



# Biotech Daily

Wednesday June 15, 2016

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: MESOBLAST UP 12%; ANTISENSE DOWN 12.5%**
- \* **CHINA APPROVES ALL ELLEX YAG LASER TREATMENTS**
- \* **ANTEO, ATOMO PARTNER FOR POINT-OF-CARE CARDIAC ARREST TEST**
- \* **UWA STUDY BACKS OBJ MICRO-ARRAY FOR DISINFECTION**
- \* **RESONANCE 2-YEAR UNNAMED COMPANY COLLABORATION**
- \* **PHYLOGICA: 'STUDY BACKS PHYLOMER ANTISENSE DELIVERY'**
- \* **ALCHEMIA SUSPENDED FOR 'INSUFFICIENT OPERATIONS'**
- \* **SAMPLE ISSUE DELAYS FACTOR THERAPEUTICS US VF001 WOUND TRIAL**
- \* **CELLMID LAUNCHES EVOLIS PROFESSIONAL HAIR PRODUCTS**
- \* **MGC PLANTS SLOVENIA MARIJUANA TEST CROP**
- \* **BIOXYNE DIRECTOR OPTIONS, DR PETER FRENCH STARTS ON \$120k**
- \* **KINETIC TAKES 5% OF IMPEDIMED**
- \* **OTTO BUTTULA, WEBINVEST BELOW 5% OF IMUGENE**
- \* **MACH7 LOSES KEN POUTAKIDIS, GAINS ALISTER WAYNE SPITTLE**

## MARKET REPORT

The Australian stock market fell 1.08 percent on Wednesday June 15, 2016 with the ASX200 down 56.2 points to 5,147.1 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, seven traded unchanged and two were untraded.

Mesoblast recovered 13.5 cents or 12.2 percent to \$1.245 with 4.8 million shares traded. Ellex climbed 7.1 percent; Anteo was up 4.65 percent; Cellmid, Factor and Viralytics were up more than three percent; Uscom was up two percent; with Actinogen, Clinuvel and Sirtex up more than one percent.

Antisense led the falls, down 0.5 cents or 12.5 percent to 3.5 cents, with 294,000 shares traded. Acrux, Admedus and Genetic Technologies lost five percent or more; Benitec and Biotron fell more than four percent; Airxpanders, Bionomics, Orthocell and Starpharma were down more than three percent; Impedimed, Nanosonics, Osprey and Prima shed more than two percent; Compumedics, CSL, IDT, Polynovo and Universal Biosensors were down more than one percent; with Medical Developments down 0.85 percent.

## ELLEX MEDICAL LASERS

Ellex says the China Food and Drug Administration has granted approval for its portfolio of glaucoma, vitreous floaters and secondary cataract treatment lasers.

Ellex said that previously the yttrium aluminium garnet (Yag) laser portfolio was restricted to a specific limited market and with the portfolio available to all ophthalmologists in China, the company expected increased sales in 2016-'17.

Ellex chief executive officer Tom Spurling said that the approval process "required a significant investment, with resources from our in-house regulatory team committed over a 12-month period".

"It marks an important milestone for our business as we expand our presence in the fast-growing market of Asia," Mr Spurling said.

"The sales outlook in China is strong, with improved access to health care and new investments in ophthalmic infrastructure and technologies driving growing sales demand for ophthalmic products," Mr Spurling said.

"Ellex sales into Asia, of which China comprises approximately 80 percent, grew by 52 percent during the half year ended December 31, 2015, accounting for 10 percent of total group sales," Mr Spurling said.

In February, Ellex said that revenue for the six months to December 31, 2015, was up 13.4 percent to \$34,809,000 (BD: Feb 26, 2016).

"The company expects the growth in sales into Asia for the full year to June 30, 2016 to be materially higher," Mr Spurling said.

"In view of the sales growth achieved to date in China with limited market access, we anticipate this approval will lead directly to higher sales in the 2017 financial year," Mr Spurling said.

Ellex said it would continue to invest in the Chinese market to obtain regulatory approval of its Integre Pro Scan retinal treatment laser.

Ellex was up seven cents or 7.1 percent to \$1.05.

## ANTEO DIAGNOSTICS, ATOMO DIAGNOSTICS

Anteo says it will partner with the Sydney-based Atomo Diagnostics to develop a clinical prototype of a point-of-care test for the diagnosis of cardiac arrests.

