Biotech Daily

Wednesday July 8, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 11%; ACTINOGEN DOWN 8%**

*** GREENLIGHT: TRIALS RESILIENT DESPITE H1 18% FALL**

*** TELIX, REFLEXION COMBINE CANCER TECHNOLOGIES**

*** TELIX: FDA SUPPORTS, CLARIFIES TLX591 PROSTATE CANCER TRIAL**

*** 4D: $56m IPO FOR XV RESPIRATORY IMAGING**

*** RECCE 327, 529 IN CSIRO, DOHERTY SARS-COV-2 PROGRAM**

*** MEDLAB SHARE PLAN RAISES $1.6m OF HOPED FOR $4m, TOTAL $7m**

*** ALLEGRA DETAILS SR-HT-GAHNITE PATENTS**

*** VISIONEERING PLEADS SCHULTZ TO ASX 100% PRICE QUERY**

*** ALTHEA: CONCIERGE FOR ONLINE MARIJUANA SALES**

*** MGC GRANTED AUSTRALIAN MARIJUANA IMPORT LICENCE**

*** CVC SELLS ALL 24m UNIVERSAL BIOSENSORS SHARES**

*** ESENSE ISSUES BLUE SCIENCE 10m CDIs**

MARKET REPORT

The Australian stock market fell 1.54 percent on Wednesday July 8, 2020, with the ASX200 down 92.6 points to 5,920.3 points. Ten of the Biotech Daily Top 40 stocks were up, 22 fell, seven traded unchanged and one was untraded. All three Big Caps fell.

Antisense was the best, up 0.9 cents or 10.6 percent to 9.4 cents, with 2.6 million shares traded. Amplia, Compumedics and Optiscan climbed more than nine percent; Universal Biosensors was up 6.1 percent; Osprey improved 4.9 percent; Mesoblast, Pharmaxis and Telix rose two percent or more; with Kazia up 0.95 percent.

Actinogen led the falls, down 0.2 cents or eight percent to 2.3 cents, with 2.2 million shares traded. Genetic Signatures and Polynovo lost more than six percent; Dimerix, