Biotech Daily

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Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ALTERITY UP 12%; AMPLIA DOWN 8%**

*** BRANDON, GLYSCEND ORAL GLY-200 FOR TYPE 2 DIABETES**

*** PHARMAXIS DOSES LAST PXS-5505 MYELOFIBROSIS COHORT**

*** PROTEOMICS, MELBOURNE UNI, RWH ENDOMETRIOSIS BLOOD TEST**

*** FIL TAKES 6% OF IMMUTEP**

*** RESAPP LICENCES RESAPPDX TO MEDGATE FOR EUROPE, PHILIPPINES**

*** RESAPP LICENCES RESAPPDX TO ALODOKTER FOR INDONESIA**

*** IMRICOR: TGA APPROVES ADVANTAGE-MR**

*** CRESO: HALUCENEX COMPLETING TESTS ON PSILOCYBIN FOR PTSD**

MARKET REPORT

The Australian stock market was up 0.38 percent on Wednesday August 4, 2021, with the ASX200 up 28.7 points to 7,503.2 points.

Twelve of the Biotech Daily Top 40 stocks were up, 21 fell and seven traded unchanged.

Alterity was the best, up 0.4 cents or 12.1 percent to 3.7 cents, with 32.1 million shares traded. Immutep and Prescient climbed more than five percent; Compumedics was up 3.75 percent; Dimerix, Genetic Signatures and Proteomics rose two percent or more; Impedimed, Mesoblast, Nova Eye, Oncosil and Resmed were up one percent or more; with Cyclopharm up 0.9 percent.

Amplia led the falls, down 1.5 cents or 7.7 percent to 18 cents, with 826,574 shares traded, followed by Patrys down 7.5 percent to 3.7 cents with 42.2 million shares traded.

Uscom lost 6.7 percent; Antisense and Pharmaxis fell more than four percent; Cynata, Resonance and Starpharma were down more than three percent; Actinogen, Paradigm, Telix and Universal Biosensors shed more than two percent; Imugene, Kazia, Opthea and Polynovo were down by more than one percent; with Avita, Clinuvel, Cochlear, CSL, Nanosonics, Next Science and Pro Medicus down by less than one percent.

BRANDON CAPITAL, GLYSCEND THERAPEUTICS

The Brandon Capital-funded Glyscend says it has begun a phase I trial of oral GLY-200 for type 2 diabetes at Adelaide's CMax clinical trial facility.

Brandon Capital told Biotech Daily that the Glyscend's technology was developed by the Baltimore, Maryland-based Johns Hopkins University Hospital staff with the University of Adelaide and Royal Adelaide Hospital's Prof Michael Horowitz and Prof Chris Rayner.

Brandon said it led a $29 million funding round with the Austin, Texas-based Santé Ventures, with support from San Francisco's Breakout Labs.

The company said that pre-clinical data suggested that Glyscend's pill, mimicked gastric bypass surgery and "could mirror the astonishing effect of gastric bypass surgery in improving sugar control in diabetes patients".

Brandon Capital said that gastric bypass surgery diverted food from the upper gastrointestinal tract and together with weight loss due to the lower amounts of calories entering the body, could put type 2 diabetes into remission, but the surgery was risky, costly and invasive.

The company said that GLY-200 mimicked gastric bypass surgery in improving sugar control in patients with type 2 diabetes "by temporarily augmenting the natural mucus barrier lining in the upper gut and affecting hormonal signalling between the [gastro-intestinal] tract, liver, pancreas and brain", without the risks associated with surgery.

Glyscend chief scientific officer Dr Thomas Jozefiak said the pre-clinical studies showed that a daily dose of GLY-200 for eight weeks "significantly reduces the post-meal glucose measurements in diabetic rat models".

"This improvement was also associated with an improved metabolic profile and weight loss, without a difference in food intake," Dr Jozefiak said.

Glyscend is a private company.

PHARMAXIS

Pharmaxis says it has begun dosing the third and final cohort its phase Ic trial of PXS-5505 for the bone marrow cancer myelofibrosis.

Pharmaxis said the higher second cohort dose led "to a predictable increase in drug blood levels in patients and showed the same good tolerability seen in the first dose cohort".

