



Biotech Daily

Tuesday January 22, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: BENITEC UP 5%; GENETIC SIGNATURES DOWN 9%**
- * **FLOREY CO-DEVELOPS BLOOD TEST FOR ALZHEIMER'S**
- * **JAPAN PATENT FOR INVICTUS TRANSMUCOSAL TOCOTRIENOLS**
- * **EYE CO TO USE ANU MOUSE MODEL FOR DRY AMD**
- * **MGC READY FOR ALZHEIMER'S, DEMENTIA MARIJUANA TRIAL**
- * **SIENNA APPOINTS MIRAX SOUTH KOREA CANCER TEST DISTRIBUTOR**
- * **SIO REDUCES TO 7% IN ADMEDUS, SELLING 15% TO RELATED ENTITIES**
- * **PHILLIP, BIOSCIENCE MANAGERS TAKE 5% OF AVITA**
- * **KARST PEAK, ADAM LEITZES INCREASE, DILUTED TO 15.6% IN AVITA**
- * **CARDIEX: C2 VENTURES, DIRECTORS \$2.5m, 19.99% NOTE**
- * **AUSCANN, KHIRON TO GROW MARIJUANA IN CHILE**
- * **CRESO REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **RACE APPOINTS PROF BORJE ANDERSSON CONSULTANT**

MARKET REPORT

The Australian stock market fell 0.54 percent on Tuesday January 22, 2019, with the ASX200 down 31.6 points to 5,858.8 points. Eight of the Biotech Daily Top 40 stocks were up, 21 fell, nine traded unchanged and two were untraded.

Benitec was the best, up half a cent or five percent to 10.5 cents, with 90,198 shares traded. Dimerix and Reva rose more than two percent; Mesoblast, Nanosonics, Pro Medicus and Proteomics climbed one percent or more; with Cochlear, Polynovo and Resmed up by less than one percent.

Genetic Signatures led the falls, down seven cents or 8.9 percent to 72 cents with 84,456 shares traded. Paradigm lost 8.3 percent; Actinogen and Kazia retreated more than five percent; LBT, Osprey, Patrys and Uscom fell four percent or more; Immutep was down 3.1 percent; Compumedics, Impedimed and Oncosil shed more than two percent; Cynata, Medical Developments, Neuren, Opthea, Pharmaxis, Starpharma and Telix were down more than one percent; with Clinuvel, CSL, Cynata and Ellex down by less than one percent.

FLOREY INSTITUTE OF NEUROSCIENCE AND MENTAL HEALTH

The Florey Institute says that a blood test it co-developed can predict inherited Alzheimer's disease "at least a decade before clinical symptoms are evident".

The University of Melbourne-based Florey Institute said that with the Perth, Western Australia Edith Cowan University, and Sydney's Neuroscience Research Australia, the 'Dominantly Inherited Alzheimer's Network' study could lead to the test becoming "part of routine medical check-ups, which would provide a cheap and efficient early warning system for Alzheimer's disease in the general community".

The Institute's Prof Colin Masters said the test "accurately predicted when members of a family with inherited Alzheimer's disease would begin to show symptoms".

The study, titled 'Serum neurofilament dynamics predicts neurodegeneration and clinical progression in pre-symptomatic Alzheimer's Disease', was published in Nature Medicine, and an abstract is at: <https://www.nature.com/articles/s41591-018-0304-3>.

"Inherited Alzheimer's is rare genetic disease," Prof Masters said. "Using this very defined patient population we were able to identify affected family members over a decade before they began to show cognitive impairments."

A media release from the Florey said the blood test might be useful for a wider range of people who might be at risk of the common form of older-onset Alzheimer's disease known as sporadic, as well as those with the genetic version.

The Institute said the blood test was based on neurofilament light, a building block of brain cells and when they started to die in Alzheimer's disease, traumatic brain injury or other neurodegenerative diseases, neurofilament light was released into the blood stream.

The Florey said that when patients converted from pre-symptomatic disease to cognitive and memory decline, neurofilament light built up in the blood at the fastest rate.

