



Biotech Daily

Tuesday August 14, 2018

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: ONCOSIL UP 12%; REVA DOWN 11%**
- * **COCHLEAR REVENUE UP 9% TO \$1,351m, PROFIT UP 10% to \$246m**
- * **TGA APPROVES POLYNOVO NOVOSORB FOR AUSTRALIAN REGISTER**
- * **FEDERAL, VC \$6m FOR PARAGEN HOOKWORM AUTO-IMMUNE DRUGS**
- * **CVC REDUCES TO 10.4% OF CYCLOPHARM**
- * **INNATE TELLS ASX: 'TRADING HALT FOLLOWED TRIAL BAD NEWS'**
- * **ADHERIUM HAILIE MONITOR DIRECT-TO-CUSTOMER O-T-C LAUNCH**
- * **CRESO: SCHMIDGALL FOR AUSTRIA, NORTHERN, EASTERN EUROPE**
- * **CSIRO APPOINTS DR CATHY FOLEY CHIEF SCIENTIST**
- * **COCHLEAR DIRECTOR PROF EDWARD BYRNE TO RETIRE**
- * **MEMPHASYS 15-TO-1 CONSOLIDATION RECORD DATE**

MARKET REPORT

The Australian stock market was up 0.76 percent on Tuesday August 14, 2018 with the ASX200 up 47.4 points to 6,299.6 points. Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and three were untraded.

Oncosil was the best, up two cents or 12.1 percent to 18.5 cents with two million shares traded. Imugene climbed 10.6 percent; Factor was up 6.7 percent; Optiscan improved 5.3 percent; LBT and Pharmaxis were up more than four percent; Clinuvel, Pro Medicus and Uscom were up more than three percent; Benitec, Opthea and Polynovo rose more than two percent; Avita, Nanosonics and Osprey were up more than one percent; with Resmed up 0.07 percent.

Reva led the falls, down three cents or 11.1 percent to 24 cents with 23,600 shares traded. Neuren lost 7.75 percent; Prescient fell 6.6 percent; Cochlear, Ellex and Impedimed retreated more than three percent; Airxanders, Cynata and Immutep shed more than two percent; Bionomics, Cyclopharm, Genetic Signatures, Mesoblast and Starpharma were down more than one percent; with CSL, Medical Developments and Sirtex down by less than one percent.

COCHLEAR

Cochlear says total revenue for the 12 months to June 30, 2018 was up 9.0 percent to \$1,351,400,000 with net profit after tax up 9.9 percent to \$245,800,000.

In a media release, Cochlear chief executive officer Dig Howitt said that the “continued to execute on our strategy of investing to retain market leadership and drive market growth”.

“Our market leadership position was enhanced by new product launches and improvements in the service offering to our customers,” Mr Howitt said.

“Market growth continued as awareness, indications and funding grew ... and the expansion of direct-to-consumer marketing and focus on sales force expansion and effectiveness continued to support overall growth,” Mr Howitt said.

Mr Howitt said that selling the 500,000th implant was “a major milestone”.

He said the company expected to report an eight to 12 percent increase in net profit after tax of \$265 million to \$275 million for the year to June 30, 2019.

Cochlear said that revenue from the Americas was up 9.0 percent, with the Europe, Middle East and Africa up 11.8 percent and the Asia-Pacific up 3.6 percent.

The company said that its cochlear implant revenue was up eight percent contributing 62 percent of total sales revenue, with services, including sound processor upgrades, composing 26 percent of sales revenue and acoustics, or bone conduction and acoustic implants responsible for 12 percent of sales revenue.

Cochlear said that the investment in research and development was up 10.4 percent to \$167.7 million or 12.4 percent of revenue, compared to the previous year’s 13.4 percent.

The company said the final 100 percent franked dividend was up 14.3 percent to \$1.60 to be paid on October 10, 2018, based on a record date of September 18, taking the full year dividend to \$3.00 compared to the previous year’s \$2.70 “and representing a payout of 70 percent of net profit.

