Biotech Daily

Thursday July 23, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTHEA UP 16%; NOVA EYE (ELLEX) DOWN 15%**

*** CLARITY STARTS 67CU-SARTATE NEUROBLASTOMA TRIAL**

*** PHARMAXIS SUBMITS FDA INDA FOR PSX-5055 MYELOFIBROSIS TRIAL**

*** AMPLIA APPOINTS NUCLEUS NETWORKS FOR PHASE I AMP945 TRIAL**

*** ADALTA BEGINS DOSING AD-214 LUNG DISEASE TRIAL**

*** INVEX: FDA, EMA ADVICE ON PRESENDIN FOR IIH**

*** INCANNEX STARTS MARIJUANA IHL-216A RAT TRAIL FOR BRAIN INJURY**

*** COGSTATE COGNITIVE ASSESSMENTS FOR ERT TRIALS**

*** RHYTHM $2.4m PLACEMENT, RIGHTS FOR $3.6m**

*** COGSTATE RECEIPTS UP 4.3% TO $41m**

*** IMMUTEP RECEIPTS $7.7m**

*** ANTERIS (ADMEDUS) H1 RECEIPTS DOWN 62% TO $3.8m**

*** NEXT SCIENCE H1 RECEIPTS UP 31% TO 3.6m**

*** RHINOMED RECEIPTS UP 5% TO $3.1m**

*** AVECHO PLEADS SCHULTZ TO ASX 86% PRICE QUERY**

*** CARDIEX REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** ESENSE REQUESTS 'ISRAEL CORONAVIRUS DEAL' TRADING HALT**

MARKET REPORT

The Australian stock market was up 0.32 percent on Thursday July 23, 2020, with the ASX200 up 19.4 points to 6,094.5 points. Nineteen of the Biotech Daily Top 40 stocks were up, 12 fell and nine traded unchanged.

Opthea was the best, up 37 cents or 16.1 percent to $2.67, with 1.6 million shares traded. Neuren climbed 10.5 percent; Dimerix was up 8.6 percent; Imugene and Prescient improved six percent or more; Cyclopharm and Medical Developments were up more than three percent; Genetic Signatures, Mesoblast, Next Science, Telix and Uscom rose two percent or more; Impedimed, Nanosonics, Paradigm and Proteomics were up one percent or more; with Avita, Polynovo, Resmed and Starpharma up by less than one percent.

Nova Eye (Ellex) led the falls, down 5.5 cents or 14.9 percent to 31.5 cents, with 1.05 million shares traded. Amplia lost 9.1 percent; Antisense, Oncosil, Optiscan and Universal Biosensors fell four percent or more; Cynata and Resonance were down more than three percent; Compumedics shed 2.3 percent; with Clinuvel, Cochlear, CSL, Kazia and Pro Medicus down by less than one percent.

CLARITY PHARMACEUTICALS

Clarity says it has started recruitment for its 34-patient phase I/IIa trial of 67Cu-Sartate for neuroblastoma in children at New York's Sloan Kettering Cancer Centre.

Clarity said the trial was a multi-centre, dose-escalation, open label, non-randomized diagnostic and therapeutic trial of peptide receptor radionuclide therapy (PRRT) administered to paediatric patients with high-risk neuroblastoma.

The company said neuroblastoma most often occurs in children younger than five years of age and presented through tumor growth and consequent symptoms.

Last year, Clarity said the US Food and Drug Administration had approved the 34-patient phase I/IIa trial, and earlier this year the FDA granted 67Cu-Sartate orphan designation and rare paediatric disease designation for neuroblastoma (BD: Oct 3, 2019, Apr 22, Jun 3, 2020).

Clarity executive chairman Dr Alan Taylor said that children with high-risk neuroblastoma had "poor prognosis as current treatment strategies have limited effect in patients with late-stage disease where cancer has metastasized".

"It is evident that the development of new treatment approaches and strategies is crucial to improving treatment outcomes for this patient population," Dr Taylor said.

"We are looking forward to progressing the development of [67Cu-Sartate] and getting closer to our ultimate goal of better treatment of children and adults with cancer," Dr Taylor said.

Clarity is a public unlisted company.

PHARMAXIS

Pharmaxis says it has filed a US Food and Drug Administration investigation new drug (IND) application for a phase I/II trial of PXS-5055 for myelofibrosis.

Pharmaxis did not state the number of patients proposed for the trial but said it had planned to begin the study by the end of 2020 and conclude in 2022.

The company said the trial would include a one-month dose escalation phase followed by a six-month open label study of patients who were not on a janus kinase (JAK) inhibitor treatment.

The company said it expected FDA feedback on the submission within 30 days and would outline the final study design and timeline at that point.

Pharmaxis chief executive officer Gary Phillips said the submission was "the next major step forward in the clinical development program of PXS-5505 for the treatment of myelofibrosis".

"We are leveraging our leadership in lysyl oxidase science to bring new treatment options for these severely under-served patients and strongly believe that our novel approach of inhibiting all of the lysyl oxidase family members could reduce bone marrow fibrosis and have beneficial effects on blood cell production and consequently other aspects of the disease," Mr Phillips said.

