



# Biotech Daily

Wednesday August 7, 2019

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: OPTHEA UP 138%; ALTERITY (PRANA) DOWN 15%**
- \* **OPTHEA JUMPS 160% ON OPT-302 WET AMD RESULT**
- \* **CSL TO MOVE 3km TO HAYMARKET; VICTORIA GOVERNMENT**
- \* **GENETIC TECHNOLOGIES ENDS BLOCKSHINE J-V; BACK ON ASX**
- \* **CORRECTION: CELLMID**
- \* **NOVITA RIGHTS OFFER FOR \$2m**
- \* **PARADIGM FILES ZILOSUL FDA IND, EXPANDED ACCESS FOR OA**
- \* **ALTHEA PRESCRIBES 1,523 MEDICAL MARIJUANA PATIENTS**
- \* **SUMMIT MEDICAL TRANSFERS BTC DISTRIBUTION TO AVANOS**
- \* **MGC COMPLETES CHINA MARIJUANA FOOD ADDITIVE MARKET TEST**
- \* **TOTAL BRAIN, CNA INSURANCE WORK ON MENTAL HEALTH**
- \* **ZHANG LISHAN, STAR BRIGHT TOOK 23% OF ADMEDUS LAST YEAR**

## MARKET REPORT

The Australian stock market rose 0.64 percent on Wednesday August 7, 2019, with the ASX200 up 41.4 points to 6,519.5 points. Twenty-three Biotech Daily Top 40 stocks were up, eight fell, seven traded unchanged and two were untraded. All three Big Caps rose.

Opthea was the best, climbing as much as \$1.385 or 160.1 percent to \$2.25 before closing up \$1.195 or 138.15 percent at \$2.06 with 8.0 million shares traded. LBT was up 10.5 percent; Pharmaxis rose 9.1 percent; Antisense improved 8.7 percent; Amplia, Avita and Patrys climbed more than four percent; Genetic Signatures, Oncosil, Polynovo, Proteomics, Resonance and Telix were up more than three percent; Clinuvel, Mesoblast, Nanosonics, Paradigm, Pro Medicus and Volpara rose more than two percent; Cochlear, Cynata, Ellex, Kazia, Medical Developments and Resmed were up more than one percent; with CSL up 0.7 percent.

Alterity (Prana) led the falls, down 0.4 cents or 14.8 percent to 2.3 cents, with 1.7 million shares traded. Actinogen lost 11.1 percent; Uscom fell 4.35 percent; Compumedics and Orthocell were down more than three percent; with Neuren, Prescient and Universal Biosensors down more than two percent.

## OPTHEA

Opthea says its 366-patient phase IIb trial of OPT-302 for wet age-related macular degeneration met its primary endpoints with statistical significance ( $p = 0.0107$ ).

Opthea said that higher dose 2.0mg OPT-302 vascular endothelial growth factor receptor 3 (VEGF-3) with ranibizumab (Lucentis, a VEGF-A inhibitor compound) showed the statistically significant difference at 24 weeks of treatment, compared to both low dose 0.5mg OPT-302 with ranibizumab and control with ranibizumab.

The company said that 2.0mg OPT-302 with ranibizumab was superior to ranibizumab alone for the measured secondary endpoints, with OPT-302 intravitreal injections “well tolerated, with the safety profile similar to the control group” and the independent data and safety monitoring board confirming that “no safety risks were identified”.

Opthea said that patients administered 2.0mg OPT-302 combination therapy gained a mean of 14.2 letters of vision from baseline on the Early Treatment of Diabetic Retinopathy Study standardized eye chart at 24 weeks, compared to 10.8 letters in the control group, a statistically significant benefit of 3.4 letters ( $p = 0.0107$ ), while the 0.5mg OPT-302 low dose group had a similar outcome to the control group with a gain of 9.4 letters compared to 10.8 letters, respectively.

Opthea said that OPT-302 2.0mg combination showed improvements in secondary endpoints, including a higher proportion of patients with stable vision (15 letters or fewer loss from baseline) and those gaining 10 letters and 15 letters or more of visual acuity.

The company said 45.0 percent of the OPT-302 2.0mg group gained 15 or more letters from baseline to week 24, compared to 40.5 percent of the Lucentis control group, with 70.0 percent gaining 10 or more letters compared with 57.8 percent, respectively.

