



Biotech Daily

Monday May 4, 2020

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH EVEN: DIMERIX UP 5%; ACTINOGEN DOWN 10%**
- * **RECCE-327: 'SIGNIFICANTLY REDUCES GONORRHOEAE IN MICE'**
- * **IDMC OKAYS IMUGENE PHASE II HER-VAXX CANCER STUDY**
- * **ONCOSIL PLACEMENT, RIGHTS OFFER TO RAISE \$19m**
- * **ONCOSIL FILES FOR APPROVAL IN SINGAPORE, HONG KONG, MALAYSIA**
- * **NUHEARA 60% UNDERWRITTEN SHARE PLAN FOR \$2.5m**
- * **CARL ZEISS PAYS OPTISCAN FINAL \$171k CONVIVO MILESTONE**
- * **KAZIA EXTENDS SHARE PLAN FOR LATE APPLICATIONS**
- * **GI DYNAMICS POTENTIAL DELISTING, EXTENDS CRYSTAL AMBER NOTE**
- * **NEUROSCIENFITIC: 'EMTINB NOT TOXIC'**
- * **BOD: 1st UK MARIJUANA MEDICABILIS PRESCRIPTIONS**
- * **ALLAN GRAY REDUCES, DILUTED TO 12% OF IMPEDIMED**
- * **PARADICE INVESTMENTS DILUTED TO 6.5% OF IMPEDIMED**
- * **REGAL FUNDS REDUCES TO 12% OF VISIONEERING**
- * **NOXOPHARM CHAIR DR GRAHAM KELLY INCREASES, DILUTED TO 21%**
- * **ELEANORE GOODRIDGE INCREASES, DILUTED TO 7% IN NOXOPHARM**
- * **PHARMAXIS APPOINTS DR NEIL GRAHAM DIRECTOR**
- * **ONCOSIL APPOINTS NIGEL LANGE EMEA HEAD**

MARKET REPORT

The Australian stock market was up 1.41 percent on Monday May 4, 2020, with the ASX200 up 73.9 points to 5,319.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and two were untraded. All three Big Caps were up.

Dimerix was the best, up one cent or 5.1 percent to 20.5 cents, with 399,241 shares traded. Universal Biosensors climbed 4.8 percent; Opthea and Polynovo were up more than three percent; CSL and Nanosonics rose more than two percent; Clinuvel, Cochlear, Kazia, Pharmaxis, Resmed, Telix and Volpara were up more than one percent; with Mesoblast, Paradigm and Pro Medicus up by less than one percent.

Actinogen led the falls, down 0.2 cents or 10 percent to 1.8 cents, with 4.1 million shares traded. Patrys, Resonance and Starpharma lost more than seven percent; both Ellex and Immutep were down 6.7 percent; Neuren fell 4.6 percent; Compumedics was down 3.8 percent; Medical Developments and Uscom shed two percent or more; with Avita, Cynata, Genetic Signatures and Proteomics down by less than one percent.

RECCE PHARMACEUTICALS

Recce says its Recce-327 antibiotic has shown statistically “significant antibacterial activity against *Neisseria gonorrhoeae* bacteria” in female mice ($p < 0.5$).

Recce said *Neisseria gonorrhoeae* was a gram-negative bacterium and the second most common sexually-transmitted infection.

The company said that three groups of 10 female mice with *Neisseria gonorrhoeae* were intravenously administered 100mg/kg, 500mg/kg and 1,000mg/kg doses of Recce-327 and compared to a vehicle infected control group and a control group given the commercially available antibiotic, Meropenem.

Recce said that all three dose levels were statistically significantly more effective than vehicle control but did not provide a statistical analysis compared to Meropenem.

The company said that Meropenem achieved a decrease to 4.08 Log₁₀ colony forming units (CFUs), the 100mg/kg of Recce-327 was less effective at 4.90CFUs but the higher doses were more effective with 500mg/kg Recce-327 reducing bacteria to 3.95CFUs and the 1,000mg/kg dose achieving 2.77CFUs.

“Recce-327 showed significant dose dependent antibacterial effect in vaginal load at 100, 500 and 1000 mg/kg given by intravenous bolus when compared to the control group, seven days post-infection,” Recce said.

The company said that due to Meropenem’s high rates of bacterial resistance, its use had been restricted to infections caused by organisms that are resistant to other anti-microbial choices.

Recce said that between the Recce-327 groups, there was a 43 percent decrease in bacterial count as the dose escalated.

Recce chairman Dr John Prendergast said that “gonorrhoeae has developed resistance to all but one class of antibiotics, so there is an urgent need to find a new class of effective antibiotics to kill the pathogen, before it develops resistance to the last recommended treatment”.

“Data from this study, along with previous other reports, continue to highlight the potential of Recce-327 to not only become a potent broad-spectrum antibiotic but most critically to continue working against antibiotic resistant bacteria or superbugs, even with numerous repeated uses,” Dr Prendergast said.

