

Biotech Daily

Thursday March 24, 2022

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: OPTHEA UP 9%; TELIX DOWN 7%
- * UNISUPER INVESTS \$75m IN UNISEED
- * DOHERTY, MODERNA EXPEDIATE mRNA VACCINE RESEARCH
- * CLARITY: US INVESTIGATOR COPPER-64 PROSTATE CANCER TRIAL
- * SERVATUS STARTS PROBIOTICS FOR INSOMNIA TRIAL
- * IMUGENE TAKES CHECKVACC TO 2nd COHORT
- * IMMUTEP: IMP321 FOR LUNG CANCER 'SAFE, ENCOURAGING ACTIVITY'
- * INCANNEX \$125m SCRIP FOR MARIJUANA COMPANY APIRX
- * PROTEOMICS: PROMARKERD INDIA PATENT
- * CARL CHARALAMBOUS TAKES 8.8% OF EXOPHARM
- * HARBOUR TAKES 11% OF VOLPARA
- * MESOBLAST APPOINTS DR PHILIP KRAUSE DIRECTOR

MARKET REPORT

The Australian stock market was up 0.12 percent on Thursday March 24, 2022, with the ASX200 up 9.2 points to 7,387.1 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell and 10 traded unchanged. All three Big Caps fell.

Opthea was the best, up nine cents or 9.1 percent to \$1.075, with 1.1 million shares traded. Prescient climbed 6.25 percent; Proteomics improved 4.5 percent; Mesoblast and Patrys were up more than three percent; Cynata, Genetic Signatures, Next Science and Nova Eye rose more than two percent; with Paradigm and Pharmaxis up by more than one percent.

Telix led the falls, down 38 cents or 7.4 percent to \$4.74, with 1.4 million shares traded. Micro-X lost 7.1 percent; Alcidion shed 5.1 percent; Actinogen, Polynovo, Resmed and Universal Biosensors fell more than four percent; Antisense, Clinuvel and Starpharma were down more than three percent; Avita, Dimerix, Oncosil and Volpara shed more than two percent; Neuren and Orthocell were down more than one percent; with Cochlear, CSL, Emvision, Medical Developments, Nanosonics and Pro Medicus down by less than one percent.

<u>UNISEED</u>

Uniseed says that the \$106 billion Unisuper fund has invested \$75 million in the Uniseed early-stage commercialization fund manager.

Uniseed said that originally a superannuation fund for university staff, Unisuper was a superannuation fund open to all Australians.

Uniseed said that it was established in 2000 and was owned by the Universities of Melbourne, Queensland, Sydney, New South Wales and the Commonwealth Scientific and Industrial Research Organisation.

Uniseed said it provided seed-funding for early-stage research and technology developed by its partners, which provided "around half of all patents created by research organizations in Australia".

Unisuper chief investment officer John Pearce says that Uniseed was a natural fit and logical choice for the fund.

"Unisuper has always championed Australia's thinkers, creators and investigators," Mr Pearce said. "This is an excellent opportunity for Unisuper to actively participate in the development and commercialization of research and technology ... [to] shape the future." Uniseed said the \$75 million would cover existing projects as well as "developments ... in biotechnology, pharmaceuticals, quantum computing and green energy".

Uniseed chief executive officer Peter Devine said the investment would "unlock more engagement with Australia's growing innovation and start-up sector".

"Unisuper is one of Australia's largest and most respected and innovative super funds, and the capital at its disposal will go a long way to ensuring we can seize opportunities presented by the brilliant minds at Australia's top research organizations," Dr Devine said.

THE PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNITY

The Doherty Institute says it has an agreement to access Moderna's Inc's mRNA Access program to develop mRNA vaccines for infectious diseases.

The Doherty said the Cambridge Massachusetts-based Moderna's mRNA Access was designed "to enable rapid acceleration of vaccine testing for a wide range of infectious diseases spanning HIV and tuberculosis, through to Japanese encephalitis virus".

The Institute said it would provide pathogen protein genetic sequence for Moderna to formulate into mRNA vaccines and return to the Institute for pre-clinical testing.

Doherty Institute director Prof Sharon Lewin said that having access to Moderna's design tools and rapid production capacity was "invaluable".

"We have seen with the Covid-19 pandemic the importance of being able to quickly create and deliver an effective vaccine," Prof Lewin said.

