



Biotech Daily

Friday December 19, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: OSPREY UP 10%, IDT DOWN 9%**
- * **VICTORIA TO LEGALIZE MEDICAL CANNABIS**
- * **WEHI DISCOVERS HOW APOPTOSIS HIDES FROM IMMUNE SYSTEM**
- * **GENERA NOTES RAISES \$2m, \$500k MORE BY MARCH**
- * **AUSTRALIAN PATENT FOR REGENEUS STEM CELL FREEZING, THAWING**
- * **PROGEN PHASE I PG545 SOLID TUMOR TRIAL UP TO 4th COHORT**
- * **NOVOGEN RAISES FURTHER \$1.75m, TOTAL RAISED \$7.75m**
- * **ANTEO MIX&GO ACTIVATION KIT FOR MULTIPLEX MICROSPHERES**
- * **ANATARA STARTS DETACH PIG DIARRHOEA TRIAL**
- * **NUSEP AGM FIGHT, REMUNERATION 1st STRIKE, MOST VOTES PASS**

MARKET REPORT

The Australian stock market climbed 2.45 percent on Friday December 19, 2014 with the S&P ASX 200 up 127.8 points to 5,338.6 points.

Fourteen of the Biotech Daily Top 40 stocks were up, nine fell, 13 traded unchanged and four were untraded. All three Big Caps were up.

Osprey was the best, up five cents or 10 percent to 55 cents with 107,413 shares traded.

Acrux, Bionomics and Mesoblast climbed more than nine percent; Anteo was up eight percent; Oncosil rose 7.5 percent; Living Cell, Optiscan and Sirtex climbed more than six percent; Admedus and Benitec were up more than four percent; Cochlear rose 2.9 percent; CSL, Medical Developments, Resmed and Tissue Therapies were up more than one percent; with Nanosonics up 0.9 percent.

IDT led the falls, down 1.5 cents or 9.4 percent to 14.5 cents with 810,000 shares traded.

Genetic Technologies and Pharmaxis fell more than seven percent; Clinuvel lost 6.2 percent; Biotron and Cellmid fell four percent or more; Analytica and Phosphagenics shed more than three percent; with Impedimed down 0.65 percent.

VICTORIA GOVERNMENT

The Victoria Government says it has taken the first steps to legalizing medical cannabis so those with terminal illnesses and life-threatening conditions can relieve their symptoms.

A media release from Premier Daniel Andrews said the State Government had asked the Victorian Law Reform Commission to review options for changes to drug laws.

"This reform will happen," the media release said.

"The Commission is not being asked whether this change should go ahead, but how the change can go ahead safely, responsibly and efficiently," the Government said.

The Government said the Commission would report back no later than August 31, 2015 with advice on how the substance could be regulated, manufactured, managed and prescribed, and who would be eligible for access.

The Government said that many Victorians with terminal illnesses or life-threatening conditions wanted to use medical cannabis to relieve pain and treat their conditions and cannabis oil could have a powerful effect treating very sick children and adults by reducing symptoms, with life-changing results, in conditions such as cancer and HIV/AIDS.

"Parents shouldn't have to choose between breaking the law and watching their children suffer," Mr Andrews said. "Children are in pain, families are suffering, people are living in fear and outdated laws are getting in the way."

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers have found how dying cells are hidden from the immune cells that patrol the body.

WEHI said the research answers how cell death sometimes alerted the immune system to potential danger, but in other circumstances occurred silently, unnoticed by immune cells.

The Institute said that silent cell death, or apoptosis, was a controlled way to eliminate damaged, old or surplus cells, without causing collateral damage and was a normal process ignored by the immune system, while the death of cells at sites of infection or damage could alert the immune system.

WEHI said that Dr Michael White, Prof Benjamin Kile and colleagues had identified how apoptotic cell death was kept silent.

The research article, entitled 'Apoptotic Caspases Suppress mtDNA-Induced STING-Mediated Type I IFN Production', was published in the journal Cell and an abstract is at: [http://www.cell.com/cell/abstract/S0092-8674\(14\)01513-X](http://www.cell.com/cell/abstract/S0092-8674(14)01513-X).

Dr White said that the team focused on the role of proteins called caspases which hastened cell death by breaking down key components in the dying cell.

"Because apoptosis can still occur without the involvement of caspases, we investigated whether these proteins play any other role during cell death ... [and] found that when cells undergo apoptosis without caspases, they release immune cell signaling molecules called interferons that set off the immune response."

