



# Biotech Daily

Tuesday March 26, 2019

*Daily news on ASX-listed biotechnology companies*

- \* **ASX FLAT, BIOTECH UP: TELIX UP 10%; ORTHOCELL DOWN 10%**
- \* **FEDERAL \$80m FOR PETER MAC CANCER CENTRE CAR T-CELL**
- \* **FEDERAL: \$66m FOR GENOMICS RESEARCH GRANTS**
- \* **WOMEN WIN 4 OF 5 VICTORIA PREMIER'S RESEARCH AWARDS**
- \* **CEO DAVID KAYSEN RESETS MEDIBIO HEART-MENTAL HEALTH TEST**
- \* **FINAL REVIEW BACKS ACTINOGEN XANADU ALZHEIMER'S TRIAL**
- \* **FDA MEETS PHARMAXIS FOR BRONCHITOL RECOMMENDATIONS**
- \* **GENERA: \$243k APPLICATIONS OF HOPED-FOR \$11.4m**
- \* **E-SENSE LAB CUTS EXPENDITURE BY \$840k**
- \* **THC'S VERTICAL CANNA BUYS 1,858m<sup>2</sup> CANADA MARIJUANA PLANT**
- \* **ALTIUM GROWTH BELOW 5% IN IMMUTEP**
- \* **BANK OF AMERICA BELOW 5% IN IDT**
- \* **OCH-ZIFF REDUCES, DILUTED TO 7% OF TOTAL BRAIN**
- \* **CLARITY APPOINTS DR THOMAS RAMDAHL DIRECTOR**

## MARKET REPORT

The Australian stock market edged up 0.07 percent on Tuesday March 26, 2019, with the ASX200 up 4.4 points to 6,130.6 points. Twenty of the Biotech Daily Top 40 stocks were up, 15 fell, four traded unchanged and one was untraded.

Telix was the best on a non-deal roadshow, up 6.5 cents or 9.7 percent to 73.5 cents, with 434,887 shares traded. Osprey climbed 9.5 percent; LBT was up 8.2 percent; Airxpanders and Uscom were up more than six percent; Imugene and Paradigm improved more than five percent; Medical Developments, Oncosil and Prana were up more than four percent; Ellex, Patrys and Pharmaxis were up more than three percent; Compumedics and Impedimed rose more than two percent; Prescient, Proteomics, Resmed and Starpharma were up more than one percent; with Nanosonics and Volpara up less than one percent.

Orthocell led the falls, down 1.5 cents or 10.3 percent to 13 cents, with 15,000 shares traded. Optiscan lost 6.4 percent; Antisense, Genetic Signatures and Immutep were down more than five percent; Cyclopharm and Pro Medicus fell more than four percent; Clinuvel and Neuren shed more than two percent; Actinogen, Cochlear, Cynata, Dimerix, Mesoblast, Polynovo and Universal Biosensors were down more than one percent; with CSL down 0.5 percent.

## FEDERAL GOVERNMENT

The Federal Government says it will invest \$80 million for a national cancer treatment centre using CAR T-cell therapies AT Melbourne's Peter MacCallum Cancer Centre. A media release from Prime Minister Scott Morrison and Health Minister Greg Hunt said that the Cancer Centre would invest \$25 million for "the Centre of Excellence in Cellular Immunotherapy" to provide chimeric antigen receptor (CAR) T-cell therapy to help "the body's own immune system to fight cancer".

The Government said CAR T-cell therapy involved "removing a patient's T-cells, a type of immune system cell, re-engineering them in a [laboratory] and reinserting them back into the body to attack and kill the cancer" and had the potential to cure certain cancers.

The media release said the centre would provide more than 200 patients with treatments for leukaemia and lymphoma cancer or clinical trials using CAR T-cell therapies.

The Government said the Centre would provide more than 140 manufacturing jobs, and 15 clinical and pre-clinical research jobs in the 1,700 square metre space for cellular immunotherapy manufacturing, along with a 900 square metre 14-bed clinical unit.

## FEDERAL GOVERNMENT

The Federal Government says it will provide more than \$65 million for genomics research for cancer, children's illnesses and low-survival diseases.

A media release from Federal Health Minister Greg Hunt said genomics involved individually testing patients with particular diseases "by looking deep into each patient's cells, analyzing their DNA to work out how to target and destroy the cancer or disease".

The Government said researchers would be able apply for grants for projects to develop the research evidence for implementing genomics knowledge and technology to deliver better-targeted treatments and cost-effective diagnostic methods to improve patient care.

