



Biotech Daily

Wednesday June 19, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: TELIX UP 14%; BENITEC DOWN 8%**
- * **FEDERAL FRONTIERS \$9.5m FOR 10 PROJECTS**
- * **PAINCHEK PLACEMENT RAISES \$4.15m**
- * **ORTHOCELL: 'CELGRO HALVES DENTAL IMPLANT TIME'**
- * **BOTANIX BTX1308 'ANTI-INFLAMMATORY, IMMUNE RESPONSE'**
- * **OBJ JOINS LITTLE GREEN PHARMA FOR MAGNETIC MARIJUANA**
- * **MGC APPOINTS ONIX BRAZIL MARIJUANA PRODUCT DISTRIBUTOR**
- * **NEXT SCIENCE PLEADS SCHULTZ, PUBLICITY TO ASX 46% QUERY**
- * **HERAMED LAUNCHES HERABEAT FOETAL HEART MONITOR**
- * **AIRXPANDERS PAYS OXFORD FINANCE \$727k FOR DEBT BREACH**
- * **INVICTUS: FDA 'BROADLY SUPPORTS' FATTY LIVER, CANCER PLANS**

MARKET REPORT

The Australian stock market was up 1.19 percent on Wednesday June 19, 2019, with the ASX200 up 78.1 points to 6,648.1 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 11 fell, five traded unchanged and three were untraded. All three Big Caps rose.

Telix was the best, on a presentation to a Macquarie Bank conference, up 14 cents or 13.9 percent to \$1.15, with 721,864 shares traded. Orthocell climbed more than 12.6 percent; LBT improved 11.5 percent; Impedimed and Polynovo were up more than nine percent; Nanosonics climbed 5.7 percent; Proteomics improved 4.2 percent; Compumedics, Genetic Signatures and Pro Medicus were up more than three percent; Antisense, Avita and Universal Biosensors rose more than two percent; Cochlear, CSL and Medical Developments were up more than one percent; with Clinuvel, Cyclopharm, Cynata, Ellex, Neuren, Opthea, Resmed and Starpharma up by less than one percent.

Benitec led the falls, down half a cent or 7.9 percent to 5.8 cents, with 2.0 million shares traded. Optiscan fell 4.3 percent; Oncosil and Osprey retreated more than three percent; Dimerix, Kazia, Pharmaxis and Prescient shed more than two percent; Volpara was down 1.2 percent; with Mesoblast and Paradigm down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says 10 organizations will receive up to \$1 million a year each under stage one of the Medical Research Future Fund Frontiers initiative.

Federal Health Minister Greg Hunt said the organizations were selected by a scientific peer review panel and would use the funds for detailed planning for conditions such as epilepsy, dementia, antibiotic resistance, cerebral palsy and stroke, and would have the opportunity to secure \$50 million or more under stage two of the initiative.

The media release said the Florey Institute of Neuroscience and Prof Graeme Jackson were granted \$999,956 for brain imaging for the diagnosis and treatment of epilepsy.

The Government said that Monash University and Prof Arthur Lowery would receive \$924,100 for a project titled 'The Cortical Frontiers: Commercializing Brain Machine Interfaces' to identify new applications for a vision restoring device.

The media release said the University of Technology Sydney and Prof Steven Djordjevic won \$998,731 for a 'Trace, Track and Tackle' national database for antibiotic resistance.

The Federal Government said Monash University and the Institute of Vector-Borne Disease's Prof Scott O'Neill were granted \$964,700 to control the spread of mosquito-borne diseases including the Zika virus and dengue fever, using the bacterium Wolbachia.

The media release said the Burnet Institute's Prof Gilda Tachedjian, along with Swinburne University of Technology, Melbourne Sexual Health Centre, Deakin University and Family Planning New South Wales would receive \$895,346 to develop 'Enhancing the Vaginal Environment and Microbiome' to improve women's sexual and reproductive health, focusing on bacterial vaginosis and sexually transmitted infections.

The media release said that 4Dx founder Prof Andreas Fouras would receive \$960,000 for the 'Australian Lung Health Initiative' for four-dimensional diagnostics of lung function.

The Government said that the Walter and Eliza Hall Institute's Prof Marc Pellegrini was granted \$1 million for 'The c-FIND: CRISPR Frontier Infection Diagnostics to Detect Infection' to identify infectious diseases using CRISPR technology.