"By dissecting the step-by-step process that occurs within dying cells, we showed one of the key roles of caspases is to suppress interferon release [which] confirmed that caspases are crucial for hiding apoptotic cell death from the immune system."

Prof Kile said that over-reaction of immune cells to apoptosis might be a factor in inflammatory diseases such as rheumatoid arthritis and the findings provided insights into how the body might tolerate new drugs, with caspase-inhibiting medications in clinical trials for their potential to keep cells alive during organ transplants.

"Our work suggests that any use of these medications should be accompanied by careful monitoring of their effects on the immune system," Prof Kile said.

GENERA BIOSYSTEMS

Genera says it has placed 20,000 convertible notes at \$100.00 a note to sophisticated and professional investors raising \$2 million before costs.

Genera said it intended to offer a second tranche of \$500,000 in notes to investors on the same terms prior to March 31, 2015.

The company said that the notes could be converted into shares at 25 cents a share from May 1, until July 31, 2015, a conversion premium of 13.6 percent to the pre-offer share price and after July 31, 2015 the notes would be converted at 23 cents a share.

Genera chairman Lou Panaccio said the company previously used convertible notes to fund progress in the commercialization of the Ampasand medical diagnostic platform while managing dilution to shareholders.

Genera chief executive officer Richard Hannebery said the funding placed the company in a strong position to integrate its Ampasand diagnostics with Beckman Coulter's flow cytometry instrumentation platform and "aggressively roll-out our two lead Ampasand-based [medical diagnostic] tests, Paptyp and RTI-Plex, to pathology customers".

Mr Hannebery said that Genera expected Australian Therapeutic Goods Administration and Conformité Européenne (CE) mark approval by July 2015.

Genera said it was targeting completion of its sexually transmitted infections diagnostic STI-Plex in 2015 while adding at least three medical diagnostic assays to the development pipeline, with an in-vitro diagnostics partner.

Genera was unchanged at 22 cents.

REGENEUS

Regeneus says the Australian Patent Office has granted a patent covering a method for freezing cells that maintains viability and functionality of the cells.

According to IP Australia the patent is entitled 'Therapeutic methods and compositions comprising cells and secretions' and was filed in April 2013

Regeneus said its method of freezing cells used molecules, including cytokines and growth factors secreted by mesenchymal stem cells, to protect the cells during the freeze and thawing process.

Regeneus said it had developed technology and protocols for the production of secretions from adipose or fat-derived mesenchymal stem cells (MSCs) and had discovered that when cells were mixed with the secretions prior to freezing, the viability and functionality of the cells was maintained.

The company said that the technology was applicable to many different cell types.

Regeneus chief scientific officer Prof Graham Vesey said that off-the-shelf cell therapy products needed to be stored and delivered to the patient in a frozen state.

"The viability, functionality and subsequent efficacy of these frozen and then thawed cells are critical for maximizing therapeutic value," Prof Vesey said.

"When cells are frozen, damage can occur that causes the cells to lose their ability to function correctly," Prof Vesey said. "The cells may still be alive but are too damaged to have a therapeutic effect."

"When cells are mixed with secretions from MSCs prior to being frozen, the cells maintain their functionality," Prof Vesey said.

Regeneus said the patent was its second granted in Australia, following patent granted in November for the treatment of acne (BD: Nov 14, 2014).

The company said it had 11 patent families covering the technology and products, which were at various stages of the patent review process.

Regeneus was unchanged at 16 cents.

PROGEN PHARMACEUTICALS

Progen says the third patient cohort in its PG545 phase I solid tumor trial has been assessed with an independent monitor and will progress to the next dose level.

Progen said that patients in the third cohort received once-weekly 100mg doses of PG545 and no dose limiting toxicities were reported following four weeks of treatment.

The company said that recruitment of the fourth cohort of three patients had begun and each patient would receive 150mg doses of PG545 at once-weekly intervals.

Progen drug development director Dr Keith Dredge said that the identification of 100mg as a safe and well tolerated dose in these cancer patients was "very encouraging, as equivalent doses in preclinical studies have been proven to be highly effective in many cancer models".

Progen said that the study was entitled 'An open-label, multi-centre phase I study of the safety and tolerability of IV infused PG545 in patients with advanced solid tumors' and was expected to enrol about 25 advanced cancer patients.

Progen was unchanged at 20.5 cents.

NOVOGEN

Novogen says it has raised a further \$1.75 million from US institutional investors taking the total raised in the past six weeks to about \$7.75 million.