Opthea said that stable vision was achieved in 99.2 percent with the OPT302 2.0mg group, compared to 96.7 percent of the Lucentis control group.

The company said excess retinal thickness was decreased and normalized across all treatment groups, with the 2.0mg OPT-302 group reducing mean central subfield thickness by 147 micrometres ( $\mu\text{m}$ ), from 414 $\mu\text{m}$  at baseline to 266  $\mu\text{m}$ , compared to 134 $\mu\text{m}$ , from 413 $\mu\text{m}$  at baseline to 278 $\mu\text{m}$  in the Lucentis group.

King’s College London surgeon and chief investigator Prof Tim Jackson said that “in testing for superiority against very intensive anti-VEGF-A therapy, the bar was set high ... [and] despite this, OPT-302 2.0mg combination therapy showed statistical superiority for the most accepted and sensitive primary efficacy outcome - mean visual acuity”.

“Taken together, these results indicate that combined suppression of VEGF A, C and D has considerable potential as a novel treatment for wet [age-related macular degeneration], Prof Jackson said.

Investigator Dr Pravin Dugel said that the “highly significant result and meaningful additional clinical efficacy .... [was] a great achievement”.

“OPT-302 has the potential to be a game-changer ... not just for wet AMD but also for other debilitating retinal vascular diseases,” Dr Dugel said.

Opthea chief executive officer Dr Megan Baldwin told a teleconference this morning that the company had funds to prepare for a phase III trial “and will move forward with the 2.0mg dose”.

Dr Baldwin said that the company needed to investigate the dose-response further and complete the pharmaco-kinetic analyses.

Opthea said it had about \$20 million in cash and expected about \$14 million from a Federal Research and Development Tax Incentive later this year, and the trial reported “six months ahead of schedule leading to substantial cost savings”.

Opthea climbed as much as \$1.385 or 160.1 percent to \$2.25 before closing up \$1.195 or 138.15 percent at \$2.06 with 8.0 million shares traded.

## [CSL, VICTORIA GOVERNMENT](#)

CSL says it will move its headquarters from Poplar Road Parkville to Elizabeth Street Haymarket to be closer to the Parkville biomedical precinct.

In media releases, both the Victoria Government and CSL said the move would increase CSL's presence in the Parkville precinct and "cement Melbourne's place as a world-class research destination".

Victoria Minister for Priority Precincts Gavin Jennings said that CSL would join the concentration of research facilities, hospitals and universities on the northern edge of Melbourne's central business district.

Mr Jennings said the headquarters was due to open in 2024 with 800 workers relocating from existing campuses on Poplar Road and Docklands and "hundreds of jobs will be created during construction".

Mr Jennings said that a currently underway Parkville railway station would add to transport options from 2025 "and the CSL vote of confidence is expected to lead to further investment in Melbourne's burgeoning biomedical precinct".

A spokesperson for CSL told Biotech Daily that CSL said it would occupy one of three planned buildings to be built at 645 Elizabeth Street on the West side of the street, just South of the Haymarket roundabout.

The CSL media release said that the new facility would "foster and support collaborations between academic biomedical research and industry, creating important linkages in the benchtop-to-bedside translation of new medicines for unmet medical needs".

CSL chief executive officer Paul Perreault said that Melbourne's reputation "as a world class centre of biomedical research excellence is well established".

"CSL's collaborations within the precinct span more than a hundred years," Mr Perreault said.

"We have opportunities all around the world and [research and development] in several countries, but we believe the density and quality of medical research activity in Parkville has enormous future potential," Mr Perreault said.

CSL said the building would include seven floors of office work spaces and nine floors of laboratories and research and clinical phase production suites.

The company said it would maintain its presence at the Bio21 Institute in Flemington Road, which currently housed 130 researchers, while Seqirus' influenza and antivenom manufacturing operations would remain at the Poplar Road campus for the foreseeable future.

CSL said its laboratories would be enclosed in floor-to-ceiling glass and circumnavigated by a continuous corridor, enabling safe, transparent viewing of biotechnology production activities for a range of precinct visitors, including educational opportunities for students and young researchers.

The company said that planning had begun with project completion scheduled for 2024.

