



Biotech Daily

Tuesday November 29, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ANTEO UP 8%; TISSUE THERAPIES DOWN 17%**
- * **REGENEUS PHASE II FAT STEM CELL TRIAL FOR OSTEOARTHRITIS**
- * **IMMURON, HADASSAH PROF ILAN: 'PHYSICIAN SCIENTISTS THE KEY'**
- * **PALADIN TRAVELAN SALES START WITH IMMURON \$486k UPFRONT FEE**
- * **AVITA ACQUIRES RECELL, CELLSPRAY IP; HONG KONG PATENT**
- * **CONSEGNA COMPLETES BREATHEASSIST DEVELOPMENT**
- * **CELLMID RAISES \$481k; SHORTFALL \$1.2m TO GO**
- * **UP TO 38% OF LIVING CELL VOTES OPPOSE DIRECTOR OPTIONS**
- * **CBIO ACTION GROUP PREVAILS WITH REDUCED BOARD**
- * **NUSEP REMUNERATION STRIKE 1; DR NISBET, TERRY O'DYWER LOSE**
- * **PATRYS REQUESTS CAPITAL RAISING TRADING HALT**
- * **GI DYNAMICS APPOINTS COO MARK TWYMAN, ROBERT SOLOMON**

MARKET REPORT

The Australian stock market climbed 1.08 percent on Tuesday November 29, 2011 with the S&P ASX 200 up 43.9 points to 4,102.1 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, three traded unchanged and six were untraded.

Anteo was the best, up half a cent or 8.1 percent to 6.7 cents with 7.8 million shares traded. Cellmid and Heartware climbed more than six percent; Universal Biosensors was up 5.3 percent; Prana was up 3.45 percent; Allied Health rose 2.9 percent; with CSL, Pharmaxis and Starpharma up one percent or more.

Tissue Therapies led the falls for the second day in a row, down eight cents or 17.0 percent to 39 cents with 1.2 million shares traded. Genetic Technologies and Neuren lost more than eight percent; Alchemia, Benitec and Living Cell were all down 6.7 percent; Sunshine Heart was down 5.6 percent; Avita, Biota and QRX fell more than four percent; Antisense, Optiscan and Phylogica were down more than three percent; Acrux, Bionomics, Mesoblast, Nanosonics, Prima and Reva shed more than two percent; with Circadian down one percent.

REGENEUS

Regeneus has treated 24 of 40 patients recruited for its phase II trial of using a patient's own or autologous adipose tissue to treat osteoarthritis.

Regeneus chairman John Martin told Biotech Daily that the randomized, double-blind, placebo controlled study at Sydney's Royal North Shore Hospital would evaluate the efficacy and safety of autologous non-expanded adipose (fat) derived stem cells in the treatment of knee osteoarthritis.

Mr Martin said Regeneus had conducted the procedure on more than 400 dogs through its animal health division and the company expected to complete the human trial by September 2012 with results evaluated by the end of the 2012.

Mr Martin said the company harvested about "a cup" of fat tissue and then processed it to separate the regenerative cells including mesenchymal stem cells, which could then be injected into a joint, muscle or intravenously.

He said the fat cells stored cells that were part of the mammalian regenerative process and his company's process, known as Hiqcell, released the cells from the fat.

On its website, Regeneus said the trial would evaluate the effects of the procedure on reduction of pain and changes in other measures of quality of life in relation to knee osteoarthritis.

The company said that medication uses before and after the procedure would be documented to determine if there was any reduction in medication use following the procedure.

Regeneus said that magnetic resonance imaging, gait and blood analysis would also be performed before and after the procedure.

In the April 2011 edition of the veterinary magazine Vetscript, Regeneus director and Macquarie University fellow Prof Ben Herbert described the mechanisms by which mesenchymal stem cells (MSCs) promote tissue repair.

In the article entitled 'The secret life of mesenchymal stem cells' Prof Herbert said that "in most animal model studies, the implanted MSCs do not differentiate into the injured tissue type".

