



Biotech Daily

Wednesday December 20, 2017

Daily news on ASX-listed biotechnology companies

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- * **MICHAELIA CASH APPOINTED INNOVATION MINISTER**
- * **BIOTECH DAILY EDITORIAL COMMENT**
- * **MESOBLAST PHASE III PAEDIATRIC GVHD ENROLLED**
- * **US PATENT BOARD DENIES AVITA REVIEW; REHEARING REQUEST**
- * **USCOM: 'BP+ ELIGIBLE FOR CE MARK'**
- * **CANN 'NORTHERN' MARIJUANA CULTIVATION, R&D FACILITY OPENS**
- * **GENETIC TECHNOLOGIES BOARD SPILL EGM**
- * **CHAIR RON DEWHURST, KROY WEN DILUTED TO 6% OF RHINOMED**
- * **NIALL CAIRNS REPLACES ATCOR DIRECTOR DUNCAN ROSS**
- * **VISIONEERING APPOINTS JEAN FRANCHI DIRECTOR**
- * **MICRO-X APPOINTS JEFF TROST FOR US CORPORATE DEVELOPMENT**
- * **PRESCIENT CSO PROF SAID SEBTI MAKES NATURE TOP 20 LIST**

MARKET REPORT

The Australian stock market edged up 0.06 percent on Wednesday December 20, 2017 with the ASX200 up 3.8 points to 6,075.6 points. Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, with 12 companies trading unchanged.

Clinuvel was the best, up 54 cents or 7.4 percent to \$7.85 with 29,629 shares traded. Telix climbed 7.1 percent; Uscom was up 6.25 percent; Ellex improved 5.3 percent; Sirtex was up 4.8 percent; Genetic Signatures, Oncosil, Polynovo and Volpara were up more than three percent; Cyclopharm, Nanosonics, Neuren and Opthea rose more than two percent; with Osprey, Pro Medicus, Psivida and Starpharma up more than one percent.

Avita led the falls, down 0.8 cents or 12.1 percent to 5.8 cents with 6.8 million shares. Immutep (Prima) lost eight percent; Bionomics, Orthocell and Universal Biosensors were down five percent or more; LBT and Mesoblast shed more than two percent; with Impedimed, Optiscan and Reva down more than one percent.

FEDERAL GOVERNMENT

Prime Minister Malcolm Turnbull has appointed Acting Innovation Minister Senator Michaelia Cash as Minister for Jobs and Innovation.

Senator Cash replaces Senator Arthur Sinodinos, who was the Minister for Industry Innovation and Science, but said that he had taken leave to be treated for cancer.

Senator Cash was formerly the Minister for Employment and Women.

A Ministerial list provided by Senator Cash's office said that Craig Laundy had been moved from Assistant Minister for Innovation to the Minister for Small and Family Business, Workplace and Deregulation; with Senator Zed Saselja appointed as Assistant Minister for Science, Jobs and Innovation, previously Assistant Minister for Social Services and Multicultural Affairs.

BIOTECH DAILY EDITORIAL COMMENT

Another day, another Minister.

As her then media officer David De Garis told Biotech Daily shortly before he took the fall for calling the cameras to the Federal Police raid on the Australian Workers Union, Senator Cash is a "pocket rocket", meaning that although small in stature, she is feisty, fierce and focussed.

If Senator Cash could focus on her portfolio rather than using it to further her Party's and her own political ambitions, that would be excellent.

Sadly, the Abbott-Turnbull Liberal National Governments have shown little or no appetite for innovation or biotechnology – despite our own large, prosperous, export-income earning companies, not to mention our close relationship with foreign large pharmaceutical firms.

The funding has been meagre (as it was under the previous Rudd-Gillard Governments) and lacking in creativity.

Mr Turnbull's penny-pinching 1.5 percent cut to the Research and Development Tax Incentive is not compensated by other initiatives.

Mr Turnbull's claim two years ago to put innovation at the centre of his Government has been shown to be utterly hollow.

Senator Cash is our fourth Innovation Minister in two years, following Christopher Pyne, Greg Hunt and Senator Arthur Sinodinos, not to mention Mr Abbott's Innovation Minister Ian Macfarlane, making five in four years.

But it gets worse. Senator Zed Saselja has distinguished himself as a conservative within the Turnbull Government and was one of three lawyers forced to withdraw disparaging comments about Victoria's Courts and its Judges.

Senator Saselja has opposed meaningful action on climate change and spoke against the Marriage Equality Bill.

He is simply "out of touch with community expectations" as they say in politics.

The only silver lining on the black cloud of this Government's innovation decision-making is that former Assistant Innovation Minister Craig Laundy has been moved sideways to Small Business which remains within the Department.

Mr Laundy has shown great interest in innovation and a talent for communicating the issues.

There has been widespread criticism of the Ministerial reshuffle and our sector has not been spared.

