Biotech Daily

Thursday September 2, 2021

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: OPTISCAN UP 13%; IMUGENE DOWN 2.5%**

*** KAZIA: FRANCE APPROVES PHASE I EVT801 FOR CANCER TRIAL**

*** CHIMERIC, ONCOBAY PARTNER TO DEVELOP CHM1101**

*** AUDEARA REVENUE UP 24% TO $1.1m, LOSS UP 176% TO $1.25m**

*** IMMUTEP DOSES LAST 2nd-LINE NSCLC IMP321-KEYTRUDA PATIENT**

*** FIL REDUCES TO 6% OF TELIX**

*** TDM TAKES 26% OF SOMNOMED**

*** AUSTRALIAN ETHICAL TAKES 8.7% OF MACH7**

*** AUSBIOTECH: REGENERATIVE MEDICINE MANUFACTURE, TRIALS**

*** LUNG HEALTH INITIATIVE: THEODORA ELIA-ADAMS DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.55 percent on Thursday September 2, 2021, with the ASX200 down 41.4 points to 7,485.7 points. Thirty-one of the Biotech Daily Top 40 stocks were up, five fell, three traded unchanged and one was untraded.

Optiscan was the best, up three cents or 13.3 percent to 25.5 cents, with 1.75 million shares traded.

Amplia climbed 10.5 percent; Prescient, Proteomics and Uscom were up seven percent or more; Alterity improved 6.25 percent; Pharmaxis was up 5.7 percent; Clinuvel, Genetic Signatures, Impedimed, Patrys, Resonance and Starpharma were up four percent or more; Kazia, Polynovo, Telix and Universal Biosensors were up three percent or more; Antisense, Mesoblast, Next Science, Oncosil and Pro Medicus rose two percent or more; Avita, Cynata, Cyclopharm, Dimerix, Opthea, Orthocell and Volpara were up one percent or more; with Cochlear, Nanosonics and Paradigm up by less than one percent.

Imugene led the falls, down one cent or 2.5 percent to 39 cents, with 36.7 million shares traded. CSL, Medical Developments, Nova Eye and Resmed lost more than one percent; with Immutep and Neuren down by less than one percent.

KAZIA THERAPEUTICS

Kazia says it has received French regulatory approval for a phase I study of EVT801 for cancer, with an undisclosed number of patients.
In April, Kazia said it would pay the Hamburg, Germany-based Evotec SE up to $477.9 million to licence its oral, small-molecule, oncology drug EVT801, originally invented by Sanofi (April 20, 2021).
Today, the company said the trial would recruit patients with advanced tumors at cancer hospitals, Oncopole in Toulouse and Centre Léon Bérard in Lyon by the end of 2021.
Kazia chief executive officer, Dr James Garner said the study design was “highly innovative, which befits the rich potential of EVT801”
The company provided no trial details saying they would be released when it began recruitment.
Kazia was up five cents or 3.5 percent to $1.48.

CHIMERIC THERAPEUTICS

Chimeric says it has “a strategic partnership” with Oncobay Clinical to advance and expand the clinical development program for CHM1101.
Chimeric said that Oncobay was “a boutique clinical research organization” and a subsidiary of the Tampa, Florida-based Moffitt Cancer Center with experience in cell therapy development.
The company said Oncobay was able to use the support of Moffitt’s scientific advisors, “imbedding scientific expertise into every project team and creating vein-to-vein control of cell therapy trials”.
Chimeric chief executive officer Jennifer Chow said Oncobay was “a natural partner for us, building upon the cell therapy expertise of our team”.
“With its experience managing the complexity of cell therapy research programs and scientific support from the Moffitt Cancer Center, we believe that the team at Oncobay is uniquely positioned to support the expansion of the CHM1101 (CLTX Car-T) development program,” Ms Chow said.
In December, Chimeric executive chair Paul Hopper said the company’s chlorotoxin chimeric antigen receptor (CLTX-Car) T-cell therapy, licenced from the Duarte, California-based City of Hope, was “an extremely promising technology” with an 18-patient, phase I trial underway (BD: Dec 11, 2020).
Chimeric was unchanged at 32 cents with 1.2 million shares traded.

AUDEARA

Audeara says revenue for the year to June 30, 2021, was up 23.5 percent to $1,115,124, with net loss after tax up 176.1 percent to $1,253,415.
Audeara said revenue came primarily from the development of its “hearing health” headphone technology and from its supply agreements with National Hearing Care, now trading as Amplifon and existing partnerships with Bloom Hearing and Sonic Innovations.
The company said the loss incurred this year included non-recurring initial public offer transaction costs of $429,239.
The company said its diluted loss per share was up 148.1 percent to 1.91 cents, net tangible assets per share was up from negative 1.91 cents in the previous corresponding period to 5.58 cents and it had cash and cash equivalents of $ 5,737,612 at June 30, 2021 compared to $8,138 at June 30, 2020.
Audeara was up 1.5 cents or 15.8 percent to 11 cents.