The company said that the third dose cohort was fully-recruited and dosing of all patients was expected to begin at sites in Australia and South Korea, later this week.

Pharmaxis said that following 28 days on the third dose, the safety and pharmaco-kinetics of PXS-5505 would be assessed to select the optimal dose for the six-month dose expansion phase IIa trial to further evaluate safety and efficacy.

The company said that sites in other countries including the US and Taiwan were being engaged in anticipation of the dose-expansion of 24 patients beginning later this year.

In February, Pharmaxis said it enrolled the first of 18 patients in the dose escalation phase of the phase Ic/IIa trial of its oral anti-fibrotic lysyl oxidase (LOX) inhibitor PXS-5505 for myelofibrosis (BD: Feb 22, 2021).

Today, Pharmaxis chief executive officer Gary Phillips said the "results from this second of three dose cohorts in our myelofibrosis clinical trial show a reassuring dose-related increase in blood drug levels and good tolerability".

"We anticipate that we will also see dose-related increases in levels of LOX and LOXL2 inhibition when that data becomes available later this month," Mr Phillips said.

"We are on track to commence dosing in the six--month dose expansion study later this year and deliver results by the end of next year," Mr Phillips said.

Pharmaxis fell 0.4 cents or four percent to 9.5 cents with 1.9 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says that with the University of Melbourne and Melbourne's Royal Women's Hospital it will develop a non-invasive test for endometriosis.

Proteomics said the partnership aimed to develop "the world's first blood test for the painful condition" which affected one-in-nine women and cost Australia $9.7 billion a year.

The company said that endometriosis occurred when tissue similar to the lining of the uterus grew outside the uterus in other areas of the body where it did not belong, most often affecting the reproductive system, as well as the bowel, bladder and other pelvic organs, with the most common symptoms being pelvic pain and infertility.

Proteomics said the collaboration would build on its study that identified protein biomarkers that could be used to test for endometriosis (BD: Mar 23, 2020).

The company said that the Royal Women's Hospital had "a world-leading endometriosis database … which contains anonymous biological samples and survey information from more than 900 women with endometriosis".

Proteomics said it was "the largest and most in-depth endometriosis database and tissue bank in Australia and would be used to validate the panel of biomarkers [it had] discovered".

The company said the University and Hospital would collaborate to identify new biomarkers for the disease.

The Royal Women's Hospital said that endometriosis symptoms often started when women were teenagers, but "because it's so hard to diagnose, girls can struggle with unexplained pain throughout their lives".

"At the moment, there is no simple way to test for endometriosis," the Hospital said.

The Hospital said that the current standard was a laparoscopy with a camera inserted into the pelvis and on average, it took women seven to 12 years to be diagnosed.

Proteomics said it expected the validation of existing biomarkers to take about one year, followed by the discovery of new biomarkers, with the parties to bear their own costs, and Proteomics contributing a nominal fee to assist sample retrieval.

The company said it would retain ownership of its background intellectual property and grant each other party a non-exclusive licence for the purpose of the collaboration, with new intellectual property to be owned jointly by each party.

Proteomics managing-director Dr Richard Lipscombe said the company was "excited to pair our Promarker technology platform, which has already been used to develop the world's first predictive diagnostic test for diabetic kidney disease, with the University of Melbourne and Royal Women's Hospital's exceptional clinical database and expertise in this field".

"It is exciting to think we could develop a world first blood test for diagnosing endometriosis," Dr Lipscombe said.

Proteomics was up 2.5 cents or 2.2 percent to $1.165.

IMMUTEP

FIL Limited says it has become a substantial shareholder in Immutep with 52,878,744 shares or 6.21 percent.

The Sydney and Hong Kong-based Fidelity Investments Limited said it bought 30,336,032 shares between April 29 and July 30, 2021 at prices ranging from 44.11 cents to 52.00 cents.

Last week, Immutep said that Karst Peak, Firetrail, IFM Investors, Regal Funds and Acorn Capital participated in the $67.2 million placement and share plan at 52 cents a share.

