



# Biotech Daily

Thursday August 9, 2018

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: PRESCIENT UP 16%; ONCOSIL DOWN 10%**
- \* **INNATE EX-DIRECTOR CHRIS COLLINS, FAMILY 'INSIDER TRADING'**
- \* **FEDERAL \$1.3m FOR 2 MEN'S HEALTH GRANTS**
- \* **FDA EXPANDS AVITA RECELL COMPASSIONATE USE TO 108 PATIENTS**
- \* **AUSCANN RAISES \$1.9m OF HOPED-FOR \$8m; TOTAL \$35.3m**
- \* **ADMEDUS, SUMMIT EXTEND DISTRIBUTION TO 2026**
- \* **QBIOTICS: VIRBAC FOR EBC-46 DOG CANCER SALES IN US, EU**
- \* **NAOS TAKES 17% OF BTC HEALTH**

## MARKET REPORT

The Australian stock market was up 0.47 percent on Thursday August 9, 2018 with the ASX200 up 29.2 points to 6,297.7 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and four were untraded. All three Big Caps fell.

Prescient was the best, up 1.5 cents or 15 percent to 11.5 cents with 8,000 shares traded.

Opthea and Optiscan climbed more than eight percent; both Imugene and Pharmaxis were up five percent; Avita was up 3.5 percent; Genetic Signatures, Polynovo and Universal Biosensors rose two percent or more; Medical Developments, Nanosonics, and Telix were up more than one percent; with Compumedics, Cyclopharm, Cynata and Mesoblast up by less than one percent.

Oncosil led the falls, down two cents or 10 percent to 18 cents with 5.3 million shares traded.

Airxpanders and Neuren lost more than seven percent; Impedimed fell 4.3 percent; Actinogen, Dimerix and LBT were down more than three percent; Clinuvel and Pro Medicus shed more than two percent; Bionomics and Starpharma were down more than one percent; with Cochlear, CSL, Resmed and Sirtex down by less than one percent.

## [INNATE IMMUNOTHERAPEUTICS.](#)

US authorities have charged former Innate director and Republican congressman Christopher Collins and relatives with insider trading in relation to Innate shares. The current Innate is effectively a new company having acquired Amplia Therapeutics, this year, with a significant change of directors, staff and shareholders (BD: Apr 26, 2018). The US Department of Justice said the New York Southern District attorney Geoffrey Berman and the Federal Bureau of Investigation arrested Mr Collins, his son Cameron and the father of Cameron Collins's fiancée Stephen Zarsky in relation to trading shares prior to the multiple sclerosis trial result announcement (BD: Jun 23, 27, 2017). On Friday June 23, 2017, Innate called a trading halt and on Tuesday June 27, said that MIS416 failed to meet its primary endpoint, with the share price falling 92.3 percent to 4.9 cents - having peaked at \$1.83, on news that Republicans close to US President Donald Trump including Health Secretary Dr Tom Price were shareholders (BD: Jan 22, 2017). The Department of Justice said Christopher and Cameron Collins and Mr Zarsky were charged with "participating in a scheme to commit insider trading" citing 12 counts of conspiracy to commit securities fraud, securities fraud, conspiracy to commit wire fraud, wire fraud and false statements, with penalties ranging from five to 20 years gaol. The media release said that Christopher Collins "possessed material, non-public information ... betrayed his duties of trust and confidence to Innate by providing inside information ... about confidential drug trial results so that his son and others, including Zarsky, could trade before the drug trial results were publicly announced". The Department said Cameron Collins, Zarsky and others who were tipped off avoided \$US768,000 (\$A1,030,900) in losses and when interviewed by the FBI the three "made false statements to cover up their participation in the insider trading scheme", with the US Securities and Exchange Commission filing a civil action against the three. The Indictment said that Cameron Collins passed the drug trial information to Zarsky and three unnamed conspirators, Zarsky passed the information to three more unnamed conspirators and all of the trades preceded the release of the negative drug trial results. The Indictment said that on June 22, at about 7pm (US EST; 9am AEST on June 23) Christopher Collins received an email with the results and contacted his son Cameron. Innate called a trading halt at 12.53pm on Friday June 23, emerging from the halt with the trial news at 9.11am on June 27, 2017, with the Indictment saying Cameron Collins placed orders to sell his shares during the Australian trading halt. A Department of Justice media officer told Biotech Daily the shares were sold through the US Over-The-Counter market. "After the public announcement, Christopher Collins took steps to prevent the public from learning that Cameron Collins had sold significant portions of his Innate stock on or about June 23, 2017 and June 26, 2017, before the public announcement," the Indictment said. The Indictment said that many of the Cameron Collins sale orders were made following discussions with his father and in one case, Cameron Collins placed an online order to sell 50,000 Innate shares "while the two were still on the phone". Last year, following an official complaint, the Australian Takeovers Panel determined that although the combined Collins family holding was more than 20 percent, an association had not been established (BD: Feb 15, 20, 21, 2017). Today, Innate said it had co-operated with US Securities and Exchange Commission information requests and none of its directors or officers were under investigation. Biotech Daily editor David Langsam bought Innate shares following the March Amplia deal announcement and confirmation that Mr Collins would resign, but prior to Mr Collins formal resignation (BD: Mar 23, 28, 2018). Innate was untraded at 29.5 cents.

## FEDERAL GOVERNMENT

The Federal Minister for Health Greg Hunt says that two medical research grants worth \$1.3 million is “the first step towards a new national male health strategy”.

A media release from Mr Hunt said that the National Male Health Strategy 2020-2030, aimed “to improve the health and wellbeing of all men in Australia over the next decade, especially those at the greatest risk of poor health”.

