Biotech Daily

Tuesday September 15, 2020

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PATRYS UP 21%; PHARMAXIS DOWN 5%**

*** CYCLOPHARM: TECHNEGAS US TRIAL MEETS ENDPOINTS EARLY**

*** CLINUVEL DOSES 1st SCENESSE XP PATIENT**

*** IP GROUP: $650k FOR AUGMENTED BIONICS NON-INVASIVE HEARING AID**

*** RHINOMED DEVELOPS URTI NASAL SWAB**

*** OSTEOPORE, SINGAPORE UNI STUDY 3-D JAW IMPLANTS**

*** EMERALD: TGA REGISTERS 'OPENLY' FOR REMOTE MONITORING**

*** MEDLAB DIRECTORS 12m OPTIONS, 100% FEES POOL HIKE AGM**

*** YUUWA CAPITAL DILUTED TO 22% OF ADALTA**

*** AVITA LOSES DIRECTOR DAMIEN MCDONALD**

*** CANN GROUP CONFIRMS JENNI PILCHER DIRECTOR**

*** EXOPHARM HIRES ALISON MEW, CANARY CAPITAL CORP ADVISOR**

MARKET REPORT

The Australian stock market was up 0.68 percent on Tuesday September 15, 2020, with the ASX200 up 40.1 points to 5,899.5 points. Twenty-four of the Biotech Daily Top 40 stocks were up, 12 fell and four traded unchanged. All three Big Caps were up.

Patrys was the best on no news, telling the ASX that Gilead and Merck had paid billions of dollars for antibody developers, up 0.3 cents or 21.4 percent to 1.7 cents, with 151.1 million shares traded. Cyclopharm climbed 13.2 percent on US trial success; Cynata was up 7.6 percent; Next Science improved 5.6 percent; Clinuvel, Imugene, Kazia, Optiscan and Osprey were up four percent or more; Genetic Signatures, Mesoblast and Orthocell were up more than three percent; Alterity, Immutep, Polynovo and Telix rose more than two percent; Actinogen, Antisense, Avita, CSL, Medical Developments, Neuren, Nova Eye and Resmed were up more than one percent, with Cochlear, Nanosonics and Pro Medicus up by less than one percent.

Pharmaxis led the falls, down 0.4 cents or 4.8 percent to 7.9 cents, with 665,700 shares traded. LBT, Paradigm, Proteomics and Resonance lost more than three percent; Starpharma and Uscom shed more than two percent; Compumedics, Dimerix, Opthea and Prescient were down more than one percent; with Volpara down 0.8 percent.

CYCLOPHARM

Cyclopharm says its 240-patient, phase III Technegas lung imaging trial has been halted after data from 200 patients met the primary efficacy endpoint.

Cyclopharm said that an independent data monitoring efficacy committee, requested by the US Food and Drug Administration as part of its assessment process, reviewed data sets of groups of 40 patients imaged with xenon-133 and then with its Technegas and unanimously recommended that the trial had successfully met its endpoints and should be stopped.

In 2016, Cyclopharm said the FDA had approved a special protocol assessment for a phase III trial comparing Technegas with xenon-133 (BD: Nov 23, 2016).

Today, Cyclopharm managing-director James McBrayer told Biotech Daily that in December 2017, the FDA approved diethylene-triamine-penta-acetate, or DTPA, against which the company had extensive comparative data.

Mr McBrayer said that decision allowed Cyclopharm to move to a comparative 505(b)(2) FDA pathway.

Mr McBrayer said he had expected that approval process to take until at least April 2021, but with the early closing of the trial the company had notified the FDA and expected to have a teleconference with the regulator “likely within the next couple of weeks”.

Mr McBrayer said he was “very pleased” to be able to announce successful trial results.

In a media release to the ASX, Cyclopharm said that due to the Covid-19 pandemic, patient recruitment had slowed significantly, but give that 85 percent of the target number of patients have been recruited, the FDA determined that it would be helpful, in its review of the Technegas new drug application, to understand the substance of the CYC-009 trial efficacy data.

The company said that to maintain the integrity of the prospective, non-inferiority trial by keeping the data blinded to the company, the FDA recommended an independent data monitoring committee conduct an interim analysis focused on efficacy.