David Langsam
Editor

MESOBLAST

Mesoblast says it has completed enrolment in its 60-patient, US phase III trial of its MSC-100-IV for paediatric steroid-refractory acute graft versus host disease (GvHD).

Last year, Mesoblast said the allogeneic or off-the-shelf, mesenchymal stem cell (MSC) treatment passed an interim futility analysis of the primary endpoint of day-28 overall response (BD: Nov 14, 2016).

Today, the company said that top-line results were expected by April 2018.

Mesoblast said there were no therapeutic products approved in the US to treat graft versus host disease, a life-threatening complication of bone marrow transplants and based on discussions with the US Food and Drug Administration, it intended to use the results of the trial to support a biologics licence application filing for accelerated approval. Mesoblast said it had US fast track status for MSC-100-IV for steroid-refractory acute GvHD in children and in 2016 Japan licensee JCR Pharmaceuticals launched the product as Temcell in Japan as a treatment for GvHD in children and adults.

Mesoblast fell 3.5 cents or 2.4 percent to \$1.45 with 1.8 million shares.

AVITA MEDICAL

Avita says the US Patent Trial and Appeal Board has denied its application for an inter-partes review to invalidate all claims in a patent owned by Renovacare Sciences Corp. According to the US Patent and Trademark Office, the patent, number 9,610,430 and entitled 'Cell spraying device, method and sprayed cell suspension', was filed on December 20, 2013 and granted on April 4, 2017.

An abstract said the invention "provides a device and methods suitable for producing a cellular spray of cells".

"The sprayed cells are of interest for covering and growing on a surface, including a skin wound," the abstract said. "In applying the method and/or using the device, cells for grafting onto a patient are dispersed in a solution and sprayed with the device for distribution over the recipient's graft site."

Avita chief executive officer Dr Mike Perry said that "Avita continues to believe that all claims in the Renovacare ...patent are unpatentable [and] Avita will continue to assertively protect its intellectual property position and pursue all available options, including promptly filing a request for rehearing on the decision by the [Board]".

Avita fell 0.8 cents or 12.1 percent to 5.8 cents with 6.8 million shares.

USCOM

Uscom says its BP+ central blood pressure monitor is eligible for Conformité Européenne (CE) mark approval.

Uscom said the monitor could be sold to hospitals and clinics in the 28 member states of the European Union as well as Iceland, Norway, Liechtenstein, Switzerland and Turkey, and potentially Asia and the Middle East.

The company said that US and Chinese Food and Drug Administration submissions were in process and approval was expected within the next 12 months.

Uscom executive chairman Prof Rob Phillips said the company had a "network of distributors waiting on manufactured product with outstanding orders".

"The development and testing of this device has taken time, but the product represents revolutionary and practice changing science, as the recent publication recommending its routine use ... demonstrated".

Uscom was up one cent or 6.25 percent to 17 cents.

CANN GROUP

Cann says its 'Northern' Melbourne marijuana cultivation, research and development facility has been commissioned.

Cann said the 600 square metre (6,458 square feet) glasshouse facility was a physical containment level-2 certified greenhouse cultivation and adjoining laboratory and research facilities, complementing the existing 'Southern' facility with 160 square metre of "flowering room capacity".

The company said that the cultivation areas were a series of individual compartments, allowing the separation of different cannabis varieties.

Cann said it received a permit to start cultivation at the Southern facility in May and had completed three harvests of medicinal cannabis material.

Cann chief executive officer Peter Crock said the Northern facility would enable the company to investigate possible efficiencies of glasshouse versus indoor growing systems.

"The Northern facility also incorporates laboratory spaces which are suitable for extraction and research activities that will enable us to advance our development programs," Mr Crock said.

Cann said the facility commissioning followed receipt of a permit from the Federal Office of Drug Control and it would receive material for several strains of medicinal cannabis under its technical services agreement with Victoria's Department of Agriculture.

The company said that the Northern facility was a component of its second phase expansion plans with the current \$78 million capital raising to fund the third phase, including a 16,000 square metre (1.6ha or 3.95acre) green field development incorporating glasshouse cultivation space, research and development laboratories and a manufacturing facility.

Cann fell four cents or 1.6 percent to \$2.52.

GENETIC TECHNOLOGIES

Genetic Technologies says it will face a board spill extraordinary general meeting at the end of January 2018.

Earlier this month, Genetic Technologies said it was seeking legal advice on the validity of the request (BD: Dec 1, 2017).

The company said that the Section 249D of the Corporations Act 2001 notice called for the removal of chairman Dr Malcolm Brandon, director Grahame Leonard and chief executive officer Eutillio Buccilli as directors and appoint Samuel Xue Lee, Peter Irwin Rubenstein and Jerzy Muchnicki in their place.

Genetic Technologies said its board recommended shareholders vote against all resolutions.

