



Biotech Daily

Thursday April 23, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH EVEN: ALTERITY UP 18%; OSPREY DOWN 17%**
- * **ONKO-INNATE, GILEAD, KITE WORK ON NK CANCER IMMUNOTHERAPIES**
- * **IMAGION 'OVERSUBSCRIBED' RIGHTS RAISE \$3m**
- * **CLINUVEL, WINHEALTH LAUNCH SCENESSE FOR EPP IN CHINA**
- * **CANADA SPECIAL ACCESS USE OF POLYNOVO'S NOVOSORB BTM**
- * **SDI: COVID-19 50% PROFIT WARNING, COST CUTTING**
- * **ADMEDUS: MORE THAN TWO QUARTERS CASH**
- * **RECCE: 'RECCE-327 REDUCES MRSA LOAD, HEALS WOUNDS IN RATS'**
- * **VISIONEERING REQUESTS CAPITAL RAISING TRADING HALT**
- * **CRYOSITE DIRECTOR ANDREW KROGER TAKES 40.3%**
- * **TDM GROWTH PARTNERS TAKES 23% OF SOMNOMED**
- * **G MEDICAL HIRES FOSUN, BOUSTEAD FOR NASDAQ IPO**
- * **POLYNOVO APPOINTS CEO PAUL BRENNAN MANAGING DIRECTOR**
- * **IMPRESSION TO TRIAL MARIJUANA IHL-216A FOR BRAIN INJURY**
- * **NOXOPHARM CLAIMS ISOFLAVONOID FOR GLIOBLASTOMA**

MARKET REPORT

The Australian stock market slipped 0.08 percent on Thursday April 23, 2020, with the ASX200 down 4.1 points to 5,217.1 points. Sixteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and two were untraded.

Alterity was the best, up 0.3 cents or 17.65 percent to two cents, with 167,222 shares traded. Dimerix climbed 12.1 percent; Compumedics and Prescient were up 10 percent or more; Impedimed improved 8.1 percent; Cynata and Paradigm rose more than six percent; Universal Biosensors was up 5.3 percent; Neuren and Resonance were up more than four percent; Antisense, Genetic Signatures, Next Science, Optiscan and Volpara rose more than two percent; Mesoblast was up 1.8 percent; with Resmed up 0.6 percent.

Osprey led the falls, down 0.2 cents or 16.7 percent to one cent, with 543,256 shares traded. Avita, Clinuvel, Immutep and Patrys lost more than six percent; Actinogen fell 4.8 percent; Starpharma was down 3.2 percent; CSL shed two percent; Cochlear, Medical Developments, Nanosonics, Orthocell, Polynovo and Proteomics were down more than one percent; with Ellex, Opthea, Pro Medicus and Telix down by less than one percent.

ONKO-INNATE PTY LTD

Melbourne's Onko-Innate says it has collaborations with Gilead Sciences and Gilead subsidiary Kite Pharma to develop natural killer (NK) drug and cell therapies.

Based at Monash University Onko-Innate said the three-year cancer immunotherapy research collaboration would support "discovery and development of next-generation drug and engineered cell therapies focused on natural killer cells".

Onko-Innate general-manager Dr Christine De Nardo told Biotech Daily that the collaboration with the Foster City, California-based Gilead would explore potential targets, while the collaboration with Kite was for NK cell therapies, including chimeric antigen receptor NK-cell (CAR-NK) therapies.

In a joint media release the companies said that Onko-Innate had "deep expertise in [natural killer] cell tumor biology".

The companies said that current cancer immunotherapy approaches primarily focussed on T-cell mediated anti-tumor immunity, including checkpoint inhibition and chimeric antigen receptor T-cell therapy.

The media release said that, like T-cells, NK-cells were a class of lymphocytes, or white blood cells, that had "a critical surveillance and effector role in the immune system".

The companies said that NK-cells and T-cells each had the potential to attack cancer cells, but had different mechanisms for tumor cell killing, so "appropriately activated and targeted NK-cells may represent a differentiated approach that would be potentially complementary and synergistic with T-cell mediated anti-tumor strategies".

Kite head of research Dr Peter Emtage said that "early clinical data utilizing adoptively transferred NK-cells has been encouraging and we are excited by the opportunity to scientifically expand our capabilities in this area and to identify novel NK cell therapies to advance toward clinical development".

Onko-Innate chief executive officer Dr Jai Rautela said his company "believed in the potential for NK-cells to play a role in cancer immunotherapy".

Onko-Innate said it would use genome-wide screening techniques and its proprietary technology platform to discover novel immune cell targets that enhanced NK-cell anti-tumor immunity and to develop NK-cell therapies.