Cyclopharm company said it was awaiting an FDA question and answer response and would inspect a manufacturing site by April 2021, with Technegas sales expected in the US in 2021.

Mr McBrayer said the company was “in a position to move to final approval for sales of Technegas in the US … this will be a great milestone for the company”.

Cyclopharm was up 18.5 cents or 13.2 percent to $1.585.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has dosed the first patient in its DNA repair program of Scenesse for xeroderma pigmentosum to confirm the safety of the drug.

Last week, Clinuvel said it would trial its Scenesse for xeroderma pigmentosum patients to test whether the drug could regenerate the DNA of ultraviolet-damaged skin, with first clinical results expected in 2021 (BD: Sep 10, 2020).

Today, the company said the first patient under a special access program was administered Scenesse and would be assessed over 42 days to confirm safety.

Clinuvel said that following confirmation of safety, it would proceed to an open-label, phase IIa pilot study of six xeroderma pigmentosa patients, using “biopsies and assays to evaluate photoproducts, repair mechanisms, disease severity and quality of life”.

Clinuvel said it would also conduct a 10-patient study of healthy volunteers, using biopsies and assays to evaluate photoproducts and repair mechanisms.

The company said details of the studies would be release in the following weeks.

Clinuvel was up 85 cents or four percent to $22.16 with 236,484 shares traded.

IP GROUP AUSTRALIA, AUGMENTED BIONICS

IP Group says that with Sydney's Artesian Venture Partners it has provided $650,000 to Augmented Bionics to develop a non-invasive alternative to cochlear implants.
Melbourne's IP Group Australia, a subsidiary of London's IP Group PLC, said the funds from a group of investors would be used for pre-clinical and clinical proof-of-concept testing for the trans-cranial magnetic stimulation bionic ear.
In a media release, IP Group said Augmented Bionics was founded as part of the University of Queensland Ventures' Accelerator program in 2017, based on research jointly developed by the founders and researchers from the University of Queensland, and transferred by the University's technology transfer company, Uniquest.
The company said that the research hoped "to demonstrate the sensation of hearing, first in a pre-clinical, guinea pig model, and then in first-in-human clinical testing".
IP Group said the device was "a world first that would change the lives of potentially tens of millions of patients globally who currently suffer from severe to profound hearing loss that cannot be addressed by hearing aids, and who are unable to access a cochlear implant".
The company said that Augmented Bionics was developing trans-cranial magnetic stimulation.
IP Group said that the company was founded by Viraj Agnihotri, Mahanthesh Chandra, and Nicholas Jabbour and received seed investment by Artesian's Actuator Medtech Venture Capital Fund.
Mr Agnihotri said the Augmented Bionics non-invasive bionic ear would "provide the convenience of wearing a hearing aid, with the hearing outcome of a cochlear implant".
IP Group said that Augmented Bionics was supported by researchers from Macquarie University and the University of New South Wales, led by Prof David McAlpine and Prof Gary Housley, respectively.
Prof McAlpine said that across the world, about 1.5 million additional patients were diagnosed every year with severe hearing loss and receive limited to no benefit from existing technologies.
"Augmented Bionics' truly non-invasive approach to stimulating the deafened ear is potentially transformative for this large and growing population," Prof McAlpine said.
IP Group Australia managing-director Dr Michael Molinari said Australia "pioneered the development of cochlear implants and has unique access to talent and clinical expertise in this area".
"This innovative technology … has the potential to benefit millions of people with severe hearing loss around the world," Dr Molinari said.
Augmented Bionics is a private company.

RHINOMED

Rhinomed says it is developing a nasal swab to detect the presence of upper respiratory tract infections, including influenza and coronavirus strains.
Rhinomed said the nasal swab would use standard electrostatically flocked nylon to capture sample material from both nostrils simultaneously.
The company said it was designed to be less invasive, more comfortable, collect samples from a greater surface area of the nose and be able to be self-administered.
Rhinomed said it was investigating manufacturing options, had begun defining the protocol for a trial at a Melbourne hospital and would register the device in Australia, the US and the European Union as a class one medical device.
Rhinomed was up 6.9 cents or 90.8 percent to 14.5 cents with 17.6 million shares traded.

