

# **Biotech Daily**

## Thursday June 11, 2020

Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH DOWN: ELLEX UP 17%; OSPREY DOWN 15%
- \* ACCC ALLOWS LUMIBIRD ELLEX LASERS, ULTRASOUND ACQUISITION
- \* AZURE ACQUIRES INVICTUS
- \* REDHILL APPLIES FOR RUSSIA OPAGANIB COVID-19 TRIAL
- \* MEDLAB 1st NANOCBD PATIENT; 'CAPITAL RAISING' HALT
- \* CRESO WELCOMES ISRAEL MARIJUANA LEGALIZATION PROPOSALS
- \* SIENNA, BARD1: FEDERAL COURT APPROVES MERGER
- \* LIFESPOT APPOINTS BODYTEL SOFTWARE DISTRIBUTOR
- \* PROTEOMICS REQUESTS 'RESULTS' TRADING HALT
- \* PHARMAUST REQUESTS 'SARS-COV-2 TEST RESULTS' TRADING HALT
- \* CANN GLOBAL: 3rd 'RESEARCH INITIATIVES' SUSPENSION EXTENSION
- \* FIL INCREASES, DILUTED TO 7.4% OF ADHERIUM
- \* JAMBER INCREASES, DILUTED TO 8.5% IN CRESO

## MARKET REPORT

The Australian stock market fell 3.05 percent on Thursday June 11, 2020, with the ASX200 down 187.8 points to 5,960.6 points. Eight of the Biotech Daily Top 40 stocks were up, 28 fell, two traded unchanged and two were untraded.

Ellex was the best, up nine cents or 17.1 percent to 61.5 cents with 1.5 million shares traded. LBT climbed 3.3 percent; Pro Medicus, Resmed, Resonance and Uscom rose more than two percent; Antisense was up 1.6 percent; with Mesoblast and Nanosonics up by less than one percent.

Osprey led the falls, down 0.2 cents or 15.4 percent to 1.1 cents, with 9.2 million shares traded. Opthea lost 14.4 percent; Oncosil shed eight percent; Cyclopharm and Impedimed fell more than seven percent; Alterity, Immutep, Paradigm and Prescient lost six percent or more; Compumedics, Genetic Signatures and Telix lost more than five percent; Avita, Medical Developments and Optiscan fell more than four percent; Actinogen, Clinuvel, Cynata and Next Science were down more than three percent; Dimerix, Orthocell, Universal Biosensors and Volpara shed more than two percent; Kazia, Neuren, Pharmaxis and Starpharma fell one percent or more; with Cochlear, CSL and Polynovo down by less than one percent.

## ELLEX MEDICAL LASERS

## AUSTRALIAN COMPETITION AND CONSUMER COMMISSION

Ellex says the Australian Competition and Consumer Commission (ACCC) will not oppose the acquisition of its lasers and ultrasounds business by Lumibird Group SA.

In December, Ellex said the Lannion, France-based Lumibird would pay \$100 million in cash for its lasers and ultrasounds business (BD: Jan 19, 2020).

Today, the company said the ACCC found that the Australian market for ophthalmic lasers and ultrasound equipment "was very small compared to the markets the companies operate in globally, and that Lumibird has relatively low sales in each of the product categories in Australia".

ACCC commission Stephen Ridgeway said that "transactions that combine two suppliers in an already concentrated industry require close scrutiny from the ACCC".

"However, feedback from customers and other industry participants suggested that this deal would not have a significant impact on competition," Mr Ridgeway said.

"As Ellex is the clear market leader in Australia, Lumibird's acquisition of Ellex would only slightly increase the market share of the combined business," Mr Ridgeway said.

In April, more than 99 percent of votes at the Ellex extraordinary general meeting voted in favor of the sale and the change of name to Nova Eye Medical, under the ASX code of EYE (BD: Mar 24, Apr 24, 2020).

Biotech Daily asked Ellex if this was the last hurdle for the transaction.

An Ellex spokesperson told Biotech Daily that an announcement would be posted to the ASX "shortly".

Ellex climbed nine cents or 17.1 percent to 61.5 cents with 1.5 million shares traded.

## AZURE HEALTH TECHNOLOGY, INVICTUS BIOPHARMA

Azure says it has acquired Invictus Biopharma and appointed Lou Panaccio as chair, Dr Glenn Tong chief executive officer and Dr David Kingston chief scientific officer. In February, Azure said it hoped to raise \$10 million to buy Invictus for its tocotrienols food

additive, supplements and pharmaceuticals business (BD: Feb 5, 2020).

In April, the company said the \$10 million capital raising failed to comply with the ASX Listing Rule 1.1 Condition 8 which stated that a company must have "300 shareholders holding a parcel of shares with a value of at least \$2,000", and would return the funds and withdraw its application for reinstatement (BD: Apr 28, 2020).

