



Biotech Daily

Wednesday July 11, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: COMPUMEDICS UP 9%; CLINUVEL DOWN 4%**
- * **RESONANCE FERRISMART WINS CE MARK, TGA APPROVAL**
- * **ADMEDUS IMPLANTS FIRST AORTIC HEART VALVE IN SHEEP**
- * **FOUNDER DR BRUCE GRAY BACK TO 5% OF SIRTEX**
- * **IMMURON GRANTED EUROPEAN NASH PATENT**
- * **ADHERIUM: CONNECTICUT CHILDREN'S TRIALS HAILIE**
- * **CELLMID: NEW ÉVOLIS PRODUCTS IN JAPAN, AUSTRALIA, US**
- * **HYDROPONICS \$2.5m SOUTHPORT FACILITY 'WORTH \$14.6m'**
- * **NOXOPHARM TO RELEASE 15.9m ESCROW SHARES**
- * **ADALTA REQUESTS CAPITAL RAISING TRADING HALT**
- * **MGC REQUESTS 'EURO MARIJUANA GMP' TRADING HALT**
- * **STEMCELL UNITED REQUESTS 'ENTRY INTO CONTRACT' TRADING HALT**
- * **MESOBLAST APPOINTS SHAWN TOMASELLO DIRECTOR**
- * **HYDROPONICS APPOINTS KEN CHARTERIS CEO, STARTS ON \$280k**
- * **ELLEX APPOINTS JOAQUIN WOLFF ITRACK PRESIDENT**

MARKET REPORT

The Australian stock market fell 0.68 percent on Wednesday July 11, 2018 with the ASX200 down 42.5 points to 6,215.6 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, five traded unchanged and five were untraded.

Compumedics was the best, up five cents or 8.85 percent to 61.5 cents with 62,848 shares traded. Admedus and Telix climbed more than six percent; Factor Therapeutics improved 5.6 percent; Imugene and Osprey were up more than three percent; Actinogen rose two percent; Avita, Bionomics, Ellex, Orthocell and Polynovo were up one percent or more; with Resmed and Sirtex up by less than one percent.

Clinuvel led the falls, down 50 cents or 4.35 percent to \$11.00 with 84,359 shares traded. Benitec fell 4.1 percent; Dimerix and Neuren lost more than three percent; Airxpanders, Immutep, Impedimed and Oncosil shed more than two percent; Cyclopharm, Mesoblast Opthea, Pharmaxis and Starpharma were down one percent or more; with Cochlear, CSL, Cynata, Medical Developments, Pro Medicus and Volpara down by less than one percent.

RESONANCE HEALTH

Resonance says its Ferrismart artificial intelligence liver-iron quantifier has Conformité Européenne (CE) mark and Therapeutic Goods Administration approval.

Resonance regulatory affairs manager Celine Royet told Biotech Daily that the CE mark approval came through last night and the TGA approval followed through a mutual recognition in place between Australia and the European Community.

The company said the Ferrismart system took “a matter of seconds” could be provided at lower cost than the Ferriscan system, and clinicians and radiologists would be able to access the pay per use service through an internet “cloud” portal, or through its partner, the Edinburgh, Scotland-based Blackford Analysis (BD: July 5, 2018).

The company said it expected to submit a 510(k) pre-market approval application to the US Food and Drug Administration by August, with approval hoped-for by the end of 2018. Resonance was up 0.2 cents or 9.5 percent to 2.3 cents.

ADMEDUS

Admedus says it has implanted its first single-piece heart valve in a live sheep, starting its transcatheter aortic valve replacement (TAVR) safety and feasibility study.

In May, Admedus said it would begin the sheep study, titled ‘Experimental assessment of the Admedus valve - ovine model of aortic valve replacement’, at an unnamed European reference laboratory, for an initial trial period of about three months after which it would test the valves in calves, with the experiments expected to be completed by early 2019 (BD: May 22, 2018).

Today, the company said the implant followed successful laboratory tests in which multiple three-dimensional valves were tested to 400 million cycles, equivalent to about 10 years of human use, with a competitor valve acting as control.

Admedus said study showed that “whilst the Admedus valves remained functional after 400 million cycles, the competitor valve showed significant fatigue at 250 million cycles”.

Admedus chief executive officer Wayne Paterson said the implant was a “significant step for the TAVR project as we move into the next stage of development”.

“This device has the potential to be a game-changer for patients, the company and the \$US3.5 billion TAVR market,” Mr Paterson said.

Admedus was up 1.5 cents or 6.25 percent to 25.5 cents.

