



Biotech Daily

Wednesday October 23, 2019

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH FLAT: DIMERIX UP 9.5%; KAZIA DOWN 7%**
- * **BOTANIX: CANNABINOID BTX1503 MISSES ACNE PRIMARY ENDPOINT; DOWN 48%**
- * **IMUGENE: \$825k US DEFENSE GRANT FOR CF33 GASTRIC CANCER RESEARCH**
- * **MEDICAL DEVELOPMENTS LAUNCHES PENTHROX IN ITALY**
- * **DIMERIX \$50k FEDERAL DMX-700 COPD GRANT**
- * **IMPEDIMED CANCER-RELATED LYMPHOEDEMA PREVENTION PROGRAM**
- * **ELIXINOL INVESTIGATES 'NON-COMPLIANT' JAPAN CANNABIDIOL**
- * **OVENTUS 570k CEO OPTIONS, 300k DIRECTORS OPTIONS**
- * **ALTHEA REQUESTS 'MATERIAL SUPPLY AGREEMENT' TRADING HALT**
- * **CAPITAL GROUP 'CLIENTS' REDUCE TO 5% OF MESOBLAST**
- * **M&G TAKES PRUDENTIAL'S 14% OF MESOBLAST**
- * **M&G TAKES PRUDENTIAL'S 5% OF MEDICAL DEVELOPMENTS**
- * **M&G TAKES PRUDENTIAL'S 12% OF STARPHARMA**
- * **WENTWORTH WILLIAMSON TAKES 8% OF PALLA PHARMA**
- * **ANTANAS GUOGA TAKES 13% OF SHAREROOT**
- * **NIV DAGAN, FREEDOM TRADER, 10 BOLIVIANOS TAKE 8% OF LIFESPOT**
- * **REGAL FUNDS BELOW 5% IN MEDIBIO**
- * **CLARITY APPOINTS DR JENNIFER ROSENTHAL FOR QUALITY, REGULATORY**

MARKET REPORT

The Australian stock market edged up 0.01 percent on Wednesday October 23, 2019, with the ASX200 up 0.9 points to 6,673.1 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, five traded unchanged and four were untraded. All three Big Caps fell.

Dimerix was the best, up one cent or 9.5 percent to 11.5 cents, with 144,294 shares traded. Actinogen and Pharmaxis climbed more than seven percent; Impedimed was up 6.45 percent; Imugene, Mesoblast, Patrys and Proteomics rose more than four percent; Clinuvel and Volpara improved more than one percent; with Avita, Ellex, Genetic Signatures, Neuren and Starpharma up by less than one percent.

Kazia led the falls, down 3.5 cents or seven percent to 46.5 cents, with 57,305 shares traded. LBT and Pro Medicus lost more than six percent; Orthocell fell 5.5 percent; Oncosil and Prescient fell more than four percent; Cyclopharm and Polynovo lost more than three percent; Compumedics, Medical Developments, Nanosonics and Resmed shed more than two percent; Cynata, Opthea, Paradigm and Telix were down more than one percent; with Cochlear, CSL and Next Science down by less than one percent.

BOTANIX PHARMACEUTICALS

Botanix says its 368-patient, phase II trial of synthetic cannabinoid BTX1503 for acne did not meet its primary endpoint for reduction of inflammatory lesions at 12 weeks.

Botanix said the randomized, double blind, controlled trial enrolled patients with moderate to severe acne at 35 sites in Australia and the US to evaluate the safety and efficacy of BTX 1503, reductions in inflammatory and non-inflammatory lesions and investigator's global assessment (IGA) score improvements.

The company said the five treatment groups included five percent BTX1503 once daily, five percent BTX1503 twice daily, 2.5 percent BTX1503 once daily and combined vehicle. Botanix said top-line data showed that inflammatory lesions were reduced in all dose groups, including the combined vehicle control group.

The company said that the highest efficacy result was for the five percent BTX1503 once daily group, which had a reduction of 11.8 inflammatory lesions or an average 40.54 percent reduction, but the combined vehicle group had a reduction of 11.3 lesions or 40.15 percent, and the difference was not statistically significant.