Novogen said it raised \$4.1 million earlier this week on the same terms of 12.5 cents a share with each share carrying an attaching option exercisable at 15 cents within five years (BD: Dec 17, 2014).

The company said that New York investment bank HC Wainwright & Co was the exclusive placement agent.

Novogen executive chairman Dr Graham Kelly said the company had identified the amount raised as "the required funding to bring at least one of our drug candidates into first-in-man studies; all with the objective of generating the clinical data that hopefully would confirm the clinical and commercial value of our super-benzopyran drug technology platform".

Novogen fell 2.5 cents or 17.9 percent to 11.5 cents with 16.0 million shares traded.

ANTEO DIAGNOSTICS

Anteo says its subsidiary Anteo Technologies has developed a new Mix&Go molecular adhesive "activation kit for multiplex microspheres".

Anteo said that the kit had been developed to be compatible with both Magplex and Microplex microspheres for use on the Austin, Texas-based Luminex platform.

Anteo chief executive officer Dr Geoff Cumming said the activation kit would "save scientists time and effort when using the Luminex multiplex systems because our product provides a stable surface chemistry platform to couple proteins onto microspheres".

"We have kept Luminex informed of our progress over the research and development phase and now as we introduce this product to market," Dr Cumming said.

"We think this kit will be of particular interest to new users of the Luminex multiplex systems, who may previously have been using the [1-Ethyl-3-(3-dimethylaminopropyl)carbodiimide or EDC] chemistry method, because it offers simplified handling and it's fast," Dr Cumming said.

Anteo said that its Mix&Go technology platform provided stability and reproducibility of results and allowed activated microspheres to remain stable for up to one year.

Anteo was up one cent or eight percent to 13.5 cents with 2.3 million shares traded.

ANATARA LIFESCIENCES

Anatara says it has begun the first pivotal field trial of the pineapple stem-based Detach to prevent and treat diarrhoea in piglets.

Anatara listed on the ASX in October, saying at that time it hoped to develop Detach for human use following the pig trials (BD: Oct 16, 2014).

Today, Anatara said the placebo controlled, randomized and blinded trial of more than 400 piglets would support an application to register Detach for sale with the Australian Pesticides and Veterinary Medicines Authority, with results expected by April 2015.

The company said that there was a need to reduce the use of antibiotics in humans and animals because of the emergence of antibiotic resistance in bacteria.

Anatara was up two cents or 7.1 percent to 30 cents.

NUSEP

Nusep faced strong opposition at its annual general meeting with two resolutions withdrawn and a remuneration report first strike, but most of the 28 resolutions passed.

In November, Nusep said that shareholders would vote on resolutions including the grant to executive chair Alison Coutts of 3,600,000 long term incentive options, the approval of the remuneration report, the employee share option plan, the 10 percent placement capacity, the ratification of a prior share issue and placement, as well as the election of directors Andrew Goodall, Michael Graham and Mark Gell, along with the issue of options, shares and convertible notes to an array of people and companies including former chairman John Manus (BD: Nov 20, 2014).

Yesterday Mr Manus told Biotech Daily that he objected to his convertible note and other resolutions, while Nusep said it had signed an enforceable undertaking with the Australian Securities and Investments Commission (BD: Dec 18, 2014).

Today, Nusep said Mr Manus's note and the placement votes were withdrawn.

The company said that with 20,510,822 votes (31.78%) against the remuneration report and 44,027,564 votes (68.22%) in favor it had recorded a "first strike".

The Corporations Act (Section 250U) provides 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.

Special resolutions including the replacement of the auditor and an additional 10 percent placement capacity required a 75 percent majority and were lost.

Five resolutions to issue shares to related parties of director Andrew Goodall were passed with 38,280,413 votes (51.50%) and 36,048,249 votes (48.50%) against.

The company's most recent Appendix 3B announcement said that Nusep had 171,259,376 shares on issue, meaning the votes against Mr Goodall's shares amounted to 21.05 percent of the company, sufficient to requisition extraordinary general meetings. Nusep chairman Alison Coutts told Biotech Daily that Mr Goodall was not able to vote his more than 32 million shares in the meeting.

Ms Coutts said that many of the resolutions related to tidying up debts and accounts and the company was in a better position after the meeting than before it.

"The balance sheet is much cleaner and these resolutions, now passed, will eliminate \$4 million of debt over the coming three years," Ms Coutts said.

Nusep climbed three cents or 60 percent to eight cents with 300,000 shares traded.