"After evaluating the safety and efficacy as a monotherapy in this first phase I/II study we plan further studies to include myelofibrosis patients being treated with JAK inhibitors which are the existing standard of care for many patients," Mr Phillips said.

"We are also actively exploring how PXS-5505 can be progressed in a number of other fibrotic diseases and cancers, including pancreatic cancer, where we have compelling pre-clinical data," Mr Phillips said.

Pharmaxis was unchanged at 8.4 cents.

AMPLIA THERAPEUTICS

Amplia says it has appointed Melbourne's Nucleus Networks to conduct a 64-volunteer, phase I trial of its AMP945 focal adhesion kinase (FAK) inhibitor.
Amplia said the trial would assess safety, tolerability, pharmacokinetics and pharmacodynamics of AMP945 in both single and multiple doses.
Last month, the company said that preliminary toxicology studies of AMP945 in rodents and non-rodent species did not identify "any toxicities that are likely to prevent a phase I trial" (BD: June 30, 2020).
Today, Amplia said that the data collected from the trial could be used to support phase II clinical trials for multiple diseases including solid cancers and fibrotic diseases such as idiopathic pulmonary fibrosis.
The company said it expected data from the phase I trial to be available by July 2021.
Amplia fell 1.5 cents or 9.1 percent to 15 cents.

ADALTA

Adalta says it has treated the first two patients in its 94-patient, phase I trial of AD-214 for interstitial lung disease, including patients with idiopathic lung disease.
Last month, Adalta said it had approval to begin the multi-centre, randomized, double-blind, placebo-controlled and dose escalating trial of AD-214 in healthy volunteers to investigate safety, tolerability, pharmaco-kinetics and pharmaco-dynamics (BD: Jun 10, 2020).
Today, the company said that one participant received AD-214 and one received placebo, and both participants had passed the 72-hour observation window without a dose limiting adverse event.
Adalta was up 3.6 cents or 38.3 percent to 13 cents with 5.8 million shares traded.

INVEX THERAPEUTICS

Invex says the US Food and Drug Administration and European Medicines Agency have advised on studies to approve Presendin for idiopathic intracranial hypertension.
Invex said that Presendin, formerly Exenatide, treated neurological conditions derived from or involving raised intracranial pressure, such as idiopathic intracranial hypertension (IIH), acute stroke and traumatic brain injury, but was not yet optimized for IIH.
The company said the European Medicines Agency (EMA) had indicated a single pivotal study of Presendin against placebo with the endpoints of efficacy, and vision and headache outcomes would be sufficient to support a filing for regulatory approval for IIH in Europe.
Invex said the FDA suggested that two well-controlled studies would be required to support registration of Presendin for IIH in the US.
The company said the proposed regulatory pathway given to the EMA and FDA included the design of a 240-patient, phase III trial with the primary endpoint of perimetric mean deviation at six months.
Invex said both regulatory bodies had deemed the pre-clinical components and its in-human pharmacokinetic study acceptable and would move forward with these studies as planned.
The company said it expected to finalize the phase III trial design by October 2020 and complete the animal tolerability and human pharmacokinetic studies of Presendin by the end of the year.
Invex fell 15 cents or 13.2 percent to 99 cents.

INCANNEX (FORMERLY IMPRESSION) HEALTHCARE

Incannex says it has started a study of its cannabidiol-based IHL-216A for traumatic brain injury and concussion in rats.
Incannex said the trial would investigate the neuro-protective capability of IHL-216A with the hope of reducing neuro-excitation, neuro-inflammation, cerebral blood flow and cerebral oxygen consumption.
The company said the trial would study eight cohorts of rats inflicted with a head injury in a controlled environment.
Incannex said the cohorts would be administered components or combinations of IHL-216A at varying doses soon after the trauma, then undertake behavioral tests at various intervals to assess their neuro-cognitive and motor function.
The company said the trial would monitor secondary injury cascades, assess structural damage to the brain using magnetic resonance imaging and perform micro-scale cellular analysis post-mortem to discern and compare neuronal damage across the cohorts.
Incannex said the study aimed to determine the combination of dosages for a planned human clinical trial and would contribute to the company's US Food and Drug Administration data package.
Incannex was up 0.2 cents or 2.9 percent to 7.2 cents with five million shares traded.

COGSTATE

Cogstate says it has a partnership with the Philadelphia, Pennsylvania-based E-Research Technology (ERT) for digital cognitive assessments in clinical trials.
Cogstate said its computerized cognitive assessments would be combined with ERT's electronic clinical outcome assessment technology platform and used in clinical trials.
The company said that ERT's technology minimized uncertainty and risk in clinical trials, and in 2019, 75 percent of all US Food and Drug Administration drug approvals came from ERT-supported studies.
Cogstate said the partnership with ERT could provide "a potentially significant distribution channel to expand use of Cogstate computerized cognitive assessments in clinical trials, with a focus on both efficacy and safety endpoints" but did not disclose the value of the agreement.
Cogstate was up 15 cents or 35.7 percent to 57 cents.

