



Biotech Daily

Tuesday December 12, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ACRUX UP 4%; CYCLOPHARM DOWN 6%**
- * **CYNATA CELLS BEAT STEROIDS, COMBINE WELL FOR ASTHMA IN MICE**
- * **22 EURO COUNTRIES OKAY MEDICAL DEVELOPMENTS PENTHROX**
- * **NUHEARA TO LAUNCH TWO HEARING PRODUCTS IN 2018**
- * **HYDROPONICS REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **ESENSE, YOUNG HENRY'S MARIJUANA TERPENE BEER**
- * **MMJ INVESTS \$2m IN TORONTO MARIJUANA GROWER WEED ME**
- * **FISHER & PAYKEL FILES AUSTRALIAN PATENT CASE AGAINST RESMED**
- * **GENETIC TECHNOLOGIES: 'BOARD SPILL COULD IMPACT SALE'**
- * **OBJ WINS PROCTOR & GAMBLE PARTNER OF THE YEAR GONG**

MARKET REPORT

The Australian stock market was up 0.25 percent on Tuesday December 12, 2017 with the ASX200 up 14.9 points to 6,013.2 points.

Ten of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and five were untraded. All three Big Caps fell.

Acrux was the best, up 0.5 cents or 3.6 percent to 14.5 cents with 432,044 shares traded.

Oncosil climbed 3.1 percent; ITL and Opthea improved more than two percent; Avita Neuren and Osprey rose more than one percent; with Medical Developments, Pro Medicus and Sirtex up by less than one percent.

Cyclopharm led the falls, down six cents or 6.4 percent to 88 cents with 21,017 shares traded.

Reva lost 6.25 percent; LBT, Psivida and Universal Biosensors fell more than four percent; Starpharma was down 3.3 percent; Telix shed 2.5 percent; Admedus, Bionomics, Clinuvel, Cochlear, Ellex, Mesoblast, Polynovo, Resmed and Volpara were down more than one percent; with Airxpanders, CSL, Impedimed and Viralytics down by less than one percent.

CYNATA THERAPEUTICS

Cynata says its Cymerus mesenchymal stem cells reduce asthma symptoms significantly greater than corticosteroid treatment in mice.

Cynata said the final report on the effects of its Cymerus cells in combination with, or in comparison to, the corticosteroid dexamethasone showed statistically significant superiority for airway hyper-responsiveness, airway remodelling and fibrosis.

In August, the company released “highly promising” preliminary data from the asthma mouse study at Melbourne’s Monash Lung Biology Network (BD: Aug 23, 2017).

Today, Cynata said that corticosteroids were considered the most effective medications for controlling asthma when taken regularly and daily administration of dexamethasone demonstrated marked anti-inflammatory effects in the study model.

The company said that dexamethasone reduced airway inflammation by about 55 percent and airway inflammation induced goblet cell metaplasia, or abnormal changes in the cells responsible for producing mucus by about 80 percent, with both having a significance of $p < 0.001$ compared to untreated mice.

Cynata said that dexamethasone showed weak anti-remodelling and anti-fibrotic effects and only reduced airway hyper-responsiveness by about 30 percent over the two week-treatment period.

The company said that once-weekly administration of one million Cymerus mesenchymal stem cells (MSCs) “resulted in striking reductions of airway remodelling, fibrosis and airway hyper-responsiveness”.

Cynata said that sub-epithelial collagen deposition, a measure of fibrosis, and airway TGF-beta-1 expression levels, a measure of airway remodelling, were normalized to levels equivalent to mice in which asthma had not been induced, while airway hyper responsiveness was reduced by 70 percent to 75 percent, with all measures $p < 0.001$ compared to untreated mice.

The company said that when Cymerus cells and dexamethasone were combined “a pronounced synergistic effect was achieved, resulting in similar anti-inflammatory effects to dexamethasone alone and similar reductions in remodelling, fibrosis and airway hyper responsiveness to Cymerus MSCs alone”.

Monash Lung Biology Network’s Prof Chrishan Samuel said that “the combination of Cymerus MSCs and dexamethasone resulted in maximal improvement for each endpoint measured”.

“Hence, it can be concluded that such a combination therapy has the potential to improve treatment outcomes in asthmatic patients,” Prof Samuel said.