The company said that as part of the Gilead collaboration it would identify and validate targets to seed internal Gilead immuno-oncology discovery programs.

Onko-Innate said that for the Kite collaboration it would develop and evaluate NK constructs for Kite's development of next-generation cell therapies.

The company said it would receive an upfront payment and be eligible for clinical, regulatory and commercial milestone payments, as well as sales royalties across the immuno-oncology and cell therapy programs.

Onko-Innate said the specific terms were confidential.

Onko-Innate is a private company.

IMAGION BIOSYSTEMS

Imagion says it has raised \$2.05 million through an oversubscribed rights issue at 1.0 cent a share and raised a further \$960,000 through a follow-on placement.

Last month, Imagion said it hoped to raise \$2,040,000 through a two-for-five pro-rata renounceable rights issue at 1.0 cent a share and each new share would have an attaching option exercisable at 3.0 cents each by April 28, 2023 (BD: Mar 25, 2020).

Today, the company said that Perth's Mahe Capital Pty Ltd was the lead manager, underwriter and adviser to the rights issue and placement.

Imagion was unchanged at 1.3 cents with 4.9 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will launch Scenesse for erythropoietic protoporphyria (EPP) in China under a named patient program in collaboration with Hong Kong's Winhealth Pharma. Clinuvel said local subsidies were available for eligible patients to receive treatment at selected large medical centres and hospitals.

The company said that about 5,000 people in China lived with erythropoietic protoporphyria with no therapy available prior to Scenesse.

Clinuvel fell \$1.40 or 6.6 percent to \$19.87 with 449,412 shares traded.

POLYNOVO

Polynovo says its Novosorb biodegradable temporizing matrix (BTM) has been used in Canada for the first time under a special exemption for a child with extensive burns.

Polynovo said it had not applied for regulatory clearance in Canada "as the country has some unique requirements compared with the US, Australian and European regulatory processes ... [but] it was working towards a Canadian regulatory filing in 2021".

The company said that Novosorb BTM was supplied under Health Canada's special access program and the child was "progressing well".

Polynovo chief executive officer Paul Brennan said that the company's US team "worked closely with the Canadian surgeon and the hospital to get Novosorb BTM into Canada for urgent use last week and over the weekend".

"Canada is a very important market for us in the near term and seeing demand for our product in advance of market entry is a reflection of the strength of the global key opinion leader network and the high regard for Novosorb BTM," Mr Brennan said.

Polynovo fell three cents or 1.5 percent to \$1.98 with 6.4 million shares traded.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says that the Covid-19 pandemic will reduce profits and has led to a more than 40 percent cut to directors and management pay and other cost reductions.

SDI said the pandemic had a minimal effect on operations for the nine months to March 31, 2020, with sales up five percent and profit in line with the previous corresponding period, but operations in the three months to June 30, 2020 would be affected and it expected a material impact, with dental procedures currently limited to emergency cases in most countries.

The company said it expected year to June 30, 2020 sales to fall 13 percent compared to last year and while the overall impact was difficult to assess, it expected profit after tax of between \$3.5 million and \$4.5 million for the year, compared to \$7.3 million last year.

The company said that along with pay and operational cost cuts it would review all project expenditure and apply for all Covid-19 government subsidy programs.

SDI fell 4.5 cents or 6.2 percent to 68.5 cents.

ADMEDUS

Admedus has told the ASX that it has more than two quarters cash.

Admedus said that although it only had \$2,952,000 in cash, it had a further \$8.1 million in a short-term deposit, maturing in May 2020.

The company said it spent \$6,002,000 in the three months to March 31, 2020 and expected its current level of cash to be reduced.

Admedus fell 53 cents or 8.1 percent to \$6.02.

RECCE PHARMACEUTICALS

Recce says Recce-327 reduces methicillin-resistant staphylococcus aureus (“golden staph” or MRSA) bacterial load in rats with topical burns and improves wound contraction. Recce said the study primary endpoints were the reduction of bacterial load in wounds, the percentage of wound contraction, the dose-dependency of Recce-327 and in-vivo antibacterial activity at day-four following dosing.

The company said five groups of eight rats were administered either 10mg of Recce-327, 50mg of Recce-327, 100mg of Recce-327, 30mg of the best in class Soframycin (framycetin sulfate) or no treatment.

Recce said the study met its primary endpoints and showed efficacy at different dose levels, reducing bacterial count when compared to the vehicle control ($p < 0.05$).