Anteo said that Atomo today won the \$100,000 medical device sector of the Advance Queensland Johnson & Johnson Innovation Quickfire Challenge, announced by Queensland Premier, Annastacia Palaszczuk.

Atomo chief executive officer John Kelly said the funding would "allow us to evaluate the feasibility of an easy-to-use test for the early detection of heart attacks away from laboratory and hospital settings".

Mr Kelly said that Anteo would develop a rapid test strip for cardiac troponin using its coating technology and Atomo would integrate the cardiac troponin strip into its Atomorapid point-of-care platform.

Anteo consultant and former chief executive officer Dr Geoff Cumming told Biotech Daily that troponin was an enzyme released when cardiac tissue died and its presence meant there had been cardiac cell death.

Anteo said that the troponin test market was one of the largest and fastest growing single cardiac biomarkers segments and the point-of-care, or non-laboratory, market was estimated to be worth about \$350 million a year.

Atomo is a public unlisted company 27 percent owned by the Auckland, New Zealand-based Lang Walker Group.

Anteo was up 0.2 cents or 4.65 percent to 4.5 cents with 2.3 million shares.

## OBJ

OBJ says University of Western Australia studies of its micro-array benzalkonium chloride confirm efficacy for surface hygiene.

OBJ said it commissioned the University of Western Australia to replicate studies into the effect of its micro-array for *Staphylococcus aureus*, or Golden Staph, a major source of infection in medical facilities with potentially life-threatening consequences.

Last year, the company said a preliminary study showed that an applicator containing its magnetic microarray technology killed more bacteria than traditional methods and the new results showed a similar bacterial kill rate (BD: Oct 30, 2015).

OBJ said that the University explored the efficacy of benzalkonium chloride with and without its micro-array technology and reconfirmed the effectiveness of the technology with the magnetic micro-array increasing the effectiveness of benzalkonium chloride two-to-three times compared to use of the disinfectant alone, over all time periods for the tests performed in bacterial suspensions.

A University of Western Australia chart provided by OBJ said that at five minutes benzalkonium chloride alone killed 10 percent of *Staphylococcus aureus* cells, while the magnetic micro-array enhanced version killed more than 25 percent of cells.

The company said that the micro-array technology improved the bacterial kill rate by driving disinfectant agents deeper into the micro-fissures and scratches found in surfaces such as stainless steel and aluminium bench-tops and flooring treatments.

OBJ said that the University of Western Australia testing program would continue across a number of influencing factors, measuring the effectiveness on different surfaces commonly found in domestic and commercial applications.

The company said it would develop prototypes of a number of potential commercial devices for use in the homecare, floor cleaning, hospitality, hospital and industrial hygiene market sectors and market research had identified applications for the use of micro-array technology including hand-held surface treatments and floor cleaning devices.

OBJ said it would design and develop surface hygiene device prototypes which would be integral to partnering discussions for the technology.

OBJ fell 0.2 cents or 2.25 percent to 8.7 cents with 1.1 million shares traded.

## RESONANCE HEALTH

Resonance says it has a two-year collaboration to provide Ferriscan and Cardiac T2 services for an unnamed pharmaceutical company phase III trial.

Resonance said its service provision for the Asia component of the trial was expected to begin "shortly".

The company said that Ferriscan was "the gold standard for the measurement of liver iron concentration due to its non-invasive nature, accuracy and standardized results".

Resonance general-manager Sander Bangma said that to assess the efficacy of the pharmaceutical company's investigational products they required "consistently accurate, quantitative measurements".

"It is a testament to Resonance Health that our [International Standards Organisation] certified analysis services are commonly chosen for this purpose," Mr Bangma said.

Mr Bangma said its imaging services had been used in more than 20 multi-center studies over the past 10 years.

The company said that its service centre was currently analyzing record volumes of scans.

Resonance said that the increased demand was driven by marketing activities resulting in increased routine use of its services, as well as the roll out of collaborative studies.

Resonance was unchanged at 2.2 cents.