Cynata head of product development Dr Kilian Kelly said the findings “further strengthen the body of evidence supporting the use of Cymerus MSCs as a potential asthma treatment”.

“In addition to confirming that Cymerus MSCs had a greater effect than corticosteroid treatment on several key manifestations of asthma in this model, these results provide clear evidence that Cymerus MSCs can work in synergy with corticosteroids,” Dr Kelly said.

“Overall, the results suggest that Cymerus MSCs could be used as a standalone treatment, for example in patients who are unable to tolerate corticosteroids, or as an add-on therapy in patients who are unable to gain control of their condition with existing medications,” Dr Kelly said.

Cynata was up 2.5 cents or 4.2 percent to 62 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its inhaled methoxyflurane analgesic Pentrox has been approved for use in an additional 22 European countries.

Medical Developments said that the Medicine and Healthcare products Regulatory Agency issued a final assessment report with the support of all European country authorities noting the decentralised procedure had been completed.

The company said that all countries had the opportunity to review the dossier and in-principle agree on the benefits of Pentrox as an analgesic.

Medical Developments said that Pentrox had been approved in Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Iceland, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

The company said that Pentrox was approved in the UK, Ireland, Belgium and France and the national phase was the administrative process in which each country approved the translation of the labelling and product information and registered Pentrox for sale in their national records, at which time it would be available for sale.

Medical Developments said it expected the 22 approvals to begin in January 2018.

Medical Developments chief executive officer John Sharman said the approval of Pentrox in Europe was “the single biggest achievement in the company’s history”.

“This is a milestone for patients and physicians, too,” Mr Sharman said.

“Pentrox can deliver outstanding value against the huge unmet need for fast, easy pain relief for patients who have experienced a trauma injury,” Mr Sharman said.

“It will be a proud moment to see Australia’s first choice, front-line analgesic being used by doctors, hospitals and ambulances throughout Europe,” Mr Sharman said.

Medical Developments rose six cents or 0.9 percent to \$6.85 with 455,564 shares traded.

NUHEARA

Nuheara says it expects to launch two new Iqbud products for hearing and sound filtering in 2018, with one aiming to improve benefits as an assisted audio product.

Nuheara said that there was “a sizeable shift away from intense regulation [such as the US] OTC Hearing Aid Act in order to provide more cost-effective solutions for those requiring hearing assistance”.

The company said its two new unnamed products targeted opposite ends of the intelligent hearing market, with a lower priced lifestyle product and a more personalized and customizable product featuring artificial intelligence functionality through neural networks.

Nuheara chief executive officer Justin Miller said “the development of a new lower priced, lifestyle orientated, intelligent hearable, demonstrates Nuheara’s aspiration to offer a diverse range of intelligent hearing solutions to a much broader market base”.

Mr Miller said that “a more personalized and customizable intelligent hearable ... will provide a complimentary product to Iqbuds but with far greater feature sets including artificial intelligence functionality”.

Nuheara fell 0.2 cents or 3.5 percent to 5.5 cents with 3.7 million shares traded.

THE HYDROPONICS COMPANY

Hydroponics has requested a trading halt “pending a material announcement of the Company related to a capital raising”.

Trading will resume on December 14, 2017 or on an earlier announcement.

Hydroponics last traded at 79 cents.

[ESENSE-LAB](#)

Esense says it has an agreement with Sydney's Young Henry's Brewing Co for the development of a terpene infused line of beer.

Esense has previously announced a terpene-based marijuana flavored chocolate deal and Creso Pharma has announced marijuana flavoured beer (BD: Nov 16, 29, 2017).

Esense chairman Brendan de Kauwe told Biotech Daily that the marijuana terpenes "provide a range of effects from taste and aroma through to associated health benefits". The company said that Young Henry's was a brewery and distillery, offering an array of craft beers and ciders under their core range, as well as seasonal and limited releases and collaborative brews and has an Australian gin.

Esense said it would collaborate with Young Henry's in the development of a terpene based line of beer, with the intention to enter into a further definitive agreement on finalization of the product, stipulating the material aspects to the agreement, with each party retaining its respective intellectual property rights.

Esense fell five cents or 13.5 percent to 32 cents.

