Biotech Daily

Monday September 7, 2020

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: OPTISCAN UP 31%; PHARMAXIS DOWN 17%**

*** FEDERAL $1.7b FOR CSL FOR UQ-CSL, OXFORD-AZ COVID-19 VACCINES**

*** BOEHRINGER INGELHEIM HANDS BACK PHARMAXIS PXS4728A**

*** NEXT SCIENCE: FDA WANTS MORE DATA FOR XPERIENCE SURGICAL RINSE**

*** ADALTA RIGHTS RAISE $4.1m; TOTAL $8.1m**

*** VICTORIA $252k FOR POLYNOVO HERNIA CLEANROOM**

*** CYNATA: CYMERUS STEM CELLS IMPROVE IPF IN MICE**

*** CARDIEX, CHINA'S ANDON PARTNER FOR REMOTE B-P MONITOR**

*** OPYL TELLS ASX: COVID-19 '1st USE' FOR AI TRIAL SOFTWARE**

*** BIOTRON: '15 COMPOUNDS SHOW ACTIVITY FOR SARS-COV-2'**

*** PHARMAUST REQUESTS 'ELANCO OPTION' TRADING HALT**

*** RECCE REQUESTS 'ANTI-VIRAL TESTING RESULTS' TRADING HALT**

*** M&G REDUCES TO 8.8% OF MESOBLAST**

*** ELIXXIR REDUCES TO 21% OF LITTLE GREEN PHARMA**

*** NEUROTECH TAKES 80 MARIJUANA SAMPLES TO IN-VITRO TESTING**

*** BIO-MELBOURNE FORUM ON BURNET COVID-19 'OPTIMISE' STUDY**

MARKET REPORT

The Australian stock market was up 0.33 percent on Monday September 7, 2020, with the ASX200 up 19.3 points to 5,944.8 points. Eight of the Biotech Daily Top 40 stocks were up, 20 fell and 12 traded unchanged.

Optiscan was the best on no news, up 2.1 cents or 30.9 percent to 8.9 cents, with 2.7 million shares traded. Patrys climbed 16.7 percent; Opthea and Universal Biosensors were up more than three percent; Cynata, Impedimed and Starpharma rose more than two percent; CSL was up 1.1 percent, with Cochlear and Kazia up less than one percent.

Pharmaxis led the falls, down 1.7 cents or 17.35 percent to 8.1 cents, with five million shares traded. Mesoblast lost 5.45 percent; Osprey fell four percent; Actinogen, Next Science, Prescient and Resonance retreated more than three percent; Dimerix, Genetic Signatures, Immutep, Nanosonics, Polynovo, Proteomics and Uscom shed two percent or more; Clinuvel, Compumedics, Cyclopharm and Resmed were down more than one percent; with Neuren, Pro Medicus and Telix down by less than one percent.

CSL, FEDERAL GOVERNMENT

CSL says it has 'heads of agreements' with the Federal Government to supply the University of Queensland and Oxford University Covid-19 vaccines.

CSL said that, subject to successful trials, subsidiary Seqirus had an agreement with the Federal Government to supply 51 million doses of the University of Queensland-CSL V451 vaccine, based on a two dose per person regime, and a separate agreement with Astrazeneca to manufacture 30 million doses of the Oxford University Astrazeneca vaccine, AZD1222, also based on a two dose per person regime.

In a separate media release, the Federal Government said it had "a $1.7 billion supply and production agreement between the Australian Government and pharmaceutical companies".

A media release posted on Prime Minister Scott Morrison's website said that the University of Oxford-Astrazeneca and the University of Queensland-CSL would "provide more than 84.8 million vaccine doses for the Australian population, almost entirely manufactured in Melbourne, with early access to 3.8 million doses of the University of Oxford vaccine in January and February 2021".

Mr Morrison said both vaccines would need to be proven safe and effective and meet all necessary regulatory requirements, prior to being made available to the public.

"Australians will gain free access to a Covid-19 vaccine in 2021 if trials prove successful," Mr Morrison said. "By securing the production and supply agreements, Australians will be among the first in the world to receive a safe and effective vaccine, should it pass late stage testing."