"By applying Moderna's mRNA technology there are opportunities to revolutionize our approach to developing both vaccines and therapeutics," Prof Lewin said.

The Institute said Moderna had identified about 100 pathogens, which could be investigated, including the human T-cell lymphotropic virus (HTLV-1), which affected up to 10 million people worldwide and was endemic in remote Aboriginal communities.

"More unfamiliar or neglected diseases like HTLV-1 are often difficult to attract funding and attention for, despite their widespread global burden," Prof Lewin said.

"Having the ability to design an mRNA vaccine candidate for HTLV-1 ... could save years and potentially thousands of lives," Prof Lewin said.

Moderna executive Hamilton Bennett said that "only a handful of institutes had been selected at this early stage to benefit from the program ... the Doherty Institute has established itself as a leader in infectious diseases research and we can see the potential for true innovation by partnering with their ... researchers."

CLARITY PHARMACEUTICALS

Clarity says a 150-patient, investigator-led, phase I/II trial of copper-64-SAR-bis-PSMA for prostate cancer will be sponsored by the Urology Cancer Centre's Dr Luke Nordquist. Clarity said that the Omaha, Nebraska-based Urology Cancer Centre and GU Research Network would investigate a broad spectrum of prostate cancer patients by imaging with copper-64 sarcophagene-bis-prostate specific membrane antigen (SAR-bis-PSMA) on the day of administration and at later timepoints.

Clarity executive chair Dr Alan Taylor said the fourth clinical trial of SAR-bis-PSMA would build on the data to date as we progress this product towards the market.

"The trial will also continue to demonstrate the numerous benefits of the centrally manufactured, on-demand distribution model of ready-to use ... products over the first-generation short half-life products using gallium-68 and fluorine-18," Dr Taylor said.

"We look forward to Dr Nordquist advancing the X-Calibur trial and hope it will improve cancer diagnosis and ensure that critical treatments will be available to patients and their treating staff on time and at a convenient location when and where they need it most," Dr Taylor said.

Dr Nordquist said that "in addition to the clinical advantages, we have also been excited about the supply and logistical benefits of SAR-bis-PSMA ... which can be distributed ondemand and in large scale from central manufacturing facilities".

Dr Nordquist said that Clarity's products could "provide universal access to radiopharmaceuticals in every zip-code in the continental US, something that is lacking with current approved agents".

Clarity was unchanged at 57.5 cents.

<u>SERVATUS</u>

Servatus says it has it has begun a 50-patient, first-in-human, 35-day phase I/II trial of probiotics for insomnia, with results expected next year.

Last year, Servatus says it raised \$7.5 million in an 'oversubscribed' capital raise to sophisticated shareholders for its "live microbial and engineered protein bio-therapeutics" (BD: Dec 9, 2021).

Today, the company said the study, at Brisbane's Prince Charles Hospital's Sleep Disorders Centre was the first of its kind in Australia and would assess the safety, efficacy and effect of probiotics on gut microbiome composition and function, and its association with sleep patterns.

Prince Charles Sleep Disorders Centre director Dr Deanne Curtin said there was "a definable gap in the development of safe and effective long-term solutions for insomnia". "Improving sleep habits and behavior therapy are typically the first approach in managing insomnia but most people do not seek professional support and may turn to over-the-counter medications to self-medicate," Dr Curtin said. "However, current medications, whether prescribed or over-the-counter are for short-term use only, may have undesirable side effects and do not treat the underlying cause."

"To date, the role of the microbiome in sleep health has been under-recognized and under-researched," Dr Curtin said.

"However, there is a link between the gut microbiome and sleep through modulating inflammation, regulating neurotransmitter synthesis and organizing human circadian rhythm," Dr Curtin said.

"That is why influencing the microbiome to a healthier composition could offer a promising new treatment option for insomnia."

Servatus is a public unlisted company.

IMUGENE

Imugene says its phase I clinical trial of Checkvacc for triple negative breast cancer will begin dosing a second, higher-dose cohort of 12 patients.

Imugene said the Duarte, California-based City of Hope reviewed the safety and tolerability data from the first, three-patient cohort and confirmed Checkvacc to be safe, with no dose-limiting toxicities or serious adverse reactions.

The company said the trial was expected to run for 24 months.

Imugene managing-director Leslie Chong said the company was "pleased with the results that we have seen so far with no observed toxicity with early encouraging results in oncolytic virus infection and replication in the [triple negative breast cancer] tumors." Imugene was unchanged at 28.5 cents with 34.1 million shares traded.