[MMJ PHYTOTECH](#)

MMJ says it will invest \$C2 million (\$A2.07 million) in secured convertible debentures in the Toronto, Ontario-based Weed Me Inc.

MMJ said the debentures were convertible into shares and warrants in Weed Me based on a pre-money valuation of \$C10 million.

The company said the investment would provide Weed Me with funds to complete the construction and fit out of its proposed cannabis facility in Pickering, Ontario to coincide with the legalisation of the recreational market.

MMJ said that Weed Me had an active application to be a licenced producer under Canada's Access to Cannabis for Medical Purposes Regulations, with the cultivation licence expected within the next 120 days.

The company said that Weed Me generated "300 percent more high quality yield per square foot than the industry average".

MMJ said Weed Me's 20,400 square feet (1,895sqm) facility in Pickering, Ontario had the capacity to produce 4,000kg of pharmaceutical grade cannabis a year and it intended to expand to an additional 100,000 square feet (9,290sqm) facility by early 2019 able to produce a total of 25,000kg a year.

MMJ managing-director Andreas Gedeon said "the Weed Me business represents a compelling and well-timed opportunity to strengthen our position in the Canadian market". "As the Canadian market continues to mature and evolve ahead of the proposed legalisation of recreational cannabis in July next year, the decision to acquire a significant stake in a soon-to-be licenced producer has the potential to deliver significant near-term value for our shareholders," Mr Gedeon said.

MMJ said that the debentures will have an interest rate of eight percent per annum, maturing in two years and secured by Weed Me and its assets, ranking behind a \$C2 million debt owing to the bank by Weed Me.

The company said the marijuana facility's property was valued at about \$C3.5 million.

MMJ said that on completion of the investment it would have more than \$6 million in cash.

MMJ was up 1.5 cents or 3.7 percent to 42.5 cents with 1.6 million shares traded.

[FISHER & PAYKEL HEALTHCARE, RESMED](#)

Fisher & Paykel says it has filed a patent infringement proceeding in the Federal Court of Australia against Resmed and several of its related companies.

Fisher & Paykel said that it and Resmed were currently engaged in patent proceedings in multiple countries.

The company said that in the proceeding filed today it alleged that Resmed's Airsense 10, Aircurve 10, S9 and S9 variable positive airway pressure flow generators, Lumis non-invasive ventilators, Climateline and Climatelineair heated air tubing and Humidair heated humidifier infringe four patents held by Fisher & Paykel for the products used to treat respiratory conditions.

Fisher & Paykel said it was seeking a range of remedies, including damages and injunctions preventing the manufacture and sale of the products by Resmed in Australia.

Fisher & Paykel was up seven cents or 0.6 percent to \$12.42 with 771,826 shares traded. Resmed fell 17 cents or 1.5 percent to \$11.27 with 1.9 million shares traded.

[GENETIC TECHNOLOGIES](#)

Genetic Technologies says a requisitioned meeting could impact the potential sale of the company and/or its assets.

Genetic Technologies said the Newport Beach, California-based Roth Capital Partners LLC review of the company identified potential interested parties and in November a target short list presented to chairman Dr Malcolm R Brandon and chief executive officer Eutillio Buccilli.

The company said that it was "in active discussions with multiple parties regarding a potential transaction(s) as those short listed interested parties now continue their due diligence".

Genetic Technologies said that the receipt of a Section 249D notification requesting a shareholder meeting and board spill meant that "no assurance as to whether or not any transaction arising out of the Roth strategic review will take place, the structure of any such potential transaction, or the ultimate timing" (BD: Dec 1, 2017).

"In part this may depend upon the results of the shareholder meeting to be convened to consider the change in the company's board composition," the company said.

Genetic Technologies was unchanged at 0.8 cents.

[OBJ](#)

OBJ says it has won the 2017 Proctor & Gamble 'partner of the year award'.

OBJ said the award was presented by Proctor & Gamble Japan president Stanislav Vecera to founder and managing-director Jeffrey Edwards at the Kobe Innovation Centre last week.

The company said that the award was given for its work in the design and development of the SK-II Eye Wand and Magnetic Power Booster products.

OBJ was unchanged at 4.6 cents with 1.1 million shares traded.