Cochlear said that basic earnings per share climbed 9.5 percent to \$4.27, compared to the previous year’s \$3.90, it reduced net debt by \$43.2 million to \$86.2 million and held cash and cash equivalents of \$61.5 million at June 30, 2018, compared to \$89.5 million the previous year.

Cochlear fell \$6.03 or three percent to \$192.75 with 732,231 shares traded.

POLYNOVO

Polynovo says its Novosorb biodegradable temporizing matrix (BTM) wound treatment has been listed as approved for sale on the Australian Register for Therapeutic Goods.

Polynovo said the wound treatment, classified as a device, was indicated for use where the dermis of the skin had been lost, regardless of cause including surgical removal, trauma, wounds or burns.

Polynovo said that the wide indication for use followed detailed presentation of the clinical use of Novosorb BTM over the past three years and the “outstanding performance, clinical outcomes and patient benefits” were well documented.

The company said it would direct-sell in Australia and a sales representative had been marketing to a limited number of hospitals under an Australian Therapeutic Goods Administration exemption, which would be “materially stepped-up and broadened”.

Polynovo said it would prepare a conformity assessment submission with a European notified body to gain Conformité Européenne (CE) mark approval for European sales.

The company said it intended to use a direct sales force in the UK and would recruit a business development person based in England to begin the hospital access processes with the National Health Service, with sales to begin in the next financial year.

Polynovo was up 1.5 cents or 2.9 percent to 53 cents with 2.2 million shares traded.

PARAGEN BIO PTY LTD, ABBVIE VENTURES, MEDICAL RESEARCH COMMERCIALISATION FUND, ONEVENTURES, FEDERAL GOVERNMENT

Paragen says three venture capital firms have invested \$6 million in the James Cook University spin-out for a hookworm-based prevention of auto-immune diseases.

The Cairns-based Paragen Bio said that Abbvie Ventures, Brandon Capital's Medical Research Commercialisation Fund and Oneventures had invested in "the first biotech startup from [the Townsville-based] James Cook University [which was] one of just a handful of biotech companies in Northern Queensland".

Separately, the Federal Health Minister Greg Hunt said that \$367,000 had been invested through the Australian Government's Biomedical Translation Fund

Paragen said that it was focused on autoimmune diseases, which caused the immune system to attack healthy tissues and organs, leading to the deterioration and potentially the complete destruction of tissue.

The media release said that Paragen's technology was based on hookworm research at James Cook University's Cairns-based Australian Institute of Tropical Health and Medicine, led by Prof Alex Loukas and his team over the past eight years.

Paragen said that hookworms were blood-sucking parasites that infected humans in tropical regions with poor sanitation, but "a modern lifestyle and access to anti-worm therapies [meant] the prevalence of hookworm infections in humans ... [was] decreasing".

The company said the lack of infection was linked to a rise in auto-immune diseases such as rheumatoid arthritis, inflammatory bowel disease, asthma, and allergic diseases.

Paragen said that in previous Australian Institute of Tropical Health and Medicine clinical trials, researchers had shown that experimental infection of human subjects with whole hookworms could protect against the onset of autoimmune diseases.

The company said that proteins from hookworm saliva could prevent the development of symptoms associated with a range of inflammatory diseases.

Paragen said the \$6 million investment would assist the development of new medicines sourced from hookworms to treat autoimmune diseases.

Paragen director and Abbvie Ventures managing-director Margarita Chavez said the syndicate of investors was 'a testament to the high-calibre research coming from Australia and James Cook University, in particular'.

"Autoimmune diseases are reaching epidemic proportions in developed countries and there is an urgent need for new therapeutic approaches," Prof Loukas said.

"At Paragen Bio we're being guided in our drug discovery efforts by millennia of co-evolution between parasitic hookworms and their mammalian hosts, and in particular the effect hookworms can have on our immune systems," Prof Loukas said.