"They promote significant improvements in tissue repair with reduced scarring and ischaemia-induced cell death and improved vascularisation," Prof Herbert said.

"It is now clear that MSCs exert powerful therapeutic and regenerative effects through the combination of their ability to modulate the immune response to injury and secrete a range of trophic factors, which promote tissue repair," he said.

"The acceptance of implanted cells as secretion factories leads directly to a discussion of the merits of mixed cell populations," Prof Herbert wrote.

"With some tissues, such as adipose, there are significant advantages in the mixed population of cells and the ability to provide therapy with uncultured autologous cells, harvested and administered at the point of care," Prof Herbert said.

Mr Martin said the company had a range of veterinarian products being used with horses and dogs including the autologous Adicell and the off-the-shelf Adishot, as well as Sytokine, currently in animal trials.

Mr Martin said that the company had raised \$3 million to \$4 million and the cost of the trial was about \$1 million.

Mr Martin said Regeneus was a private company in the process of converting to a public unlisted company.

HADASSAH MEDICAL CENTRE, IMMURON

Hadassah Medical Center Department of Medicine director Prof Yaron Ilan says translational research requires physician research scientists.

Interviewed at the North Melbourne office of Immuron where he is chief medical officer, Prof Ilan told Biotech Daily that an essential part of the "chain of discovery" was the need to bridge the gap between scientific research and working doctors.

"The chain of discovery starts in the lab and then goes to translation research to clinical trials to implementation," Prof Ilan said. "We have good scientists and plenty of patients, but the gap requires the physician scientist to take projects from bench to bedside."

Prof Ilan said the Hadassah private hospital had two sites in Jerusalem with 1,130 beds, 670 doctors, treated more than one million outpatients a year and had its own clinical research centre.

He said his department could cite seven examples of commercial success with 18 start-up companies, of which three, including Immuron, were publicly-listed.

"I run a big lab and department and most of my time is seeing patients. Many researchers don't see patients and physicians who only see patients use old technologies and do what they were taught at medical school 30 years ago."

"What we try to do at Hadassah is provide protected research time so that two-thirds the doctors are treating patients and one-third is research," Prof Ilan said.

He said the policy required money which came from Israel Government grants, the private hospital, the Hadassah women's organization and private investors.

Prof Ilan said Hadassah created the Hadasit commercialization arm which owned about 20 percent of Immuron.

Explaining Hadassah's commercialization strategy, Prof Ilan said a project would begin with the physician research scientist, be taken up by Hadasit and either spun-out into its own company or partner with a company like Immuron and then develop the technology to be acquired by or licenced to a major pharmaceutical company.

Prof Ilan said he had been working on oral immune therapies when he met the previous directors of Immuron (then Anadis) and found common cause through the production of antibodies and adjuvants in cow colostrum.

"What comes from the cow is perfect and we have tried in the lab and not improved it," Prof Ilan said. "We can inject any antigen and the cow will create the antibody and all the adjuvants ...and one cow can produce thousands of pills from its colostrum."

He said the E coli basis of the travel sickness treatment Travelan was used in influenza treatment to boost the immune system to fight "any strain of influenza" with trials completed in mice and ferrets and the same formulation appeared to be effective for "leaky gut syndrome" which related to many other illnesses.

Prof Ilan said the company was conducting animal trials for cancer and human clinical trials for HIV and the platform technology appeared to have efficacy for "metabolic syndrome" including type 2 diabetes and non-alcoholic steatohepatitis (NASH).

He said that a different dose of Travelan's anti-lipo-polysaccharides had been trialed in 10 patients with metabolic syndrome and most responded to treatment including changes to hormone expression.

Prof Ilan said American Association for the Study of Liver Disease past-president Dr Arun Sanyal was so impressed with the results he offered to be the principal investigation for the six centre, 120-patient trial.

Immunon chief executive officer Joe Baini said the trial would require \$5 million.

Prof Ilan was also the guest of the Bio-Melbourne Network Bio-Briefing at the Royal Melbourne Hospital discussing commercialization of clinical research, today.

