



Biotech Daily

Tuesday November 17, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ALTERITY UP 24%; ONCOSIL, OPTISCAN DOWN 6%**
- * **QBIOTICS: US FDA APPROVES STELFONTA FOR DOG SKIN CANCER**
- * **CHIMERIC \$30m IPO FOR CAR-T GLIOBLASTOMA THERAPIES**
- * **BRANDON MRCF \$8.2m FOR UK'S MYRICX PHARMA**
- * **REDHILL COMPLETES PHASE II COVID-19 ENROLMENT**
- * **VOLPARA LAUNCHES BREASTED BREAST DENSITY TRAINING TOOL**
- * **CARDIEX 160.5m DIRECTORS PERFORMANCE RIGHTS AGM**
- * **CREDIT SUISSE BELOW 5% IN ALTERITY**
- * **CANNVALATE DILUTED TO 18% OF LIFESPOT**
- * **NIV DAGAN, FREEDOM TRADER, 10 BOLIVIANOS AT 7.1% OF LIFESPOT**
- * **IMMUTEP REQUESTS 'INSTITUTIONAL PLACEMENT' TRADING HALT**
- * **MGC: 'MARIJUANA KILLS GLIOBLASTOMA, IN-VITRO'**

MARKET REPORT

The Australian stock market climbed 0.21 percent on Tuesday November 17, 2020, with the ASX200 up 13.9 points to 6,498.2 points. Sixteen of the Biotech Daily Top 40 stocks were up, 22 fell and two traded unchanged.

Alterity was the best for the second day in a row on no news, up 0.8 cents or 24.2 percent to 4.1 cents, with 319.4 million shares traded. Imugene improved 14.9 percent; Impedimed climbed 9.4 percent; LBT and Neuren were up more than eight percent; Proteomics was up 7.9 percent; Universal Biosensors rose 6.9 percent; Actinogen, Osprey and Patrys were up more than four percent; Cyclopharm climbed 3.4 percent; Compumedics rose two percent; Volpara was up 1.5 percent or more; with Avita, Cochlear, Kazia and Telix up by less than one percent.

Oncosil and Optiscan led the falls, both down 5.7 percent to 16.5 cents and 9.9 cents, respectively, with 2.1 million shares and 779,039 shares traded, respectively. Orthocell and Prescient lost more than five percent; Antisense and Nova fell more than four percent; Pharmaxis and Polynovo were down more than three percent; Amplia, Cynata, Next Science, Starpharma and Uscom shed two percent or more; CSL, Dimerix, Genetic Signatures, Medical Developments, Mesoblast, Paradigm and Resmed were down more than one percent; with Clinuvel, Nanosonics, Opthea and Pro Medicus down by less than one percent.

QBIOTICS GROUP

Qbiotics says the US Food and Drug Administration has approved tigilanol tiglate, or Stelfonta, for canine non-metastatic mast cell tumors.

Qbiotics said the approval made Stelfonta the first FDA-approved treatment for all grades of canine non-metastatic mast cell tumors, the most frequently diagnosed cancer in dogs. The company said that Stelfonta followed recent marketing approvals in Europe, the UK and Switzerland (BD: Jan 20, 2020).

The company said it would launch Stelfonta with US veterinary oncologists in the coming months and with primary care veterinarians from early 2021 through its marketing and distribution partner Virbac.

Qbiotics chief executive officer Dr Victoria Gordon said that the FDA approval was “a pivotal achievement for both Stelfonta and Qbiotics”.

“Stelfonta has the potential to be a category igniter, given it is easy to administer, provides 75 percent complete tumor resolution after just one injection and dogs quickly regain pre-treatment quality of life,” Dr Gordon said.

“European sales of Stelfonta have been impressive and we are excited to be working with Virbac to bring the drug to the US market to help treat the three million dogs there that each year are diagnosed with cancer,” Dr Gordon said.

“This approval also provides strong validation of our highly efficient business model, where veterinary product sales provide repeatable revenue for the company and the strong veterinary data underpins our human drug development program,” Dr Gordon said.

“Clinical efficacy and safety responses reported in [dogs] are also being mirrored in our human patients,” she said. “In a phase I/IIa human safety trial, tigilanol tiglate, the active ingredient in Stelfonta, demonstrated anti-tumor responses in a range of solid tumors”.

“This included complete responses, where the tumor is completely destroyed, in head and neck squamous cell carcinoma and melanoma,” Dr Gordon said.

