Biotech Daily

Wednesday April 7, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: IMUGENE UP 19%; TELIX DOWN 8.5%**

*** VARONIS WARNS OF HEALTHCARE CYBER ATTACKS**

*** ISLAND: $44m BIDS FOR $7.5m IPO**

*** IMPEDIMED OPTIONS RAISE $17.9m**

*** CONTROL BIONICS APPOINTS NUMOTION US TRILOGY DISTRIBUTOR**

*** IMUGENE BEGINS 3rd COHORT PD1-VAXX DOSING; MAYO JOINS TRIAL**

*** RECCE 'R327 CLEARS DRUG-RESISTANT INFECTION'**

*** US PATENT FOR VOLPARA ENTERPRIZE, LIVE SOFTWARE**

*** IMMUTEP EURO PATENT FOR IMP701 COMBINATION THERAPY**

*** MEDLAB EURO PATENT FOR NANOCELLE DRUG DELIVERY**

*** PHARMAUST: MONEPANTEL ANTI-VIRAL AGAINST SARS-COV-2, IN-VITRO**

*** BOD: H&H ORDERS $312k MARIJUANA OIL FOR US**

*** MGC RECEIVES $425k ARTEMIC RESCUE ORDER**

*** PERENNIAL REDUCES TO 7.7% OF HYDRIX**

*** SUDA APPOINTS PROF GUNNAR BIRGEGÅRD SCIENTIFIC ADVISOR**

MARKET REPORT

The Australian stock market was up 0.5 percent on Wednesday April 7, 2021, with the ASX200 up 34.2 points to 6,920.1 points. Seventeen of the Biotech Daily Top 40 stocks were up, 18 fell and five traded unchanged.

Imugene was the best for the second day in a row, up 2.5 cents or 19.2 percent to 15.5 cents, with 71.4 million shares traded. Optiscan climbed 17.8 percent; both Actinogen and Patrys were up 11.1 percent; Oncosil rose 9.4 percent; Antisense was up 8.9 percent; Nanosonics improved five percent; Kazia, Prescient and Volpara were up more than four percent; Immutep was up 3.5 percent; Compumedics, Cyclopharm and Resmed rose two percent or more; Clinuvel, Neuren and Pro Medicus were up more than one percent; with Cochlear and Polynovo up by less than one percent.

Telix led the falls, down 39 cents or 8.5 percent to $4.19, with 1.2 million shares traded. Osprey lost 5.3 percent; Resonance and Universal Biosensors fell more than four percent; Alterity, Amplia, Orthocell and Proteomics were down more than three percent; Medical Developments, Next Science, Nova, Opthea and Paradigm shed more than two percent; Avita, Genetic Signatures and Mesoblast were down more than one percent; with CSL, Cynata and Starpharma down by less than one percent.

VARONIS SYSTEMS

New York-based data security firm Varonis Systems says biotechnology, pharmaceutical, healthcare companies and hospitals are at risk of disruptive data breaches.

Varonis said its 2021 Healthcare Data Risk Report analyzed the state of data security across the industries in the US, Europe and Australia.

The company said that "healthcare remains one of the most at-risk sectors for malicious attacks in 2021, with Covid-19 enabling hackers to take advantage of organizations on the front lines".

Last week, Cann Group said it had begun proceedings in the Hong Kong's High Court against Er Ya Trade Ltd to recover EUR2.25 million ($A3.47 million) following a February "a cyber security incident, involving an unknown third party" resulting in a missing payment to an overseas contractor with the payments "received by an unknown third party as a result of a complex and sophisticated cyber fraud perpetrated against the company and its overseas contractor" (BD: Feb 8, Mar 29, 2021).

Varonis said that variants of ransomware like Maze and Ryuk had been used against "hundreds of hospitals, and state-sponsored actors zeroed-in on pharma and biotech companies to harvest Covid-19 research".

The company said the healthcare industry was under-prepared for cyber attacks in 2020, with an average data breach cost of $US7.13 million in 2020.

Varonis said that 2020 was the first year that a patient's death was directly linked to a cyberattack.

The company said that one-in-five files were open to every employee in healthcare organizations, increasing to one-in-four in small and mid-sized companies.

Varonis said that the average organization had 31,000 sensitive files containing financial and proprietary research open to all staff.

The company said that 77 percent of organizations had more than 500 accounts with passwords that never expired and every healthcare employee had access to more than 11 million files overall.

"All it takes is one account to be compromised to let a hacker in," Varonis said.

The report is available at: https://bit.ly/2RcINrw.

ISLAND PHARMACEUTICALS

Executive chair Dr Paul MacLeman says Island Pharmaceuticals $7.5 million initial public offer at 25 cents a share was oversubscribed to $44 million (BD: Mar 1, 2021).

Dr MacLeman told Biotech Daily the company had bids for $44 million for the program to repurpose ISLA-101 for mosquito-borne viruses and expected Island to list on the ASX under the code ILA at 10.30am (AEST) on April 13, 2021.