Immunon was up 0.7 cents or 16.3 percent to five cents with 1.1 million shares traded.

IMMURON

Immuron says it will receive a \$C500,000 (\$486,089) up-front fee from Paladin Labs to sell its Travelan travel sickness medication in Canada, Latin America and sub-Saharan Africa. Immuron said potential sales performance milestone payments could total \$C115 million. The company said it retained all production and manufacturing rights and would supply finished packs of Travelan to Paladin for each territory.

Immuron said Paladin was granted an option over the rights to Immuron's potential influenza product (IMM255) in the same territories, subject to a separate agreement.

The company said that subject to certain closing conditions, Paladin would provide up to \$C1.5 million in the form of a secured convertible debenture to be used primarily for the ongoing commercialization of Travelan and future product development.

Immuron chief executive officer Joe Bains said the deal was "a major event in the history of Immuron and an important step in our expanded market-focused commercialization strategy".

"This agreement highlights the global appeal of our in-market and flagship product Travelan," Mr Bains said.

Paladin chief executive officer Mark Beaudet said Travelan provided Paladin with "a unique and differentiated product for the prevention of travellers' diarrhoea that will further expand both our [over-the-counter] portfolio in Canada and our strategic footprint across emerging markets".

AVITA MEDICAL

Avita says it has completed the transfer and acquisition of intellectual property licensed from the McComb Foundation of Western Australia.

Avita said all patents, patent applications and other patent rights licenced to Avita, including worldwide rights to all intellectual property representing two patent families including: "Cell Suspension Preparation Technique and Device" and "Cell Suspension Preparation Kit", have been assigned and transferred to Avita by the McComb Foundation.

The company said the commercial manifestation of the patented technologies included Cellspray for the rapid culture of autologous epithelial cells for reapplication to a wound in the form of cultured epithelial sheets and Recell Spray-On Skin for the rapid dissociation of epithelial tissue, creation of a suspension of non-culture cells and the immediate delivery of the cell suspension to the patient.

Avita said it would pay McComb an on-going one percent royalty on revenue generated through application of the transferred intellectual property, for the life of the patents.

Avita said the Hong Kong Patent Registry had granted a patent entitled 'Cell Suspension Preparation Technique and Use' for 16 specific claims over the method, resulting cell suspension and apparatus for delivery of disaggregated skin cells.

Avita chief executive officer Dr William Dolphin said the importance of intellectual property protection had increased as Avita expanded into the global markets.

"Strong intellectual property protection is a major competitive advantage and a cornerstone of the company's valuation," Dr Dolphin said.

Dr Dolphin said the ownership of the technology underlying Avita's regenerative products was "a significant milestone for the company".

Avita maintains a close working relationship with the scientists at the McComb Foundation and will continue to support sponsored research through McComb to the mutual benefit of Avita, McComb and the general public," Dr Dolphin said.

Avita fell half a cent or 4.8 percent to 10 cents.

CONSEGNA GROUP (FORMERLY HELICON GROUP)

Consegna says it has completed the final development phase of its Breatheassist device so that it could be commercially manufactured.

Consegna said it was ready to start negotiations with potential licencees in the sporting industry.

The company said that a clinical study confirmed the device enhanced nasal airflow by 37 percent and there were multiple licencing opportunities for the product including drug delivery, snoring cessation, sleep apnea, the filtration of pollen and other pollutants.

Consegna managing director Fabio Pannuti said that APS Innovations had completed the development of the finished product invented by Paz Maryanka.

"Although there are several applications for Breatheassist, it is clear the most immediate path to cash flow is through the sports market," Mr Pannuti said.

Consegna fell 0.3 cents or 10.3 percent to 2.6 cents.

CELLMID

Cellmid says its rights issue raised \$480,564 of the maximum subscription of \$1,685,695.

Cellmid said the \$1.2 million shortfall would be applied to late acceptances received before 5pm (AEDT) on November 30, 2011 and any remaining shortfall could be placed at the discretion of the directors within three months.