SIRTEX MEDICAL

Sirtex founder and former chief executive officer Dr Bruce Gray says he has returned to a substantial holding with 2,812,822 shares or 5.04 percent of the company

A substantial shareholder notice from Hanate Pty Ltd signed by director Dr Gray said that between June 20 and July 8, 2018 the company bought 799,850 shares for \$29,217,650, or \$36.53 a share, but according to Sirtex trade history on Commsec, during that period the maximum share price was \$31.68.

Dr Gray was involved in a lengthy legal battle with Sirtex, with the courts ruling he had breached his duties as chairman and misled the company in failing to disclose correspondence with the vice-chancellor of the University of Western Australia in 1999, relating to a settlement between Sirtex and the University (BD: Jun 11, 2010).

In the years following the court ruling, Dr Gray requisitioned, or attempted to requisition, extraordinary general meetings and voted against meeting resolutions on several occasions (BD: Jun 4, Jul 9, Oct 27, 2009; Oct 26, 2010; Oct 27, 2011; Sep 21, 2012).

Sirtex was up nine cents or 0.3 percent to \$31.86 with 430,515 shares traded.

IMMURON

Immuron says the European Patent Office has granted it a patent “for the use of a composition for the treatment of non-alcoholic steatohepatitis (NASH)”.

Immuron said the patent, titled ‘Anti-LPS enriched immunoglobulin preparations for the treatment and/or prophylaxis of a pathological disorder’, would provide coverage until April 2030, with potential for supplementary protection and extension.

The company said the patent comprised five claims related to the composition of an enriched immunoglobulin preparation derived from cow colostrum.

Immuron interim chief executive officer Dr Jerry Kanellos said the patent claims were “particularly broad and represent the primary intellectual property rights sought by the company in this important and commercially large jurisdiction”.

Immuron said it had been granted patents in Australia, Russia, Japan, Israel and South Korea.

Immuron was unchanged at 33 cents.

ADHERIUM

Adherium says the Connecticut Children’s Medical Centre will use its Hailie device, formerly the Smartinhaler, to help manage patients asthma.

Adherium said the program with the Hartford, Connecticut-based Center would be led by Dr Tregony Simoneau and enrol more than 100 patients with existing asthma.

Dr Simoneau said that the Centre looked “for innovative ways of providing care to patients and families”.

“By leveraging smarter technology, we help underserved populations, which in turn could produce tremendous cost savings for payers,” Dr Simoneau said.

The company said the Hailie device wrapped around a patient’s inhaler to monitor and promote asthma adherence, to record the date and time when the inhaler was used, with the data transmitted to an application on the patient’s phone or tablet to be used as part of a self-management plan.

Adherium was unchanged at 11 cents.

CELLMID

Cellmid says it will launch its Évolis hair loss products in Japan, add new lines to the US and Australian range with two US shops taking the products permanently.

Cellmid said it would sell its Évolis FGF5 inhibitor anti-aging hair products in Japan for the first time, with Évolis Professional to be sold online and at hair salons this month and the Évolis Pharmacy to be sold at independent chemists by October 2018.

The company said it would increase its number of products sold at Australian pharmacies from four to 15, including its Évolis White facial mask and its Fillerina “anti-aging transdermal filler” with initial locations secured and 70 percent of the first order allocated to participating pharmacies.

Cellmid said that it would launch its Évolis Promote ultra-violet light protector spray online in a beta test mode this month.

Cellmid said US retailers and Australian pharmacies were expected to sell its Évolis Professional Reverse dry shampoo in October, 2018.

The company said the Dallas, Texas-based Neiman Marcus and New York-based Bloomingdales would permanently sell its Évolis Professional products in US shops and online, having been available online since last year (BD: Apr 24, Aug 3, 2017).

Cellmid was up 2.5 cents or 5.75 percent to 46 cents.

THE HYDROPONICS COMPANY

Hydroponics says its Southport manufacturing facility has been valued at \$14.58 million at market price, or \$16.68 million including land and building at acquisition price.

In April, Hydroponics said it had bought the Brisbane production facilities from Copenhagen-based Leo Pharma for \$2,550,000 (BD: Apr 26, 2018).

Today, the company said it had assessed the replacement value of the facility to be about \$35 million and had insured the property on that basis, although advised that it could revisit the valuation as the company moved closer to revenue-generating production.

Hydroponics said that following the start of marijuana operations at the facility it would be able to produce oils, powders and crystals to a pharmaceutical-grade and export-ready quality.

Hydroponics was up 2.5 cents or 4.5 percent to 58 cents with 1.1 million shares traded.