"[Neurofilament light] levels rise whenever the brain is damaged and as Alzheimer's disease affects 30 percent of people over the age of 80 [years], we hope that [neurofilament light] will become part of a [doctor's] standard battery, like annual cholesterol testing," Prof Masters said.

"We would send patients off for more specific Alzheimer's tests if the results come back showing a cause for concern," Prof Masters said.

The Institute said that if a patient was identified as being in the early phase of the disease, they could be referred to a pharmacological clinical trial, make diet and lifestyle modifications and be placed on existing medications in the hope of slowing down disease progression.

The Florey said the researchers hoped to replicate the results in sporadic Alzheimer's disease patients, who are older and often have other health issues, using the Australian Imaging Biomarker and Lifestyle patient samples to validate the test results.

INVICTUS BIOPHARMA

Invictus says the Japan Patent Office has allowed a patent for the transmucosal delivery of tocotrienols.

Invictus said that the patent, titled 'Transmucosal Delivery of Tocotrienol' would provide commercial rights in Japan until November 13, 2032.

The company said the patent covered the use of the vitamin and drug delivery technology for the treatment or prevention of post-exercise muscle soreness and delayed onset muscle soreness.

A divisional application has been filed to pursue different aspects of the drug and vitamin delivery technology.

Invictus is a public unlisted company.

[EYE CO](#)

Eye Co says it has a consultancy agreement with the Australian National University for access to its mouse model of dry age-related macular degeneration.

Eye Co said the agreement was with the ANU's Clear Vision Research Laboratories, Medical School and John Curtin School of Medical Research.

The company said the ANU mouse model was "state-of-the-art" and would enable it to evaluate "several high potential candidate-drugs indicated for the treatment of dry-AMD". Eye Co said the ANU's mouse model developed a dry AMD-like lesion, that resulted from exposure to bright light and was known to be mediated by the 'complement pathway' of the immune system.

The company said the lesion was anatomically and immunologically consistent with the human condition.

Eye Co said there were no treatments for dry age-related macular degeneration.

The company said that it began a phase Ib human study to evaluate the safety of fludrocortisone acetate in the treatment of dry AMD at the Sydney Retina Clinic, and access to the ANU mouse model would allow it to evaluate additional high potential candidates.

Eye Co said that evaluation of the first candidate using the mouse model had begun.

Eye Co is a private company.

[MGC \(MEDICAL GRADE CANNABIS\) PHARMACEUTICALS](#)

MGC says it is recruiting patients for a 50-patient, phase IIb, 16-week trial of its marijuana-derived Cognicann for Alzheimer's disease and dementia.

MGC said the trial at the Perth, Western Australia-based University of Notre Dame would recruit patients over the age of 60 years, "focus on the effects of the medical cannabis treatment on the symptoms of mild dementia and Alzheimer's and the improvement of ... quality of life" and was expected to begin by July 1, 2019.

MGC Australia general-manager Keren Bar-Zakay told Biotech Daily that the trial was a randomized, controlled trial.

Ms Bar-Zakay said the primary outcome was the neuropsychiatric inventory questionnaire and secondary outcomes were the Cohen-Mansfield agitation inventory, quality of life Alzheimer's disease and Abbey pain assessment scale.

The company said the trial would use focus groups and pre and post-treatment surveys to assess the effect of Cognicann on patients.

MGC said it had received a permit from the Slovenian Ministry of Health to operate its phyto-cannabinoid active pharmaceutical ingredient extraction at its facility in Ljubljana.

The company said it was one of the first European facilities to gain extraction permission.

MGC said it received small and medium-sized enterprise (SME) qualification from the European Medicines Agency for all of its phyto-medicines.

The company said the qualification allowed it to apply for scientific advice, drug evaluation and registration of Cannepil, Cognicann and all other phyto-medicines currently under development, in addition to the opportunity to obtain fee reductions of up to 100 percent during the evaluation and registration process of priority medicines and access to the EMA's SME user guide designed to help enterprises navigate regulatory requirements and incentives available throughout a medicine's product lifecycle.

MGC executive chairman Brett Mitchell said, "the achievement of these major milestones by our team demonstrates significant progress on [the company's] pathway to commercialization".