"There are no guarantees that these vaccines will prove successful, however the agreement puts Australia at the top of the queue, if our medical experts give the vaccines the green light," Mr Morrison said.

Federal Health Minister Greg Hunt said the Federal Government was "a strong supporter of immunization in that it is a safe and effective way to prevent the spread of many diseases in the community that can cause hospitalization, serious ongoing health conditions, or even death".

"While the Government supports immunization, it is not mandatory and individuals maintain the option to choose not to vaccinate," Mr Hunt said.

CSL said it had begun vaccine production, was currently in a phase I safety and immune-genicity study in healthy volunteers, and a phase IIb/III trial would begin later this year.

CSL said the Government would also provide funding to support the manufacture of AZD1222, under contract to Astrazeneca, subject to regulatory approval.

In a media teleconference, CSL chief scientific officer and head of research Dr Andrew Nash said the company was the only one in Australia with the capability of mass production of the two vaccines.

Seqirus head of research and development Dr Russell Basser said that to describe a vaccine as "successful" it would need to be 50 to 60 percent effective, with a minimum of 30 percent.

Dr Basser said that the severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) which caused Covid-19 had "minor mutations" but there appeared to be no significant differences between variants and a vaccine effective against one strain should be effective against all strains.

"We are acting with a sense of urgency but not cutting corners," Dr Basser said.

Dr Basser said that the University of Queensland-CSL vaccine was using a tried and tested process of combining antigen and adjuvant, whereas the Oxford-Astrazeneca vaccine was using newer technology.

CSL was up $3.08 or 1.1 percent to $282.13 with 822,571 shares traded.

PHARMAXIS

Pharmaxis says Boehringer Ingelheim has terminated the development of BI 1467335, or PXS4728A, for moderate to severe non-proliferative diabetic retinopathy.

Last year, Pharmaxis said the Ingelheim, Germany-based Boehringer Ingelheim had terminated the BI1467335 program for non-alcoholic steatohepatitis, but said the second program for diabetic retinopathy would continue (BD: Dec 18, 2019).

Today, the company said that a Boehringer Ingelheim 79 patient, phase IIa, randomized, double-blinded trial for moderate to severe non-proliferative diabetic retinopathy met its primary endpoint in ocular safety with the treatment well-tolerated.

Pharmaxis said Boehringer Ingelheim "decided not to further develop BI 1467335 in this indication based on the lack of a clear efficacy signal and risk of dose-dependent drug interactions of the compound in … patients identified in another phase I study".

The company said patients were treated with either BI 1467335 or placebo for 12 weeks and followed up for 12 weeks, with the primary objective safety and tolerability and the secondary objective the improvement in diabetic retinopathy severity score.

In 2015, Pharmaxis said it sold the anti-inflammatory AOC3 inhibitor PXS4728A to Boehringer Ingelheim for an upfront fee of $39.2 million and up to $750 million in milestone payments (BD: May 18, 2015).

Today, Pharmaxis chief executive officer Gary Phillips told Biotech Daily the company had earned $83 million in up-front and milestone payments from Boehringer Ingelheim for the two indications of non-alcoholic steato-hepatitis and diabetic retinopathy.

Mr Phillips said that while the retinopathy study showed safety concerns with a "relatively high dose" it also demonstrated some efficacy and Pharmaxis was looking forward to a close look at the Boehringer Ingelheim data.

In a media release, Pharmaxis said it would continue development of small molecule amine oxidase inhibitors with a phase II study in myelofibrosis due to begin this year.

Mr Phillips said the company understood the decision to stop development based on the risk of dose dependent drug interactions at the dose level tested in the trial and the company would review the data to evaluate opportunities in other indications that had supportive pre-clinical data and where the risk of drug interactions was of less concern.

Pharmaxis fell 1.7 cents or 17.35 percent to 8.1 cents with five million shares traded.

NEXT SCIENCE

Next Science says the US Food and Drug Administration has required a further animal study and laboratory test for the 510 (k) class II clearance of Xperience surgical rinse.

Next Science said it expected the additional requirements and would complete the study and trial in time to lodge the submission to the FDA in November 2020 with an expected US launch by July 2021.

Next Science fell four cents or 3.1 percent to $1.26.

