Biotech Daily

Tuesday December 15, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MESOBLAST UP 9%, COMPUMEDICS DOWN 10.5%**

*** INTERNATIONAL STEM CELL MELBOURNE PARKINSON'S TRIAL**

*** AUSTRALIAN PATENT FOR REGENEUS CANCER VACCINE**

*** EUROPEAN PATENT FOR PARADIGM RESPIRATORY TREATMENT**

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*** SIMAVITA DISSENT ON DIRECTOR NUMBERS, FEES**

*** WA SUBSIDISES ANALYTICA PERICOACH FOR INCONTINENCE**

*** SOLAGRAN HOPES TO RAISE $3m, RESUME OPERATIONS**

*** FIL TAKES 8% OF STARPHARMA**

*** ONCOSIL APPOINTS EX-SIRTEX US CHARLES ROWLAND US HEAD**

MARKET REPORT

The Australian stock market fell 0.39 percent on Tuesday December 15, 2015 with the ASX200 down 19.0 points to 4,909.6 points. Thirteen of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and two were untraded. All three Big Caps rose.

Mesoblast was best, up 13 cents or 9.15 percent to $1.55, with 1.3 million shares traded.

Both Actinogen and Cellmid climbed 4.2 percent; Biotron and Oncosil were up more than three percent; Ellex, Pharmaxis and Tissue Therapies rose more than two percent; Admedus, Avita and Benitec were up more than one percent; with Cochlear, CSL, Impedimed, Resmed and Sirtex up by less than one percent.

Compumedics led the falls, down 4.5 cents or 10.5 percent to 38.5 cents with 610,831 shares traded.

Neuren retreated 8.7 percent; Atcor and Psivida lost more than six percent; Genetic Technologies, Living Cell, Orthocell and Prana fell more than four percent; Nanosonics, Opthea (Circadian) and Prima lost more than three percent; Anteo, Bionomics, Optiscan, Osprey and Universal Biosensors fell more than two percent; Clinuvel and IDT were down more than one percent; with Medical Developments and Reva down by less than one percent.

INTERNATIONAL STEM CELL CORP

International Stem Cell says the Australian Therapeutic Goods Administration has approved a 12-patient phase I/IIa dose-escalation Parkinson's disease stem cell trial.

The Carlsbad, California-based International Stem Cell said the approval of the Royal Melbourne Hospital trial of its human partheno-genetic stem cells-derived neural stem cells for patients with moderate to severe Parkinson's disease followed an application from its wholly-owned subsidiary Cyto Therapeutics.

The company said there was no cure for Parkinson's disease, which was the second most common neurodegenerative disease affecting more than seven million people worldwide.

International Stem Cell chief executive officer Dr Andrey Semechkin said there was "a large unmet medical need for new treatments that may halt or reverse the progression of Parkinson's disease and we believe our human neural stem cells may fill this need for the millions of people with this disease".

The company said it had "positive results from its preclinical studies" for its stem cell candidate, demonstrating an improvement in Parkinson's disease symptoms and increase in brain dopamine levels following the intracranial administration of its human partheno-genetic stem cells-derived neural stem cells (ISC-hpNSC).

International Stem Cell said that the stem cells "provided neurotrophic support and cell replacement to dying dopaminergic neurons".

The company said that the open-label, single centre, uncontrolled, phase I/IIa study was a dose escalation safety and preliminary efficacy study of the stem cells intra-cranially transplanted into patients with moderate to severe Parkinson's disease at three doses ranging from 30,000,000 to 70,000,000 neural cells.

International Stem Cell said that following transplantation, the patients would be monitored for 12 months at specified intervals, to evaluate the safety and biologic activity of the stem cells, with a positron emission tomography (PET) scan performed at baseline, at six months and 12 months after surgical intervention.

The company said that clinical responses compared to baseline would be evaluated using various neurological assessments.

International Stem Cell chief scientific officer Dr Russell Kern said his company was "the first company in the world to conduct clinical trials of human pluripotent stem cells based product for the treatment of Parkinson's disease".

"We believe the outcome of the study will produce findings in-line with our preclinical studies, where we demonstrated not only safety of our proprietary neural stem cells, but also their functional efficacy," Dr Kern said.

"The cells were able to successfully integrate into the brain and provide a significant increase of dopamine levels in the nigrostriatal system," Dr Kern said.

International Stem Cell said that Parkinson's disease was a central nervous system degenerative disorder, mainly affecting the motor system, with motor symptoms resulting from the death of dopamine-generating cells in the midbrain's substantia nigra, more common in older people, with most cases occurring after the age of 50 years.

The company said that early in the course of the disease, the most obvious symptoms were movement-related, include shaking, rigidity, slowness of movement and difficulty with walking and gait, followed by thinking and behavioral problems, with dementia commonly occurring in the advanced stages of the disease and depression the most common psychiatric symptom.

International Stem Cell said its stem cells consisted of "a highly pure population of neural stem cells derived from human partheno-genetic stem cells".

Last night on the US over-the-counter market, International Stem Cell climbed 68 US cents or 15.74 percent to $US5.00 ($A6.89) with 44,461 shares traded.