Today, Azure said it has successfully acquired acquire all of the shares in Invictus for 35,000,000 Azure shares and the assumption of up to \$1,200,000 of Invictus' liabilities, with Invictus Nutraceuticals Inc to continue as a US-based wholly owned subsidiary of Azure with Richard Estalella continuing as the chief executive officer of Invictus Nutraceuticals.

The company said all existing members of the Invictus scientific advisory board would continue as members of the Azure scientific advisory board, including Prof Richard Pestell, as head of the pancreatic cancer program.

Azure said the acquisition of Invictus included the acquisition of biotechnology assets, including two patented food additives products, NE1-Elite and NE1-Heart, and a pipeline of drug candidates including IVB001 for non-alcoholic fatty liver disease and non-alcoholic steato-hepatitis, and IVB003 for pancreatic cancer.

The company said the food additives were scheduled to launch in the "next three months" and a phase II trial of IVB001 would "commence shortly".

Azure and Invictus are public unlisted companies.

#### **REDHILL BIOPHARMA**

Redhill says it has filed an application to the Russian Federation's Ministry of Health for a 270-patient phase II/III trial of opaganib for severe Covid-192 and pneumonia. In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and

Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010)

Today, the company said the multi-center, randomized, double-blind, parallel-arm, placebo-controlled phase II/III trial would evaluate the effect of cancer drug opaganib, formerly Yeliva or ABC294640, in patients with severe Covid-19 pneumonia, requiring hospitalization and treatment with supplemental oxygenation.

In April, Redhill said Italy and Israel had approved the compassionate use of opaganib for patients with Covid-19 infections, "with several patients treated to date, with preliminary positive outcomes" in Israel, and treatment planned for 160 Italian patients with life-threatening clinical manifestations of Covid-19 (BD: Apr 7, 2020).

Later in April, the company said an investigational new drug application had been submitted to the US Food and Drug Administration to evaluate opaganib in a clinical study in 40 adults diagnosed with Covid-19 and pneumonia (BD: Apr 21, 2020).

Today, Redhill said the primary endpoint of the phase II/III trial was to evaluate the proportion of patients requiring intubation and mechanical ventilation by day-14. The company said that an unblinded futility interim analysis would be conducted when about 100 subjects had been evaluated for the primary endpoint.

Redhill said it expected the trial to be conducted in clinical sites across Russia, Europe and other unspecified countries.

Redhill medical director Dr Mark Levitt said the company was "moving rapidly to advance our development program with opaganib for Covid-19".

"We are expanding the development program to Russia and additional countries, in parallel with the US clinical study, in order to accelerate the collection of robust data on the potential efficacy of opaganib against Covid-19," Dr Levitt said.

Redhill said that a total of 141 subjects had been dosed with opaganib to date in ongoing and completed phase I and phase II clinical studies in oncology indications, in

pharmacokinetic studies in healthy volunteers in the US and Israel, establishing safety and tolerability in humans.

On the Nasdaq, Redhill was up 47 US cents or 6.55 percent to \$US7.65 (\$A11.03) with 529,805 shares traded.

## MEDLAB CLINICAL

Medlab says its marijuana-derived Nanocbd spray has been delivered to Australia and its first special access scheme patient has been treated.

Mediab said Nanocbd used its Nanocelle oro-buccal membrane delivery platform to deliver a 5mg/0.3mL spray to treat chemotherapy-induced nausea and vomiting. The company said Nanocbd was manufactured in the US and Mediab was discussing expanding the product's distribution beyond Australia and Hong Kong and into the US. Mediab said Nanocbd would undergo clinical trials for the treatment of chemotherapy induced nausea and vomiting for drug approvals in Australia.

Medlab chief executive officer Dr Sean Hall said Nanocbd was a cannabidiol-product, "but like Nanabis it is a further example of the optionality of our Nanocelle delivery system". Separately, Medlab requested a trading halt "pending an announcement in relation to a placement and share purchase plan".

Trading will resume on June 15, 2020 or on an earlier announcement, Medlab last traded at 20.5 cents.

#### **CRESO PHARMA**

Creso says it welcomes Israeli Government legislation proposing the legalization and further decriminalization of marijuana.

Creso said the reform included the legalization of cannabidiol (CBD) and its related products, would allow Creso to sell its CBD-based products to the human and animal sectors in Israel.

The company said that the Israeli Government parties Likud and Kahol Lavan (Blue and White) had detailed steps towards easing marijuana restrictions for recreational and medical use through "a responsible model that will suit the state of Israel and the Israeli population".

