



# Biotech Daily

Monday June 25, 2018

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: CLINUVEL UP 13%; AIRXPANDERS DOWN 16%**
- \* **CLINUVEL FILES US SCENESSE FOR EPP NDA; 2019 RESPONSE**
- \* **TELEX APPOINTS ISOLOGIC TO MANUFACTURE TLX-250**
- \* **MEDICAL DEVELOPMENTS: PENTHROX IN SWITZERLAND, PORTUGAL**
- \* **CVC TAKES 6.25% OF IDT**
- \* **IMMURON REQUESTS 'NEW DIRECTOR' TRADING HALT**
- \* **RACE TO RELEASE 27m ESCROW SHARES, 10m PERFORMANCE SHARES**
- \* **OBJ APPOINTS CAMERON REYNOLDS DIRECTOR**
- \* **ORTHOCELL APPOINTS DR JONATHAN BELL TO ADVISORY BOARD**
- \* **AUSCANN APPOINTS 'MASTER GROWER'; JADE RESEARCH AGREEMENT**
- \* **HYDROPONICS: 1st MARIJUANA PRODUCTS FROM ENDOCA**
- \* **MMJ TO SELL PHYTOTECH TO HARVEST ONE**
- \* **CRESO, JOINT VENTURE RELEASE 2 MARIJUANA BEERS**

## MARKET REPORT

The Australian stock market fell 0.24 percent on Monday June 25, 2018 with the ASX200 down 14.8 points to 6,210.4 points. Ten of the Biotech Daily Top 40 stocks were up, 22 fell, six traded unchanged and two were untraded.

Clinuvel was the best, up \$1.34 or 12.6 percent to \$11.97 with 44,015 shares traded. ITL climbed 8.3 percent; Orthocell improved 4.35 percent; Cynata was up 3.75 percent; Oncosil and Universal Biosensors rose more than two percent; with Nanosonics, Opthea, Pro Medicus, Resmed and Volpara up by less than one percent.

Airxpanders led the falls for the second trading day in a row, down 1.8 cents or 16.4 percent to 9.2 cents with 4.2 million shares traded. Impedimed lost 12.0 percent; Dimerix, Neuren and Prescient fell four percent or more; Benitec, Compumedics, Immutep, Imugene and Pharmaxis were down more than three percent; Admedus, Bionomics, Factor Therapeutics and Polynovo shed more than two percent; Avita, Ellex, LBT and Medical Developments were down more than one percent; with Cochlear, CSL, Mesoblast, Sirtex, Starpharma and Telex down by less than one percent.

## CLINUVEL PHARMACEUTICALS

Clinuvel says it has completed its US regulatory submission for Scenesse (afamelanotide 16mg) for the rare metabolic disorder erythropoietic protoporphyria.

Clinuvel said the new drug application to the US Food and Drug Administration was for Scenesse as “the first proposed therapy” for patients with erythropoietic protoporphyria (EPP) in the US, with approval or a “complete response” letter expected in 2019.

The company said that since 2005, it had been “in regular and frequent communication with the [FDA] to discuss the development program for Scenesse as a preventative treatment for adult EPP patients” and was granted orphan drug designation for EPP in 2008, with fast track designation awarded in July 2016.

Clinuvel said that in 2016 the FDA initiated a public scientific workshop on erythropoietic protoporphyria to gain more, and first-hand, information on the characteristics and impact of the disease from patients and their families and in November 2016, concluded that the scientific data was ready to be filed as part of a rolling review (BD: Nov 9, 2016).

The company said that the rolling review enabled it to make its submission in parts, with the FDA review time starting when the final module was filed and validated.

Clinuvel said the regulatory validation of the dossier was expected to take two months, after which a target date for the completion of the review might be provided, known as the Prescription Drug User Fee Act (Pdufa) date.

The company said it had filed for priority review and was awaiting the FDA’s answer to the request for scientific review on an abbreviated basis.

Clinuvel said that under a priority review, the FDA aimed to make an assessment within six months, whereas a standard scientific review was estimated to take up to 10 months.

The company said that Scenesse was approved in Europe in 2014 and launched in June 2016 (BD: Oct 27, 2014; Jun 22, 2016).

Clinuvel said that it had submitted data and analyses from five EPP clinical trials, data from compassionate use and special access schemes and data from patients receiving treatment in Europe.

