



Biotech Daily

Tuesday July 24, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: REVA UP 11%; IMUGENE DOWN 8%**
- * **CARDIEX: BLUMIO SENSOR 'GOOD FOR CARDIOVASCULAR MONITORING'**
- * **ORTHOCELL: CELGRO ON TRACK FOR FDA 510(k)**
- * **MMJ: 'SATIPHARM MARIJUANA CBD REDUCES PAEDIATRIC EPILEPSY'**
- * **HYDROPONICS COMPLETES MARIJUANA PROPERTY LEASE**
- * **BRAIN, TLEX PARTNER FOR 'ANCIENT WISDOM'**
- * **CRESO: ADAM BLUMENTHAL CONVERTS 1.5m PERFORMANCE SHARES**
- * **EDINBURGH UNI BELOW 5% IN ACTINOGEN**
- * **MMJ 'LESS THAN TWO QUARTERS CASH, \$1m COMING'**

MARKET REPORT

The Australian stock market was up 0.61 percent on Tuesday July 24, 2018 with the ASX200 up 38.2 points to 6,265.8 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and two were untraded. All three Big Caps were up.

Reva was the best, up three cents or 11.1 percent to 30 cents with 1,150 shares traded.

LBT climbed 7.7 percent; Avita and Optiscan were up more than six percent; Pro Medicus and Uscom improved five percent or more; Bionomics was up 4.2 percent; Clinuvel and Compumedics were up more than three percent; Airxpanders, Cochlear, Oncosil and Starpharma rose two percent or more; Nanosonics, Polynovo and Resmed were up more than one percent; with CSL, Medical Developments, Sirtex and Telix up by less than one percent.

Imugene led the falls, down 0.2 cents or 8.3 percent to 2.2 cents with 27.8 million shares traded.

Actinogen and Cyclopharm lost more than six percent; Dimerix fell five percent; Prescient was down 4.55 percent; Cynata, Impedimed, ITL, Opthea and Prana shed more than two percent; Neuren, Universal Biosensors and Volpara were down more than one percent; with Ellex and Mesoblast down by less than one percent.

CARDIEX (FORMERLY ATCOR MEDICAL)

Cardiex says that an initial trial of its pulse wave analysis technology with Blumio's sensor shows the sensor could be used for cardiovascular monitoring applications.

Cardiex said the eight week, 15-patient trial showed that the combination of the Cardiex technology together with Blumio's sensor could accurately extract cardiovascular signals from a variety of trial patient subjects with differing cardiovascular conditions as well as track changes in cardiovascular events in those patients.

The company said the results showed that the combination made "the sensor suitable for specific cardiovascular monitoring applications".

Cardiex said the trial's objective was to determine the degree of blood pressure data that could be extracted from Blumio's radar frequency sensor using the Cardiex pulse wave analysis technology and the comparison of that sensor data to Cardiex's non-sensor-based Xcel device, formerly the Sphygmocor Xcel.

The company said the trial showed that Blumio's sensor returned "a high degree of cardiovascular blood pressure data as measured by Cardiex technology".

The company said the study "gave a strong indication" that further central blood pressure readings could be extracted from the sensor in a wearable device using its neural learning and proprietary algorithms.

Cardiex said that the trial was with Macquarie University's Faculty of Medicine and Health Sciences and was part of a collaboration with the San Francisco-based Blumio Inc blood pressure sensor company.

The company said the trial assessed the feasibility of obtaining cardiovascular blood pressure-related data using Blumio's radar frequency sensor and analyzing it with the Cardiex pulse wave analysis technology.

Cardiex chief executive officer Craig Cooper said that "to develop a commercial wearable blood pressure sensor it requires the extraction of precise cardiovascular and blood pressure data from the relevant sensor".

"This initial trial is extremely encouraging as a clear demonstration of the use of our technology to extract specific blood pressure data from a wearable sensor," Mr Cooper said.

"We are continuing to refine the data obtained in the trial but our analysis to date has shown that with further neural learning and the application of our proprietary algorithms we have the ability to extract a wide range of commercially viable medical and consumer data from the sensor," Mr Cooper said.

Cardiex said that a 60-person Blumio sensor trial would begin in late August 2018 at the Browns Mills, New Jersey-based Deborah Heart and Lung Centre.

Cardiex was up 0.2 cents or 5.7 percent to 3.7 cents with 7.2 million shares traded.

ORTHOCELL

Orthocell says that a meeting with the US Food and Drug Administration indicated that its Celgro collagen scaffold is likely to achieve 510(k) clearance.

Orthocell managing director Paul Anderson said that Orthocell was "well placed to achieve 510(k) clearance of Celgro in dental bone and soft tissue applications".

"The meeting provided the opportunity for both parties to review the status of Orthocell's regulatory submission," Mr Anderson said.

"Orthocell remains on track to achieve FDA approval in 2019," Mr Anderson said.

Mr Anderson told Biotech Daily that the FDA meeting was held last Friday, July 20, 2018 Orthocell was unchanged at 33 cents.

MMJ PHYTOTECH

MMJ says its phase II trial of cannabidiol capsules “significantly reduced monthly seizure frequency in the treatment-resistant children when added to current medications”.

MMJ said the 16-patient study of the Satipharm cannabidiol (CBD) capsules by its wholly-owned subsidiary Phytotech Therapeutics demonstrated “promising evidences of efficacy”.