RHYTHM BIOSCIENCES

Rhythm says it has "firm, binding commitments" to raise $2.4 million in a placement at six cents a share and hopes to raise $3.6 million in a rights offer at the same price.
Rhythm said the placement was supported by sophisticate and profession investors, including chairman Otto Buttula, who had subscribed for $1.5 million worth of shares.
The company said the rights offer was non-renounceable and partially underwritten for $2.25 million by third parties.
Rhythm said the rights offer record date was July 28, it would open on July 31 and close on August 28, 2020.
The company said the funds raised would be used for research and development of its Colostat test kit for colorectal cancer, manufacturing, trial recruitment, regulatory application preparation in Europe and Australia, marketing, business development and working capital.
Rhythm fell 2.1 cents or 20 percent to 8.4 cents with 3.75 million shares traded.

COGSTATE

Cogstate says its receipts from customers for the year to June 30, 2020 were up 4.3 percent to $US29,301,575 ($A41,000,765).
Cogstate said that customer receipts from sales of its patient cognition assessment technology used in clinical trials for the three months to June 30 were up 42.1 percent to $US9,607,010 ($A13,442,785) compared to the previous corresponding period
The company said it had cash and cash equivalents of $US10,360,661 ($A14,498,651) at June 30, 2020, compared to $US3,216,019 ($A4,500,479) at June 30, 2019.

IMMUTEP

Immutep says its customer receipts for the 12 months to June 30, 2020 were up 528.0 percent to $7,737,000 compared to the previous corresponding period.
Immutep told Biotech Daily that the receipts were primarily a milestone payment of $7.4 million from Glaxosmithkline last year (BD: Sep 23, 2019).
Today, Immutep said it had cash and cash equivalents of $26,322,000 at June 30, 2020 compared to $16,568,000 at June 30, 2019.
Immutep was unchanged at 20 cents with 3.8 million shares traded.

ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS)

Anteris says customers receipts for the six months to June 30, 2020 were down 62.3 percent to $3,780,000 compared to the previous corresponding period.
Anteris said receipts from customers for the three months to June 30, 2020 fell 50.7 percent to $2,036,000.
Last year, the company said it had sold its hospital infusion business to BTC Health for $6.3 million and distribution rights to its cardiac patch business to the Burlington, Massachusetts-based LeMaitre Vascular for $36.2 million (BD: May 31, Oct 14, 2019).
Today, Anteris said its revenue primarily came from manufacturing its cardiac patch for LeMaitre.
The company said it had cash and cash equivalents of $6,896,000 at June 30, 2020 which would fund 2.15 quarters, compared to $4,887,000 at June 20, 2019.
Anteris fell four cents or 1.1 percent to $3.65.

NEXT SCIENCE

Next Science says customer receipts for the six months to June 30, 2020 were up 31.0 percent to $US2,538,000 ($A3,556,000) compared to the previous corresponding period.
Next Science said that receipts from customers for the three months to June 30, 2020 were up 59.2 percent to $US1,904,000 ($A2,667,000).
The company said the receipts came from sales of its Bactisure surgical lavage for the removal of bacteria, fungus and infection from wounds, and its Surgx and Blastx anti-microbial gels.
Next Science said the sales of Bactisure, Surgx and Blastx for the three months to June 30, 2020 had been impacted by the Covid-19 pandemic.
The company said it had cash and cash equivalents of $US11,907,000 ($A16,689,000) at June 30, 2020 which would fund operations for six quarters, compared to $US22,980,000 ($A32,184,000) at June 30, 2019.
Next Science was up 3.5 cents or 2.7 percent to $1.335.

RHINOMED

Rhinomed says customer receipts for the 12 months to June 30, 2020 were up 5.4 percent to $3,137,000 compared to the previous corresponding period.
Rhinomed said receipts from customers for the three months to June 30, 2020 were down 51.5 percent to $742,000 compared to the three months to June 30, 2019.
The company said the receipts came from sales of its over-the-counter Pronto nasal dilator technology for sleep and decongestion.
Rhinomed said that sales for the three months to June 30 were down due to Covid-19 related restrictions which reduced pharmacy foot traffic.
The company said it had cash and cash equivalents at June 30, 2020 of $7,838,000, which would fund 13.9 quarters, compared to $1,456,000 at June 30, 2019.
Rhinomed fell 0.4 cents or 5.3 percent to 7.2 cents.

AVECHO BIOTECHNOLOGY

Avecho has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 85.7 percent from 0.7 cents yesterday to a high of 1.3 cents today and noted a "significant increase" in the trading volume.
Avecho fell 0.2 cents or 18.2 percent to 0.9 cents with 20.5 million shares traded.

CARDIEX

Cardiex has requested a trading halt "pending an announcement regarding the company's capital raising activity".
Trading will resume on July 27, 2020 or on an earlier announcement.
Cardiex last traded at 3.1 cents.

ESENSE-LAB

Esense has requested a trading halt "pending an announcement regarding a research agreement with the Israeli Ministry of Health" for coronavirus.
Trading will resume on July 27, 2020 or on an earlier announcement.
Esense last traded at 1.8 cents.