Biotech Daily

Tuesday June 9, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: LBT UP 18%; USCOM DOWN 10%**

*** CSL BUYS VITAERIS FOR KIDNEY TRANSPLANT REJECTION DRUG**

*** LBT: 1st US APAS INDEPENDENCE SALE TO HENNEPIN COUNTY**

*** OSPREY SHORTFALL RAISES $2.6m; TOTAL $12.8m**

*** IMMURON, US NAVY COW COLOSTRUM DRUG RESUMES**

*** OPTHEA REQUESTS 'OPT-302 PHASE IIa DME RESULTS' TRADING HALT**

*** CRESO LAUNCHES CANNAQIX MARIJUANA IN SOUTH AFRICA**

*** EMVISION TO RELEASE 1.3m VOLUNTARY ESCROW SHARES**

*** PHILLIP, BIOSCIENCE MANAGERS TAKE 17.3% OF ADHERIUM**

*** SUMMATIX DILUTED TO 5.9% OF ADHERIUM**

*** EGP CAPITAL DILUTED BELOW 5% IN ADHERIUM**

*** L1 CAPITAL TAKES 6.4% OF CRESO**

*** RHYTHM APPOINTS EDUARDO VOM DIRECTOR**

*** PYC APPOINTS DR MAY ORFALI CMO**

*** ESENSE LOSES DIRECTOR AMIT EDRI**

MARKET REPORT

The Australian stock market was up 2.44 percent on Tuesday June 9, 2020, with the ASX200 up 146.2 points to 6,144.9 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 13 fell, five traded unchanged and one was untraded.

LBT was the best, up 2.5 cents or 17.9 percent to 16.5 cents, with 1.7 million shares traded. Actinogen was up 13.6 percent; Cyclopharm, Ellex and Immutep climbed more than six percent; Next Science, Oncosil and Polynovo were up four percent or more; Amplia was up 3.85 percent; Impedimed, Imugene, Neuren, Optiscan, Paradigm and Proteomics rose more than two percent; Compumedics and Genetic Signatures were up more than one percent; with Clinuvel, Cochlear, Mesoblast, Nanosonics and Volpara up by less than one percent.

Uscom led the falls, down 2.5 cents or 10 percent to 22.5 cents, with 265,636 shares traded. Patrys lost 6.7 percent; Alterity and Kazia were down more than five percent; Antisense fell 4.55 percent; Pharmaxis and Prescient were down more than three percent; CSL and Resonance shed more than two percent; with Avita down one percent.

CSL

CSL says it has bought Vitaeris Inc for its phase III kidney transplant rejection treatment, expecting to spend $30 million to $50 million on research and development.

A CSL spokesperson told Biotech Daily that “the cost of acquisition is modest and commercial in confidence … [and] does not materially change the company’s profit expectation for 2019-’20”.

The company said that it entered a strategic partnership with the Vancouver, British Columbia-based Vitaeris in 2017 to expedite a phase III drug development program to treat rejection in solid organ kidney transplant patients, which included the option to acquire Vitaeris in full.

CSL said the phase III program was investigating the role of a monoclonal antibody, clazakizumab, in treating a naturally-occurring inflammatory gene, interleukin-6, which was the leading cause of long-term rejection in kidney transplant recipients.

The company said Vitaeris’ research assets would join its portfolio of products, CSL842 and CSL964, which were in late-stage development to address unmet needs in human organ transplantation.

CSL head of research and development Dr Bill Mezzanotte said that “clazakizumab has been a promising monoclonal antibody in the transplant therapeutic area since we started working with Vitaeris several years ago”.

“Acquiring Vitaeris and their associate expertise helps us to continue to grow our strategic scientific platform of recombinant proteins and antibodies,” Dr Mezzanotte said. “We look forward to continuing to advance this treatment candidate as a potential option for people experiencing rejection, an area where current treatment options for transplant recipients are limited, at best,” Dr Mezzanotte said.

CSL fell $6.83 or 2.4 percent to $278.50 with 2.2 million shares traded.

LBT INNOVATIONS

LBT says it has sold its first APAS Independence automated plate assessment system in the US to Hennepin County Medical Centre for an undisclosed amount.