The company said the data set contained “nearly 6,700 doses in more than 800 patients”, the safety profile of Scenesse was positive to date and included longer term exposure of more than 12 years from patients involved in multiple consecutive programs in Europe.

Clinuvel said that a post-authorization pharmaco-vigilance plan for the long-term monitoring of US patients was part of its NDA submission.

Clinuvel climbed \$1.34 or 12.6 percent to \$11.97.

## TELIX PHARMACEUTICALS

Telex says that the Burlington, Ontario-based Isologic Innovative Radiopharmaceuticals with manufacture its TLX-250 antibody for imaging clear cell renal cell cancer.

Telex said that it had a technology transfer and manufacturing agreement with Isologic to manufacture TLX-250, or 89Zr-girentuximab, an antibody used for imaging clear cell renal cell cancer with positron emission tomography, for the confirmatory phase III clinical trial in North America.

The company said that Isologic would be its commercial partner in Canada.

Telex US president Dr Bernard Lambert said the agreement would “not only deliver material for clinical trials in the US but [also] initiate commercial access for TLX-250 in Canada”.

“We selected Isologic for their experience in ... manufacturing and comprehensive geographic coverage,” Dr Lambert said.

Telex fell half a cent or 0.8 percent to 65 cents.

### MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says Switzerland and Portugal have approved for sale its inhaled methoxyflurane analgesic Pentrox, with sales to begin by July 2019. Medical Developments fell seven cents or 1.2 percent to \$5.83.

### IDT AUSTRALIA

CVC has increased its substantial shareholding in IDT from 12,372,781 shares (5.05%) to 15,320,102 shares (6.25%).

The Sydney-based CVC said it bought 2,947,231 shares between April 4 and June 21, 2018 for \$250,216 or 8.5 cents a share.

IDT was up half a cent or 6.4 percent to 8.3 cents.

### IMMURON

Immuron has requested a trading halt pending an announcement regarding "the appointment of a new director".

Trading will resume on June 27, 2018 or on an earlier announcement.

Immuron was up three cents or 9.5 percent to 34.5 cents.

### RACE ONCOLOGY

Race says it will release from ASX escrow 27,341,434 ordinary shares and 10,000,000 performance shares on July 13, 2018.

Race said that 10,000,000 options expiring on July 1, 2018 and 9,000,000 options expiring on July 1, 2021 would also be released from escrow on July 13, 2018.

According to its most recent Appendix 3B new issue announcement, Race will have 75,735,813 shares available for trading on the ASX following the release from escrow.

Race fell 3.5 cents or 14.0 percent to 21.5 cents.

### OBJ

OBJ says it has appointed Cameron Reynolds as a non-executive director, effective from July 1, 2018.

OBJ said Mr Reynolds was the founder, president and chief executive officer of the Singapore-based Volitionrx and had 25 years' experience in the management, structuring and strategic planning of start-up companies and had held positions including chief financial officer and director in various sectors for both public and private enterprises.

OBJ fell 0.2 cents or eight percent to 2.3 cents with 6.1 million shares traded.

### ORTHOCELL

Orthocell says it has appointed UK orthopaedic surgeon Dr Jonathan Bell to its medical and scientific advisory board.

Orthocell said Dr Bell was a consultant orthopaedic surgeon who specialised in sports injuries, ligament reconstruction, tendinopathy and degeneration conditions, and consulted at the Wimbledon clinic in London and the New Victoria Hospital in Glasgow.

The company said it would issue Dr Bell 500,000 unlisted options, each exercisable at 34 cents within three years from the date of issue.

Orthocell was up 1.5 cents or 4.35 percent to 36 cents.

## AUSCANN

Auscann says it has appointed Luke Pigeau as its “master grower” and has a research and development agreement with Jade Cannabis to optimize its systems.

Auscann said the research and development agreement with the Ontario, Canada-based Jade Cannabis was to develop and optimize its cannabis cultivation system.

The company said that the design of its Australian facility had been completed, with cultivation rooms and monitoring systems ordered from Canada.

Auscann said that Jade Cannabis would undertake research and development work at its Canadian facility for an initial three-year period and Auscann’s medical cannabis genetics would be supported by cultivation systems piloted and implemented by Jade.

The company said the aim of the research was to obtain greater yield, resulting in more cost-effective cannabinoid pharmaceuticals for patients.