ADALTA

Adalta says it has raised $4.1 million through a one-for-four, non-renounceable entitlement offer at 10 cents a share, taking the total raised to $8.1 million.

Last month, Adalta said it had commitments to raise $4 million through a placement and hoped to raise a further $4.1 million in the rights offer (BD: Aug 11, 2020).

Today, the company said it had received applications for 74 percent of total entitlements, with the remaining shares subscribed under its shortfall facility.

Adalta was up 1.1 cents or 11.1 percent to 11 cents with 1.3 million shares traded.

POLYNOVO, VICTORIA GOVERNMENT

Polynovo says the Victorian Government has provided a grant of up-to $252,000 to purchase equipment and develop a hernia cleanroom at its Port Melbourne facility.
Polynovo said the hernia cleanroom would manufacture its Novosorb Syntrel hernia product.
Polynovo managing-director Paul Brennan said the hernia plant would “produce a product that will change the way hernias are managed world-wide”.
It is a matter of pride that these products will be manufactured in Port Melbourne using Australian technology,” Mr Brenna said.
Polynovo fell five cents or 2.3 percent to $2.15 with 2.3 million shares traded.

CYNATA THERAPEUTICS

Cynata says its Cymerus mesenchymal stem cells improve the harmful effects of idiopathic pulmonary fibrosis in mice.
Cynata said the study at Melbourne’s Monash University, assessed its stem cells in a bleomycin induced idiopathic pulmonary fibrosis (IPF) model compared to a placebo.
The company said it administered either a single dose three weeks following bleomycin administration or a double dose at three and four weeks after bleomycin administration.
Cynata said the treatment with its stem cells “led to statistically significant improvements in multiple harmful effects of IPF, including interstitial lung fibrosis, dynamic lung compliance and airway resistance” along with interstitial lung inflammation and epithelial and sub-epithelial thickness.
Cynata said that control animals suffered a 40 percent loss of dynamic lung compliance following bleomycin which was expected, but Cymerus treated mice had an average 15 percent loss of dynamic lung compliance.
Cynata was up 2.5 cents or 2.9 percent to 89.5 cents.

CARDIEX

Cardiex says it has a three-year partnership with China’s Andon Health to develop remote monitoring devices based on its Sphygmocor technology.
Cardiex said the agreement, through its wholly owned subsidiary Atcor Medical, would pair its Sphygmocor central blood pressure and arterial stiffness measurement technology with its Arty remote monitoring application, to be included in the Atcor Pulse, “the world’s first [internet] cloud-connected home use [blood pressure] monitor”.
The company said the vital sign monitoring device, Atcor Pulse, and would include video, chat, messaging, customizable screens and vital signs sharing features.
Cardiex said it would retain intellectual property and distribution rights and payment would be based on product development and US Food and Drug Administration clearance milestones.
The company said Andon would be responsible for regulatory approvals targeting a commercial launch in the US, Europe, Australia and China by December 31, 2021.
Cardiex chief executive officer Craig Cooper said it was “the most significant announcement … since I became CEO and represents a major value milestone for all shareholders”.
“We will continue to expand our product portfolio with new devices including new partnerships in medical and clinician based vital signs monitoring, wearables, and other health technologies,” Mr Cooper said
Cardiex was unchanged at 5.7 cents with 8.4 million shares traded.

OPYL

In a six-page response to ASX queries, Opyl said that the Covid-19 model of its trial prediction software was not proof-of-concept, as stated on September 3, 2020.
Last week, Opyl said that a proof-of-concept study of its artificial intelligence clinical trial prediction software had analyzed the probability of Covid-19 vaccine and antibody therapy trial success (BD: Sep 3, 2020).
Today, the company said "a more accurate statement is that Covid-19 is the model's first major use case" and it had applications beyond Covid-19 for a range of applications.
Opyl fell one cent or 4.35 percent to 22 cents with 4.9 million shares traded.

