Biotech Daily

Thursday July 9, 2020

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ANTISENSE UP 17%; AMPLIA DOWN 9%**

*** RAGE: IP GROUP, MONASH, UWA UP TO $10m FOR LUNG DISEASE**

*** LBT PLACEMENT FOR $8m, SHARE PLAN FOR $1m MORE**

*** MEDIBIO APPLICATIONS FOR $513k, $1m SHORTFALL; TOTAL $2m**

*** ORTHOCELL ORTHO-ATI TENDON INJURY SURVEY: 87.5% SATISFIED**

*** RACE REQUESTS 'PLACEMENT' TRADING HALT**

*** KINGHORN JOINS STARPHARMA DEP-IRINOTECAN TRIAL**

*** INCANNEX APPLIES FOR MARIJUANA IHL-42X SLEEP APNOEA TRIAL**

*** CELLMID TELLS ASX: 'WONDFO EXTENSION NOT MATERIAL', UP 30%**

*** CELLMID TO DISTRIBUTE IMMUNODIAGNOSTICS SARS-COV-2 TESTS**

*** ELEANORE GOODRIDGE REDUCES TO 9.6% IN NYRADA**

MARKET REPORT

The Australian stock market was up 0.59 percent on Thursday July 9, 2020, with the ASX200 up 35.2 points to 5,955.5 points. Eighteen of the Biotech Daily Top 40 stocks were up, 18 fell, three traded unchanged and one was untraded.

Antisense was the best for the second day in a row, up 1.6 cents or 17.0 percent to 11 cents, with 6.1 million shares traded. Osprey climbed 11.6 percent; Resonance was up 9.7 percent; Prescient improved 5.1 percent; Actinogen, Cyclopharm, Dimerix, Genetic Signatures and Oncosil were up four percent or more; Immutep, Medical Developments, Neuren and Paradigm were up three percent or more; Kazia and Orthocell rose more than two percent; Mesoblast, Nanosonics and Resmed were up more than one percent; with CSL and Volpara up by less than one percent.

Amplia led the falls, down one cent or 8.7 percent to 10.5 cents, with 114,454 shares traded. Optiscan lost 6.4 percent; Alterity fell five percent; Proteomics and Universal Biosensors were down more than three percent; Clinuvel, Compumedics, LBT and Pharmaxis shed more than two percent; Impedimed, Next Science, Nova Eye (Ellex), Opthea, Polynovo and Uscom were down more than one percent; with Avita, Cochlear, Pro Medicus and Starpharma down by less than one percent.

RAGE BIOTECH

Rage Biotech says IP Group Australia, Monash University and the University of Western Australia will invest up to $10 million for inflammatory lung disease treatments.

Rage said it was backed by an initial investment of $500,000 from IP Group (a subsidiary of London's IP Group PLC), Melbourne's Monash University and Perth's University of Western Australia (UWA), to demonstrate efficacy in pre-clinical models, with further investment of $7 million to $10 million to complete phase I clinical trials.

The company said it was developing new approaches to modulate the receptor for advanced glycation end-products (RAGE), "an important target in multiple acute and chronic inflammatory lung diseases, including severe asthma, cystic fibrosis, chronic obstructive pulmonary disease (COPD), and acute respiratory distress syndrome (Ards).

Rage founder and chief scientific officer, Monash University's Prof Merlin Thomas, said that inflammation was the driving force in many important diseases".

"Rage is a key protein that amplifies inflammation, so targeting RAGE helps bring inflammation back under control," Prof Thomas said.

The company said that as well as addressing unmet needs in chronic conditions such as COPD and cystic fibrosis, its formation was an extremely timely venture in a time of serious respiratory health challenges posed by Australia 2020 black summer bushfires and the Covid-19 pandemic.

Rage said its lead therapeutic candidate was an inhaled antisense oligonucleotide, a class of drug that had been demonstrated to be able to be fast-tracked to the clinic.

Prof Thomas said that the funding for the company was "the beginning of an exciting translational journey towards a new therapy targeting RAGE, that would not have been possible without collaboration and funding from our universities and IP Group".

Rage said it was a spinout company from Monash University and the University of Western Australia, partnered with the Sydney's Centenary Institute, and with intellectual property from Perth's Murdoch University and Melbourne's Baker Heart and Diabetes Institute.

Rage said the company team included Murdoch University's Prof Steve Wilton the developer of the first US Food and Drug Administration approved antisense oligonucleotide drug, and the University of Western Australia's Prof Kevin Pfleger, an expert in peptide signalling and chief scientific advisor to Dimerix, along with the Centenary Institute's Prof Phil Hansbro, an expert in respiratory disease.