Recce was up two cents or 5.3 percent to 39.5 cents.

IMUGENE

Imugene says an independent data monitoring committee has no safety concerns for its phase II HER-Vaxx cancer trial and recommends it “continue without modification”.

Last year, Imugene said it had dosed the first of 68 patients in its open-label, randomized, multi-centre phase II trial of HER-Vaxx, or IMU-131, for HER-2-positive gastric cancer.

The company said that the trial was designed to measure the efficacy, safety and immune response in patients with metastatic gastric cancer overexpressing the HER-2 protein, with a primary endpoint of overall survival and secondary endpoint of progression-free survival (BD: Mar 14, 2019).

Imugene said HER-Vaxx was a B-cell peptide cancer immunotherapy designed to treat tumors that over-expressed the human epidermal growth factor receptor-2 (HER-2) protein, such as gastric, breast, ovarian, lung and pancreatic cancers.

Imugene chief executive officer Leslie Chong said that she was “happy to report that we have achieved this significant milestone and I’m highly encouraged by the positive outcome of this first [independent data monitoring committee] meeting”.

Imugene was unchanged at 2.6 cents with 15.2 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has commitments to raise \$14 million in a placement at nine cents a share and will raise \$5 million in a fully underwritten rights offer at the same price.

Oncosil said the price was an 18.2 percent discount to the closing price on April 28 and a 19.3 percent discount to the 5-day volume weighted average price to April 28, 2020.

The company said the rights offer was fully underwritten by Bell Potter Securities, had a record date of May 7, would open on May 12 and close on May 21, 2020.

Oncosil says that the funds would be used to commercialize its Oncosil device for cancer in the UK, Europe and the US, to obtain regulatory approval in the Asia Pacific region and South East Asia, to begin US clinical trials and for general working capital.

The company said that Bell Potter was the lead manager of the capital raising.

Oncosil was unchanged at 11 cents with 9.3 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has filed for registration of its Oncosil radioactive isotope device for advanced pancreatic cancer in Singapore, Hong Kong and Malaysia.

Oncosil said that all three countries recognized the Conformité Européenne (CE) mark, which the company received last month (BD: Apr 1, 2020).

The company said that its registration in Singapore was under the priority review scheme for breakthrough devices, which allowed accelerated approval.

NUHEARA

Nuheara says it hopes to raise \$2.5 million in a share plan, partially underwritten by Canaccord Genuity Australia for \$1.5 million.

Nuheara said the share price would be a 20 percent discount to the 5-day volume weighted average price to the issue date.

The company said the record date for the share plan was May 1, with the plan opening on May 6 and closing on May 27, 2020.

Nuheara said the funds would be used to continue to drive sales of its hearing devices by increasing advertising of its direct-to-customer online sales platform in North America, the UK and Europe and increase inventory levels with its contract manufacturer.

Nuheara was unchanged at 1.6 cents with 1.7 million shares traded.

OPTISCAN IMAGING

Optiscan says the Jena, Germany-based Carl Zeiss Meditec has paid the final milestone of EUR100,000 (\$A171,042) for its in-vivo Convivo microscope.

In 2017, Optiscan said Carl Zeiss unveiled the Convivo, which received US Food and Drug Administration clearance in 2018 (BD: Oct 10, 2017; Nov 7, 2018).

Today, the company said the payment reflected that both parties had agreed for the project to move to the production phase.

Optiscan said it was in discussions with Carl Zeiss regarding future orders as Carl Zeiss continues its commercial rollout plans and for research and development services as part of planning future technology enhancements for the Convivo microscope.

Optiscan was unchanged at 3.8 cents with 1.1 million shares traded.

KAZIA THERAPEUTICS

Kazia says it has extended its share plan closing date from May 1 to May 5, 2020, after reminding shareholders of the original date on April 29.

In April, Kazia said it had launched the share plan at 40 cents a share, after raising \$7.2 million through a placement at the same price (BD: Apr 9, 2020).

Today, the company said it had extended the closing date to give shareholders sufficient time to apply, after receiving “a large volume of [applications] in the last two days”.

Kazia said it was aware that Australia Post was experiencing significant delays and the additional two business days would provide an opportunity for cheques currently in the mail to be banked and processed.

The company said that any shareholders who intended to apply were encouraged to pay electronically.

Kazia was up half a cent or 1.3 percent to 40 cents.

GI DYNAMICS

GI Dynamics says it is considering delisting from the ASX and has extended the Crystal Amber Fund convertible note maturity date from May 1 to May 15, 2020.

In 2017, GI Dynamics said it had a \$US5,000,000 (\$A6,595,767) convertible note financing with Crystal Amber for working capital and today said the extension applied to that convertible note (BD: Jun 15, 2017).

GI Dynamics said that “as part of its ongoing financing efforts, the company has also been considering the possibility of delisting from the official list of the ASX and has recently applied to the ASX for in-principle advice in this regard”.