IMMUTEP

Immutep says eftilagimod alpha or IMP321 with pembrolizumab shows 'encouraging signs of anti-tumor activity' against refractory metastatic non-small cell lung cancer. Immutep said that two of 36 patients had a durable partial response, with 13 patients having "disease control".

Last year, Immutep said it had dosed the last patient of 185 patients in the part A expansion of its phase II Tacti-002 combination study of IMP321, or eftilagimod alpha, with Keytruda, or pembrolizumab, for first and second-line patients with non-small cell lung cancer and second line head and neck small cell carcinoma (BD: Nov 19, 2021). Today, the company published an abstract, titled 'Results of a phase II study investigating eftilagimod alpha (soluble LAG-3 protein) and pembrolizumab in 2nd line PD-1/PD-L1 refractory metastatic non-small cell lung carcinoma pts', ahead of the European Society for Medical Oncology's European Lung Cancer Conference.

The abstract is available at: <u>https://bit.ly/3ujjgN8</u>.

Immutep was unchanged at 44.5 cents with 2.1 million shares traded.

INCANNEX

Incannex says it intends to acquire the Scottsboro, Alabama-based medical marijuana company Apirx for \$US93.3 million (\$A124.6 million) in scrip.

Incannex said Apirx had a portfolio of 19 granted and 23 pending patents, calling it "the largest privately held patent portfolio pertaining to pharmaceutical cannabinoid inventions". The company said it would acquire Apirx's 22 active clinical and pre-clinical research and development projects, which included chewing gum for sustained oral delivery of cannabinoids and cannabinoid combinations, topical compositions and suppositories.

The company said the targeted indications included multiple sclerosis, post-herpetic neuralgia, Parkinson's disease, dementia, restless leg syndrome, gingivitis, periodontitis, psoriasis, gastrointestinal diseases, glaucoma and smoking cessation.

Incannex said Apirx founders Dr George Anastassov and Lekhram Changoer would be employed on a full-time basis on completion of the acquisition to drive the Apirx projects, and assist the development of the Incannex existing projects.

Incannex managing-director Joel Latham said the merger would "bolster our position as a leader in the medicinal cannabinoid sector and will further set [our company] apart from other players in the industry".

"We're positioning Incannex to be a significant player in the pharmaceutical sectors of the future," Mr Latham said.

Incannex fell 4.5 cents or 6.4 percent to 65.5 cents with 7.5 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says Intellectual Property India has granted a patent for its Promarkerd predictive diagnostic for diabetic kidney disease.

Proteomics said the patent, titled 'Biomarkers associated with pre-diabetes, diabetes and diabetes related conditions,' would protect Promarkerd to September 2031.

The company said the India patent was in addition to patents already granted in the US, Europe, Australia, Brazil, Canada, China, Indonesia, Russia, Singapore and Japan. Proteomics was up five cents or 4.5 percent to \$1.17.

EXOPHARM

Carl Charalambous says he has increased his substantial holding in Exopharm from 11,371,818 shares (7.23%) to 13,786,272 shares (8.77%) of the company. The Brisbane-based Mr Charalambous said that from October 18 to 28, 2021 he sold shares and from November 15, 2021 to March 15, 2022, he bought shares, with the largest single purchase 191,000 shares for \$105,166, or 55.0 cents a share. Exopharm was unchanged at 25 cents.

VOLPARA HEALTH TECHNOLOGIES

Harbour Asset Management says it has increased its substantial holding in Volpara from 25,207,679 shares (10.029%) to 27,796,124 shares (11.033%).

The Wellington, New Zealand-based Harbour said that between September 22, 2021 and March 23, 2022 it bought and sold shares, with the largest single acquisition 818,200 shares for \$908,202 or \$1.11 a share.

Volpara fell two cents or 2.7 percent to 73 cents.

MESOBLAST

Mesoblast says it has appointed former US Food and Drug Administration deputy chief for vaccines Dr Philip Krause as a director.

Mesoblast said that Dr Krause had more than 30 years of regulatory experience and was currently the chair of the World Health Organization Covid Vaccines Research Expert Group, having most recently shared responsibility for regulatory authorizations of Covid-19 vaccines in the US.

Mesoblast was up 3.5 cents or 3.2 percent to \$1.14 with 1.85 million shares traded.