



Biotech Daily

Thursday November 12, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: OPTISCAN UP 9%; PRO MEDICUS DOWN 11%**
- * **NZ APPROVES 18-PATIENT LIVING CELL IIB NTCELL PARKINSON'S TRIAL**
- * **TGA APPROVES BPH, CORTICAL DYNAMICS' ANAESTHESIA MONITOR**
- * **STARPHARMA RECEIVES \$3.4m FEDERAL R&D TAX REFUND**
- * **3D MEDICAL SHARE PLAN FOR \$5m**
- * **BENITEC 39% OPPOSE 7m DIRECTOR OPTIONS, 18% REMUNERATION**
- * **UP TO 43% OF NOVOGEN OPPOSE DIRECTORS**
- * **PROF PERRY BARTLETT WINS AIPS \$50k CSL FLOREY MEDAL**
- * **PROF JOHN GREENWOOD SOUTH AUSTRALIAN OF THE YEAR**
- * **NOVOGEN APPLIES FOR AUSTRALIAN SUPER-BENZOPYRAN PATENT**
- * **WISCONSIN'S MEDICO-MART TO DISTRIBUTE IMMURON'S TRAVELAN**
- * **BANK OF AMERICA 'RETURNS', SELLS TO BELOW 5% IN SUDA**

MARKET REPORT

The Australian stock market edged up 0.06 percent on Thursday November 12, 2015 with the ASX200 up 3.1 points to 5,125.7 points. Seventeen of the Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and one was untraded.

Optiscan was the best, up 0.3 cents or 8.6 percent to 3.8 cents with 325,681 shares traded. Living Cell climbed 7.1 percent; Polynovo was up 6.9 percent; Anteo and Avita were up more than four percent; Cellmid and Ellex were up more than three percent; Viralytics and Universal Biosensors rose more than two percent; Actinogen, Antisense, Clinuvel, Cochlear, Compumedics, Nanosonics and Osprey were up more than one percent; with Psivida and Sirtex up by less than one percent.

Pro Medicus led the falls, down 42 cents or 11.1 percent to \$3.36 with 274,602 shares traded. Biotron lost 9.1 percent; Atcor fell 8.3 percent; Oncosil was down 5.9 percent; Orthocell was down 3.5 percent; Benitec, Prima and Tissue Therapies shed two percent or more; Circadian, Medical Developments, Neuren and Starpharma were down more than one percent; with Acrux, Bionomics and Resmed down by less than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says the New Zealand's Minister of Health Dr Jonathan Coleman has approved an 18-patient phase IIb study of NTCCell for Parkinson's disease.

Last month, Living Cell said that at 42 weeks post-implant the NTCCell encapsulated pig choroid plexus cells "stopped the progression of Parkinson's disease" in the four patients in its phase I/IIa clinical study of NTCCell (BD: Oct 27, 2015).

The company said that all four patients were well, with no safety concerns and a clinically and statistically significant improvement in the patients' neurological score equivalent to five years of Parkinson's disease remission maintained 74 weeks after NTCCell transplant in the first patient.

Today, Living Cell said the study protocol would be submitted to the ethics committee for approval.

The company said that the study would involve up to 18 patients under the age of 65 who had Parkinson's disease for at least five years.

Living Cell said that patients would be treated in three groups receiving bilateral implants of NTCCell at a range of doses, with two patients in each group receiving a placebo dose. The company said that at the end of the 26-week follow-up, the study would be unblinded, at which point the patients who received the placebo would receive an implant of NTCCell at the dose determined to be most effective.

Living Cell said it intended to begin patient recruitment in December 2015, with the first patient to be implanted in February 2016 and the study to be completed in 2017.

Living Cell chief executive officer Dr Ken Taylor said the study was the next step in the development of NTCCell as a disease-altering treatment for Parkinson's disease.

"We're looking to confirm the ability of NTCCell to halt disease progression and restore quality of life for people with Parkinson's disease," Dr Taylor said.

In a chief executive officer presentation to today's annual general meeting Dr Taylor included the presentation by Auckland City Hospital's Dr Barry Snow at the International Congress of Movement Disorders in San Diego, California.

Dr Taylor said that the pig choroid plexus cells secreted cerebrospinal fluid, provided neurotrophic and neuroprotective factors, removed toxins including drugs and metals and cleared waste products.

Living Cell said that Dr Coleman authorized an amendment to the phase I/IIa study protocol to enable on-going monitoring of the four patients.

The company also released a promotional video including comments from a trial patient and investigators.

The video is available at: <https://vimeo.com/145458852>.

Living Cell was up 0.3 cents or 7.1 percent to 4.5 cents with 408,992 shares traded.

BPH ENERGY (FORMERLY BIOPHARMICA)

BPH says that investee company Cortical Dynamics' Brain Anaesthesia Response Monitor had been approved by the Australian Therapeutic Goods Administration.

BPH said that it owned 3.89 percent of Cortical Dynamics with an option to increase to more than 10 percent through the conversion of a secured loan.