BIOTRON

Biotron says 15 of 47 of its compounds screened in cell culture studies have shown antiviral activity against severe acute respiratory syndrome-coronavirus-2 (Sars-Cov-2).
Biotron said Melbourne's 360 Biolabs screened the 47 compounds for cellular toxicity, 17 showed promising activity and undertook further testing, with 15 compounds confirmed.
The company said it expected to complete screening of additional compounds by the end of 2020, which it hoped could progress to animal testing and clinical trials for Covid-19.
Biotron managing-director Dr Michelle Miller said the results were "encouraging".
"There is a need for new ways to treat this disease, and Biotron believes that these results open-up a promising new therapeutic pathway," Dr Miller said.
Biotron was up 1.5 cents or 15.8 percent to 11 cents with 69.8 million shares traded.

PHARMAUST

Pharmaust has requested a trading halt pending "an announcement in relation to … Elanco regarding its intention regarding exercising its option agreement".
In 2018, Pharmaust said it had an agreement with Eli Lilly subsidiary Elanco to develop its monepantel for sheep round-worm as a treatment for cancer in dogs (BD: Apr 18, 2018).
Trading will resume on September 9, 2020 or on an earlier announcement.
Pharmaust last traded at 19 cents.

RECCE PHARMACEUTICALS

Recce has requested a trading halt "pending the release of an announcement relating to anti-viral testing results".
Trading will resume on September 9, 2020 or on an earlier announcement.
Recce last traded at $1.475.

MESOBLAST

The London-based M&G Investments Funds says it has reduced its substantial shareholding in Mesoblast from 58,000,971 shares (9.91%) to 51,752,865 shares (8.84%).
M&G said its previous substantial shareholder notice was on August 21, 2020.
In August, M&G said it reduced its holding from 65,668,769 shares (11.24%) to 59,684,727 shares (10.21%) and later said it had reduced its holding from 64,531,906 shares (11.04%) to 58,000,971 shares (9.91%) (BD: Aug 21, 24, 2020).
Today, M&G said that it sold the shares between August 21 and September 3, 2020, with the single largest sale 947,475 shares on August 26 for $4,860,562 or $5.13 a share.
Mesoblast fell 27 cents or 5.45 percent to $4.68 with 12.9 million shares traded.

LITTLE GREEN PHARMA

Elixxir says it has reduced its substantial shareholding in Little Green Pharma from 29,488,316 shares (22.09%) to 28,150,074 shares (20.95%).
The Montreal-based Elixxir said that it sold 1,381,312 shares between July 20 and August 24, 2020 at prices ranging from 31.0 to 36.5 cents a share.
Little Green Pharma was unchanged at 25.5 cents.

NEUROTECH INTERNATIONAL

Neurotech says Melbourne's ACS Laboratories has conducted genetic profiling and potency analysis of 80 marijuana samples from Dolce Cann Global.
In July, Neurotech said it was investigating marijuana for neurological disorders, including autism, epilepsy and attention deficit hyperactivity disorder (BD: Jul 27, 2020).
Today, the company said that ACS found that the samples contained varying amounts of all major cannabinoids and its lead samples contained cannabidiolic acid (CBDA) levels about 12 percent.
Neurotech said it would begin in-vitro testing of priority strains on human derived cell lines this month and if successful, would start clinical trials with an Australian university.
Neurotech was unchanged at 1.4 cents with 10.1 million shares traded.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says it will hold a Bio-Forum, titled 'The Optimise Study: The Role Science Plays in Optimising Isolation, Quarantine and Distancing for COVID-19'.
The Network said that the event would discuss Burnet Institute-led Optimise Study, which was providing epidemiological information and modelled predictions on the impacts of isolation, quarantine and physical distancing measures on Covid-19 transmission.
The Bio-Melbourne Network said that "without an effective vaccine or preventative drug treatment for Covid-19, isolation, quarantine and physical distancing are the crucial tools we can use to reduce the impact of the virus".
"These interventions rely on the support and engagement of communities to ensure this response strategy is successful," the Network said.
The industry organization said that the Burnet Institute deputy director, Prof Margaret Hellard and presenters, Dr Nick Scott, Dr Rachel Sacks-Davis and Dr Alisa Pedrana would discuss how the multidisciplinary Optimise team would engage with government, community organizations, advocates, and leaders "to ensure strategies and interventions are informed by the diverse needs of our society".
The Network said the Bio-Forum would be held on September 17, 2020 from 4pm to 5:30pm (AEST).
To register go to: https://bit.ly/2G2PKpu.