory cytokine interleukin-10 (IL-10), 24 hours following administration" as well as significantly reduced plasma levels of the inflammatory markers, fibrinogen and serum amyloid A and increased high-density lipoprotein (HDL).

The article said that coronary arteries from sheep treated with mesenchymal precursor cells (MPCs) "demonstrated a significantly greater maximal relaxation to bradykinin when compared to untreated [rheumatoid arthritis] sheep ... and digital arteries also demonstrated greater endothelium-dependent vaso-dilation".

"This study demonstrated that MPCs given intravenously are able to attenuate systemic inflammatory changes associated with a monoarthritis, including the development of endothelial dysfunction," the article concluded.

Mesoblast said that since patients with rheumatoid arthritis had about a 50 percent higher risk of death from cardiovascular disease than the general population, the results suggested that the anti-inflammatory effect of MPC therapy "may have an additional benefit in reducing cardiovascular risk associated with rheumatoid arthritis".

The company said that rheumatoid arthritis was a chronic disease driven by multiple cytokines, including tumor necrosis factor-alpha (TNF-alpha), interleukin-6, and interleukin-17, produced by pro-inflammatory monocytes and macrophages and activated T-cells, and while existing biologic therapies targeted these pathways individually, none targeted all concomitantly.

Mesoblast said its MPCs concurrently modulated both pro-inflammatory monocytes and activated T-cells to reduce multiple pro-inflammatory cytokines produced by these cell types in the inflammed joints.

Mesoblast said it was conducting a 48-patient, double-blinded, randomized, placebo-controlled, dose-escalation phase II trial of its stem cells in patients with biologic-refractory rheumatoid arthritis in the US and Australia, evaluating the safety, tolerability and effectiveness of a single intravenous infusion of either of two dose levels for active rheumatoid arthritis in patients who had failed at least one biologic agent.

The company said that the high cardiovascular mortality in rheumatoid arthritis was thought to be due to persistent inflammation and endothelial dysfunction of the coronary arteries leading to thrombosis and plaque rupture.

Mesoblast said that the authors concluded that mesenchymal precursor cells showed "significant promise in modulating not only local disease activity in chronic inflammation such as a poly or mono-arthritis, but also the systemic sequelae of the condition".

Prof Itescu said that "endothelial dysfunction caused by chronic inflammation is particularly important in rheumatoid arthritis where there is a significantly increased risk of coronary artery disease and death and in diabetes where it is a major contributor to both kidney failure and cardiovascular events".

"These results suggest that our intravenously delivered product candidate, MPC-300-IV, may have a clear therapeutic role in addressing the consequences of diseases of chronic systemic inflammation," Prof Itescu said.

Mesoblast fell three cents or 0.81 percent to $3.68.

ACTINOGEN MEDICAL

Actinogen says the first stage of its phase I trial of Xanamem for Alzheimer's disease has confirmed safety and tolerability across the dose range of 10mg to 35mg twice daily.
Actinogen said that the next stage of the trial would be a fed versus fasted dosing of 12 participants with 35mg of Xanamem, expected to begin on May 19, 2015 with top-line results due in late July 2015.
The company said the 24 healthy volunteers study demonstrated how the body absorbed and metabolized Xanamem and would help define the optimal dose for the drug.
Actinogen said that the independent safety review committee reviewed the data from the final and highest dose cohort and was satisfied the data showed no safety or tolerability concerns with Xanamem and the drug demonstrated its expected pharmacokinetic profile.
The company said that the results would enable an investigational new drug application to the US Food and Drug Administration for a phase II trial of Xanamem in the US, which would also be run in Australia, New Zealand and the UK.
Actinogen said that the trial was executed on-time and on-budget.
Actinogen chief executive officer Dr Bill Ketelbey said the results, "combined with the successful capital raising from our shareholders last month, sets us up well to start the phase II study of Xanamem in patients with Alzheimer's disease".
Actinogen fell 0.4 cents or 4.4 percent to 8.6 cents with 4.5 million shares traded.