Botanix said that all dose groups reduced the number of non-inflammatory lesions and the 17.3 lesion reduction (34.99%) by the five percent BTX1503 once daily group was statistically significant compared to the 8.3 lesion reduction (19.08%) for the combined vehicle group ($p = 0.006$).

Botanix said the results were affected by an unusually high vehicle response, limited to the US clinical sites, with Australian results at week 12 showing statistical significance for the five percent BTX1503 twice daily group and all three treatment groups for non-inflammatory lesion reductions.

The company said the combined vehicle showed 7.7 reductions for inflammatory lesions and 4.6 reductions for non-inflammatory lesions in Australia compared to 11.3 and 8.3 for the whole trial.

Botanix said the IGA scores were similar across all treatment groups, ranging from an improvement of 13.2 percent for the 2.5 percent BTX1503 once daily group to 14.1 percent for combined vehicle, 15.2 percent for the five percent BTX1503 once daily and 16.3 percent for the five percent BTX1503 twice daily group.

The company said BTX 1503 was well-tolerated and adverse events were low across all treatment groups, with upper respiratory tract infections.

Botanix said it was planning an end-of-phase II meeting with the US Food and Drug Administration and was preparing for a phase III trial of BTX1503.

Botanix fell 11.5 cents or 47.9 percent to 12.5 cents with 138.8 million shares traded.

IMUGENE

Imugene says City of Hope researchers have received a \$US564,173 (\$A825,429) US Department of Deference grant to study CF33 for stomach or gastric cancer.

Imugene said Dr Yanghee Woo and Dr Yuman Fong would use oncolytic virus CF33, to express an anti-programmed death-ligand 1 (anti-PD-L1) antibody as an immune modulator to specifically kill cancer cells.

The company said its CF33 virus would convert the 'cold' peritoneal carcinomatosis (PC) environment, an untreatable evolution of gastric cancer (GC), into a 'hot' environment to enhance overall efficacy of gastric cancer therapy.

In July, Imugene said it would acquire Vaxinia for its CF33 oncolytic vaccine and an extraordinary general meeting to approve the acquisition is scheduled for November 18, 2019 (BD: Jul 17, Oct 14, 2019).

Imugene was up 0.1 cents or 4.8 percent to 2.2 cents with 22.8 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has launched its Pentrox inhaled methoxyflurane fast onset, non-opioid analgesic for pain relief in Italy.

Medical Developments chief executive officer John Sharman said the company was “delighted to finally launch Pentrox in ... Italy”.

“There has been a number of clinical studies completed in preparation for the launch of Pentrox in Italy,” Mr Sharman said.

“In particular, a study of 272 trauma patients in 15 Italian emergency units showed that Pentrox was superior to standard of care, including opioids for adult trauma pain patients in Italy,” Mr Sharman said.

Medical Developments fell 14 cents or 2.4 percent to \$5.65 with 287,042 shares traded.

DIMERIX

Dimerix says it has been awarded a second \$50,000 Federal Government Department of Industry, Innovation and Science Innovation Connections grant.

Dimerix said it would match the \$50,000 and would use expertise from Perth’s Harry Perkins Institute of Medical Research and the University of Western Australia to research “molecular pharmacology profiling of targets of interest ... including DMX-700”.

The company said University of Western Australia director of biomedical innovation Prof Kevin Pflieger would oversee the project.

Earlier this month, Dimerix said it was developing DMX-700 for chronic obstructive pulmonary disease (BD: Oct 10, 2019).

Dimerix was up one cent or 9.5 percent to 11.5 cents.

IMPEDIMED

Impedimed says it has a lymphoedema prevention program to test cancer survivors and end cancer-related lymphoedema.

Impedimed said cancer survivors would be routinely tested for lymphoedema through its prevention program, using its Sozo device with bioimpedance spectroscopy (BIS) (L-Dex) technology to measure extracellular fluid.

The company said high L-Dex scores would trigger a patient evaluation and intervention as part of its test, trigger, treat protocol for early detection and intervention of cancer-related lymphoedema, and it aimed to educate healthcare providers and patients that lymphoedema could be detected and managed.

Impedimed was up one cent or 6.45 percent to 16.5 cents with 1.7 million shares traded.