LBT chief executive officer Brent Barnes told Biotech Daily that the list price for a new APAS Independence was $US300,000 with annual service charges of $US20,000 to $US40,000 depending on the number of modules licenced.

Mr Barnes said the company was in the process of applying to the US Food and Drug Administration for approval of the methicillin resistant Staphylococcus aureus (MRSA or golden Staph) module.

Mr Barnes said the APAS Independence sold to the Minneapolis-based Hennepin County Medical Centre was a pre-production model installed two years ago and he expected Clever Culture Systems to receive annual recurring revenue of about $US40,000 a year, of which part would be recognized by LBT.

In a media release, LBT said the sale, by joint venture company Clever Culture Systems, included a five-year service agreement and followed installation of the APAS middleware driver, connecting the APAS to the Hennepin County Medical Centre laboratory information management system, enabling the automated reporting capability of the system.

The company said the APAS driver was in a testing and validation phase before expected routine clinical use of the urine analysis module.

LBT said the Centre processed about 500 specimens a day, including 300 urine plates.

LBT was up 2.5 cents or 17.9 percent to 16.5 cents with 1.7 million shares traded.

OSPREY MEDICAL

Osprey says that placing $2.6 million of the shortfall from its three-for-one rights offer at 1.2 cents per Chess depositary interest (CDI) takes the total raised to $12.8 million.
In April, Osprey said it had raised $10,244,920 through the entitlement offer and reserved the right to place the remaining shortfall of 441,648,780 shares, worth $5,299,785, within three months (BD: Apr 29, 2020).
Today, the company said the funds would be used to accelerate commercial expansion in the US, to support GE Healthcare's commercial efforts and to undertake ongoing clinical evidence and product portfolio development.
Osprey was unchanged at 1.4 cents with 3.5 million shares traded.

IMMURON

Immuron says its research collaboration on campylobacter and Escherichia coli with the US Naval Medical Research Center is back on-track.
Immuron said the collaboration to develop and clinically evaluate a new therapeutic against campylobacter and enterotoxigenic Escherichia coli (Etec or E-coli) was delayed by the Covid-19 pandemic, but the US Naval Medical Research Center (NMRC) had recently requested a pre-investigational new drug application (IND) meeting with the US Food and Drug administration for the new investigational drug to treat moderate to severe campylobacteriosis and E coli infections.
Immuron chief executive officer Dr Jerry Kanellos told Biotech Daily that Immuron was importing vaccines from the Center for campylobacteriosis and E coli infections and would inject cattle to obtain cow colostrum as a treatment for the infections.
The company said that with the NMRC it intended to conduct two phase II trials in 2021, one focussed on the ability of the hyperimmune product to protect volunteers against moderate to severe campylobacteriosis and the second trial to focus on E coli infections
Immuron said that the FDA would provide written comments on the non-clinical information in the pre-IND information package which was planned to be submitted on June 10, 2020 and the NMRC planned to file an investigational new drug application later this year and begin the phase II clinical studies by July 2021.
"We received a formal start work notification and approval at the end of January 2020 from the Henry Jackson Foundation for the Advancement of Military Medicine to commence work on the sub award, Dr Kanellos said.
"The Australian importation permit required to ship the vaccines from the NMRC was approved by Biosecurity Australia and the NMRC vaccines were shipped to our contract research partner to commence the project," Dr Kanellos said.
"The Covid-19 pandemic put the brakes on this and all our research and development activities," Dr Kanellos said. "With the easing of restrictions around Australia work on the development of the clinical product can now recommence."
"The plan is to have the product completed by the end of this year and have it ready for clinical evaluation next year," Dr Kanellos said.
Immuron said that the Covid-19 pandemic impacted the IMM-124E paediatric clinical study in non-alcoholic fatty liver disease.
The company said that the principle investigator Dr Miriam Vos at the Emory University School of Medicine closed the study earlier this year with 22 subjects of a target 40 subjects completing the study protocol and the study findings were reported as negative as there was no substantial changes in the primary study endpoint in the active arm of the study, compared to placebo.
Immuron was up 0.3 cents or 3.75 percent to 8.3 cents.