IMMUTEP

Immutep says the last of 13 patients has been dosed in stage 2 of part B of its planned 183-patient, phase II, Tacti-002 combination study of IMP321 for cancer.
Immutep said that the study was also designated the Keynote-798 trial and 154 of the planned 183 patients had been enrolled.
In 2018, the company said it had filed its investigational new drug application to the US Food and Drug Administration for a then 120-patient combination trial of IMP-321 and Keytruda for cancer (BD: Mar 12, Jun 2, 2018).
Immutep said at that time the trial of two active immunotherapies would investigate IMP-321, or eftilagimod alpha, in combination with the Merck & Co drug Keytruda, or pembrolizumab, for non-small cell lung cancer (NSCLC) and head and neck cancer HNSCC).
The company said that it had completed recruitment of second-line, refractory, non-small cell lung cancer patients into the trial.
Immutep said it expected to report further data from the trial at a scientific conference this year or early next year 2022.
The company said that recruitment had been completed for the NSCLC part B and HNSCC part C of the trial, with 43 patients recruited for the expansion stage of up to 74 first-line NSCLC part A patients.
Immutep said the trial was being conducted with the Kenilworth, New Jersey based Merck & Co Inc, known as Merck Sharp and Dohme outside North America, as a non-comparative, open-label, single-arm study in Australia, Europe, the UK and US.
Immutep fell half a cent or 0.9 percent to 56.5 cents with 2.35 million shares traded.

TELIX PHARMACEUTICALS

FIL Limited says it has reduced its substantial holding in Telix Pharmaceuticals from 22,280,031 shares (7.91%) to 16,927,987 (6.01%).
The Hong Kong and Tadworth, England-based FIL, also known as Fidelity Investments, said it sold 5,352,044 shares for prices ranging from $6.87 and $7.068 between August 27 and 30, 2021.
Telix was up 22 cents or 3.25 percent to $6.99 with 644,429 shares traded.

SOMNOMED

TDM Growth Partners and associates say they have increased their substantial holding in Somnomed from 21,372,597 shares (25.83%) to 21,465,787 shares (25.94%).
TDM said it bought 93,190 shares at $2.27 a share on August 26, 2021.
TDM said its shares were held by TDMAM, Madleowill Investments and Zoolander Investments.
Somnomed was up three cents or 1.4 percent to $2.22.

MACH7 TECHNOLOGIES

Australian Ethical Investment says it has increased its substantial shareholding in Mach7 from 17,855,057 shares (7.55%) to 20,647,645 shares (8.73%).
The Sydney-based Australian Ethical said that between August 16 and 31, 2021 it bought shares with the single largest purchase 430,000 shares for $406,294 or an average of 94.5 cents a share.
Mach7 was up one cent or one percent to 99 cents.

AUSBIOTECH

Ausbiotech says it has released two reports detailing the manufacturing and clinical trial prospects for regenerative medicine.

Last month, Ausbiotech said medicine included gene therapies, cell therapies and tissue-engineered products intended to regenerate or replace injured, diseased, or defective cells, tissues, or organs (BD: Aug 13, 2021).

Today, the industry organization said that 'Australia's Regenerative Medicine Manufacturing Capacity and Capability' report detailed the manufacturing sites across the continent with seven Australian Therapeutic Goods Administration-licenced good manufacturing practice sites and five non-TGA-licenced sites.

Ausbiotech said regenerative medicine required highly specialized good manufacturing practice capabilities and infrastructure, a highly skilled workforce and complex supply chains.

Ausbiotech said the report was at: www.ausbiotech.org/documents/item/666.

The industry organization said the second report, titled 'Regenerative Medicine Clinical Trials Database', "captured the portion of clinical trials in regenerative medicine and sought to categorize them into type and phase".

Ausbiotech said there were more than 1,220 ongoing clinical trials investigating regenerative medicine across the world in 2021, with 130 trials in Australia.

Ausbiotech said the clinical trials report was at: www.ausbiotech.org/documents/item/667.

AUSTRALIAN LUNG HEALTH INITIATIVE

The Australian Lung Health Initiative says it has appointed Theodora Elia-Adams as a director, effective from July 14, 2021.

The Initiative said Ms Elia-Adams was a taxation and finance consultant and was currently the principal of Elia Adams Advisory and formerly a partner with Ernst and Young.

The Lung Health Initiative said Ms Elia-Adams held a Bachelor of Commerce and a Master of Taxation from the University of Melbourne.

Australian Lung Health Initiative said it was "a partnership of Australian companies, universities, and research institutes" intending to integrate 4D Medical's XV technology into the first dedicated lung function scanners, with a vision towards lower dose.