NOXOPHARM

Noxopharm says it will release 46,885,465 shares from ASX escrow on August 8, 2018, with 31,027,568 shares remaining in voluntary escrow until May 8, 2019.

Noxopharm said that 12,075,000 options exercisable at 30 cents each by February 28, 2021, held in the name of Milligene Pty Ltd and in ASX escrow until August 9, 2018 would also continue in voluntary escrow until May 8, 2019.

According to the most recent Noxopharm annual report Milligene is also the GE PR Kelly Family Trust.

Dr Graham Kelly is the founder and chief executive officer of Noxopharm and Prue Kelly is his wife.

According to the company's most recent Appendix 3B new issue announcement, following the release of the 15,857,897 shares from ASX and voluntary escrow on August 8, 2018 the company would have 90,873,742 shares available for trading on the ASX.

Noxopharm fell two cents or 3.3 percent to 58 cents.

ADALTA

Adalta has requested a trading halt "pending an announcement in relation to a capital raising".

Trading will resume on July 13, 2018 or on an earlier announcement.

Adalta last traded at 35 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC has requested a trading halt pending an announcement regarding "good manufacturing practice certification approval process" for its European facility.

Earlier this year, MGC requested a trading halt for a similar reason and soon after said it had been granted interim good manufacturing practice certification its European medicinal cannabis production facility and that it expected to be granted full certification (BD: Jan 23, 2018).

Trading will resume on July 13, 2018 or on an earlier announcement.

MGC last traded at 6.3 cents.

STEMCELL UNITED

Stemcell United has requested a trading halt pending an announcement “in relation to the entry into a contract”.

Trading will resume on July 13, 2018 or on an earlier announcement.

Stemcell last traded at 2.5 cents.

MESOBLAST

Mesoblast says it has appointed Shawn Tomasello as a director.

Mesoblast said Ms Tomasello had more than 30 years of experience in the pharmaceutical and biotechnology industries and was previously Kite Pharma chief commercial officer and held the same role at Pharmacyclics.

The company said Ms Tomasello was previously Celgene Corp’s head of the Americas haematology and oncology.

Mesoblast said that Ms Tomasello had worked at Genentech, Pfizer Laboratories, Miles Pharmaceuticals and Procter & Gamble, and was currently a director of Centrexion Therapeutics, Oxford Biotherapeutics and Diplomat Rx.

The company said that Ms Tomasello held a Bachelor of Science in marketing from the University of Cincinnati in Ohio and a Master of business Administration from Kentucky’s Murray State University.

Mesoblast fell 1.5 cents or one percent to \$1.545.

THE HYDROPONICS COMPANY

Hydroponics says it has promoted Canndeo director Ken Charteris to group chief executive officer starting on \$280,000, effective from July 11, 2018.

In April, Hydroponics said it had appointed Mr Charteris director of its wholly-owned subsidiary Canndeo (BD: Apr 12, 2018).

At that time, the company said that Mr Charteris was involved in its acquisition of Canndeo and obtaining operating licences from the Australian Office of Drug Control and partnership deals with Endoca and BOL Pharma.

Today, Hydroponics said it had appointed Mr Charteris “after an extensive executive search” but provided no further information about Mr Charteris previous employment or educational qualifications.

According to Mr Charteris LinkedIn page, he was previously the chief executive officer of One Link Resources (KGC & Associates), Frigrite managing-director, CPR International group chief executive officer and RTS/TMO interim chief executive officer and director. Hydroponics said that Mr Charteris was an “experienced biotech and pharmaceuticals executive ... [and] a veteran of multiple biotech and pharmaceutical companies over the past three decades as CEO, managing director and chairman”.

Hydroponics said that Mr Charteris would be paid \$280,000 a year plus statutory superannuation, be issued 500,000 shares, along with 1,500,000 “performance” options exercisable at 75 cents each by July 11, 2021, vesting on a two-week volume weighted average price of 75 cents a share by July 11, 2020 and 2,500,000 performance options exercisable at \$1.20 each by July 11, 2021, vesting on a two-week volume weighted average price of \$1.20 a share by July 11, 2020, subject to shareholder approval.

ELLEX MEDICAL LASERS

Ellex says it has appointed Joaquin Wolff to the newly-created position of president of Itrack, to manage the invasive glaucoma surgery business.

Ellex said the Fremont, San Francisco Bay, California-based Mr Wolff had more than 25 years of executive experience, previously working for Novartis and Johnson & Johnson, where he was responsible for the US launch of several product platforms.

The company said that Mr Wolff had worked as a commercialization strategist for a health market consultants' consortium for emerging and early stage start-up companies in Silicon Valley.

Ellex was up one cent or 1.5 percent to 67 cents.