Creso chairman Boaz Wachtel said that although the company was "potentially still a few months from having new laws passed, this latest development signals that the foundations are now in place for legislative reform".

"This latest move by the Government to adopt a more progressive approach towards cannabis legislation, and the opening of the CBD consumer market only adds further momentum to this strategy, and we look forward to pursuing additional growth opportunities in due course," Mr Wachtel said.

Creso fell 0.1 cents or 1.9 percent to 5.2 cents with three million shares traded.

## BARD1 LIFE SCIENCES, SIENNA CANCER DIAGNOSTICS

Sienna says the Federal Court of Australia has approved a scheme booklet and meeting for the acquisition of Sienna by Bard1 Life Sciences.

In April, Sienna and Bard1 said they agreed for Bard1 to acquire Sienna through a scheme of arrangement to combine their cancer diagnostic tests (BD: Apr 9, 2020). Today, the company said the scheme booklet would be released following its registration with the Australian Securities and Investments Commission and the scheme meeting would be held virtually on July 15, 2020 at 11am (AEST).

Bard1 fell 0.2 cents or 6.7 percent to 2.8 cents with 1.3 million shares traded. Sienna fell 0.2 cents or 2.6 percent to 7.6 cents.

## LIFESPOT HEALTH

Lifespot says it has appointed Jayex Healthcare to distribute its Bodytel software and integrated Bluetooth technology products for diagnostics and patient monitoring. Lifespot said the Melbourne-based Jayex had an exclusive licence to market and sell Bodytel in the UK and a non-exclusive licence for Australia and New Zealand which would apply to future telehealth products and services developed by Lifespot.

The company said the Bodytel software used Bluetooth technology combined with diagnostic, monitoring and sensor technology, digital drug delivery systems and self-learning algorithms to allow patients or their caregivers to monitor chronic diseases and critical conditions with their smartphones.

Lifespot said Jayex would pay a licence fee to Lifespot based on revenue generated from the technology, as well as maintenance service fees and development fees.

The company said Jayex would buy the Bluetooth connected hardware from Lifespot to sell to its customers for access to the Bodytel software.

Lifespot said Jayex would offer Bodytel to more than 20,000 general practitioners in its UK network, and both parties recognized "the importance of providing remote monitoring capacity to [general practitioner] clinics in a post Covid-19 world".

Lifespot was unchanged at 3.5 cents with 1.3 million shares traded.

## PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics has requested a trading halt pending the release "of the results from the first stage collaborative study to target treatment of diabetic kidney disease". Proteomics said the results would be jointly presented with Janssen Research and Development at the American Diabetes Association meeting on June 13, 2020. Trading will resume on June 15, 2020 or on an earlier announcement. Proteomics last traded at 56.5 cents.

#### PHARMAUST

Pharmaust has requested a trading halt "pending an announcement regarding disclosure of results from the Sars-Cov-2 repeat experiments".

Last week, Pharmaust said results from tests undertaken by Melbourne's Walter and Eliza Hall Institute showed that monepantel and monepantel sulfone reduced severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) replication and cell-to-cell infectivity in tissue culture by 50 percent to 95 percent, in-vitro (BD: June 4, 2020).

Pharmaust has been trialling the Elanco monepantel sheep round worm drench, previously PPL-1, for human cancer since June 2014, and for dog cancer since September 2014 (BD: Jun 23, Sep 9, 2014).

Trading will resume on June 15, 2020 or on an earlier announcement. Pharmaust last traded at 11 cents.

#### CANN GLOBAL

Cann Global has requested a third extension to a voluntary suspension following a trading halt for "research initiatives". (BD: May 18, 2020).

Cann Global took the trading halt to a suspension on May 20 and requested two subsequent extensions on May 25 and June 3, 2020 (BD: May 20, 25, Jun 3, 2020). Today, Cann Global said it expected the announcement to be made by June 5, 2020. Cann Global last traded at 0.7 cents.

#### <u>ADHERIUM</u>

The Hong Kong-based FIL says it has increased and been diluted in Adherium from 44,164,642 shares (8.89%) to 44,681,769 shares (7.43%).

FIL said it bought 517,127 shares between February 12 and 19, 2020 at prices ranging between 3.1 cents and 3.4 cents a share, and was diluted on June 5, 2020.

In May, Bioscience Managers raised \$5 million for Adherium (BD: May 26, 2020). Adherium was up 0.1 cents or 3.7 percent to 2.8 cents.

#### **CRESO PHARMA**

Sydney's Jamber Investments says it has increased and diluted in Creso from 22,635,938 shares (11.24%) to 23,735,938 shares (8.50%).

Jamber said that between February 25 and June 5, 2020 it bought 1,100,000 shares for \$79,694 or an average of 7.2 cents a share.