The company said it was seeking a bridging loan to sustain its operations until the closing of any substantial financing,

GI Dynamics said that if it could not secure a bridging loan and if it did not have enough cash reserves, it “would need to cease operations”.

GI Dynamics fell 0.1 cents or 25 percent to 0.3 cents with 1.3 million shares traded.

NEUROSCIENTIFIC

Neuroscientific says Emtinb “did not cause any toxicity in the tissues analysed” during the animal glaucoma study.

In March, Neuroscientific said that Emtinb indicated a neuroprotective effect for glaucoma-like damage in pigs (BD: Mar 11, 2020).

Today, the company said that toxicity biomarkers used in the study showed negative results.

Neuroscientific said it hoped to start human clinical trials “later this year”

Neuroscientific was unchanged at 18.5 cents.

BOD AUSTRALIA

Bod says it has received the first prescriptions for its marijuana-based Medicabilis from patients in the UK.

Bod said the prescriptions were a major milestone.

Bod was up 4.5 cents or 17.65 percent to 30 cents.

IMPEDIMED

Allan Gray Australia says it has decreased its holding in Impedimed and been diluted from 131,597,400 shares (17.22%) to 124,661,287 shares (12.45%).

The Sydney-based Allan Gray said that between April 27 and 29, 2020 it sold 6,936,113 shares for \$270,508 or 3.9 cents a share.

Last month, Impedimed said it had raised \$18.2 million in a capital raising at 3.75 cents a share (BD: Apr 3, 28, 2020).

Impedimed was unchanged at 3.9 cents with 2.5 million shares traded.

IMPEDIMED

Paradise Investment Management says its substantial shareholding in Impedimed of 65,941,454 shares has been diluted from 8.626 percent to 6.583 percent.

Last month, Impedimed said it had raised \$18.2 million in a capital raising at 3.75 cents a share (BD: Apr 3, 28, 2020).

VISIONEERING TECHNOLOGIES

Regal Funds Management says it has reduced its substantial shareholding in Visioneering from 64,626,403 shares (13.87%) to 57,761,403 shares (12.40%).

The Sydney-based Regal Funds said that between January 28 and April 28, 2020 it sold 6,865,000 shares at prices ranging between 1.61 cents and 3.92 cents a share.

Visioneering was up 0.1 cents or 6.7 percent to 1.6 cents with 3.3 million shares traded.

NOXOPHARM

Noxopharm executive chair Dr Graham Kelly says he has increased and been diluted in Noxopharm from 31,410,203 shares (25.78%) to 31,540,756 shares (20.71%).

Dr Kelly said that between February 8 and September 10, 2019 he, Phytose Corp for Boundary One Super Fund and Milligene Pty Ltd for the GE an PR Kelly Family Trust, bought 130,553 shares at prices ranging from 35.79 cents to 41.61 cents a share.

Dr Kelly said the shareholding was diluted in a placement on February 21, 2020.

In February, Noxopharm said raised \$8.1 million through a \$3.09 million placement at 18 cents a share and \$5 million loan from an unnamed shareholder (BD: Feb 14, 2020).

Noxopharm was up half a cent or 2.6 percent to 20 cents.

NOXOPHARM

Eleanore Goodridge and Goodridge Nominees say they have increased but been diluted in Noxopharm from 9,713,964 shares (7.95%) to 10,628,590 shares (6.99%).

The Sydney-based Goodridge Nominees said that on March 25, 2019 it received a placement fee of 414,626 shares in lieu of cash and on February 21, 2020 it bought 500,000 shares at 18 cents a share in Noxopharm's placement (BD: Feb 14, 2020).

PHARMAXIS

Pharmaxis says it has appointed Dr Neil Graham as a non-executive director, effective from May 4, 2020.

Pharmaxis said Dr Graham was an experienced pharmaceutical and biotechnology executive with expertise in medicine development and epidemiology and was a professor of epidemiology at the Baltimore, Maryland-based Johns Hopkins University between 1993 and 1997.

The company said Dr Graham was the chief development officer at Evelo Biosciences and previously held executive positions at Regeneron, Vertex, Trimeris and XTL Biopharmaceuticals.

Pharmaxis said Dr Graham held a Bachelor of Medicine, Bachelor of Surgery and a Master of Public Health from South Australia's University of Adelaide.

Pharmaxis was up 0.1 cents or 1.1 percent to nine cents.

ONCOSIL MEDICAL

Oncosil says it has appointed Nigel Lange as head of Oncosil in Europe, the Middle East and Africa.

Oncosil said Mr Lange had more than 30 years' experience in the medical devices industry and was previously Sirtex Medical chief commercial officer, head of European business and interim chief executive officer.

The company said Mr Lange held a Bachelor of Commerce from Ontario's University of Windsor and a Bachelor of Arts from Ontario's York University.