## PHYLOGICA

Phylogica says Murdoch University studies confirm its cell-penetrating Phylomer “significantly enhanced” delivery of an antisense oligonucleotide drug inside cells. In February, Phylogica said it began a collaboration with Murdoch University’s Centre for Comparative Genomics Prof Sue Fletcher and Prof Stephen Wilton to assess whether a cell-penetrating Phylomer could improve the delivery of an antisense oligonucleotide drug. The company said the studies confirmed that its cell-penetrating Phylomer “significantly enhanced intracellular delivery of the drug relative to a control oligonucleotide that was not linked to the [cell-penetrating Phylomer]”, with similar outcomes achieved when the drug was delivered into cultured human cells and a mouse animal model.

The company said that antisense oligonucleotides worked by binding to the genetic message, or messenger RNA, and editing mutated regions that caused disease and such drugs showed promise as therapies to reduce the severity of genetic diseases.

Prof Fletcher said she was “encouraged” by the pilot studies and would expand the collaboration to develop more effective treatments for Duchene muscular dystrophy.

Phylogica chief executive officer Dr Richard Hopkins said “we’ve now shown we can deliver a whole new class of drug that has the potential to open up commercial opportunities in the oligonucleotide field, which has seen a significant resurgence over recent years”.

Phylogica said the collaboration would target the genetic mutations underlying Duchene muscular dystrophy in cell and animal models and determine whether the technology could improve drug activity without compromising drug safety.

Phylogica was unchanged at 1.4 cents with 1.4 million shares traded.

## ALCHEMIA

Alchemia says the ASX has suspended trading from the close on June 14, 2016 as it “did not have sufficient operations to warrant the continued quotation”.

Alchemia said that the suspension would continue until either the company was able to demonstrate compliance with Chapter 12 of the Listing Rules, or it complies with Chapters 1 and 2 of the Listing Rules.

The company has divested most of its assets following the failure of its hyaluronic acid-irinotecan to meet its primary endpoint in its 415-patient, phase III trial for metastatic colorectal cancer (BD: Oct 27, 2014).

In 2015, Alchemia said Panther Biotechnology would buy its oncology assets including the Hyact platform for cash and stock worth more than \$US16 million (\$A20.7 million), but that deal was reported as being delayed; Vast Bioscience acquired Alchemia’s versatile assembly on stable templates (VAST) drug discovery platform, for \$100,000 upfront and royalties; and Alchemia said it would sell the global rights to its fondaparinux generic heparin to distribution partner Dr Reddy's Laboratories for \$US17.5 million (\$A24.3 million) (BD: Jul 1, 3, Aug 3, Sep 25, 2015).

At the time of publication, the status of the Panther acquisition was unknown, with no one available at Alchemia.

Today, the company said it had “provided a submission to the ASX to demonstrate its on-going compliance with Chapter 12 and specifically 12.1 of the Listing Rules” and the ASX was reviewing the submission.

Since the sale of Fondaparinux in November 2015, the company has received a Federal Research and Development Tax Incentive and returned capital to shareholders but not announced any activity other than board appointments and share dealing.

Alchemia last traded at 0.8 cents.

### [FACTOR THERAPEUTICS \(FORMERLY TISSUE THERAPIES\)](#)

Factor Therapeutics says its US phase II trial of its VF001 (formerly Vitrogro) wound treatment has been delayed by up to six weeks from July to August, 2016.

Factor executive director Dr Christian Behrenbruch told Biotech Daily that the company expected to file outstanding documentation to the US Food and Drug Administration, including certificates of analysis for the proposed clinical materials to be used in the trial by the end of June 2016, which had been delayed by four to six weeks.

Factor said it completed a US-based fill-and-finish manufacture and the contract laboratory conducting the release testing determined that samples from one of the three batches (low-dose, high-dose and placebo) for the trial were "out of specification".

The company said that an analysis linked the sample to a carbonic acid gas contamination of the pre-filled syringes, originating from dry ice cooling used during the shipping of test samples from the manufacturer to the contract analytics laboratory.

Factor said that due to the detailed nature of the investigative process, the need to document the root-cause and experimental validation of a revised shipping protocol to avoid this situation in the future, the company expected a delay of about four to six weeks. Factor chief executive officer Nigel Johnson said that the "inadvertent and unforeseen contamination of samples via the shipping process between manufacturer and test lab was not anticipated, however both the Factor team and our manufacturing and laboratory partners responded rapidly, enabling us to quickly identify the root cause and modify protocols to ensure this issue is eliminated".