Rage is a private company.

LBT INNOVATIONS

LBT says it had commitments to raised $8 million in a placement at 16 cents a share and hopes to raise a further $1 million in a share plan.

LBT said the share price was a 21.9 percent discount to the 15-day volume weighted average price and a 15.8 percent discount to the closing price on July 6, 2020.

The company said the funds would be used for the commercialization of its automated plate assessment system (Apas) Independence in Europe and the US, as well as APAS analysis module development and working capital.

LBT said the share plan would offer shares at 16 cents each to eligible shareholders at the record date of July 8, the share plan would open on July 17 and close on August 7, 2020.

LBT said Hawkesbury Partners and Bell Potter were the joint lead managers to the placement.

LBT fell half a cent or 2.6 percent to 18.5 cents with 4.4 million shares traded.

MEDIBIO

Medibio says it has had applications for $513,201 shares in its fully underwritten, one-for-four, rights offer at 0.6 cents a share, taking the total raised to $2 million.
Last month, Medibio says it had commitments to raise $500,000 through a placement and hoped to raise a further $1,517,195 through a rights offer, underwritten by capital raising lead manager the Perth-based CPS Capital Group (BD: Jun 10, 2020).
Today, the company said that the underwriter CPS Capital had applied for all shortfall shares including the additional shares applied for under the offer valued at $1,003,994, "accordingly no additional shares will be issued to eligible shareholders".
Medibio managing-director Claude Solitario said the funds would be used for "the commercialization of Ilumen, the development of the much-anticipated consumer [application] and of course to further advance our trials for the world's first objective measure for depressive burden".
Medibio was up 0.1 cents or 14.3 percent to 0.8 cents with 76.2 million shares traded.

ORTHOCELL

Orthocell says its four annual quality studies of Ortho-ATI for tendon repair have shown that 87.5 percent of shoulder injury patients were "satisfied" with results.
Orthocell said the annual quality studies of its Autologous Tenocyte Implantation (Ortho-ATI) conducted between 2015 and 2019 recorded self-reported chronic tendon injury patient outcomes for reduction of pain, functional improvement and overall satisfaction, on a scale ranging from extremely dissatisfied to extremely satisfied, where somewhat satisfied was a neutral answer.
The company said the surveys showed a 74.2 percent satisfaction rating from all patients, including patients with tendon injuries in the elbow, shoulder, hip, knee, Achilles, ankle and foot.
Orthocell said the term "satisfied" included the survey responses of satisfied, very satisfied and extremely satisfied.
Orthocell managing-director Paul Anderson, said the surveys "provided further evidence that Ortho-ATI is a breakthrough technology that significantly improves patients' lives returning them to normal function at home and at work, pain free".
"This is important real-world evidence that adds to our growing body of supporting data," Mr Anderson said.
Orthocell was up one cent or 2.9 percent to 35 cents with 2.7 million shares traded.

RACE ONCOLOGY

Race has requested a trading halt "pending an announcement regarding a share placement to strategic investors".
Trading will resume on July 13, 2020 or on an earlier announcement.
Race last traded at 77.5 cents.

STARPHARMA

Starpharma says the Sydney-based Kinghorn Cancer Centre will join its up-to 30 patient, phase II, DEP-irinotecan trial for colorectal, pancreatic and breast cancer.
In May, Starpharma said that recruitment for the dendrimer-enhanced product (DEP) irinotecan open-label trail was underway at sites in the UK and Sydney (BD: May 7, 2020).
Starpharma fell one cent or 0.85 percent to $1.17.

INCANNEX HEALTHCARE (FORMERLY IMPRESSION HEALTHCARE)

Incannex says it will apply to Melbourne's Alfred Hospital to begin a 60-patient, phase IIb trial of the marijuana-based IHL-42X for obstructive sleep apnoea.

Incannex said the phase IIb dose finding, crossover trial would be held at the Alfred Hospital and it had hired contract research organization Novotech to manage the trial, with the Alfred Hospital's Prof Terence O'Brien as lead investigator.

The company said the trial would study the effect of IHL-42X on the apnoea hypopnea index (AHI) in adults with obstructive sleep apnoea.

Incannex said the trial's primary endpoint was the "improvement in AHI from baseline as measured by an overnight polysomnography".

The company said that secondary endpoints included the reduction in oxygen desaturation index, daytime somnolence measured by the Epworth Sleepiness Scale, improvement in mood and well-being, and safety.