The two media releases said that the Victoria Government and the University of Melbourne intended to commission a feasibility study to maximise the jobs and economic development potential of Parkville similar to powerhouse biotechnology and innovation precinct developments elsewhere in the world.

CSL said that clusters of geographically close or co-located research and clinical facilities could be highly significant.

"Innovation depends on the exchange of ideas among individuals and in the biotechnology and pharmaceutical space, real ecosystems are created by the co-location or geographic closeness of pharmaceutical companies, research institutes, hospitals and world-class universities," CSL said.

CSL was up \$1.45 or 0.7 percent to \$218.88 with 701,340 shares traded.

## GENETIC TECHNOLOGIES

Genetic Technologies says it has cancelled its joint venture with Blockshine Health and the ASX has cancelled its suspension.

Last week, the ASX suspended Genetic Technologies pending an announcement of an ASX listing rules chapter 10 breach, dealing with “transactions between an entity ... and persons in a position to influence the entity” (BD: Aug 2, 2019).

In 2018, Genetic Technologies said that subsidiary, Gene Ventures, signed an agreement with the Shanghai, China-based Blockshine Technology Corp to provide \$250,000 for a 49 percent stake in a joint venture company called Blockshine Health (BD: Dec 21, 2018).

Today, the company said it considered Blockshine Health to be an associate of a related party to the company because former non-executive director Sam Lee had a shareholding in both Blockshine Technology and Genetic Technologies.

Last month, Genetic Technologies said Mr Lee failed to tell the company that he sold all of his 59,594,850 company shares on May 13 until June 3 and later said he had resigned from the company (BD: Jun 11, Jul 9, 2019).

Today, the company said Mr Lee was a director and related party and his spouse was a related party and held 100 percent of shares in Blockshine Technology at the joint venture agreement date.

Genetic Technologies said Blockshine Technology was therefore a related party because it was controlled by a related party.

The company said Blockshine Health was a Blockshine Technology subsidiary, which held 51 percent of shares in the joint venture company.

Genetic Technologies said it breached Listing Rule 10.1.4 by agreeing to pay \$250,000 to Blockshine Health, an associate of a related party, without shareholder approval.

The company said it sought legal advice at the time of the joint venture agreement but the requirement for shareholder approval was not raised, which it considered “an unfortunate and inadvertent oversight”.

Genetic Technologies said an investment of \$235,000 or less would not have required shareholder approval and would not have breached the ASX listing rules.

Last year, the company said it had a framework agreement with Blockchain Global, approved by shareholders, to combine genetic screening and blockchain technology and it would issue 486,000 shares to Blockchain in three tranches subject to the achievement of certain milestones. (BD: Aug 2, Nov 29, 2018).

Today, Genetic Technologies said no shares had been issued to date as no milestones had yet been achieved and it needed to reach and maintain a share price of 2.5 cents prior to the issue of milestone shares, which would lapse between December 27, 2019 and June 27, 2020.

Genetic Technologies was unchanged at half a cent with 3.2 million shares traded.

## CELLMID

Last night’s edition incorrectly reported that Cellmid’s South Korea distributor was the Channai, Tamil Nadu, India-based K2B Co.

Cellmid chief executive officer Maria Halasz told Biotech Daily that the distributor was based in Seoul, South Korea.

An internet web design company, K2B Solutions, is based in Channai.

The mistake was made by a contract sub-editor who formerly relied on hurried Google searches for information and has been dismissed.

Biotech Daily apologises unreservedly to both Cellmid and the Seoul-based K2B Co.

Cellmid was unchanged at 22 cents.

### [NOVITA HEALTHCARE](#)

Novita says it hopes to raise up to \$2 million in a five-for-11, pro-rata, non-renounceable rights offer at one cent a share.

Novita said the offer price was a 10 percent discount to the last traded price on August 6, 2019 and an 18.9 percent discount to the 15-day volume weighted average price.

The company said the record date for the rights offer would be August 12, with the offer opening on August 13 and closing on August 22, 2019.

The company said the funds would be used for its Tali Detect and Tali Train products, along with associated capital expenditures, operating costs and working capital.

Novita said PAC Partners Securities was the lead manager to the offer, which was not underwritten.

Novita was unchanged at 1.1 cents with 2.7 million shares traded.

### [PARADIGM BIOPHARMACEUTICALS](#)

Paradigm says it has filed its first investigational new drug application to the US Food and Drug Administration to treat 10 patients with Zilosul for early-onset osteoarthritis.

