

Biotech Daily

Wednesday April 8, 2020

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: NEXT SCIENCE UP 36%; ACTINOGEN, OPTISCAN DOWN 11%
- * ADHERIUM: 'UNTIMELY DEATH OF CHAIR THOMAS LYNCH'
- * US EPA APPROVES NEXT SCIENCE LMN8 SURFACE DISINFECTANT
- * FDA EXPEDITES COCHLEAR NUCLEUS 7 REMOTE CHECK
- * PARADIGM RAISES \$35m
- * IMAGION RECEIVES \$2.2m R&D TAX INCENTIVE
- * TELIX: CARDINAL FOR TLX591-CDX FOR PROSTATE CANCER US SALES
- * POLYNOVO: AUSTRALIA GRANTS 4 NOVOSORB PATENTS
- * IMMUTEP: EOC ADVANCES IMP321 FOR BREAST CANCER IN CHINA
- * USCOM, UNI OF TASMANIA PARTNER FOR 'IDEAL' BP STUDY
- * PYC: 'CPP SAFE, LESS TOXIC IN MICE'
- * ASX SUSPENDS MGC FOR SWISS MARIJUANA COVID-19 J-V QUERIES
- * G MEDICAL EXTENDS MAGNA NOTES TO APRIL 30
- * US FDA GRANTS G MEDICAL PRIZMA O-T-C APPROVAL

MARKET REPORT

The Australian stock market fell 0.86 percent on Wednesday April 8, 2020, with the ASX200 down 45.4 points to 5,206.9 points. Fifteen of the Biotech Daily Top 40 stocks were up, 19 fell, three traded unchanged and three were untraded. All three Big Caps fell.

Next Science was the best, up 43.5 cents or 36.25 percent to \$1.635 with 775,517 shares traded. Alterity climbed 18.75 percent; Immutep was up 16.7 percent; Prescient improved 14.7 percent; Imugene and Medical Developments were up more than nine percent; Osprey rose 8.3 percent; Antisense was up 7.1 percent; Opthea climbed 6.4 percent; Avita and Volpara were up more than four percent; Proteomics improved 3.6 percent; Ellex and Telix rose more than two percent; with Polynovo up 1.55 percent.

Actinogen and Optiscan led the falls, both down 11.1 percent to two cents and 2.4 cents, respectively, with 3.4 million and 858,195 shares traded, respectively. Patrys fell 7.1 percent; both Compumedics and Dimerix lost 6.7 percent; Starpharma and Universal Biosensors were down more than five percent; Cynata, Pharmaxis and Resonance fell four percent or more; Clinuvel and Paradigm were down more than three percent; Impedimed, Orthocell and Pro Medicus shed two percent or more; Nanosonics, Resmed and Uscom were down more than one percent; with Cochlear, CSL, Genetic Signatures and Mesoblast down by less than one percent.

ADHERIUM

Adherium has announced "the unfortunate and untimely death of its chairman Thomas Lynch", who has been chairman since he joined the board in September 2016.

Adherium said that "the directors and staff of Adherium send their deepest condolences to Tom's family at this very sad and difficult time".

The company said it expected to announce a replacement by the end of this week. Adherium was up 0.2 cents or 10.5 percent to 2.1 cents.

NEXT SCIENCE

Next Science says it the US Environmental Protection Agency has approved its LMN8 hospital cleaner surface disinfectant, including a claim for effectiveness against biofilm. Next Science said it was "one of only three companies who have been awarded that claim by the [Agency] at this time".

The company said that its surface disinfectant was "the only EPA-approved product with a biofilm claim that is non-toxic to humans, with safety glasses the only required form of personal protection equipment".

Next Science said that the US EPA registration was "a significant milestone ... in that it reflects more than six years work to gain the EPA's approval for a biofilm standard to be used as a product claim".

The company said that unlike bleach and many other disinfectants in the market, its surface disinfectant was "a non-toxic product which uses ... [its] Xbio technology to eliminate biofilm based and free-floating bacteria".

Next Science said that Xbio's effectiveness against many types of bacteria had been validated by extensive clinical testing, multiple FDA clearances and more than 130,000 patient treatments since 2017, with no evidence of bacterial resistance.

The company said it was in negotiations with potential commercialization partners. Next Science managing-director Judith Mitchell said that "receipt of EPA registration of our hospital cleaner surface disinfectant LMN8 now gives us the opportunity to more widely assist hospitals and communities in the fight against infection".

Next Science was up 43.5 cents or 36.25 percent to \$1.635 with 775,517 shares traded.

COCHLEAR

Cochlear says the US Food and Drug Administration has approved its remote check system for recipients of its Cochlear Nucleus 7 sound processor hearing implant. Cochlear said remote check would be its first telehealth patient assessment tool, designed for at-home testing, to allow patients to complete a series of hearing checks from their Apple Iphone operating system smartphone using its Nucleus application.

The company said it would begin a controlled release of remote check in the US and intended to accelerate the release in countries in which it had regulatory clearance, including Canada, the UK and some countries in Western Europe.

Cochlear chief executive officer Dig Howitt said that "remote care has been a core pillar of Cochlear's long-term innovation strategy, with access to care crucial to people who rely on a cochlear implant".

"Remote check provides recipients with the ability to continue to access a level of care at a time when many clinics are closed to in-person visits," Mr Howitt said.

"The FDA's expedited approval of remote check during the Covid-19 crisis underscores the importance of remote hearing care," Mr Howitt said.

Cochlear fell 27 cents or 0.15 percent to \$182.91 with 400,754 shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has raised \$35 million through a placement to institutional and sophisticated investors at \$1.30 a share.