ELIXINOL GLOBAL

Elixinol says it is investigating non-compliant marijuana-derived cannabidiol products that were being sold by Elixinol Japan.

Elixinol said the breach “was discovered internally following the recent review of each global business unit’s operations” and it took compliance with all legislation and regulations seriously.

Elixinol said that the non-compliance related to the strict requirements in Japan on sourcing cannabidiol from only hemp stalk and seed.

The company said the investigation would be completed by mid-November 2019 and said it would assess “the commercial viability of the hemp-derived [cannabidiol] business unit”.

Elixinol fell 23 cents or 10.9 percent to \$1.88 with 1.7 million shares traded.

OVENTUS MEDICAL

Oventus says it will vote to issue chief executive officer Chris Hart and directors Neil Anderson, Dr Mel Bridges, Sue MacLeman and Sharad Joshi 870,000 options.

Oventus said it would vote to issue Mr Hart up to 570,000 directors' options as part of its employee option plan as a reward for achieving increases in the company's value.

The company said 23,333 options would vest on December 14, 2019, 2020 and 2021, exercisable at 42.28 cents a share within five years, 166,667 options would vest on October 4, 2020, 2021 and 2022, exercisable at \$1.0626 each within five years.

Oventus said it would vote to issue directors Mr Anderson, Dr Bridges and Ms MacLeman up to 50,000 directors' options each, vesting in three equal tranches on December 14, 2019, 2020 and 2021 exercisable at 42.28 cents a share.

The company said it would vote to issue Mr Joshi up to 150,000 director options, vesting in three equal tranches on December 14, 2019, 2020 and 2021, exercisable at 42.28 cents a share.

Oventus said the options were part of its employee option plan as a reward for achieving increases in the company's value.

The company said it would vote to adopt its remuneration report, to re-elect directors Mr Joshi and Ms MacLeman and to approve a 10 percent placement facility.

The meeting will be held at Thomson Geer, Level 28, Waterfront Place, 1 Eagle Street, Brisbane on November 22, 2019 at 11am (AEST).

Oventus fell one cent or 1.5 percent to 66 cents.

ALTHEA GROUP HOLDINGS

Althea has requested a trading halt "pending the release of an announcement regarding a material supply agreement".

Trading will resume on October 25, 2019 or on an earlier announcement.

Althea fell 1.5 cents or 2.8 percent to 52.5 cents.

MESOBLAST

Capital Group Companies says it has reduced its holding in Mesoblast from the equivalent to 30,755,583 shares (6.17%) to 27,562,803 shares (5.135%).

The Los Angeles, California-based Capital said it sold 2,076,860 shares for an average price of \$1.87 per share and 223,184 American depository receipts (ADRs), convertible at five shares per ADR, at an average price of \$US6.43 (\$A9.40).

The company said it did not hold shares in its own right but for mutual funds, other pooled investment vehicles, as well as individual and institutional clients.

Mesoblast was up 7.5 cents or 4.35 percent to \$1.80 with 1.3 million shares traded.

MESOBLAST

London's M&G says following a demerger it has taken Prudential's Mesoblast shares, increasing and diluted from 68,041,831 shares (13.67%) to 73,009,156 shares (13.6%).

In a ceasing substantial shareholder notice, Prudential said it had ceased its substantial holding in Mesoblast due to the demerger with M&G.

The company said that between October 22, 2018 and October 4, 2019 it bought and sold shares with the single largest purchase 5,000,000 shares for \$10,000,000 or \$2.00 a share on October 4, 2019.

MEDICAL DEVELOPMENTS

M&G says following a demerger it has taken Prudential's shares in Medical Developments, increasing from 3,284,528 shares (5.02%) to 3,295,094 shares (5.02%). In a ceasing substantial shareholder notice, Prudential said it had ceased its substantial holding in Starpharma due to the demerger with London's M&G Plc.

The company said that between April 17 and July 16, 2019 it bought and sold shares with the single largest purchase 3,295,094 shares for \$18,913,840 or \$5.74 a share.

STARPHARMA

M&G says following a demerger it has taken Prudential's Starpharma shares, increased and been diluted from 37,069,789 shares (13.06%) to 45,186,512 shares (12.15%).