On December 1, the company said that the notice was received from Antanas Guoga, Ugnius Simelionis, Security and Equity Resources, SH Rayburn Nominees Pty Ltd, Irwin Biotech Nominees Pty Ltd, MJGD Nominees Pty Ltd and Samuel Lee who claimed to hold about 5.5 percent of the issued shares of the Company.

The requisition notice included Melbourne-based shareholders who also had holdings in Paradigm and Benitec (BD: Jul 26, 2013; Mar 6, 2014; Aug 24, 2015).

The meeting will be held at K&L Gates, Level 25, 525 Collins Street, Melbourne on January 31, 2018 at 10am (AEDT).

Genetic Technologies was untraded at 0.8 cents.

RHINOMED

Rhinomed chairman Ron Dewhurst says that through Kroy Wen he has increased his holding but been diluted from 5,000,000 shares (8.14%) to 7,284,680 shares (6.22%). In November, Rhinomed said it had raised \$3.6 million at 15 cents a share in a placement to institutional and sophisticated private investors, with Mr Dewhurst and chief executive officer Michael Johnson participating in the placement, pending shareholder approval. Today, Mr Dewhurst said that through Kroy Wen (“New York” backwards) he acquired 2,083,333 shares for \$500,000 or 24 cents a share on May 19, 2016, a further 101,347 shares for \$19,129 or 18.9 cents a share between May 19, 2016 and April 21, 2017 and 100,000 shares for \$14,000 or 14 cents on December 14, 2017). Rhinomed fell 0.5 cents or 3.6 percent to 13.5 cents.

ATCOR MEDICAL

Atcor says it has appointed Niall Cairns as a non-executive director, replacing former chief executive officer Duncan Ross, with effect from today, December 20, 2017. Atcor said that Mr Ross would continue with the company as an executive responsible for business development, among other duties. The company said that Mr Cairns was a Sydney based “technology growth investor” with 25 years’ experience in restructuring and exits of listed and unlisted companies. Atcor said that Mr Cairns was currently the chairman of Comops and a non-executive director of Chant West Holdings and Tru-Test. Atcor was untraded at 3.2 cents.

VISIONEERING TECHNOLOGIES

Visioneering says it has appointed Jean Franchi as a director and chair of the audit and risk committee. Visioneering said Ms Franchi had more than 20 years’ experience in corporate and divisional financial teams from the research and development stage to product launch and commercial operations in public and private pharmaceutical, biotechnology and diagnostic companies. The company said that Ms Franchi was currently Merrimack Pharmaceuticals’ chief financial officer/ Visioneering chief executive officer Dr Stephen Snowdy said that as the company “readies for international expansion, Ms Franchi’s experience in international operations is a highly valuable asset”. The company said that prior to Merrimack, Ms Franchi was with Genzyme Corp for 16 years and previously worked in accounting, finance and sales for Biomérieux and API, a former division of American Home Products, now Pfizer. Visioneering said that Ms Franchi held a Bachelor of Business Administration from New York’s Hofstra University. Visioneering was up two cents or 4.4 percent to 47 cents.

MICRO-X

Micro-X says it has appointed Jeff Trost as its US-based corporate development consultant.

Micro-X said that Mr Trost would assist managing strategic partnering and business development activities of its carbon nano-tube-powered x-ray units with companies in the global security and healthcare industries.

The company said that Mr Trost would assist formalizing potential partnering opportunities.

Micro-X said that Mr Trost had more than a decade of strategic advisory and transaction experience at San Francisco-based investment bank GCA, where he was the director of healthcare investment banking, securing a \$US35 million investment from KKR into Adelaide-based Signostics for its hand-held medical ultrasound.

The company said that in selecting partners it was “focused on parties that are prepared to make a strategic investment ... as part of a broader collaboration commitment”.

Micro-X fell half a cent or 1.4 percent to 35.5 cents.

PRESCIENT THERAPEUTICS

Prescient says its chief scientific officer Prof Said Sebti has been named as eleventh of the top 20 translational researchers by the Nature Publishing Group.

Prescient said it was the second time Prof Sebti had won the accolade, having made the list in 2014.

The company said that the list had been published in the December 2017 edition of Nature Biotechnology and was based on an examination of researchers’ most-cited patents from the previous five years and the H-index published work impact score.

Prescient said that Prof Sebti was a co-inventor of its technology, was overseeing its oncology programs and was the Florida-based Moffitt Cancer Centre chair of the Department of Drug Discovery.

Prescient chief executive officer Steven Yatomi-Clarke said that Prof Sebti’s ranking was “reflective of how frequently the international scientific community cites his work in Ras and Akt pathways”.

“This gives us confidence that our area of cancer research is not just globally relevant, but that those in the field consider Said’s work a point of reference,” Mr Yatomi-Clarke said.

Prescient was up 0.3 cents or 4.3 percent to 7.3 cents.