Dr MacLeman said Island intended to complete phase II studies on off-patent, former developmental cancer drug, the anti-viral ISLA-101, which had been through 48 phase I and II clinical trials before being re-purposed and had been verified as safe in humans by multiple regulators, including the US Food and Drug Administration.

In March, the lead broker to the offer, PAC Partners, said there had been "promising results in human and animal studies for dengue, Zika and other viruses" and claimed that the drug was "eligible for a priority review voucher (PRV) for each of dengue, Zika and Chikungunya" (BD: Mar 1, 2021).

PAC said Island was valued at $12.5 million before the public offer and the board included Dr MacLeman, Dr Anna Lavelle, Dr David Brookes, Dr David Foster and Al Hansen.

PAC said Dr William Garner was a co-founder and US seed-investor and the advisory board included Prof Stephen Thomas, Prof Leigh Farrell and Dr Simon Tucker.

IMPEDIMED

Impedimed says it has raised $17.9 million of a possible $18.2 million through the exercise of options at 3.75 cents each, issued as part of a rights offer in April 2020.
Last year, Impedimed said its 13-for-10 retail rights offer at 3.75 cents a share raised $8.2 million of a hoped for $14.9 million, taking the total raised to $18.2 million, with investors to receive one free attaching unquoted option for each share purchased, exercisable at 3.75 cents each (BD: Apr 3, Apr 28, 2020).
Impedimed said that all remaining rights offer options had lapsed.
Impedimed was unchanged at 12 cents with 2.3 million shares traded.

CONTROL BIONICS

Control Bionics says it has appointed Numotion to distribute its Trilogy speech generating devices in New Hampshire, New York and Vermont.
Control Bionics said that under the reseller agreement, the Brentwood, Tennessee-based Numotion would distribute the Trilogy products to individuals with a range of indications and disabilities, including motor neurone disease or amyotrophic lateral sclerosis, spinal muscular atrophy, cerebral palsy, traumatic brain injury and spinal cord injury.
The company said the Trilogy products were classified as an augmentative and alternative communication product which offered “offering a customizable solution that complements the individual’s abilities as their needs change over time alongside industry-leading customer support”.
Control Bionics said Numotion would purchase products at a set price for resale in New Hampshire, New York and Vermont, excluding New York City and Long Island.
Last year, the company listed on the ASX after raising $15 million at 60 cents a share to commercialize its Neuronode technology for conversion of thoughts to computerized actions (BD: Dec 8, 2020)
Control Bionics was up 8.5 cents or 14.2 percent to 68.5 cents.

IMUGENE

Imugene says it has begun dosing the third cohort in its 32-patient, phase I trial of PD1-Vaxx for non-small cell lung cancer, with the Mayo Clinic joining the trial.
Last year, Imugene said it had recruited the first patient in the dose-escalation trial, and earlier this year dosed the first and second cohorts with a 10 micrograms dose and a 50mcg dose, respectively (BD: Dec 17, 2020; Jan 21, Feb 12, 2021).
Today, the company said the cohort review committee confirmed that PD1-Vaxx was safe with no dose-limiting toxicities and no serious adverse reactions at 10mcg or 50mcg.
Imugene said that early clinical results had indicated that PD1-Vaxx was “showing early signs of an immune responses in patients, with antibodies to the target biomarker [programmed death-1 or PD-1] evident in validated assays”.
The company said that at day-43 of treatment with PD1-Vaxx, one patient’s tumor was “non-measurable indicating a complete response with three patients showing stabilization of disease and a single patient progressing”.
Imugene chief executive officer Dr Leslie Chong said phase I trials were generally designed for safety, tolerability and early response signals to determine the optimal dose for further development so “I am encouraged that we are seeing positive signals at such an early stage of our PD1-Vaxx phase I trial”.
Imugene said that the Phoenix, Arizona-based Mayo Clinic had joined the trial.
Imugene was up 2.5 cents or 19.2 percent to 15.5 cents with 71.4 million shares traded.

RECCE PHARMACEUTICALS

Recce says its R327 synthetic antibiotic has shown a positive response against multidrug-resistant Pseudomonas aeruginosa sinusitis infection in one patient.
Recce said that the 59-year-old male patient received R327 for the drug-resistant sinus infection under the Therapeutic Goods Administration Special Access Scheme and the result was not part of a clinical trial.
The company said the patient was treated using a dose-escalating protocol of five-to-10 drops per 20ml of R327 in saline solution, three times a day into the infected area.
Recce said that after applying R327 in the infected area the patient noted a minor stinging sensation as the solution reached the area of infection in both nasal passages, which subsided after about three minutes, and lessened in subsequent days.
The company said that within 90 minutes of the application the patient "recorded their sinuses began to feel clearer, less inflamed and reported less discharge".
Recce said that over a three-day period, the patient reported a substantial reduction in infected discharge, termination of sweating and a return to normal sleeping patterns with no side effects.
The company said that blood samples taken after the dosing period showed "no detectable signs of [Pseudomonas aeruginosa] infection and no abnormalities".
Recce said that R327 was not used as part of a clinical trial and the results "must therefore be considered anecdotal".
Recce was up six cents or 6.1 percent to $1.04.