Paradigm said the issue price was at a 23.1 percent discount to its last trading price at \$1.69 a share on April 1, 2020, the funds would be used for its second phase III osteoarthritis trial and it would be funded until the trial read out expected "in late 2022". Paradigm said Bell Potter Securities was the lead manager to the placement. Paradigm fell 6.5 cents or 3.85 percent to \$1.625 with 5.6 million shares traded.

IMAGION BIOSYSTEMS

Imagion has it has received \$2,197,028 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Imagion said the rebate related to research and development expenditure for the year to December 31, 2019.

Imagion was unchanged at 1.1 cents with 6.9 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has a distribution agreement with Cardinal Health for radio pharmacy and logistics services to support its prostate cancer imaging product TLX591-CDx. Telix said the Columbus, Ohio-based Cardinal Health would prepare and deliver patient-specific unit doses of TLX591-CDx in the US.

The company said prostate cancer was the most common male cancer in the US, with about 190,000 new cases a year and three million men living with prostate cancer. Telix was up 2.5 cents or 2.1 percent to \$1.24.

<u>POLYNOVO</u>

Polynovo says it has four new Australian patents for its Novosorb polymers, covering its hernia and beast products, and other new products in development.

Polynovo said the patent, titled 'Oriented biodegradable polyurethanes' would assist in the design of products that stretch or rebound in only one direction to address movement needs in various areas of the body in which devices would be placed.

Polynovo said two patents, both titled 'Tissue repair laminates', covered the use of Novosorb in a non-adherent hernia repair device and other applications.

The company said that Novosorb had a very low adherent property and one application was for the Novosorb extruded film to be placed in the peritoneal cavity for hernia repair with minimal risk of creating bowel adhesion.

The second 'Tissue repair laminates' patent covered the use in a hernia device and other applications "where tissue grew into both sides of the device" for reconstructive surgery "where there has been significant excision, tissue loss or trauma".

The company said the patent entitled 'Soft tissue implant pocket' covered the use of other devices and implants to encourage tissue ingrowth and address potential 'dead spaces', useful in breast surgery "and other areas where a bulky device may need to be implanted into the body".

Polynovo chief executive officer Paul Brennan told Biotech Daily that the patents protected the company's intellectual property until December 21, 2038.

Polynovo was up three cents or 1.55 percent to \$1.97 with 8.0 million shares traded.

IMMUTEP

Immutep says Shanghai, China partner EOC Pharma will continue advancing IMP321 or eftilagimod alpha, designated as EOC202 in China, for metastatic breast cancer. Immutep said EOC had analyzed progression free survival (PFS) data and subgroup analysis from its phase IIb Aipac study, which last month showed that it failed to meet its primary and secondary endpoints (BD: Mar 26, 2020).

Today, the company said EOC had safely dosed the final patient in its phase I study of eftilagimod alpha or IMP321 for metastatic breast cancer in China, and expected data during 2020 and expected to complete the study by December 31, 2020.

Immutep said EOC had the exclusive licence to IMP321 in China and would make further milestone payments to Immutep, along with undisclosed royalties on sales.

Immutep was up two cents or 16.7 percent to 14 cents with 3.2 million shares traded.

<u>USCOM</u>

Uscom says it will work with the University of Tasmania in the Ideal study to use its blood pressure device for early detection and management of cardiovascular disease. Uscom said its BP+ would be used as the front-end blood pressure sensor in the Ideal study, supported by a \$1 million National Health and Medical Research Council grant. The company said patients would be examined with the BP+ device, along with a cardiovascular assessment, including a risk-profiling questionnaire, blood sample and cholesterol assessment.

Uscom said the outcomes of the study would be shared among collaborators and it would work with the University of Tasmania, the Menzies Institute, the National Heart Foundation, the Tasmania Department of Health, Primary Health Tasmania and Healthcare Software, to develop and integrate new waveform analysis approaches. Uscom executive chairman Prof Rob Phillips said the BP+ device was perfectly suited to the study and "while [electronic] health is leading the new era of clinical care, its application depends on the quality of the patient sensors" with BP+ providing improved data on blood pressure "all information that increases the strength of the study". Uscom fell half a cent or 1.7 percent to 29 cents.

PYC THERAPEUTICS (FORMERLY PHYLOGICA)

PYC says a toxicology study of its cell penetrating peptide (CPP) technology in mice has shown that it is safe and less toxic than a third-party delivery peptide.

PYC said that it compared its CPP technology with a third-party delivery peptide, PepK, and a control group that received no treatment.

The company said it found that its peptide was substantially less toxic than PepK and showed no significant difference in retinal stress levels to the untreated control group. PYC was unchanged at 7.9 cents with 2.4 million shares traded.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

The ASX says it has suspended MGC "pending a response to [the] ASX's queries ... regarding a strategic joint venture with a Swiss company in relation to Covid-19". On March 19, MGC requested a trading halt pending the announcement and requested its first suspension on March 23, 2020, followed by seven extensions to the suspension (BD: Mar 19, 23, 24, 25, 26, 27, 31; Apr 2, 3, 2020). MGC last traded at 1.7 cents.

G MEDICAL INNOVATIONS HOLDINGS

G Medical says it has extended its Magna Equities convertible note settlement repayment date to April 30, 2020.

G Medical said it had reduced the sum owing to \$US3,260,665 (\$A5,306,295.36). In February, G Medical said it would pay Magna \$US3,425,665 (\$A5,108,865) to cancel convertible notes (BD: Feb 11, 2020).

G Medical was up nine cents or 200 percent to 13.5 cents with 58.7 million shares traded.

G MEDICAL INNOVATIONS HOLDINGS

G Medical says the US Food and Drug Administration has granted over-the-counter authorization of its Prizma vital sign monitor.

G medical said the FDA had confirmed that its Prizma device met the criteria of the remote monitoring guidance document and would be expanded from prescription to over-the-counter permanently.