OSTEOPORE

Osteopore says it has a research agreement with the National University of Singapore for an animal study of its three-dimensional printed implants for mandibular reconstruction.
Osteopore said that the unspecified, large mammal study, funded by Singapore's National Additive Manufacturing Innovation Cluster, would investigate the potential for its 3-D printed bioresorbable implants for mandibular, or lower jaw, reconstruction.
The company said that the study would combine its implant with bone marrow aspirates to regrow bone, following mandibular reconstruction surgery.
Osteopore said the main objective of the study would be to assess the effectiveness of the technology to reconstruct mandibular defects, to provide pre-clinical data for further evaluation in future studies and to support future first-in-human studies.
The company said that following the study, it would assess the potential to take the project into first-in-human and clinical studies with the National University of Singapore and National University Hospital.
Osteopore was unchanged at 52 cents.

EMERALD CLINICS

Emerald says the Australian Therapeutic Goods Administration has registered its Openly application as a class one medical device for remote digital health monitoring.
Emerald said the registration followed its self-assessment of the Openly platform, which collected clinical information from individuals remotely and presented it to a clinical team.
The company said the application incorporated smartphone technologies that, once validated, would enable the collection of contactless vital signs.
Emerald was up 0.7 cents or 8.1 percent to 9.3 cents with 5.5 million shares traded.

MEDLAB CLINICAL

Medlab says shareholders will vote to increase its non-executive remuneration pool by 100 percent to $600,000 and issue 12,000,000 'incentive' options to directors.
Medlab said its annual general meeting it would vote to issue non-executive director Laurence McAllister 4,000,000 options, exercisable at 18 cents each by October 31, 2022.
Medlab said it proposed to issue 4,000,000 options to chief executive officer Dr Sean Hall and 2,000,000 options each to chair Michael Hall and director Drew Townsend, exercisable at 20 cents each, by October 31, 2022.
The company said the meeting would vote on the remuneration report, to re-elect Michael Hall as a director, ratify the appointment of Mr McAllister as a director, ratify the prior issue of 17,857,143 placement shares and to increase its placement capacity up to 10 percent.
The meeting will be held at Hall Chadwick, Level 40, 2 Park Street, Sydney on October 16, 2020 at 10am (ADST).
Medlab was up two cents or 12.1 percent to 18.5 cents with 1.9 million shares traded.

ADALTA

The Nedlands, Western Australia-based Yuuwa Capital says its 54,059,848 share-holding in Adalta has been diluted from 26.51 percent to 22.05 percent.
The substantial shareholder notice, signed by Yuuwa partner and Adalta director Elizabeth McCall, said Yuuwa was diluted on September 11, 2020 in the $4.1 million rights issue at 10 cents a share (BD: Sep 7, 2020).
Adalta was unchanged at 10.5 cents.

AVITA THERAPEUTICS

Avita says director Damien McDonald, who was appointed in January 2016, will not stand for re-election at its annual general meeting on October 29, 2020.
Avita was up 14 cents or 1.9 percent to $7.54 with 582,368 shares traded.

CANN GROUP

Cann Group says it has formally appointed Jenni Pilcher as a director.
In July, Cann Group said it has appointed Ms Pilcher, pending statutory clearance from the Department of Health's Office of Drug Control (BD: Jul 17, 2020).
Cann Group was up 1.5 cents or 3.6 percent to 43.5 cents with one million shares traded.

EXOPHARM

Exopharm says it has appointed Alison Mew as interim director of manufacturing and development and has hired Canary Capital as corporator advisors.
Exopharm said Ms Mew was formerly Genetic Technologies chief operating officer and chief executive officer and held operations and general management roles for CSL.
The company said Ms Mew was currently a director at the Centre for Biopharmaceutical Excellence and McPherson Ltd.
Exopharm said it would pay Canary a $6,000 monthly fee as part of a 12-month corporate advisory mandate, following its $10 million placement, in which Canary was the lead manager (BD: Aug 27, 2020).
The company said it would also issue Canary 3,000,000 unlisted options, with half exercisable at 60 cents a share and half exercisable at 90 cents a share within five years.
Exopharm fell 1.5 cents or 4.8 percent to 29.5 cents.