“Notably, a maximum tolerated dose was not declared for this study,” Dr Gordon said.

“We are currently investigating the drug’s potential as both a monotherapy and an immune checkpoint inhibitor combination therapy through a series of phase II clinical trials,” Dr Gordon said.

Qbiotics is a public unlisted company,

CHIMERIC THERAPEUTICS

Biotech Daily understands that Chimeric is planning a \$30 million ASX initial public offer at 20 cents a share to develop chimeric antigen receptor T-cells for glioblastoma.

In September, the Sydney-based Chimeric said it had raised \$4.3 million through Baker Young’s exercise of a convertible note, for its 20-patient, phase I trial of chlorotoxin chimeric antigen receptor T-cells (Car-T cells) for glioblastoma and appointed Baker Young and Bell Potter Securities as advisors, having licenced the technology from California’s City of Hope (BD: Sep 22, 24, 2020).

Chimeric executive chairman Paul Hopper said at that time that the licence was “an exceedingly rare opportunity to acquire a promising phase I technology in one of the most exciting areas of immuno-oncology”.

“The ... therapy has completed years of pre-clinical research and development, and recently enrolled its first patient in a phase I clinical trial for brain cancer,” Mr Hopper said.

Chimeric said that Car-T cells used a patient’s own re-engineered T-cells, which carried chimeric antigen receptors, to target cancer cells.

Biotech Daily was unable to find further information about the planned initial public offer.

Chimeric is a public unlisted company.

[BRANDON CAPITAL, MYRICX PHARMA](#)

Brandon Capital says it is investing \$8.2 million in the Stevenage UK-based Myricx Pharma through its Medical Research Commercialisation Fund and with Sofinnova Partners.

Brandon said Myricx was developing small molecule inhibitors that selectively targeted human N-myristoyl-transferases, an enzyme emerging as a novel drug target for cancers and viral infections.

The company said that Myricx technology was based on research from Imperial College London and the Francis Crick Institute.

Myricx director Dr Stephen Thompson told Biotech Daily that Brandon Capital had invested in several UK firms and Myricx chief executive officer Dr Roberto Solari was a UK venture partner with the company.

Myricx is a private company.

[REDHILL BIOPHARMA](#)

Redhill says it has completed enrolment of its 40-patient, phase II US safety and efficacy study of opaganib, or Yeliva, for severe Covid-19-related pneumonia.

Redhill said the randomized, double-blind, placebo-controlled study was not powered for statistical significance, but topline data was expected in the coming weeks.

The company said that its parallel 270-patient, 21-site, phase II/III study was half enrolled, it expected to undergo its first pre-planned safety analysis in the coming days and report topline data by April 2021.

Redhill said it was compiling a robust data set to support planned emergency use applications, which were expected as early as the end of March 2021, subject to results.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

On the Nasdaq, Redhill fell 15 US cents or 1.83 percent to \$US8.04 (\$A10.99) with 313,023 shares traded.

[VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says it has launched an on-line, internet cloud-based breast density training platform, Breasted, through a collaboration with the Sydney-based Detected-X.

Volpara said the Densityed training module integrated technology from both companies to test radiologists' ability to rate and classify more than 60 mammogram images, providing feedback on reading performance and accuracy.

The company said the tool would provide feedback when classifications differed from those made by the software in order to identify and correct errors.

Volpara said the technology helped lower recall rates and improved cancer detection by more than 34 percent.

The company said it was designed to improve breast density category identification to comply with the American College of Radiology's Breast Imaging-Reporting and Data System and allowed radiologists to compare accuracy, globally and regionally, with users receiving continuing education credits.

The company said it would be sold independently through Detected-X in 39 countries and through the partnership, it would make Breasted available for clinicians.

Volpara said that Detected-X was founded by University of Sydney radiation and imaging experts,

Volpara was up two cents or 1.5 percent to \$1.37.

CARDIEX

Cardiex says its annual general meeting will vote to issue up to 160,500,000 performance rights to non-executive directors as long-term incentives.

Cardiex said it would vote to issue up to 68,000,000 performance rights each to Niall Cairns and Craig Cooper, with 4,000,000 each vesting when the company share price reached 12 and 15 cents, 10,000,000 each vesting at 20 cents and 25,000,000 each vesting at 25 and 50 cents by December 11, 2023.