The media release said the University of Queensland's Prof Juergen Goetz would receive \$1 million to use therapeutic ultrasounds for brain disorders including dementia.

The Government said Saluda Medical founder and University of New South Wales professor Prof John Parker would receive \$747,596 to test biomedical technology to deliver spinal cord stimulation to treat cerebral palsy.

The Government said the University of Melbourne's Prof Geoffrey Donnan won \$1 million for lightweight brain imaging technology for stroke patients in the first hour before hospital.

For details go to: <https://www.greghunt.com.au/funding-vital-medical-research/>.

PAINCHEK

Painchek says it has raised \$4.15 million through the placement of shares at 14.5 cents a share to sophisticated shareholders.

Painchek said the placement was at a 10 percent discount to the 10-day volume weighted average price of 16.11 cents.

The company said subscribers to the placement would receive one free attaching unlisted option for every two shares acquired, exercisable at 25 cents each by June 30, 2022.

Painchek said the funds would provide working capital for two years, including European market expansion of its adult pain software, market development for the software for consumer and hospital use, its US Food and Drug Administration application, and to complete its children's software clinical study for Australian, European and US approvals.

The company said RM Corporate Finance was the lead manager to the placement.

Painchek was up two cents or 11.8 percent to 19 cents with 15.1 million shares traded.

ORTHOCELL

Orthocell says all patients in its 10-patient, single-stage, dental implant Celgro treatment marketing study regenerated high quality bone in about four months.

Orthocell said the study assessed effectiveness and predictability when accelerating treatment timeframes in 10 patients with damaged, missing or diseased teeth and who suffered from irritation, bleeding gums and an inability to chew, eat or enjoy a normal diet. The company said patients treated with Celgro in a single-stage procedure completed the treatment in four months, “almost half the time of the usual two-stage, eight-months, dental implant treatment”.

Orthocell said the performance marketing study validated Celgro as a superior medical device for bone and soft tissue repair and in high-quality guided bone regeneration in single-stage dental implant treatments.

Orthocell managing-director Paul Anderson said that Celgro’s “ability to deliver superior bone growth has the potential to revolutionize dental implant techniques”.

“The latest results provide further evidence that positions Celgro as the best in class collagen membrane,” Mr Anderson said.

Orthocell was up 5.5 cents or 12.6 percent to 49 cents with 19.6 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says its 15-patient, phase Ib, mechanism-of-action study of BTX1308 for psoriasis shows an anti-inflammatory response and immune cell modulating activity.

Last year, Botanix said it treated the first of 15 patients at the Hamburg, Germany-based Bioskin GmbH and an Australian dermatology clinic (BD: Nov 7, 2018).

Today, the company said it collected normal and psoriatic skin biopsies from 10 of the 15 patients after 19 days of treatment BTX1308, an active comparator or placebo.

Botanix said it compared differences in gene expression between normal, treated and untreated psoriatic skin.

The company said it found that inflammatory disease pathways, including the p38 mitogen-activated protein (MAP) kinase pathway and interleukin-6 (IL-6) pathway, were downregulated in psoriatic skin treated with BTX 1308, compared to normal and untreated skin.

Botanix said in psoriasis, MAP kinases and IL-6 molecular targets encouraged excessive skin cell growth and inflammation.

The company said both pathways were associated with excessive growth, differentiation, immune response and death of cells in the skin.

Botanix said the study showed that BTX1308 could be used to modify psoriasis severity and progression.

The company said it also found that T-helper cells that play a role in the immune response, Th17 and Th2, shared common elements that contributed to inflammation, skin barrier dysfunction and increased susceptibility to infection and allergic sensitization.

Botanix said the study showed down-regulation of genes involved in atopic dermatitis, primarily through the interleukin-13 (IL-13) cytokine pathway.

Botanix executive director Matt Callahan said the insights into the mechanism of action for BTX1308 “provides us with further excitement and justification for our lead programs currently in phase II clinical development for acne [BTX 1503] and atopic dermatitis [BTX 1204], that both have significant inflammatory and immune components”.

Mr Callahan said the two programs were expected to be completed this year.

Botanix was up half a cent or 3.7 percent to 14 cents with 1.4 million shares traded.

OBJ

OBJ says it will collaborate with Perth's Little Green Pharma and Curtin University to adapt its magnetic transdermal delivery technology for marijuana-based therapies. OBJ said it had a term sheet to establish a 50 percent each joint venture with Little Green Pharma to fund research and development and commercialize transdermal cannabis technologies.

