



Biotech Daily

Monday February 4, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: OPTISCAN UP 18%; KAZIA DOWN 9%**
- * **FEDERAL \$55m FOR TYPE 1 DIABETES**
- * **NEUREN, ACADIA: 'PHASE III TROFINETIDE RETT TRIAL THIS YEAR'**
- * **SIENNA SIGNS MEDIWELL AS SINGAPORE DISTRIBUTOR**
- * **OVENTUS LAUNCHES O2VENT OPTIMA IN CANADA**
- * **CHINA STUDY 'VALIDATES' CARDIEX SPHYGMOCOR**
- * **NIALL CAIRNS REPLACES CARDIEX CHAIRMAN DONAL O'DWYER**
- * **DR WILLY HSU REPLACES TBG COO EUGENE CHENG**
- * **MMJ LOSES CEO JASON CONROY**

MARKET REPORT

The Australian stock market was up 0.48 percent on Monday February 4, 2019, with the ASX200 up 28.4 points to 5,891.2 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and three were untraded.

Optiscan was the best on no news, up 0.9 cents or 18.0 percent to 5.9 cents with 697,363 shares traded.

Actinogen climbed 5.45 percent; Genetic Signatures improved 4.9 percent; Airxpanders and Nanosonics were up more than three percent; Compumedics, Pro Medicus and Starpharma rose more than two percent; Proteomics was up 1.4 percent; with Clinuvel, Cochlear, Cynata, Ellex, Neuren, Opthea, Paradigm and Polynovo up by less than one percent.

Kazia led the falls, down four cents or 8.8 percent to 41.5 cents with 54,398 shares traded.

Antisense lost 7.3 percent; Oncosil fell 5.6 percent; Avita and Orthocell were down more than three percent; Dimerix, Prana and Telix shed more than two percent; Immutep, Pharmaxis, Prescient, Resmed and Volpara were down one percent or more; with CSL and Medical Developments down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it will provide \$54.5 million for research into type 1 diabetes, through the Medical Research Future Fund.

A media release from Federal Health Minister Greg Hunt said that the Juvenile Diabetes Research Foundation would receive \$25 million for its type 1 diabetes clinical research network, \$25 million would go to diabetes research under the \$125 million MRFF Targeted Translation Research Accelerator, with \$4.5 million for the JDRF over three years to assist with strategy and leadership of the research network.

The media release said the \$25 million would go “to broader diabetes research under the ... Targeted Translation Research Accelerator initiative, to help progress early stage health and medical research discoveries to reach proof-of-concept and progress to clinical trials” with projects to be funded following a competitive grant round.

Mr Hunt said that type 1 diabetes was “a life-long auto-immune disease that usually occurs in childhood but can be diagnosed at any age”.

Mr Hunt said that 120,000 Australian children and adults lived with type 1 diabetes.

“It is one of the most common chronic diseases in children and most newly diagnosed cases are in people less than 15 years old,” Mr Hunt said.

“At present, there is no cure for type 1 diabetes and no proven approach to prevent the disease occurring,” Mr Hunt said.

“Our Government will expand free access to glucose monitoring devices for pregnant women, children and more adults with type 1 diabetes, saving people up to \$7,000 a year,” Mr Hunt said.

“This investment over the next four years will ensure that free glucose monitoring devices are available to over 37,000 eligible people with type 1 diabetes from March 1, 2019,” Mr Hunt said.

NEUREN PHARMACEUTICALS

Neuren says that Acadia Pharmaceuticals plans to start a 180-patient, phase III trial of trofinetide for Rett syndrome by the end of 2019.

Last year, Neuren said that Acadia would pay it \$630 million in upfront fees, milestones and royalties for North American rights to trofinetide for Rett syndrome, Fragile X and other indications for North America, alone, with a right of first negotiations for the rest of the world (BD: Aug 7, 2018).

Last week, the company said that the offer from Acadia for the rest of the world rights “would not be in the best interests of ... shareholders” (BD: Feb 1, 2019).

Today, Neuren published a letter from Acadia to the Rett syndrome community announcing a three-month, phase III, double-blind, randomized, placebo-controlled study to evaluate efficacy and safety of trofinetide and placebo in about 180 females ages five to 20 years with Rett syndrome.

Acadia said participants would be randomized in equal numbers to receive trofinetide or placebo and the study would use the Rett syndrome behaviour questionnaire (RSBQ), a caregiver assessment and the clinical global impression scale-improvement (CGI-I) as co-primary efficacy endpoints.

The company said the phase III study would be followed by an open label extension study in which all participants, including those on placebo would be eligible to receive trofinetide and they would be followed to evaluate long-term tolerability and safety of trofinetide.

Acadia said that, with positive results, it planned to submit a new drug application to the US Food and Drug Administration in 2021.

Neuren was up one cent or 0.8 percent to \$1.27.

SIENNA CANCER DIAGNOSTICS

Sienna says it has appointed Mediwell Enterprise Pte Ltd as a distributor for its telomerase-based cancer diagnostics in Singapore.

Sienna said the agreement would allow Mediwell to sell its in-vitro hTERT adjunct test for bladder cancer to pathology labs and hospitals.

The company said that Mediwell would manage Singapore product approval and registration.

Sienna was unchanged at 6.4 cents.

OVENTUS MEDICAL

Oventus says it has launched its nylon O2Vent Optima device for obstructive sleep apnoea in Canada.

Oventus said the Canada launch followed the January O2Vent Optima launch in Australia (BD: Jan 20, 2019).

The company said it expected to launch the O2Vent Optima in the US by July 2019, pending US Food and Drug Administration approval.

Oventus was up 1.5 cents or five percent to 31.5 cents.

CARDIEX

Cardiex says it has been validated in a Chinese clinical study in Shanghai of its Sphygmocor technology for central blood pressure monitoring.

Cardiex said the study, led by the Shanghai Jiatong School of Medicine was a collaboration with Shanghai's Rujin Hospital North and Sydney's Macquarie University, and showed that central blood pressure monitoring improved prediction of cardiovascular events, compared to standard peripheral pressure measurements.

The company said that the Sphygmocor technology was approved by the China Food and Drug Administration.

Cardiex fell one cent or 1.85 percent to 5.3 cents with 5.3 million shares traded.

CARDIEX

Cardiex says Donal O'Dwyer will step down as chairman at the February 26, 2019 extraordinary general meeting, be replaced by Niall Cairns on an interim basis.

Cardiex said through C2 Ventures, director Mr Cairns and chief executive officer Craig Cooper owned 19.99 percent of the company (BD: Jan 22, 2019).

The company said it intended to appoint a US-based non-executive chairman "over the coming months".

TBG DIAGNOSTICS

TBG says it has appointed Dr Willy Hsu as its chief operating officer, replacing Eugene Cheng, who will continue as a non-executive director.

TBG said Dr Hsu had 10 years' experience as the marketing and sales manager with its subsidiary TBG Biotechnology and had a scientific research background in both immunology and bioinformatics.

TBG said Dr Hsu held a Bachelor of Science and a Doctor of Philosophy from the University of California-Davis.

TBG was untraded at 4.2 cents.

MMJ GROUP

MMJ says Jason Conroy will resign after 12 months as chief executive officer, effective from March 1, 2019.

MMJ said pending a new appointment, chief financial officer Jim Hallam would ensure the share purchase plan and portfolio administrative matters were completed.

In February last year, the company said Mr Conroy was appointed chief executive officer (BD: Feb 19, 2018).

MMJ fell 1.5 cents or six percent to 23.5 cents.