Cortical Dynamics said that inclusion on the Australian Register of Therapeutic Goods would allow sales in Australia and through the TGA's mutual recognition agreement enable Cortical to apply for Conformité Européenne (CE) mark to sell the monitor in Europe.

BPH was unchanged at 0.7 cents.

STARPHARMA

Starpharma says it has received \$3.4 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Starpharma said the rebate related to Australian expenditure for the year to June 30, 2015, for work on its Vivagel, dendrimer (DEP) docetaxel and agricultural chemicals programs as well as eligible overseas expenditure for its DEP docetaxel program.

Starpharma chief executive officer Dr Jackie Fairley said the Federal Government Tax Incentive program was important and provided "a significant incentive to Starpharma in researching, developing and advancing commercially attractive innovative products".

"In addition to more advanced products such as Vivagel, the R&D tax incentive has provided important support to the development of Starpharma's DEP platform," Dr Fairley said.

Starpharma fell one cent or 1.35 percent to 73 cents.

3D MEDICAL TECHNOLOGIES

3D Medical says it hopes to raise up to \$5 million through a share plan at 7.5 cents.

3D said that shareholders eligible at the record date of October 23, 2015 would be able to apply for parcels of shares up to \$15,000.

The company said the offer would open on November 16 and close on December 7, 2015.

3D said that the share plan was part of a capital raising to provide working capital to support further research and development, sales and marketing activities for Mach7, build its data products, retire about \$US 2 million in Mach7 debt and pay for the costs of the transaction and capital raisings.

In October, the company said it had raised \$3,984,080 in a placement as part of the agreement with Mach7 to raise at least \$10 million (BD: Oct 26, 28, 2015).

3D said it expected to raise a further \$2 million through the exercise of existing options.

3D fell 0.2 cents or 2.7 percent to 7.2 cents.

BENITEC BIOPHARMA

All Benitec annual general meeting resolutions were passed, despite strong dissent especially against the issue of 6,720,000 options to directors.

Resolutions to issue 1,400,000 options to chairman Peter Francis, 2,800,000 options to chief executive officer Dr Peter French and 840,000 options each to directors Mr Kevin Buchi, Dr John Chiplin and Iain Ross, all exercisable at 77 cents within five years from the date of issue, were all defeated on the first round of voting and were only passed after the exercise of proxy votes (BD: Oct 14, 2015).

The strongest opposition was against the issue of options to Mr Buchi with 14,734,807 votes (38.6%) against and 23,440,323 votes (61.4%) in favor, with other director option resolutions passed by slightly larger margins.

The remuneration report initially fell, with 28.3 percent of votes against, but after the proxy votes were polled the report avoided a first strike and was passed with 30,762,972 votes (81.6%) in favor and 6,931,485 votes (18.4%) against.

The re-election of Mr Buchi, the company option plan, the 10 percent placement capacity and the ratification of the prior issue of options were passed by a wider margin.

Benitec's most recent Appendix 3B new issue announcement said it had 146,529,096 shares on issue, meaning that the votes against Mr Buchi's options amounted to 10.06 percent of the company, sufficient to requisition extraordinary general meetings.

Benitec fell one cent or 2.4 percent to 40 cents.

NOVOGEN

Novogen annual general meeting voted strong dissent against the re-election of directors Steven Coffey, Bryce Carmine and Ian Phillips.

The largest opposition was against the re-election of Mr Phillips with 28,386,172 votes (42.52%) against, with 38,381,255 votes (57.48%) in favor, with the votes against Mr Coffey and Mr Carmine slightly lower.

The remuneration report and renewal of the 10 percent placement capacity were passed by wider margins.

The company's most recent Appendix 3B new issue announcement said that Novogen had 424,226,774 shares on issue, meaning that the votes against Mr Phillips amounted to 6.7 percent of the company, sufficient to requisition extraordinary general meetings.

Novogen was up half a cent or 3.6 percent to 14.5 cents.

AUSTRALIAN INSTITUTE OF POLICY & SCIENCE, CSL, FEDERAL GOVERNMENT

The Australian Institute of Policy and Science says that Prof Perry Bartlett has won the \$50,000 CSL [Prof Howard] Florey medal for biomedical science and human health.

The Institute said that Prof Bartlett was the foundation professor of neuroscience at the University of Queensland and the founding director of the Queensland Brain Institute.

The Institute said that Prof Bartlett won the biennial award "for his discoveries that have transformed our understanding of the brain and for his leadership of neuroscience in Australia".

A media release from the Institute said that in 1982 Prof Bartlett predicted that there were stem cells in the brain and in 1992 he found them in mouse embryos, then in adult mice, and a decade later he isolated them from the forebrain.

The media release said that Prof Bartlett built the Queensland Brain Institute from 10 people to 500 staff in a little more than a decade and the Brain Institute had "unleashed a new generation of neuroscientists whose discoveries range from using ultrasound to treat Alzheimer's disease, to finding stem cells associated with mood, spatial learning and more".