The company said that Little Green Pharma was "the only Australian producer and supplier of [good manufacturing practice] quality medicinal cannabis products".

OBJ said it would conduct trials with Little Green Pharma at Curtin University to assess the effectiveness of its magnetic microarray technology in delivering specific cannabinoids for unnamed specific ailments.

OBJ was up 0.3 cents or 21.4 percent to 1.7 cents with 2.3 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has a three-year distribution agreement with the Brazil-based Onix Empreendimentos e Participações to distribute Cannepil and Cognicann in Brazil. MGC said it would access the Brazilian market through Onix subsidiary and "phyto-cannabinoid" distributor Onixcann.

The company said it would commercialise both Cannepil for epilepsy and Cognicann for dementia and Alzheimer's disease, using Onixcann's Cantera digital platform, which connected patients with medical professionals and phyto-cannabinoid products.

The company said it would collate results from treatments to form a database for medical professionals, enabling it to ship products directly to patients.

MGC said Onix must reach an unstated minimum number of purchase orders in the second year of the three-year minimum agreement or it would terminate exclusivity.

The company said products would be commercialized solely under its brand and Onix would be responsible for market approvals.

MGC was unchanged at 5.1 cents with 3.3 million shares traded.

NEXT SCIENCE

Next Science has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose \$1.50 or 46.4 percent from \$3.23 on June 13 to \$4.73, today, and noted a "significant increase" in the volume of shares traded.

Next Science said it was aware of publicity yesterday in various media.

Next Science closed up 35 cents or 8.2 percent to \$4.60 with 2.3 million shares traded.

HERAMED

Heramed says its Herabeat foetal heart rate monitor Australian business to consumer website is "live" and it expects to begin sales "in the coming months".

Heramed said it would begin a marketing campaign for the website, with Perth-based advertising agency Meerkats, from June 26, 2019.

The company said Meerkats would receive a pre-negotiated commission from its Australian distributor Dale Group International, for each device sold.

Heramed said the website is at: www.hera-beat.com.au.

Heramed was unchanged at 21 cents.

[AIRXPANDERS](#)

Airxpanders says it will transfer \$US500,000 (\$A727,238) to an account under the control of Oxford Finance.

Last month, Airxpanders said it expected to breach the minimum net revenue covenant under its Oxford Finance debt facility and was in discussion with Oxford in relation to the previous and current breach (BD: Mar 29, Apr 2, May 13, 2019).

Airxpanders was in an extended suspension and last traded at 3.5 cents.

[INVICTUS BIOPHARMA](#)

Invictus says the US Food and Drug Administration “broadly supports the ... development pathway” for tocotrienols for fatty liver disease and pancreatic cancer.

Invictus said that the FDA was responding to its pre-investigational new drug application consultation for a phase II clinical study.

The company said the FDA “broadly supports the preclinical and clinical development pathway proposed by Invictus Biopharma and provided helpful suggestions in the company’s preparations for an investigational new drug application”.

Invictus said it proposed a proof-of-concept phase II trial “to assess the efficacy of tocotrienols delivered sublingually via ... [its] drug delivery platform on fatty liver disease.

The company said that the FDA agreed with its clinical development strategy in pursuing a 505(b)(2) abbreviated pathway for development.

Invictus said that 75 million to 100 million people in the US had non-alcoholic fatty liver disease or non-alcoholic steato-hepatitis, which were associated with a range of other diseases including insulin resistance and the metabolic syndrome, hyper-lipidaemia, diabetes and high blood pressure.

The company said it was “addressing the oxidative stress caused by fatty deposits around the liver which in turn leads to the inflammation which in turn leads to the scarring of the liver” by potentially switching off the disease earlier than other approaches which target the individual inflammatory pathways.

Invictus said that the FDA’s oncology division agreed in-principle with the proposed proof-of-concept phase II study in pancreatic cancer and invited the company to discuss the development program.

The company said it intended to apply for orphan drug status for its pancreatic cancer drug candidate when it opens an investigational new drug application (IND) prior to US clinical studies.

Invictus executive chairman Dr Glenn Tong said the company was “in the process of finalizing a pre-[initial public offer] capital raising which will assist in progressing this fatty liver disease clinical study”.

Invictus is a public unlisted company.