VOLPARA HEALTH TECHNOLOGIES

Volpara says the US Patent and Trademark Office has granted a patent relating to its Enterprize and Live breast mammography clinical software systems.
Volpara said the patent, titled 'System and Apparatus for Clinical Decision Optimisation' protected features of the software which improved breast care clinics' diagnosis and treatment options for women at risk of developing breast cancer, while reducing costs.
Volpara chief executive officer Dr Ralph Highnam told Biotech Daily that the patent granted protection for the software until 2037.
The company said that Enterprize helped clinical workflow efficiency by measuring image acquisition, patient breast screening and how effectively technologists positioned patients.
Volpara said that Live analyzed patient positioning and compression and provided real-time feedback to technologists.
The company said it held 96 patents across 25 countries.
Volpara was up six cents or 4.5 percent to $1.39.

IMMUTEP

Immutep says the European Patent Office has granted a patent for its IMP701 lymphocyte-activation gene-3 (LAG-3) antibody combination therapy for cancer.
Immutep said the patent, titled 'Combination therapies comprising antibody molecules to LAG-3' granted protection for the antibody until July 28, 2036.
The company said the patent specifically covered LAG-525, a humanized form of IMP701, combined with spartalizumab, an anti-programmed death (PD)-1 antibody molecule, and related methods of use of the combination in the treatment of cancer.
Immutep said the patent was co-owned by Novartis AG, which had licenced IMP701.
Immutep was up 1.5 cents or 3.5 percent to 44 cents with 2.5 million shares traded.

MEDLAB CLINICAL

Medlab says the European Patent Office intends to grant a patent relating to its Nanocelle drug delivery platform for drug solubility.
Medlab said the patent, titled 'Transmucosal and transdermal delivery systems' would protect its intellectual property until 2036 in and European Union and in the UK.
The company the Nanocelle drug delivery system produced "nano-sized water-soluble particles that enable optimized delivery of particles, overcoming issues with solubility and degradation".
Medlab chief executive officer Dr Sean Hall said that "receiving notice of intent from the European Patent Office represents another important validation of our Nanocelle drug delivery platform".
Medlab was up one cent or 4.2 percent to 25 cents.

PHARMAUST

Pharmaust says that Leiden University Medical Centre research shows that monepantel has anti-viral activity against Sars-Cov-2, in-vitro.
Last year, Pharmaust said that the Netherlands' Leiden University Medical Centre would use cultured cell infection models of severe acute respiratory syndrome-coronavirus-2 (Sars-Cov-2) to test monepantel and monepantel sulfone, originally developed as sheep roundworm drench, and later tested for cancer in humans and dogs (BD: Sep 24, 2020).
Today, Leiden University's Prof Martijn van Hemert said the in-vitro tests has shown "indications for an anti-viral effect in these assays, but solubility issues under the conditions required for cell-based screening complicate analysis".
"Additional experiments will now be performed on Sars-Cov-2 infected human lung cell lines," Prof van Hemert said.
Pharmaust was up 0.7 cents or 7.1 percent to 10.5 cents with 1.7 million shares traded.

BOD AUSTRALIA

Bod says it has received an order from Hong Kong's Health & Happiness Group for $312,000 of its full-spectrum cannabidiol oils for sale in the US.
Bod said that the order was "the first of multiple binding purchase orders expected in the coming months".
The company said it expected to launch its cannabidiol (CBD) oils in the US through e-commerce by July 2021.
Bod said it would receive an undisclosed royalty on net sales, as well as a "cost plus" margin for the supply of the finished goods from Health & Happiness.
Bod was up 2.5 cents or 5.3 percent to 49.5 cents with one million shares traded.

MGC PHARMACEUTICALS

MGC says it has received an order from Swiss Pharmacan AG for $425,000 of its Artemic Rescue food supplement for Covid-19.
MGC said Swiss Pharmacan would distribute Artemic Rescue, focussing "on countries currently reporting high numbers of Covid-19 patients".
MGC was up 0.7 cents or 11.5 percent to 6.8 cents with 24.0 million shares traded.

HYDRIX

Perennial Value Management says it has reduced its substantial shareholding in Hydrix from 14,285,714 shares (8.79%) to 12,588,900 shares (7.73%).
Sydney's Perennial said it sold 1,696,814 shares between March 23 and 31, 2021 for $364,093 or an average of 21.5 cents a share.
Hydrix was unchanged at 21.5 cents.

SUDA PHARMACEUTICALS

Suda says it had appointed Prof Gunnar Birgegård to its scientific advisory board to inform the development of anagrelide for solid tumors and thrombo-cytosis.
Suda said Prof Birgegård was a professor of haematology at Sweden's Uppsala University, a member of Leukemia Network, and was previously the chair of the Nordic Study Group for Myeloproliferative disorders.
The company said Prof Birgegård had been involved in studies analyzing the clinical use of anagrelide for the treatment of essential thrombo-cythemia and other myeloproliferative neoplasms, or blood and bone marrow cancers.
Suda fell 0.2 cents or 4.4 percent to 4.3 cents with 1.1 million shares traded.