Incannex said it would register the trial with the Alfred Hospital ethics committee by July 27, 2020.

Incannex chief executive officer Joel Latham said that the trial had been "modestly delayed by limitations experienced by Covid-19 measures".

"After the recent protocol changes, each patient will have their own room for the sleep study, adhering to social distancing rules," Mr Latham said.

"The company has also been advised by its regulatory consultants that its newly designed trial in partnership with the Alfred will provide a more robust and comprehensive trial, which will be important in its pursuit of registration under the FDA 505b(2) pathway," Mr Latham said.

Incannex said that Novotech would "ensure the integrity of the IHL-42X program, further ensuring that the IHL-42X clinical trial meets the requirements of the [US Food and Drug Administration] in relation to site management, data collection, analysis, and safety monitoring".

Incannex was up 0.4 cents or 6.45 percent to 6.6 cents with 5.0 million shares traded.

CELLMID

Cellmid has told the ASX that it did not expect its 'Extension Of Wondfo Rapid Test Distribution Agreement' announcement to have a material effect on its trading price.

The ASX said the company's share price rose 30 percent from 10 cents on July 1 to a high of 13 cents on July 3, 2020 and noted a closing price of 12 cents on July 2, the day of the Wondfo extension announcement, which was marked "market sensitive".

Cellmid said it did not consider the information to have a material effect on the price or value of its securities on the basis that "there was no material change to the existing agreement between Cellmid and Australia Application".

Last week, Cellmid said that Guangzhou Wondfo Biotech had extended the distribution agreement with Australia Application to December 30, 2020, with chief executive officer Maria Halasz telling Biotech Daily that the original agreement between Wondfo and Australian Application expired on June 30, 2020 (BD: Jul 2, 2020).

Today, the company said it first became aware of the information on June 17, 2020 when Australia Application executed and delivered the amended agreement.

Cellmid told the ASX it was in compliance with Listing Rule 3.1, which required a listed entity to immediately give ASX any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities.

Cellmid was unchanged at 15 cents with 4.5 million shares traded.

CELLMID

Cellmid says it will distribute Immunodiagnostics' enzyme linked immunosorbent assays and a point-of-care serology test for Sars-Cov-2 in Australia and New Zealand.

Cellmid said the Hong Kong-based Immunodiagnostics' laboratory-based enzyme linked immunosorbent assays (Elisa) tests could quantify the absolute level of antibodies and identify the type of antibodies against different severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) antigens.

The company said Immunodiagnostics had different Elisa devices, but it would focus on the Conformité Européenne (CE) marked Sars-Cov-2 S1 Immunoglobulin-G (IgG) Elisa kit for the detection of IgG antibodies specific for the viral spike protein, which detected the viral spike protein in 94.03 percent of 67 patients between days zero to seven of infection, and in 100 percent of 127 patients at day 14 of infection.

Cellmid said the point-of-care serology test detected both immunoglobulin-M (IgM) and immunoglobulin-G (IgG) antibodies which were specific to the nucleo-capsid protein of Sars-Cov-2, differentiating it from the viral spike protein detecting kits already accessed by Cellmid from Wondfo Biotech (BD: Mar 30, Jul 2, 2020).

The company said that the serology test was evaluated with a dataset of 273 Covid-19 patients and 542 pre-Covid-19 control samples and showed an IgG sensitivity of 96.1 percent and specificity of 96.1 percent at the most relevant period of 14 days following onset of symptoms, with an IgM sensitivity of 91.0 percent and specificity of 97.4 percent at the most relevant period of up to seven days from symptoms.

Cellmid said it would seek Australian Therapeutic Goods Association regulatory approval and import permits for the Sars-Cov-2 S1 Immunoglobulin-G (IgG) Elisa kit and the serology test.

The company said the distribution agreement with Immunodiagnostics had an exclusivity period of six months from the date of signing with the option to extend.

Cellmid said it would order commercial quantities of the tests following regulatory approval.

NYRADA

Nyrada says Eleanore Goodridge's substantial holding has reduced from 12,424,832 Chess depository instruments (CDIs) (11.36%) to 10,474,832 CDIs (9.58%).

Nyrada said the change in the Sydney-based Ms Goodridge's holding occurred on July 6, 2020 but did not provide further information.

In January, Nyrada said that Ms Goodridge had become substantial with 12,424,832 CDIs or 11.36 percent of the company.

Nyrada was up 1.75 cents or 8.9 percent to 21.5 cents.