Paradigm said the request for the expanded access program of Zilosul, or injectable pentosan polysulfate sodium (PPS), would include retired National Football League players, who were three times more likely to have early-onset osteoarthritis and had failed the standard-of-care.

The company said that if the application was granted, it would treat a small group of patients with bone marrow oedema lesion-associated pain and joint stiffness in knee osteoarthritis and failed standard-of-care by October 2019, to prepare for a phase III trial. Paradigm was up three cents or 2.2 percent to \$1.40.

### [ALTHEA GROUP](#)

Althea says 245 healthcare professionals have prescribed 1,523 Australian patients with its medical marijuana products.

Althea said 334 patients were added in July, the largest number of new patients prescribed in any month, to date.

The company said it had an agreement with the Sydney-based Tetra Health to use its online education portal to educate its network of doctors about medical marijuana, including Althea products.

Althea was up three cents or 3.1 percent to \$1.00 with 2.05 million shares traded.

### [BTC HEALTH](#)

BTC says Summit Medical will transfer its products and distribution agreements to the Atlanta, Georgia-based Avanos Medical, including its BTC distribution agreement.

In May, BTC said it completed a \$6.3 million acquisition of the Admedus hospital infusion business, including Admedus' renewed agreement to distribute Summit products in Australia and New Zealand until 2026 (BD: Aug 9, 2018, May 31, 2019).

Today, the company said Summit Medical's rights and obligations under its exclusive distribution agreement with BTC Speciality Health would be assigned to Avanos and it would continue to exclusively distribute its products in Australia and New Zealand until December 31, 2026.

BTC fell 0.2 cents or two percent to 9.7 cents with 1.5 million shares traded.

## MGC PHARMACEUTICALS

MGC says it has completed an eight-week market test with Yushop Global to distribute its marijuana-based food additives in China.

MGC said it would begin marketing and sales through Yushop immediately and had shipped initial products to China to complete first orders.

MGC was up 0.3 cents or 6.4 percent to five cents with 2.6 million shares traded.

## TOTAL BRAIN

Total Brain says it has a two-year collaboration with Chicago's CNA Insurance to prove the link between mental health support and the quality of life of policy holders.

Total Brain said its digital mental health platform would assess and optimize users' core brain capacities to target resources and recommend daily use of digital brain exercises, breathing and meditation techniques.

The company said it hoped to reduce incidents and claim rates for a pre-identified large population of individuals.

Total Brain was unchanged at 2.2 cents.

## ADMEDUS

Zhang Lishan, Star Bright Holdings and associates say they increased their holding in Admedus in December from 70,556,169 shares (19.99%) to 133,453,435 shares (22.62). Last year, the Hong Kong-based Zhang Lishan, Star Bright and associates said they had become substantial shareholders in Admedus with 70,556,169, shares or 19.99 percent (BD: Sep 17, 2018).

Today, Melbourne law firm Norton Rose Fulbright said it had filed the substantial shareholder notice on behalf of the Star Bright Group, saying there was a change in interests on December 18, 2018, following an entitlement offer at eight cents a share on November 28, 2018.

Referring to Section 671B(6)(a) of the Corporations Act 2001, the Australian Securities and Investments Commission Regulatory Guide 5 says that a "substantial holding notice must be given within two business days of ... a movement of at least one percent in the person's substantial holding in the listed entity".

The notice, signed by Ms Zhang, said the holders of the shares included Star Bright, Constellation International Holdings Limited (CIHL), Constellation Immunotherapy Limited (CIL) and Carron Services Ltd, all of which had Hong Kong addresses.

Last year, Admedus said Star Bright Holding intended to take 60 percent of subsidiary Admedus Vaccines Pty Ltd for \$18 million with Admedus chief executive officer Wayne Paterson to be its chairman for five years (BD: Apr 27, 2017).

In 2017, Admedus said it was looking for alternative funding for the subsidiary, formerly known as Coridon, with research led by Gardasil inventor and head of the Brisbane-based Translational Research Institute Prof Ian Frazer (BD: Oct 30, 2017).

Earlier this year, the company said that sale had been terminated (BD: Apr 23, 2019)

Admedus was in a second extended suspension for a "recapitalization" and last traded at six cents.