COGSTATE

Cogstate says it has appointed Dr Alan Finkel as a director and companies associated with Dr Finkel have bought 8,000,000 shares at 25 cents a share raising $2 million.
Cogstate said that Dr Finkel was the chancellor of Monash University and president of the Australian Academy of Technological Sciences and Engineering.
The company said that Dr Finkel was a respected neuroscientist, electrical engineer, entrepreneur and philanthropist.
Cogstate said that Dr Finkel founded Axon Instruments, supplying electronic and robotic instruments for neuroscience research and pharmaceutical drug development, which was sold to the US-based Molecular Devices Corporation for $140 million in 2004 and Dr Finkel was appointed chief technology officer.
The company said that Dr Finkel was previously chief technology officer for Better Place Australia and continued as the executive chairman of Stile Education and as the executive publisher of Cosmos Magazine.
Cogstate said that Dr Finkel held a Doctorate of Philosophy form Monash University and served as a neuroscience research fellow at the Australian National University's John Curtin School of Medical Research.
Cogstate said that the placement shares would be issued under the 15 percent placement capacity and would provide additional working capital.
In an initial substantial shareholder notice, Dr Finkel said that Nebula Neuro Pty Ltd had acquired 8,000,000 shares taking his holding, along with 1,000,000 shares held by Howitt Nominees Pty Ltd, to 9,000,000 or 8.41 percent of the company.
A separate change in substantial shareholder notice said that the Myer Family, a related entity to Cogstate chairman Martyn Kenneth Myer, held 18,493,214 million shares, which was diluted in the placement from 18.68 percent to 17.27 percent, with the registered holder National Nominees as custodian for Mpyer Investments as trustee for the MK Myer Family Settlement, Myer & Myer Pty Ltd for Whereabouts Superannuation Pty Ltd, Martyn K Myer, Max Myer, Edwina Myer and Lucy Myer.
Cogstate was up 5.5 cents or 25.6 percent to 27 cents.

BONE MEDICAL

Bone says it will acquire the Perth, Western Australia-based geospatial imaging company Takor Group and quit biotechnology.

Bone was created by investors in Proxima and licenced Capthymone and BN006 compounds from four subsidiary companies within the Proxima Group and had the use of the Proxima Laboratory and Research Services laboratory.

Proxima co-founder and research director Dr Roger New was formerly Bone's chairman (BD: Jul 11, Sep 22, 2011; Jan 29, Apr 4, May 12, Jun 20, 2014).

Last year, Bone said it would "terminate the agreements with the Proxima Group" having evaluated its technologies and near completion of product development studies and concluded it was "not in the commercial interests of the company or its shareholders to continue with the Proxima Group under the current structure" (BD: Nov 19, Dec 9, 2014).

Bone said at that time that the Capthymone oral treatment for osteoporosis had not generated meaningful parathyroid hormone levels in blood, when compared to the commercially available injectable Forteo and a Proxima Concepts report showed that on only one of the important measures of efficacy and at one dose did BN006 appear to be close in its effects to the market leaders.

Today, Bone said it would acquire Takor subject to shareholder approval and re-compliance with chapters 1 and 2 of the ASX Listing Rules.

The company said that Takor was formed in 2009 as Scantherma Pty Ltd, providing access to satellite imaging technologies and in 2011 the company started research and development of mobile mapping technologies, particularly offline systems for broad scale use in defence, environmental and conservation, disaster management, transport and mining and in March 2014, was hired for the search for the missing flight MH370.

Bone said the acquisition would include loan funds of $300,000 to Takor, 387,000,000 Bone shares, repayment of Takor loans of $266,000, 20,000,000 Bone options and 350,000,000 performance shares to the founder and major shareholder Amir Farhand converting to shares, subject to ASX approval.

Bone climbed 0.6 cents or 66.7 percent to 1.5 cents with 88.3 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that it established an electronic data room for prospective Penthrox distribution l partners which has attracted more than 30 companies.

Medical Developments said it had concluded Penthrox agreements for the UK, the Republic of Ireland, South Africa, Mexico, Singapore, Saudi Arabia, Taiwan, Hungary, the United Arab Emirates and Hong Kong, providing significant minimum sales quantities.

The company said it was in advanced negotiations with companies to distribute Penthrox in Germany, Spain, Italy, and with others interested in the whole of Western Europe.

Medical Developments chief executive officer John Sharman said he expected the distribution deals to be "in a similar form to that signed with Galen and therefore are expected to involve significant upfront and other milestone payments".

"We expect sales into the major markets of the EU over the next 12 months, starting with sales into the UK and Ireland where preparations are well advanced for a July launch and followed shortly after in France and Belgium," Mr Sharman said.

Mr Sharman said that subject to mutual recognition regulations the company was expecting sales into Germany, Italy and Spain by July 2016, with "several companies ... in negotiations for the rights to countries outside the EU, including Turkey, Israel, Canada, Russia, Japan, Malaysia, South Korea, Bahrain and Latin America," Mr Sharman said.