A Paragen spokesman said the company would complete pre-clinical work ahead of potential human clinical trials.

CYCLOPHARM

CVC says that it has reduced its substantial shareholding in Cyclopharm from 8,137,729 shares (11.92%) to 7,142,729 (10.39%).

The Sydney-based CVC said the shares were held directly and through Stinoc Pty Ltd.

CVC said that on August 8, 2018, Stinoc sold 1,000,000 shares on-market for \$898,155 or 89.82 cents a share; and between June 29 and July 4, 2018 it bought 5,000 shares for \$5,013 or \$1.00 a share.

CVC director Alexander 'Sandy' Beard is a former director of Cyclopharm appointed in April 2011 and resigning in July 2011 and (BD: Apr 29, 2011).

Cyclopharm fell one cent or 1.1 percent to 89 cents.

INNATE IMMUNOTHERAPEUTICS

Innate has told an ASX aware query that it called a trading halt for its MIS416 multiple sclerosis trial results four hours after receiving the news (BD: Jun 27, 2017).

Last week, US authorities charged former Innate director and Republican congressman Christopher Collins and relatives with insider trading in relation to Innate shares and the announcement of the failure of MIS416 to show a statistically significant benefit for multiple sclerosis (BD: Aug 9, 2018).

The US Department of Justice indictment said that Mr Collins had telephoned his son Cameron Collins with the bad news and Cameron Collins and Stephen Zarsky sold shares through the US over-the-counter market during the Australian trading halt.

The US Department of Justice said Christopher Collins learned of the results about 7pm June 22, 2017 US EST, about 9am AEST time on June 23, 2017.

The timelines provided in the indictment showed that no share sale orders were sent by Cameron Collins until about 7.42am US EST on June 23; or 9.42pm AEST June 23, about nine hours after the trading halt was imposed, and they were executed at 9.30am US EST when the over-the-counter market opened.

In its query, the ASX said that "it appears that Innate was aware of the relevant information prior to requesting the trading halt".

"Please explain why Innate did not request the trading halt prior to 12.26pm on June 23, 2017, commenting specifically on why Innate did not request the trading halt prior to the commencement of trading.

Innate said that chief executive officer Simon Wilkinson "received the initial drug trial results on Friday June 23, 2017 through a telephone call which ended at 8:30am AEST, and not on June 22, as referred to in the indictment".

"The company, its directors, officers and staff had no knowledge whatsoever of the initial drug trial results prior to Friday June 23, 2017 (AEST)," Innate said.

The ASX did not ask Innate when it first became aware that millions of shares had been sold in the US during the trading halt.

The ASX asked whether Christopher Collin sold shares during the relevant closed period and the company said he did not and had "never sold a share in the company" in the lead up to events in question.

The indictment said that Christopher Collins did not trade shares at that time, losing millions of dollars in value and he was "virtually precluded from trading his own shares for practical and technical reasons" because he was already under investigation by the Office Of Congressional Ethics in connection with his holding in and promotion of, Innate and his shares were held in Australia subject to the trading halt.

Innate was up 2.5 cents or 7.8 percent to 34.5 cents.

ADHERIUM

Adherium says that it has officially launched its Haille inhaler monitoring device for over-the-counter and direct to customer sales.

Adherium said the Haille device, formerly known as Smartinhaler, measured the use of inhalers for asthma and chronic obstructive pulmonary disorder through sensors and a smartphone application (BD: May 17, 2018).

In March, the company said it had US Food and Drug Administration approval for the then Smartinhaler (BD: Mar 27, 2018).

Adherium said that Haille device had a sensor that attached to inhaler medication devices, tracked medication use and reminded users when it was time to take doses.

Adherium fell 0.9 cents or 10 percent to 8.1 cents.

CRESO PHARMA

Creso says that Dr A & L Schmidgall GmbH & Co KG will market its cannabidiol (CBD) Cannaqix and other products in Austria and Eastern and Northern Europe.