In a ceasing substantial shareholder notice, Prudential said it had ceased its substantial holding in Starpharma due to the demerger with London's M&G Plc.

The company said that between April 26, 2013 and October 4, 2019 it bought, sold and transferred shares, with its single largest purchase 5,000,000 shares for \$10,000,000 or \$2.00 a share on October 4, 2019, which does not appear to be correct.

M&G said that on July 10, 2019 it bought 3,639,633 shares for \$5,568,638 or \$1.53 a share.

Starpharma was up one cent or 0.9 percent to \$1.13.

PALLA PHARMA (FORMERLY TASMANIAN POPPY INDUSTRIES ENTERPRISES)

Sydney's Wentworth Williamson Management says it has increased its holding in Palla Pharma from 5,795,086 shares (7.15%) to 10,390,074 shares (8.28%).

Wentworth Williamson said that between November 30, 2018 and October 22, 2019 it acquired 4,594,988 shares in on-market transactions and a placement, but failed to disclose the prices paid as required under the Corporations Act 2001.

On Monday, Palla Pharma said it raised \$8.4 million in a placement and \$12.2 million in the "institutional component" of a rights offer at 70 cents a share (BD: Oct 21, 2019).

Palla Pharma fell one cent or 1.1 percent to 88 cents.

SHAREROOT

Antanas Guoga says he has increased his substantial shareholding in Shareroot from 155,667,934 shares (9.92%) to 372,396,564 shares (12.63%).

The Melbourne-based Mr Guoga said that on October 3, 2019 he acquired 100,000,000 shares as repayment of a \$100,000 debt to share conversion at 0.1 cent a share and on October 17, 2019, he bought 4,533,333 shares on market at 0.2 cents a share.

Shareroot was unchanged at 0.2 cents with 28.1 million shares traded.

LIFESPOT HEALTH

Niv Dagan, Freedom Trader and 10 Bolivianos say they have increased their holding in Lifespot Health from 5,363,916 shares (6.88%) to 6,405,717 shares (8.26%).

The Melbourne-based Mr Dagan, Freedom Trader and 10 Bolivianos said that between September 27 and October 21, 2019 they acquired 1,041,801 shares on market for \$52,329.90 or an average of 5.0 cents a share.

Lifespot was untraded at 5.2 cents.

MEDIBIO

The Sydney-based Regal Funds Management says it has ceased to be a substantial shareholder in Medibio.

Regal Funds said that between October 9 and 18, 2019 it sold 62,000,000 shares for \$721,430 or an average of 1.2 cents a share.

Last month, Regal Funds said it became a substantial shareholder with 100,000,000 shares or 10.05 percent of the company (BD: Sep 3, 2019).

Biotech Daily calculates that Regal retains 38,000,000 shares or 3.8 percent of the company.

Medibio was up 0.1 cents or 9.1 percent to 1.2 cents with 3.4 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has appointed Dr Jennifer Rosenthal as its director of quality and regulatory affairs.

Clarity said that Dr Rosenthal had more than 20 years' management experience in the biotechnology industry, including as a director and executive in oncology, and had developed strategy and managed teams and projects in regulatory affairs, clinical trials, quality assurance and intellectual property.

The company said that Dr Rosenthal was previously at Viralytics which was acquired by Merck & Co for \$502 million last year (BD: Feb 22, 2018).

Clarity said that prior to Viralytics, Dr Rosenthal was with Alchemia for 10 years and was responsible for the clinical and regulatory management of the Hyact platform, including a pivotal phase III trial of hyaluronic acid-irinotecan.

In 2014, Alchemia fell on news that HA-irinotecan, as part of the standard combination of folinic acid, fluorouracil and irinotecan (Folfiri) for metastatic colorectal cancer, failed to meet its phase III primary endpoint (BD: Oct 27, 2014).

Today, Clarity said that Dr Rosenthal worked for Florigene for five years, responsible for a genetically modified organisms regulatory framework, and was employed by Davies Collison Cave patent and trademark attorneys for two years managing client portfolios.

The company said that Dr Rosenthal held a Bachelor of Science from Melbourne's La Trobe University and a Doctor of Philosophy from Melbourne's Monash University.

Clarity is a public unlisted company.