Mr Hunt's media release said the Government would provide \$15 million over three years to cancer and diseases with high mortality and low survival, \$15 million over three years for paediatric acute care genomic research for critically ill children and \$3.7 million over three years for "ethical, legal and social issues related to genomics in health care".

The Government said that it would give \$32 million over four years to "flagships" for pathogen genomics, including infectious respiratory diseases.

The media release said the projects grants would open on March 28 and the flagships for pathogen genomics grants would open on May 14, 2019.

The Government said it would be the first funding from its \$500 million Genomics Health Futures Mission, designed to develop better testing, diagnosis and treatment.

The media release said the grants would be funded by the Medical Research Future Fund and would be available at its Grantconnect website, at <https://www.grants.gov.au/>.

## VICTORIA GOVERNMENT

The Victoria Government says four of the five Premier's Awards for Health and Medical Research last night were won by women researchers.

A media release from Victoria's Minister Jenny Mikakos said the awards recognized "breakthroughs in immunotherapy, development of cancer drugs, the prevention of HIV, cardiac arrest survival and indigenous childrearing".

The Government said Dr Kate McArthur won the Premier's Excellence Award, with the Walter and Eliza Hall Institute's Dr Mary Ann Anderson, Monash University's Dr Vincent Cornelisse and Dr Kylie Dyson, and La Trobe University Bendigo' Dr Mishel McMahon also winning awards.

## MEDIBIO

Medibio chief executive officer David Kaysen is in Australia to encourage investors to take up the shortfall in the \$4.01 million rights offer and explain the company.

In December, Medibio said it had commitments for \$2.5 million in convertible notes at two cents a share and hoped to raise \$4.01 million in a rights issue (BD: Dec 10, 2018).

Earlier this month, Medibio said the one-for-one rights issue raised \$923,465 leaving 156,455,043 shortfall shares, worth a further \$3,129,101 if placed (BD: Mar 12, 2019).

A veteran biotech executive, Mr Kaysen told Biotech Daily that Medibio effectively had all new senior staff and a review of the original technology had led to a change in approach. "We are convinced of the technology as focused on sleep studies to provide guidance to clinicians to address people's mental health status," Mr Kaysen said.

Mr Kaysen said that the fact that two US-based directors, Olympic multiple gold medalist Michael Phelps and former US Congressman Patrick Kennedy, had remained with the company was strong support for the heart rhythm-based mental health test.

The previous language that the cardiac rhythm and company-developed algorithm could diagnose major depressive disorder or other specific psychiatric disorders has been dropped from the company's material.

Last year, Medibio said that then managing director and chief executive officer Jack Cosentino would "cease ... effective from August 28, 2018" but provided no explanation for his departure (BD: Aug 29, 2018).

In October, the company said it had received a board spill requisition from Elias Leo 'The Gun' Khouri, a former director and major shareholder of predecessor company Bioprospect, and associates; and in November Medibio said that the spill resolutions were overwhelmingly defeated (BD: Oct 1, 16, Nov 16, 2018).

Today, Mr Kaysen said the company was continuing with a de-novo application to the US Food and Drug Administration, which had raised concerns about the previous application and provision of data.

Mr Kaysen said that the technology required sleep centre monitoring and the previous ambulant wearable monitors were not ideal.

He said that discussions with the FDA were "ongoing" but he did not expect the application to be filed until "well into 2020 or the end of that year".

"We're also working on a 510k application with the FDA and expect to file that by June 2019," Mr Kaysen said.

He said the company was developing a commercial opportunity for clinicians.

"A third part is Illumen as a corporate or personal tool to provide screening and direction to the individuals mental health status and if it is at the high end, encourage them to seek professional help," Mr Kaysen said.

Mr Kaysen said that he was convinced that the technology could help determine the mental state of users and could be commercialized.

Medibio was unchanged at 1.5 cents with 1.1 million shares traded.

## ACTINOGEN MEDICAL

Actinogen says the Xanadu data safety monitoring board's final review of 162 patients has reaffirmed its recommendation that the phase II trial continue without modification.

Actinogen said that the trial was "on-track to report ... results within the next three months" and it had initiated nine additional studies, including a target occupancy study, the Xanahes higher dose safety study and multiple safety toxicology studies.

Actinogen fell 0.1 cents or 1.8 percent to 5.4 cents with 2.96 million shares traded.

## PHARMAXIS

Pharmaxis says the US Food and Drug Administration will hold a committee meeting in May to make recommendations on the use of Bronchitol for adult cystic fibrosis.