Auscann said it was working with Jade on the design and construction of prototype scale cultivation equipment and pilot scale experiments showed “substantial increases in yield when compared with current indoor cultivation approaches”.

The company said that Jade co-founder Kenneth Langford co-founded Peace Naturals, the first commercially-licensed medical cannabis company in Canada in 2011 and as Peace Natural’s chief innovation officer, Mr Langford developed a commercial schedule that was able to harvest a crop every two weeks from four flowering rooms.

Auscann said that last year it began an agreement with Tasmanian Alkaloids to jointly establish the cultivation, manufacturing and distribution operations for cannabinoid pharmaceuticals (BD: May 17, 2017).

Today, the company said the partnership had Federal Office of Drug Control, licences associated with Australian Therapeutic Goods Administration-certified facilities in Tasmania, enabling the manufacture of dose form cannabinoid medicines, with Canadian-developed, Conviron grow rooms and Argus Controls systems ordered for the facility. Auscann said Conviron’s grow rooms delivered uniform and controlled conditions to ensure consistent and repeatable yields and Auscann was developing analytics to support the cultivation operation.

Auscann said that Mr Pigeau had more than a decade of cannabis cultivation experience and would be responsible for oversight of the company’s medical cannabis cultivation operation in Tasmania.

The company said that Mr Pigeau worked under Canada's first cannabis licensing program for companies including Agripharm and Mettrum Health Corp.

Auscann managing-director Elaine Darby said that Mr Pigeau “brings a wealth of experience to the role and in conjunction with the research being done by Jade Cannabis will ensure that Auscann and Tasmanian Alkaloids can maximize the yields from our joint operation”.

Auscann was up 8.5 cents or 6.8 percent to \$1.34 with 1.3 million shares traded.

## THE HYDROPONICS COMPANY

Hydroponics says it has received the first medicinal cannabis products from its European partner Endoca.

Last year, Hydroponics said it would distribute the Hoofddorp, Netherlands-based Endoca BV’s medical cannabis products in Australia (BD: Nov 15, 2017).

Today the company said the initial shipment of cannabis products from Endoca would be accessible to Australian patients and healthcare professionals through its online portal [www.mcmp.com.au](http://www.mcmp.com.au).

Hydroponics was up 1.5 cents or 2.8 percent to 54.5 cents.

## [MMJ PHYTOTECH](#)

MMJ says it will sell its 100 percent owned subsidiary Phytotech Therapeutics to its 30.7 percent-owned subsidiary Harvest One Cannabis for \$C8,000,000 (\$A8,105,430).

In 2015, Phytotech said it had merged with the Vancouver, British Columbia-based MMJ Bioscience to form MMJ Phytotech, and this year the company said it would rename itself MMJ (BD: May 26, Jul 28, 2015, Apr 11, 2018).

MMJ originally listed on the ASX as Phytotech to commercialize medical, and later recreational marijuana, but last year said it would become a marijuana company incubator and change its name to MMJ Capital (BD: Jan 22, 2015, Nov 28, 2016, Oct 10, 2017).

Today, the company said the ASX told it that the transition to an investment entity was a significant change in the company's activities requiring shareholder approval to re-comply with chapters 1 and 2 of the ASX Listing Rules.

MMJ said that if it did not receive shareholder approval and compliance with the ASX Listing Rules the sale of Phytotech would not proceed.

The company said that, in addition to Phytotech, it had seven other subsidiaries, including Harvest One Cannabis, Weed Me, Fire & Flowers, Cannabis Access, Martha Jane Medical, Bien Ventures and Bevcanna Enterprises.

MMJ fell 1.5 cents or 4.1 percent to 35 cents.

## [CRESO PHARMA](#)

Creso says its joint venture CLV Frontier Brands will release two marijuana-flavoured beers and the brewing facility in Tallinn, Estonia has been completed.

In April, Creso said it had launched the joint venture CLV Frontier Brands with the London-based Baltic Beer Company and the Montreal-based LGC Capital to produce cannabis-infused beers and tonics (BD: Apr 18, 2018).

Today, the company said under the brand name Old Boy Mary Jane it would release two beers in July, called 'Ghost Bog Hazy IPA' and 'Improper Kölsch', as well as begin recipe testing this month for the company's Gypsy brand, that included cannabis-flavored sparkling water, soft drinks and tonic water.

Creso fell 2.5 cents or 3.5 percent to 69 cents.