The company said there was a further decrease of 13.28 percent in bacterial load as the dosage increased from 10mg to 100mg.

Recce said there was a 30.5 percent decrease in bacterial load when administered 10mg of Recce-327, a 33.0 percent decrease when administered 50mg and a 39.5 percent decrease when administered 100mg, compared to 29.5 percent when administered Soframycin.

The company said it showed a significant dose-dependent antibacterial effect compared to the control ($p < 0.05$), with Recce-327 dosed once daily compared to Soframycin applied twice daily showing that Recce-327 “may be a more potent antibiotic without additional toxicity considerations associated with similar doses of Soframycin”.

Recce said Recce-327 also showed significant dose-dependent wound healing activity compared to the vehicle control ($p < 0.05$) and was 180 percent more effective in wound healing as the dose escalated, compared to no treatment.

Recce was up 2.5 cents or 7.25 percent to 37 cents.

VISIONEERING TECHNOLOGIES

Visioneering has requested a trading halt “pending an announcement ... in relation to a proposed capital raising”.

Trading will resume on April 29, 2020 or on an earlier announcement.

Visioneering last traded at 2.3 cents.

CRYOSITE

Cryosite director Andrew John Kroger says he has increased his substantial shareholding from 18,840,190 shares (40.21%) to 18,889,612 shares (40.31%).

The London-based Mr Kroger said that on April 17, 2020 he acquired 49,422 shares on market at 8.0 cents a share.

Cryosite was untraded at eight cents.

SOMNOMED

TDM Growth Partners says it has increased its substantial shareholding in Somnomed from 17,065,333 shares (22.79%) to 18,863,038 shares (22.95%).

The Sydney-based TDM said that on April 17, 2020 it bought 1,797,705 shares for \$1,438,164 or 80 cents a share.

Last week, Somnomed said it completed the \$15.5 million one-for-3.24 rights offer at 80 cents a share (BD: Apr 17, 2020)

Somnomed was up 10 cents or 9.8 percent to \$1.12.

[G \(GEVA\) MEDICAL INNOVATIONS](#)

G Medical says it has hired Hong Kong's Fosun Hani Securities and California's Boustead Securities to advise on a Nasdaq listing, targeted by September 30, 2020.

Last year, G Medical said it hoped to raise \$US17,000,000 (\$A24,570,907) to list its American depository shares on the Nasdaq and later said it would withdraw its Nasdaq registration statement (BD: May 20, Aug 26, 2019).

Last week, the company said it was reconsidering a listing on the Nasdaq and had commenced preliminary discussions with various third parties (BD: Apr 14, 2020).

Today, G Medical said both companies would act as underwriters, subject to the finalization of the initial public offering offer price and a formal agreement.

G Medical was up one cent or 10 percent to 11 cents with 1.7 million shares traded.

[POLYNOVO](#)

Polynovo says it has appointed chief executive officer Paul Brennan as managing director.

[IMPRESSION HEALTHCARE](#)

Impression says it could make a 505(b)(2) submission to the US Food and Drug Administration for marijuana product IHL-216A for traumatic brain injury.

Impression said that it hired the Cincinnati, Ohio-based Camargo Pharmaceuticals Services to assess a US Food and Drug Administration approval pathway for IHL-216A.

The company said that it proposed IHL-216A as a treatment for secondary brain injuries associated with concussion and traumatic brain injury.

Impression said that a 505(b)(2) FDA submission would reduce time and cost to commercialization, subject to successful clinical assessment.

The company said its indicative program would begin with a 60-rodent study by July this year, leading to a phase IIb trial on up to 50 mixed martial arts fighters to begin by October 2020, a phase II dose-finding study by April 2021 and a phase III clinical trial in 2022.

The company said it planned to bring a registered drug to the prescription market within three years but had potential for unregistered sales before then.

Impression said that traumatic brain injury accounted for about 10 million deaths and hospitalizations each year and there was currently no approved treatment.

Impression was up 0.1 cents or two percent to 5.2 cents with 1.4 million shares traded.

[NOXOPHARM](#)

Noxopharm says an isoflavonoid drug candidate "has passed ... [a] proof-of-principle test" as a new treatment for the brain cancer glioblastoma multiforme.

Noxopharm said it would aim to confirm the lead candidate and move into a pre-clinical program to target a clinical study in late 2021.

In 2011, Noxopharm chief executive officer Dr Graeme Kelly's previous company, Novogen, sold its isoflavone-based intellectual property portfolio to Marshall Edwards for shares worth \$4 million (BD: May 10, 2011).

Noxopharm was up one cent or 5.6 percent to 19 cents.