Cellmid was up 0.1 cents or 6.25 percent to 1.7 cents.

LIVING CELL TECHNOLOGIES

All nine Living Cell annual general meeting resolutions were passed but there was significant opposition to director options and a share issue.

The closest votes were on the issue of 900,000 options to chairman Roy Austin, 400,000 options each to directors Dr Bernard Tuch and Robert Willcocks, with more than 36 million proxy votes (62.1%) in favor and more than 22 million proxy votes (37.9%) against.

The ratification of the issue of 2,767,528 shares to Springtree Special Opportunities Fund faced similar opposition.

The remuneration report and the election of directors Mr Austin, Dr Tuch, Mr Willcocks and Laurie Hunter were passed easily, with 1.8 million votes cast against each resolution.

Living Cell's most recent Appendix 3B share issue announcement said there were 339,119,692 shares on issue, meaning that the strongest opposition came from 6.6 percent of all shares on issue, sufficient to requisition extraordinary general meetings.

Living Cell fell 0.4 cents or 6.7 percent to 5.6 cents.

CBIO

CBio says founder and chairman Dr Michael Monsour and newly-appointed directors Ross Mangelsdorf and Warren Brooks have resigned.

Mr Mangelsdorf and Brooks were immediately prior to the election of three shareholder action group nominated directors earlier this month (BD: Nov 4, 2011).

Acting chairman Dr Ralph Craven thanked Dr Monsour "for his service and for his long-standing commitment to the company".

The three action group nominated directors hold a majority of the continuing five-member board, a reduction from the previous 10-member board.

CBio was up 0.5 cents or 2.9 percent to 18 cents.

NUSEP

The Nusep remuneration report was opposed by 27.3 percent of all proxy votes cast, tripping the first of two triggers for a board spill.

The remuneration report vote was passed with 53,746,626 proxy votes (72.7%) in favor and 20,200,350 proxy votes (27.3%) against.

Changes to the Corporations Act (Section 250U) provide for a 'two strikes and re-election' process if a company's remuneration report is opposed by more than 25 percent of votes on two consecutive occasions, taking the company to a vote on a board spill motion.

The reelection of directors John O'Connor David Roffe and Ward Wescott were passed with more than 67 million proxy votes in favor and more than 17 million proxy votes against.

But director candidates, opposed by the existing board, Dr Ian Nisbet and Terry O'Dwyer were defeated by more than 67 million proxy votes against and 20 million proxy votes in favor.

Nusep has 93,773,272 shares on offer making the vote against the remuneration report 21.5 percent of the company.

Nusep climbed 3.5 cents or 50 percent to 10.5 cents with 19,377 shares traded.

PATRYS

Patrys has requested a trading halt "pending an announcement ... in respect of a capital raising".

Trading will resume on December 1, 2011 or on an earlier announcement.

Patrys last traded at four cents.

GI DYNAMICS

GI Dynamics **says it has** appointed Mark Twyman as chief commercial officer reporting to chief executive officer Stuart Randle.

GI Dynamics said Mr Twyman would be responsible for executing the company's commercial strategy, including overseeing the expansion of the sales and marketing efforts to commercialize the Endobarrier, obesity and diabetes device.

GI said Mr Twyman had more than 20 years in commercializing healthcare products at companies including Genzyme, Medimmune and Merck.

The company said that most recently, Mr Twyman was the general manager at Genzyme Biosurgery, where he had responsibility for Genzyme's \$400 million visco-supplement franchise and managed a team of 175 sales, marketing and other professionals.

GI said Mr Twyman held a Masters of Business Administration from the University of Pennsylvania and a Bachelor of Arts from Dickinson College.

GI Dynamics said it had also appointed Robert Solomon as its vice president of finance reporting to chief financial officer Robert Crane and would be responsible for accounting and financial reporting activities.

The company said Mr Solomon held a Masters of Business Administration from New York University and a Bachelor of Science from Cornell University.

GI Dynamics was up half a cent or 0.5 percent to 93 cents.