Medical Developments fell 15 cents or 5.7 percent to $2.47 with 7,357,636 shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that chairman David Williams has sold 7,000,000 shares at $2.40 to mainly institutional investors to increase liquidity in the company.
Medical Developments said that it expected a substantial shareholding notice from an Australian institution to be made shortly.
The company said that Mr Williams remained a substantial shareholder with an indirect interest in 23,370,890 shares (40.5%) held through Lawn Views Pty Ltd, Moggs creek Pty Ltd, Pari Passu Pty Ltd, Kidder Peabody Pty Ltd, Ward Williams and Saul Williams.

MEDLAB CLINICAL

The Sydney-based Medlab hopes to raise up to $9 million in an initial public offer of 45,000,000 shares at 20 cents each for medical research and its food additives program.
Medlab said that its research was “based on overcoming poor gut health, which it sees as the cause of certain health problems as well as disrupting the effectiveness of orally administered targeted medicines”.
The company said that funds raised in the offer would be used to development its existing food additives business, with six products currently on the market and 16 in the pipeline, for research and development of new bacteria-based medicines or pharmaco-biotics of which two were currently in human trials and development of delivery platforms for these medicines to allow more effective dosing.
Medlab said that the offer, which opened on May 11 and would close on May 29, 2015, had a minimum of 30,000,000 shares to raise $6,000,000 and a maximum of 45,000,000 shares to raise $9,000,000.
The company said it had 130,000,000 shares currently on offer and the minimum after the offer would be 160,000,000 shares and the maximum would be 175,000,000 shares.
Medlab said it was “backed by the Hall family ... [which had] built and then sold four nutraceutical companies” including Fit-Bioceuticals to Blackmores in 2012 for about $40 million.
Medlab said it developed nutritional pharmaceutical products or nutraceuticals with an initial focus on probiotics, which took advantage of the growing scientific evidence of the links between certain bacteria and gastrointestinal health.
The company said its initial five products sought to improve gut health, energy levels and protein absorption.
Medlab said it had “an extensive patent portfolio” with 10 provisional patents lodged and five more at the draft stage.
The company said its bacteria-based medicines targeted anti-ageing, chronic kidney disease, depression, obesity and pain management, with human trials for obesity and depression begun in February 2015 and trials for pain management using medicinal cannabis awaiting supply approval from the New South Wales Government.
Medlab said that the funds raised would be spent primarily on development of the existing food additive business and research and development of new products.
The company said the current top three shareholders were Sean Hall with 54,922,222 shares, Fit Investments with 10,967,778 shares and the Realm Group with 10,500,000 shares.
Medlab said its current directors were non-executive chairman Michael Hall, managing director and chief executive officer Sean Hall and non-executive director Drew Townsend.
The company said that Prof Luis Vitetta was the company’s director of medical research.
Medlab said that BBY was the lead manager to the initial public offer.
The prospectus is available at: http://www.medlab.co/investors/prospectus.

PHOSPHAGENICS

Phosphagenics says that chairman Lawrence Gozlan has resigned from the board and will be replaced by recently-appointed director Peter Lankau (BD: Apr 13, 2015).

Phosphagenics said that Mr Gozlan "decided to step down from the board to focus on all his other business interests and commitments, which are significant and growing".

Mr Gozlan joined the Phosphagenics board last year with Nathan Drona and Dr Geert Cauwenbergh replacing Jonathan Addison, Stuart James, Sandra Webb and Don Clarke. (BD: Mar 3, 2014).

Also last year, Mr Gozlan was appointed a director of Oncosil, but resigned from Oncosil last week (BD: Feb 27, 2014; May 4, 2015).

Mr Gozlan continues as a director of Prana and Ausbiotech.

Mr Drona was formerly the chairman of Avexa and Alchemia and continues as a director of Alchemia (BD: Mar 22, 2013).

Today, Phosphagenics said that Mr Gozlan "made important contributions to the company since joining in February 2014".

"In particular he had a key role in the 2014 capital raising and the appointments of the [chief executive officer] Dr Ross Murdoch and other new board members, Dr Greg Collier and Mr Peter Lankau".

Phosphagenics said that as a result the resignation, the first item of business at the annual general meeting to re-elect Mr Gozlan as a director would be withdrawn.

Phosphagenics fell 0.3 cents or 9.7 percent to 2.8 cents with 4.1 million shares traded.