Immutep was up 2.5 cents or 5.3 percent to 50 cents with 2.3 million shares traded.

RESAPP HEALTH

Resapp says it has licenced its Resappdx smart-phone respiratory diagnostic to Medgate AG for tele-health in Europe and the Philippines, and to Alodokter for Indonesia.
Resapp said the Basel, Switzerland-based Medgate was a provider of tele-health services and “since 2000 operated the largest tele-medical centre run by doctors in Europe”.
The company said the Resappdx had Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approval.
Resapp said the agreement follows a successful pilot program on Medgate’s tele-medicine services (BD: Nov 9, 2020; Mar 4, Jun 3, 2021).
Resapp managing-director Dr Tony Keating said that Medgate was “a long-standing, global leader in tele-health” and the agreement was the company’s first commercial tele-health licence agreement in Europe.
Medgate chief executive officer Dr Andy Fischer said his company was “absolutely convinced that the use of new technologies like Resappdx will enable an advancement of our digital health platform”.
Resapp said Medgate had a non-exclusive licence for Europe and the Philippines, for an initial one-year term, with specified pricing on a monthly subscription basis.
Separately, Resapp said it had licenced the Resappdx to Jakarta’s Alodokter for its “chat and tele-health services” with an expected launch by December 1, 2021.
The company said that Alodokter connected more than 50,000 doctors and 1,500 hospitals and clinics with millions of Indonesian patients, providing tele-medicine services such as doctor booking, insurance, e-pharmacy and digital healthcare.
Resapp said the launch required Indonesian regulatory approval expected by October.
The company said the initial two-year agreement was exclusive in Indonesia for the first 12 months and non-exclusive after that, with specified pricing on a monthly subscription basis with tiered pricing based on number of tests performed per month.
Resapp did not disclose the commercial terms for either agreement but said neither was expected “to have a material impact on its operating results”.
Resapp was up 0.9 cents or 22.5 percent to 4.9 cents with 25.2 million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says that the Australian Therapeutic Goods Administration has approved its Advantage-MR EP recorder and stimulator system.
The Minneapolis, Minnesota-based Imricor said it was commercializing its magnetic resonance imaging (MRI)-guided cardiac ablation products, primarily for atrial flutter.
A company spokesperson told Biotech Daily the entire system was approved in Europe, with Australia and the US expected to follow.
Imricor said Australian approval of its MRI-guided cardiac ablation system was expected by the end of 2021, with the TGA review of the Vision-MR Ablation Catheter underway.
The company said that New Zealand’s Medsafe had approved all of its products, which were registered in the Government database for medical devices.
Imricor executive chair Steve Wedan said the first TGA approval was “a great milestone in our strategy of geographical expansion”.
“While it will still be some time before we see first sales in Australia and New Zealand, we are working through the logistical issues brought about by the current travel restrictions,” Mr Wedan said.
Mr Wedan said that the potential existed for Australian and New Zealand sites to join the company’s ventricular tachycardia ablation clinical trial in 2022.
Imricor fell 7.5 cents or 4.8 percent to $1.475.

CRESO PHARMA

Creso says, Halucenex is completing United States Pharmacopeia (USP) protocol conditions to validate the use of its psilocybin.

Creso said that the USP 62 test evaluated a product for the presence or absence of potential pathogens and was necessary for cosmetic and personal products to determine that any micro-organisms that may be present in a product are not specific pathogenic microorganisms of particular concern if found in a consumer product.

The company said that once that test was complete and, if successful, it would deem the product safe for human consumption.

Creso said it was in “advanced discussions with [Canada’s] regulatory body regarding the status of its Controlled Drugs and Substances Dealer’s licence” which it believed to be “imminent” allowing further steps towards a phase II trial of psilocybin for treatment-resistant post-traumatic stress disorder (PTSD).

Halucenex chief executive officer Bill Fleming said “the work that has gone into these two testing phases should not be underestimated”.

“Both datasets will provide significant validation of our psilocybin and also indicate that it is safe for human consumption, prior to the commencement of our planned phase II clinical trial,” Mr Fleming said.

Creso was up half a cent or 4.55 percent to 11.5 cents with 18.4 million shares traded.