Creso said that the Hedoga Group subsidiary Schmidgall was an over-the-counter pharmaceutical sales and marketing company.

The company said that the marijuana-based Cannaqix food additive was developed “to help reduce stress and to support mental and nervous functions”.

Creso chief executive officer Dr Miri Halperin Wernli said “we are really excited to commercialize Cannaqix in Austria with Dr A & L Schmidgall GmbH & Co KG and we are looking forward to expanding with them to other markets in Europe, such as the Eastern European and Nordic countries”.

Creso was up half a cent or one percent to 52 cents.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation says it has appointed Dr Cathy Foley as its chief scientist, effective from September 24, 2018.

The CSIRO said that Dr Foley was a physicist and science leader “most noted for her work developing superconducting devices and systems which have assisted in unearthing over \$6 billion in minerals worldwide”.

The Organisation said that Dr Foley’s priority would be promoting science, technology engineering and mathematics (STEM) and women in science.

“Australia’s future prosperity will be fuelled by science,” Dr Foley said.

“Science which creates new industries, new jobs and shapes the minds and aspirations of our future leaders,” Dr Foley said.

“We can’t keep thinking about science as something which is locked away in a lab,” Dr Foley said. “It connects and drives everything we touch and do.”

The CSIRO said that Dr Foley was currently the deputy director and science director of its manufacturing business unit.

The Organisation said that Dr Foley had been “an advocate for women in science, for the communication of science and science education over the past 30 years” and helped develop Landtem, which uses superconductors to detect underground minerals.

CSIRO chief executive Dr Larry Marshall said Dr Foley was “an incredible leader and scientist ... a great contributor, with a passion for turning excellent science into powerful solutions for Australia”.

The Organisation said that Dr Foley was awarded a public service medal on Australia Day 2003 and in the same year won the Eureka Prize for the promotion of science.

The CSIRO said that Dr Foley won the New South Wales Premier's Award for Woman of the Year in 2013.

The Organisation said that Dr Foley was a fellow of London’s Institute of Physics and past president of both the Australian Institute of Physics and Science and Technology Australia representing 65,000 Australian scientists, a fellow of the Academy of Technological Sciences and Engineering and winner of the Telstra Business Women’s Award for Innovation in 2009.

CSIRO said she joined its Division of Applied Physics in 1985 as a national research fellow, was promoted to senior research scientist in 1991, principal research scientist in 1996, senior principal research scientist in 2000 and chief research scientist in 2008.

Dr Foley is a Biotech Daily reader.

COCHLEAR

Cochlear says that non-executive director Prof Edward Byrne will retire at the end of the next annual general meeting to be held on October 16, 2018.

Cochlear said that Prof Byrne joined Cochlear on July 1, 2002 and was chairman of the medical science committee.

Cochlear chairman Rick Holliday-Smith said that Prof Byrne “has provided invaluable counsel in his 16 years of service to Cochlear’s board”.

“His extensive experience in medicine and clinical neurology and research as well as his dedication to Cochlear have contributed greatly to Cochlear’s strategic direction and success over many years,” Mr Holliday-Smith said.

“On behalf of the board, I would like to sincerely thank Ed for his service and contribution to Cochlear and wish him well for the future,” Mr Holliday-Smith said.

Cochlear said that in anticipation of Prof Byrne’s retirement it had appointed Prof Bruce Robinson as a director in December 2016 and he assumed the role of chairman of the medical science committee in December 2017 (BD: Dec 13, 2016).

MEMPHASYS

Memphasys says that the record date for the 15-to-one consolidation of its issued capital is August 17, 2018.

Memphasys said that a total of 5,458,839,182 ordinary shares and 224,971,876 options would be consolidated.

The company said that on a post-consolidation basis, it would have 363,922,613 shares and 14,998,126 options on issue.

On August 6, 2018, Memphasys said its extraordinary general meeting approved the consolidation.

Memphasys was untraded at 0.1 cents.