OPTHEA
Opthea has requested a trading halt pending “an announcement in relation to the results of Opthea’s phase IIa clinical trial of OPT-302 in [diabetic macular oedema].
Separately, Opthea said it would host a conference call to discuss the results tomorrow.
Trading will resume on June 10, 2020 or on an earlier announcement.
Opthea last traded at $3.36.

CRESO PHARMA
Creso says its partner Pharma Dynamics has launched its Cannaqix marijuana as Cannamics in South Africa.
Creso said Cannamics would be sold through independent and pharmacy retailer chains.
Creso fell 0.1 cents or 1.9 percent to 5.1 cents with 4.05 million shares traded.

EMVISION MEDICAL DEVICES
Emvision says 1,300,000 shares will be released from voluntary escrow on June 13, 2020, with 16,789,351 shares under ASX escrow until December 13, 2020.
According to Emvision’s most recent Appendix 3B new issue announcement, the company had 46,870,481 shares on issue, including the 1,300,000 voluntary escrow shares.
Emvision was up one cent or 0.8 percent to $1.22.

ADHERIUM
Phillip Asset Management for Bioscience Managers Translation Fund 1 says it has become a substantial shareholder in Adherium with 104,261,036 shares (17.3391%).
In May, Bioscience Managers raised $5 million for Adherium (BD: May 26, 2020).
Adherium was unchanged at 2.7 cents.

ADHERIUM
Melbourne’s Summarix Pty Ltd says its 35,496,341 share substantial holding in Adherium has been diluted from 7.14 percent to 5.90 percent (see above).

ADHERIUM
EGP Capital says it has ceased to be a substantial shareholder in Adherium.
EGP said it was diluted on June 5, 2020 (see above).

CRESO PHARMA
L1 Capital Global Opportunities Master Fund says it has become a substantial shareholder in Creso, again, with 17,968,888 shares or 6.44 percent of the company.
L1 previously became substantial in Creso in March and at that time the Melbourne and Cayman Islands-based L1 Capital, also did not disclose the date(s) or price(s) paid for the shares (BD: Mar 9, 2020)
In February, Creso said it had a convertible note agreement with L1 Capital for up to $17,482,500, including the ability to request an initial $1,750,000 advance in two equal tranches in exchange for 9,000,000 collateral shares, a four percent fee of the advance, and a potential 11,000,000 additional collateral shares (BD: Feb 5, 2020).

RHYTHM BIOSCIENCES

Rhythm says it has appointed Eduardo Vom as a non-executive director.
Rhythm said Mr Vom had more than 20 years' experience in technology development and commercialization in the biotech industry and was the co-founder and executive director of Planet Innovation.
The company said Mr Vom was a shareholder in, and advisor to, Rhythm and had held leadership roles at Vision Biosystems and Genetic Technologies.
Rhythm said Mr Vom held a Bachelor of Engineering from Melbourne's Monash University.
Rhythm was up 0.2 cents or 2.15 percent to 9.5 cents.

PYC (FORMERLY PHYLOGICA) THERAPEUTICS

PYC says it has appointed Dr May Orfali as chief medical officer at its Boston office.
PYC said Dr Orfali had more than 20 years' experience in the pharmaceutical and biotechnology industries, previously held roles as chief medical officer and advisor and practiced as an oncology clinical research physician at Boston's Dana-Farber Cancer Institute.
The company said Dr Orfali was previously a fellow in paediatric oncology and haematology at Massachusetts General Hospital and Boston's Children's Hospital.
PYC said Dr Orfali held a Doctor of Medicine from the University of Baghdad and a Masters of Business Administration from Cambridge University.
PYC was up 0.2 cents or 2.3 percent to nine cents with 4.7 million shares traded.

ESENSE-LAB

Esense says non-executive director Amit Edri has resigned, ahead of today's annual general meeting and the resolution to re-elect him has been withdraw.
In 2018, Esense said it had appointed former Israeli Special Air Force Unit major Mr Edri as a non-executive director (BD: Nov 30, 2018).
Esense fell 0.1 cents or 5.3 percent to 1.8 cents.