Pharmaxis said the pulmonary-allergy drugs advisory committee (PADAC) would hold a hearing on May 8, 2019, following the resubmission of its Bronchitol new drug application last year by licensee Chiesi Group (BD: Dec 20, 2018).

The company said the committee would evaluate safety and effectiveness data for the treatment of pulmonary disease and would make recommendations to the commissioner of food and drugs.

Pharmaxis said the committee consisted of 11 voting members including a chair and members selected from authorities on pulmonary medicine, allergy, clinical immunology and epidemiology or statistics.

Pharmaxis was up one cent or 3.9 percent to 26.5 cents.

## GENERA BIOSYSTEMS

Genera says it has applications for \$243,062 of the hoped-for \$11,446,428 in its four-for-five non-renouncement entitlement issue at 13 cents a share (BD: Feb 1, 2019).

Genera said it had the right to place the shortfall of 86,179,833 shares by June 19, 2019 and if it reached the minimum subscription by April 30, it would issue new shares by May 7, 2019.

Genera said if it did not receive minimum subscription by April 30, it would repay application amounts without interest or would issue a supplementary or replacement prospectus and allow applicants one month to withdraw applications.

Genera remained in a suspension at 16 cents.

## ESENSE-LAB

E-sense Lab says it will cut expenditure by \$US600,000 (\$A840.000) a year, with significant reductions in external consultancy fees.

E-sense said it would focus on its existing products and the development of new medicinal and recreational marijuana products.

The company said it would also focus on commercialization in different markets through recent distribution agreements and trade conferences to promote its products.

E-sense was up 0.3 cents or 16.7 percent to 2.1 cents.

## THC GLOBAL

THC says its subsidiary Vertical Canna has acquired a 20,000 square foot (1,858 square metres) Nova Scotia, Canada site for marijuana production.

THC said it would build the initial stage facility to focus on profit-generating cultivation on the four-acre property.

The company said the facility would have an estimated yield of 37,000kg of dried flower a year, and it would negotiate with agricultural technology partners to develop higher yields.

The company said it would obtain project funding and would consider debt and hybrid facilities within Vertical Canna.

THC was up three cents or 5.5 percent to 57.5 cents.

### [IMMUTEP](#)

Altium Growth GP, LLC says it has ceased to be a substantial shareholder in Immutep from 250,000,000 shares or 7.48 percent of the company.

The Delaware and New York-based Altium said that Jacob and Mark Gottfried were holders of the relevant interests, which were sold between January 7 and March 22, 2019, with a single largest sale of 18,673,300 shares for \$510,017 or 2.7 cents a share. Immutep fell 0.2 cents or 5.6 percent to 3.4 cents with 4.6 million shares traded.

### [IDT AUSTRALIA](#)

Bank of America Corp says it has ceased its substantial shareholding in IDT.

The Sydney-based Merrill Lynch said on November 1, 2018 it returned 45,920 shares and on March 22, 2019 it sold 6,000,000 shares for \$900,000 or 15 cents a share and returned 2,454,080 shares.

IDT was up half a cent or 3.3 percent to 15.5 cents.

### [TOTAL BRAIN \(FORMERLY BRAIN RESOURCE\)](#)

Och-Ziff Holding Corp says it has reduced and diluted its holding in Total Brain from 47,272,206 shares (8.90%) to 47,136,884 shares (7.10%).

The New York-based Och-Ziff said that on January 15, 2019 Gordel Capital and OZ ELS Master Fund sold 119,247 shares and 16,165 shares for \$3,339 and \$453 or 2.8 cents a share and it was diluted on March 22, 2019 in a placement (BD: Mar 18, 2019).

Total Brain was unchanged at 2.7 cents.

### [CLARITY PHARMACEUTICALS](#)

Clarity says it has appointed Dr Thomas Ramdahl as a director.

Clarity said Dr Ramdahl had 20 years' experience, as the chief executive officer, chief technology officer and then chief operating officer of the Oslo, Norway-based Algeta ASA. The company said Dr Ramdahl was the managing-director of Algeta following its 2014 Bayer acquisition, before being appointed managing-director of Bayer Norway.

Clarity said Dr Ramdahl was the co-inventor of several patents, authored more than 40 publications.

The company said that Dr Ramdahl held a Master of Science from the Norwegian Institute of Technology and a Doctor of Philosophy from the University of Oslo.

Clarity is a public unlisted company.