Mr Hunt said that two National Health and Medical Research Council grants totaling \$1.3 million would “go towards new approaches for prostate cancer and research into understanding male infertility”.

The media release said the recipients were Monash University’s Prof Melissa Southey and the University of Newcastle’s Prof Brett Nixon.

Mr Hunt said Prof Southey was “working on a new way to manage prostate and breast cancer using precision medicine, which will substantially improve health outcomes”.

The media release said that Prof Nixon was “working to improve our understanding of sperm function and the causes of male infertility”.

Yesterday, Mr Hunt announced 29 medical research grants worth \$18 million as “the first step towards a new national women’s health strategy” (BD: Aug 8, 2018).

Today, Mr Hunt said that “we know that men have different health challenges to women, and that their outcomes are often worse”.

“Experts in male health, representatives of disadvantaged populations and peak medical bodies met in Canberra today to develop the new 10-year plan,” Mr Hunt said.

“Together we identified key issues and priorities to help us improve the health outcomes for men across the country,” Mr Hunt said.

## AVITA MEDICAL

Avita says the US Food and Drug Administration has approved a 20-patient increase for the use of Recell under the compassionate use investigational device exemption.

Avita said the FDA had approved the use of its “autologous cell harvesting device” to up to 108 patients with life-threatening injuries, including severe burns.

The company said the FDA had given approval for up to 26 US burn centers to participate in the program.

Earlier this year, Avita said it had received its fifth expansion to the compassionate use protocol for Recell when the FDA granted it a 20-patient increase to 88 patients (BD: Feb, 12, 2018).

Today, Avita said that 82 patients had been treated using Recell under the compassionate use protocol for patients who had insufficient healthy skin for standard skin grafting treatment of injuries and whose treating physicians believed there to be no suitable alternative treatment.

Avita chief executive officer Dr Michael Perry said the company was “encouraged by the fact that 24 US burn centers have treated patients with the Recell device through a combination of our clinical trials, continued access program and compassionate use program, giving the product candidate broad exposure within the US burn community”.

“Combined with the over 7,000 patients who have been treated with the Recell device globally, these programs provide us with a large body of experience regarding the potential clinical benefits as well as the costs savings associated with use of the Recell device,” Dr Perry said.

Avita was up 0.3 cents or 3.5 percent to 8.9 cents with 11.1 million shares traded.

## AUSCANN

Auscann says its share purchase plan has raised \$1,934,200 of a hoped-for \$8 million, bringing the total raised to \$35.33 million.

Auscann said the share plan for existing shareholders was at \$1.05, a 4.5 percent discount to the July share placement price of \$1.10 and a 5.6 percent discount on the five-day volume weighted average price prior to July 16, 2018.

Last month, Auscann said it had raised \$33.4 million in a placement to Australian and North American institutional and sophisticated investors (BD: Jul 5, 2018).

Today, the company said the funds would be used for cannabinoid research and development and clinical studies, expansion of its operations in Chile and Australia, medical outreach programs in new markets and working capital.

Auscann was untraded at 96.5 cents.

## ADMEDUS

Admedus says it has renewed its agreement to distribute Summit Medical Products in Australia and New Zealand until 2026.

Admedus said the renewed agreement meant Admedus would remain the exclusive distributor of the Utah-based Summit's Ambit infusion products in Australia and New Zealand.

The company said the renewed agreement confirmed "the longstanding relationship between the two companies, which began in 2007".

Admedus is in a capital raising suspension and last traded at 13.5 cents.

## QBIOTICS

Qbiotics says Virbac will market and distribute its EBC-46, or tigilanol tiglate, for solid tumor cancers in dogs in the US, Switzerland, Norway, the UK and the EU.

In 2016, Qbiotics said its eight-patient phase I/II human trial of EBC-46 for solid tumors showed the drug was well-tolerated with evidence of efficacy (Aug 15, 2016).

At that time, the company said the human response was "very similar to what has been seen in the successful veterinary studies with EBC-46 where full tumor destruction is noted".

Today, Qbiotics said it had completed a US efficacy registration trial in more than 120 dogs and had found that tumor destruction "usually occurred within five to seven days of administration with the site fully healed within approximately three to four weeks".

The company said it planned to submit marketing registrations with the US Food and Drug Administration Center for Veterinary Medicine and the European Medicines Agency by October 2018.

The company said that after receiving approval, the Carros, France-based Virbac would market and distribute EBC-46 in the US and Europe and that it intended to register and expand into "other focus territories including Australia, New Zealand and Canada".

Qbiotics said EBC-46 had "demonstrated anticancer potential in a range of solid tumors in over 500 companion animals" including dogs, cats and horses.

The company said that EBC-46 was administered by injection directly into the tumor and that treatments generally did not require the local or general anaesthetics.

Qbiotics said that the only main side effects of the drug were "a function of its tumor destruction action, resulting in localized and transient swelling and moderate pain for the first few days".

Qbiotics is a public unlisted company.

### [BTC HEALTH \(FORMERLY BIOTECH CAPITAL\)](#)

Naos Asset Management says it has increased its substantial shareholding in BTC Health from 20,698,986 shares (15.89%) to 22,038,246 shares (16.91%).

The Sydney-based, Naos said it was the investment manager for “various trustee companies” and the registered holder was Australian Executor Trustees, but yet again failed to cite the cost of the 1,339,260 shares acquired on-market, as required under the Corporations Act 2001 (BD: Feb 24, Jun 14, Aug 1, Nov 14, 2017; Feb 7, 2018). Biotech Capital was untraded at 18.5 cents.