REGENEUS

Regeneus says it has been granted an Australian patent covering the use of vaccine technology for a range of cancers in humans and animals.
Regeneus said that under a licence agreement from Northern Sydney Local Health District it had exclusive rights to develop and commercialize the cancer vaccine technology for human and animal health applications in all major territories.
The company said that the patent, entitled 'Vaccines for the treatment or prevention of cancer' provided coverage to April 11, 2033.
Regeneus said the patent was being pursued for grant in other territories including the US, Japan and Europe.
The company said that the technology used a patient's own cancer cells combined with an immune-stimulant designed to re-educate the immune system to target cancer cells in both existing and new tumors.
Regeneus said that the technology was developed by researchers at the Bill Walsh Translational Cancer Research Laboratory, the research arm of the Royal North Shore Hospital's medical oncology department and part of the Northern Sydney Local Health District's Kolling Institute.
The company said that in a pre-clinical brain tumor model, vaccination led to remission rates of up to 60 percent and significantly extended survival in all vaccinated animals and re-challenging animals in remission demonstrated 100 percent tumour rejection indicating acquired immunity.
Regeneus said that the patent supported its phase I RGSH4K program for human tumors and Kvax for canine osteosarcoma and in combination with chemotherapy for canine lymphosarcoma.
Regeneus said that it had 49 patents or patent applications across 14 patent families.
Regeneus fell half a cent or five percent to 9.5 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says the European Patent Office intends to grant a patent covering pentosan polysulfate sodium for respiratory diseases.
Paradigm said that the patent would be granted once it had provided the translations and paid the fees, providing market exclusivity until May 30, 2028.
The company said the diseases covered were allergic rhinitis, or hay fever, allergic asthma and chronic obstructive pulmonary disease.
Paradigm said that its bone marrow oedema, or bone bruising, patent had been granted in the US, Australia and New Zealand and the respiratory patent had been granted in China, Australia and New Zealand.
The company said the prosecution of both the bone marrow oedema and respiratory patents continued in Japan, Canada and China.
Paradigm said it had registered the trademarks Zilosul for the bone marrow oedema product and Rhinosul for allergic rhinitis.
Paradigm was untraded at 31 cents.

BLUECHIIP

Bluechiip has requested a trading halt "pending an announcement to the market in connection with a proposed placement".
Trading will resume on December 17, 2015 or on an earlier announcement.
Bluechiip last traded at four cents.

SIMAVITA

The Simavita annual general meeting passed all resolutions but an increase in fees was withdrawn and there was 16.5 percent opposition to “fixing” the number of directors.
Simavita had proposed to increase the non-executive director fee pool by $150,000 or 42.9 percent to $500,000 and fix the board at six directors (BD: Nov 13, 2015).
The company currently has six directors all of whom were up for re-election.
Simavita said that 7,153,666 votes (16.5%) opposed fixing the number at six directors, with 36,210,599 votes (83.5%) in favor.
The company said that four directors Ari Bergman, Warren Bingham, Damien Haakman and Craig Holland faced 7.2 million votes “withheld” with 36.1 million votes in favor.
Simavita said that chief executive officer Philippa Lewis and Michael Brown were re-elected overwhelmingly, with the increased placement capacity and option plan passed overwhelmingly.
The company said it had 92,245,233 shares on issue meaning that 7,153,666 votes opposing the fixing of the directors amounted to 7.8 percent of the company’s total shares on issue, sufficient to requisition extraordinary general meetings.
Simavita was up two cents or 10 percent to 22 cents.

ANALYTICA

Analytica says the Western Australia Continence Management and Support Scheme has listed its intra-vaginal Pericoach pelvic floor incontinence training tool.
The company said that the Support Scheme was a product subsidy scheme specifically for adults to assist with meeting the costs of continence products, managed and operated by Independence Australia on behalf of the Disability Services Commission.
Analytica said that to access the product subsidy, individuals must be assessed as eligible by the Continence Management and Advice Service.
Analytica chief executive officer Geoff Daly said that the funding had been available for products designed to manage long term incontinence.
“Pelvic floor muscle exercises performed regularly can actually reduce or eliminate urinary incontinence and are in fact recommended as first line treatment,” Mr Daly said.
“We are encouraged by the Western Australian Government’s recognition of the benefits to supporting the treatment of this common problem and are hopeful that over time that other states will follow suit,” Mr Daly said.
Analytica was untraded at 0.6 cents.

SOLAGRAN

Solagran says it hopes to raise $3 million through a loan and converting note for 100,000,000 shares to meet “growth in orders and to retire debt”.
Since listing in 2002, Solagran has attempted to commercialize its pine-needle derived Ropren and Bioeffectives claiming they were treatments for liver cancer, Alzheimer’s disease and a raft of other indications (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.

STARPHARMA

The Sydney and Hong Kong-based FIL Limited says it has increased its substantial holding in Starpharma from 19,654,406 shares (6.16%) to 25,675,108 shares (8.01%).
FIL said it acquired the shares between June 29 and December 10, 2015 at prices ranging from 61 cents to 90 cents, with 4,135,322 shares of the 6,020,702 share increase acquired in the recent $32 million placement at 73 cents (BD: Dec 9, 2015).
Starpharma was unchanged at 70 cents.

ONCOSIL MEDICAL

Oncosil says it has appointed former Sirtex head of US operations Charles Rowland as the head of Oncosil Medical US.
Oncosil said that Mr Rowland was the president of Sirtex Medical US from 2002 to 2006 and was “a highly experienced healthcare executive with a successful record of commercializing medical devices” and building medical device companies in the diagnostics, cardiac patient management and liver cancer markets.
The company said that Mr Rowland would be responsible for developing and executing its US business plan and would be the US Food and Drug Administration contact as it worked towards a US licence for its phosphorus32-silicon localized radiation treatment for cancer.
Oncosil said that Mr Rowland was responsible for establishing the Sirtex team that launched and commercialized SIR-Spheres for liver cancer in the US market, with the US business increasing to about $20 million and accounting for more than 80 percent of Sirtex global revenues at the time.
The company said Mr Rowland held a Bachelor of Economics from Bristol University and a Masters of Business Administration from the London Business School.
Oncosil was up half a cent or 3.2 percent to 16 cents with 1.7 million shares traded.