Dr Behrenbruch said that the delay was "unlikely to be material from a cost or trial impact perspective, [but] we recognise that shareholders are closely monitoring the company's turn-around progress and we wish to keep shareholders fully informed of any potential slippage from our previously articulated milestone dates".

Factor was up 0.1 cents or three percent to 3.4 cents.

### [CELLMID](#)

Cellmid says it has launched Evolis Professional hair products for salons at Hair Expo in Melbourne over the Queen's Birthday public holiday weekend, June 11-13, 2016.

Cellmid said that the launch was "the culmination of over 12 months of planning, product development and manufacturing" by subsidiary, Advangen.

The company said that all 13 products in the range included its FGF5 inhibitor hair growth technology to prevent hair loss and increase hair growth, as well as selected organic antioxidants to maximise scalp health and hair condition.

Cellmid said that sales would begin in New South Wales, targeting a national network of 400 salon customers in a market test period.

Cellmid was up 0.1 cents or 3.45 percent to three cents with 24 million shares traded.

### [MGC \(MEDICAL GRADE CANNABIS\) PHARMACEUTICALS](#)

MGC says it has planted its first marijuana test crop at its farm in Slovenia and the test crop will be used to evaluate the best conditions for high cannabinoid production.

MGC said the cannabis would be used for cosmetics and medicinal marijuana.

The company said that it expected to harvest the crop by October 2016.

MGC Pharmaceuticals expects to cultivate, harvest and produce its first full production crop for high quality non-psychoactive cannabinoid resin extract in 2017 from its Slovenian operations and through the Panax acquisition in the Czech Republic.

MGC fell 0.1 cents or 1.96 percent to five cents with 8.7 million shares traded.



## BIOXYNE

Bioxyne says executive director Dr Peter French has a base part-time salary of \$120,000 a year plus superannuation and up to 6,000,000 incentive options.

Bioxyne said that the 6,000,000 equity incentive package included the first 1,000,000 options vesting on August 31, 2016, with an exercise price of 2.82 cents, 2,000,000 options vesting on the company's budgeted net profit after tax for the 2016-'17 exercisable at 3.17 cents and 3,000,000 options vesting on the achievement of the company's budgeted net profit after tax for the 2017-'8 financial year, exercisable at 3.52 cents each. The company said that chairman Tony Ho would be issued 1,500,000 options, with directors Patrick Ford to be issued 1,250,000 options and George Cameron-Dow 1,000,000 options all exercisable at 2.82 cents.

Bioxyne said that the options were subject to shareholder approval.

Bioxyne was up 0.1 cents or 4.2 percent to 2.5 cents

## IMPEDIMED

The Melbourne-based Kinetic Investment Partners says it has become a substantial shareholder in Impedimed with 19,302,767 shares (5.17%).

Kinetic said that between February 10 and June 10, 2016 it bought 6,813,078 shares for \$6,518,131 or 95.7 cents a share.

Kinetic is part of Challenger Financial Services, its principals are Jonathan Findlay, Richard Sharp and Mark Skocic.

The company said that the registered holders of the shares were JP Morgan Nominees, National Nominees, Cogent Nominees, Northern Trust and Citigroup Nominees.

Impedimed fell two cents or two percent to 97 cents.

## IMUGENE

The Ashgrove East, Queensland-based Webinvest said it has reduced its substantial holding in Imugene from 107,000,000 shares (6.18%) to 86,425,000 shares (4.99%).

Webinvest director Otto Buttula said that between February 5 and June 10, 2016 the 20,575,000 shares were sold on-market for \$209,788 or an average of 1.02 cents a share.

Mr Buttula resigned as an Imugene director on December 17, 2015.

Imugene was unchanged at one cent.

## MACH7 TECHNOLOGIES (FORMERLY 3D MEDICAL)

Mach7 says that Alister Wayne Spittle has been appointed a director, replacing chairman Ken Poutakidis, with Damien Lim appointed chairman.

Mach7 said that Mr Spittle was previously Samsung Medison and Samsung Health and Medical Equipment executive vice-president since 2013 and was involved with the planning for Samsung's entry into the health care arena three years ago.

Mach7 was unchanged at 4.5 cents.