The company said that children aged two to 15 years were observed for four weeks, dosed-titrated and treated for 12 weeks and followed-up for two weeks, with 11 patients completing the trial.

MMJ said that there was a median reduction in epileptic seizures of 82 percent comparing the 12-week treatment period with the week observation period.

The company said that nine of the 16 patients who started the treatment “had a reduction of at least 50 percent in total number of seizures during the entire treatment period, compared to observation”.

MMJ said that following 12 weeks of treatment, eight of 11 patients were rated as “very much improved [or] improved” in overall condition on the Caregiver Global Impression of Improvement scale and nine of the 11 patients were rated as “very much reduced [or] reduced” on that scale.

The company said that the open-label, single-centre study intended to evaluate the safety, tolerability and efficacy of oral administration of the Satipharm CBD capsules as an adjunctive treatment to children suffering from refractory, or treatment-resistant epilepsy.

MMJ said that patient adherence to treatment was “very high” with a mean of 96 percent.

Tel Aviv Sourasky Medical Center Pediatric Epilepsy Service director and principal investigator Prof Uri Kramer, Director said that “notwithstanding the small number of patients treated, the efficacy of Satipharm’s CBD capsules as add-on therapy in the treatment of paediatric, intractable epilepsy has been shown”.

“Moreover, these results compare favourably to other similar studies of cannabidiol, including those published by GW Pharmaceuticals,” Prof Kramer said.

“Importantly, the significant reductions in seizure frequency while demonstrating satisfactory safety and tolerability profile, in these very difficult to treat patients, have the potential to be a life-altering event for these patients and their families,” Prof Kramer said.

“I would be greatly interested in prescribing such standardized and clinically-tested product as Satipharm’s CBD,” Prof Kramer said.

MMJ said that it was in the process of selling Phytotech to its 30.7 percent subsidiary, the Vancouver, British Columbia-based Harvest One Cannabis (BD: Apr 11, Jun 25, 2018).

MMJ fell 1.75 cents or 5.6 percent to 29.5 cents with 1.5 million shares traded.

THE HYDROPONICS COMPANY

Hydroponics says it has completed the marijuana off-take and supply agreements required for the lease of Jenbrook’s northern New South Wales property.

In May, Hydroponics said it had leasing rights with the Alstonville, New South Wales-based Jenbrook Pty Ltd for the use of its property to grow marijuana (BD: May 4, 2018).

Hydroponics said the off-take agreement was to supply Meluka honey medicinal cannabis, with the supply agreement to allow it access to Meluka’s tea tree extract.

Hydroponics was unchanged at 60 cents.

BRAIN RESOURCE

Brain Resource says it will partner with the TLEX Institute to incorporate “mind body training” in its Mybrainsolutions diagnosis and brain-training website.

Brain said the Washington, DC-based Transformational Leadership for Excellence (TLEX) Institute would contribute “restorative practices, practical wisdom, brain-based tips and healthy habit-formation” based on ancient wisdom and meditation.

The company said it would rebrand Mybrainsolutions as Totalbrain.

Brain Resource fell 0.1 cents or 1.8 percent to 5.5 cents.

CRESO PHARMA

Creso says director Adam Blumenthal has acquired 1,500,000 shares through the vesting of performance rights.

Yesterday, Creso filed an Appendix 3B new issue announcement which said it would convert 3,500,000 performance rights, 750,000 of which were issued to Mr Blumenthal vesting on the acquisition of the Nova Scotia, Canada-based Mernova Medicinal and 750,000 vesting on completion of a \$1,000,000 capital raising, with 2,000,000 performance shares awarded to an unnamed “contractor”.

Today, Mr Blumenthal filed an Appendix 3Y which said he held 5,500,001 shares after the vesting and according to the Appendix 3B, the company had 113,075,544 shares on issue, making Mr Blumenthal’s holding 4.86 percent of the company with 750,000 more performance rights subject to vesting conditions and escrowed until October 20, 2018.

Creso was up four cents or 6.1 percent to 70 cents.

ACTINOGEN MEDICAL

The University of Edinburgh’s Edinburgh Technology Fund says its 48,147,864 share-holding in Actinogen has been diluted to below five percent.

According to Actinogen’s most recent Appendix 3B new share issue announcement the company had 1,087,443,558 shares, implying the Fund held 4.43 percent of the company.

In 2014, the University said it had received the 48,147,864 shares for its holding in spin-out company Corticine, after Actinogen acquired it for its UE2343 compound for Alzheimer’s disease and in 2015, the University said the 48,147,864 share-holding was diluted from 10.76 percent to 8.06 percent (BD: Aug 27, Dec 8, 2014; May 14, 2015).

Earlier this year, Actinogen said it had raised \$16 million in a placement and share plan at five cents a share (BD: May 23, July 12, 2018).

Actinogen fell 0.4 cents or 6.6 cents to 5.7 cents with 3.05 million shares traded.

MMJ PHYTOTECH

MMJ Phytotech says its expected net operating cash burn for the three months to September 30, 2018 was \$922,000 with cash at the end of the quarter of \$1,414,000.

MMJ said that the expenditure included \$300,000 associated with the sale of its Phytotech subsidiary.

MMJ chief executive officer Jason Conroy told Biotech Daily the company would receive another \$1 million from the sale of Phytotech with shareholder approval in mid-September.