The Institute said that Prof Bartlett was about to start clinical trials to determine if exercise could reverse dementia in humans.

CSL chief scientist Dr Andrew Cuthbertson said that "thanks to Prof Bartlett we now know the adult brain can repair itself".

"His work offers the potential to transform treatment and management of dementia and depression," Dr Cuthbertson said.

"CSL is proud to support this award which both recognises excellence in research, and creates role models for the next generation," Dr Cuthbertson said.

The Federal Minister for Industry, Innovation and Science Christopher Pyne congratulated Prof Bartlett on winning the Florey Medal for medical research.

"Prof Bartlett is a pioneer in his field, who is best known for breaking the scientific dogma that the adult brain can't change and regenerate, and for establishing the Queensland Brain Institute in 2002," Mr Pyne said.

"Prof Bartlett's current work to discover if exercise can reverse dementia has the potential to revolutionise treatment of this devastating condition," Mr Pyne said.

"Prof Bartlett's work has been supported by the Australian Government through the National Health and Medical Research Council and Australian Research Council," Mr Pyne said.

"As well as this the Government committed \$200 million over five years to focus on dementia research in the 2014-'15 Budget," Mr Pyne said.

POLYNOVO

Polynovo says that the Royal Adelaide Hospital's burns surgeon Prof John Greenwood has won the South Australian of the Year award.

The Australia Day Council of South Australia said that the State's Governor Hieu Van Le and President of the Legislative Council Russell Wortley presented the award last night. The Council said that Prof Greenwood cared for 450 acute burns patients each year but had "set his sights on excellent and affordable burn care for every patient around the world".

The Council said that Prof Greenwood was a plastic surgeon and medical director of the Hospital's adult burn centre, responsible for all adult burn injuries in South Australia, Northern Territory, western New South Wales and western Victoria.

The Council said that Prof ran state-wide education services, headed Australia's only mobile burn response unit for burn injuries in disasters and was dispatched to Darwin in the aftermath of the 2002 Bali bombings.

The Council said that since 2003, Prof Greenwood had been developing innovative burn care and skin substitute products based on a biodegradable polyurethane platform that replaced the skin graft.

In 2011, Polynovo's collaboration with Prof Greenwood showed in a six pig trial of full thickness burns that the Novoskin bioresorbable temporizing matrix was superior to a collagen-based "current leading dermal replacement product" (BD: Mar 3, 2011).

Last month, Polynovo said the fifth and final deep burn patient had been implanted in the trial of Novosorb biodegradable temporizing matrix (BTM) at the Royal Adelaide Hospital, in a proof-of-concept study entitled 'Using a biodegradable polyurethane dermal matrix in the management of deep burn injury' conducted by Prof Greenwood (BD: Oct 20, 2015).

The company said time that four previous patients had "excellent results with the BTM including outstanding cosmetic and functional outcomes in the BTM-grafted areas".

Polynovo was up one cent or 6.9 percent to 15.5 cents with 1.2 million shares traded.

NOVOGEN

Novogen says that a "cornerstone patent [application] covering Cantrixil and Trilexium" has been accepted in by Intellectual Property Australia.

Novogen was not able to provide the title of the patent at the time of publication but said that it provided "protection around [the] method of manufacture, composition of matter and method of use ... to 2032" and covered two of its super-benzopyran drug candidates.

Novogen North America chief executive officer Dr Andrew Heaton said the patent application encompassed "a suite of [super-benzopyran] compounds, including the two lead [super-benzopyran] drug candidates Cantrixil and Trilexium".

IMMURON

Immuron says that it has a confidential, non-exclusive distribution agreement with the Waukesha, Wisconsin-based Medico-Mart for its Travelan for travellers diarrhoea.

Immuron said Medico-Mart supplied US physician offices, clinics and healthcare organisations, was founded in 1935 and was "a leading distribution healthcare company ...servicing customers across a wide variety of specialist areas including paediatrics, internal medicine, family practice, travel medicine and occupational medicine".

Immuron fell one cent or 2.2 percent to 45 cents.

SUDA

The Bank of America and related bodies say they have reduced their holding in Suda from 77,387,842 shares (6.81%) to below five percent.

Last year, the Charlotte, North Carolina-based Bank of America said it had “borrowed” and “returned” shares under a prime brokerage agreement and the Sydney-based Merrill Lynch (Australia) Futures and London-based Merrill Lynch International were the holders of the shares as beneficial owner and as the borrower of securities in a prime brokerage agreement, respectively (BD: Jul 22, Dec 5, 2014).

In March, Suda raised \$5.3 million in a placement of 146.5 million shares at 3.6 cents a share (BD: Mar 27, 2015).

Today, Bank of America said that between May 25 and November 9, 2015 Merrill Lynch “returned” 26,287,000 shares for \$5,382 or 0.02 cents a share and sold 6,660,308 shares for \$176,330 or 2.65 cents a share.

Suda was up 0.1 cents or 3.6 percent to 2.9 cents with 1.2 million shares traded.