The company said it would issue up to 21,000,000 rights to Jarrod White, with 2,500,000 each vesting at 12 and 15 cents, 4,000,000 vesting at 20 cents and 6,000,000 each vesting at 25 and 50 cents.

Cardiex said it would issue Randall King Nelson up to 3,500,000 rights, with 500,000 each vesting at 12, 15 and 20 cents and 1,000,000 each vesting at 25 and 50 cents by December 11, 2023.

The company said it would also vote to issue 1,000,000 shares to Mr White in lieu of a cash payment for director's fees for the year to June 30, 2021 and 1,000,000 shares to Zihan Lin in lieu of cash for services as an employee, issued at five cents a share within 28 days of the meeting.

In 2018, Cardiex said the Orange County, California-based Mr Lin had been appointed director of corporate development (BD: Jul 3, 2018).

Cardiex said it would vote to issue 17,681,818 shares and 4,420,455 options to the Niall Cairns and Craig Cooper owned C2 Ventures to pay a \$500,000 convertible loan, issued at 2.75 cents a share to develop its new product range.

The company said it would also vote to adopt its remuneration report, to re-elect Mr Cairns and elect Mr White as directors, ratify the prior issue of placement shares and options, approve an additional 10 percent placement facility and approve the performance rights and option plan.

The meeting will be held at BDO, Level 11, 1 Margaret Street, Sydney on December 11, 2020 at 9am (AEDT).

Cardiex fell 0.2 cents or 3.85 percent to five cents with 1.1 million shares traded.

ALTERITY THERAPEUTICS

In a replacement notice, the Sydney-based Credit Suisse Australia says it has ceased to be a substantial shareholder in Alterity.

Last week, Credit Suisse said it had become substantial in Alterity with 68,047,174 shares or 5.02 percent of the company (BD: Nov 13, 2020).

Today, Credit Suisse said that on November 12, 2020 it sold 953,944 "common stock" or US shares, equivalent to 57,236,640 Australian shares for \$25,756 or 0.045 cents per Australian share.

Credit Suisse said it bought 590,000 "common stock" or US shares, equivalent to 35,400,000 Australian shares, for \$15,300 or 0.043 cents per Australian share and returned 2,022,241 shares under a master prime brokerage agreement.

At that time, Alterity was trading between 2.4 cents and 2.7 cents.

Biotech Daily believes that today's replacement notice from Credit Suisse was in reference to Australian shares, not US shares, implying that it bought shares at 2.6 cents and sold them at 2.7 cents.

Biotech Daily calculates that Credit Suisse now holds 67,683,230 shares or 4.99 percent of Alterity.

Alterity was up 0.8 cents or 24.2 percent to 4.1 cents with 319.4 million shares traded.

LIFESPOT HEALTH

Cannvalate says it has increase and been diluted in Lifespot from 24,000,000 shares (19.72%) to 24,112,097 shares (17.89%).

The Melbourne-based Cannvalate said it was diluted following a placement in September and bought 97,092 shares at 6.2 cents each and 15,005 shares at 6.6 cents each. Lifespot was up 0.8 cents or 10 percent to 8.8 cents.

LIFESPOT HEALTH

Niv Dagan, Freedom Trader and 10 Bolivianos say they have increased and been diluted in Lifespot from 8,266,590 (9.43%) to 9,618,198 shares (7.14%).

The Melbourne-based Mr Dagan, Freedom Trader and 10 Bolivianos said that between June 5 and November 9, 2020 they acquired 693,162 shares at between 3.1 and 6.3 cents a share, sold 150,000 shares at 3.6 cents a share and transferred out 4,010,954 shares.

Mr Dagan, Freedom Trader and 10 Bolivianos said they also acquired 508,446 shares for \$26,779 or 5.3 cents a share in a private placement for \$300,000 and were diluted following the \$720,500 private placement to MID Wealth (BD: Nov 4, 2020).

IMMUTEP

Immutep has requested a trading halt pending an announcement "in relation to a proposed capital raising ... by way of an institutional placement".

Trading will resume on November 19, 2020 or on an earlier announcement. Immutep last traded unchanged at 29.5 cents with 1.1 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says in-vitro research of 18 patient tumor samples shows that its marijuana derivatives kill glioblastoma cells in the laboratory.

MGC said the preclinical research was conducted in collaboration with the Ljubjana, Slovenia-based National Institute of Biology and University Medical Centre.

MGC was unchanged at 2.2 cents with 5.7 million shares traded.