MGC was up 0.1 cents or 2.5 percent to 4.1 cents.

SIENNA CANCER DIAGNOSTICS

Sienna says it has appointed the Seoul-based Mirax Corp as a distributor for its in-vitro diagnostic for the diagnosis of bladder cancer in South Korea.

Sienna said Mirax would distribute its human telomerase reverse transcriptase (hTERT) product to Korean pathology laboratories and would seek Korean regulatory approval. Sienna was unchanged at six cents.

ADMEDUS

New York's Sio Partners says it has reduced its substantial holding in Admedus from 131,120,851 shares (22.2%) to 41,811,817 shares (7.08%).

Sio said that it sold 89,309,034 shares at 5.7 cents a share "to entities that are managed by Sio Capital Management LLC" on January 7, 2019.

Admedus fell 0.8 cents or 16.7 percent to four cents with 4.96 million shares traded.

AVITA MEDICAL

Phillip Asset Management as trustee for Bioscience Managers Translation Fund I says it has become a substantial shareholder in Avita with 95,833,334 shares or 5.14 percent.

Phillip Asset Management said it bought 33,333,334 shares at 4.5 cents each on November 10, 2018 and 62,500,000 shares at eight cents each in the December placement which raised \$40 million (BD: Dec 4, 2018).

Avita was unchanged at 12 cents with 4.6 million shares traded.

AVITA MEDICAL

Karst Peak Capital and Adam Leitzes say they have increased but have been diluted in Avita from 285,895,857 shares (17.30%) to 290,226,056 shares (15.57%).

Karst Peak said the shares were acquired in the December placement which raised \$40 million (BD: Dec 4, 2018).

CARDIEX

Cardiex says that pending approval it has a \$2.5 million convertible note for C2 Ventures, owned by chief executive officer Craig Cooper and director Niall Cairns.

In December, Cardiex says it has raised \$5.5 million through an "oversubscribed" placement at three cents a share to acquire the Los Angeles-based Inhealth Medical Services with C2 Ventures taking \$2.5 million of the placement, pending regulatory and shareholder approvals (BD: Dec 6, 2018).

In October, the company said it had received a \$1,500,000 subscription payment from C2 Ventures as part of a previous \$5,000,000 capital raising (BD: Oct 11, 2018).

Today, Cardiex the interim subscription by C2 Ventures was in advance of shareholder approval and would take the holding to 19.99 percent.

The company said it had ASX and Australian Securities and Investments Commission approvals for the extraordinary meeting notice, which would be dispatched later this week.

Cardiex fell 0.6 cents or 12.0 percent to 4.4 cents with 11.6 million shares traded.

[AUSCANN GROUP](#)

Auscann says it will work with the Toronto, Canada-based Khiron Life Sciences Corp to grow marijuana in Chile.

Auscann said its Dayacann Chilean joint venture with Fundación Daya had an agreement with Khiron to develop medical marijuana for Chile (BD: Oct 1, 2018).

The company said that Dayacann was “the only company in Chile to hold a medicinal cannabis production licence”.

Auscann said Dayacann would provide cultivation and manufacturing services to Khiron for patients and clinical trials and would receive staged payments of \$US1,200,000 (\$A1,678,596).

Auscann executive director and interim chief executive officer Dr Paul MacLeman said the agreement with Khiron would “result in supply of quality medicinal cannabis material to Khiron, allowing them to help Chilean patients”.

Auscann fell 3.5 cents or 4.96 percent to 67 cents.

[CRESO PHARMA](#)

Creso has requested a trading halt “pending an announcement regarding a capital raising”.

Trading will resume on January 24, 2019 or on an earlier announcement.

Creso last traded at 54 cents.

[RACE ONCOLOGY](#)

Race says it has appointed haematologist Prof Borje Andersson to consult on trials of Bisantrene for acute myeloid leukemia and new product development.

Race said that Prof Andersson was a professor at the Houston, Texas-based MD Anderson Cancer Research Centre and a professor at the University of Houston College of Pharmacy.

The company said that Prof Andersson held a medical degree from the Stockholm, Sweden-based Karolinska Institute.

Race was unchanged at nine cents.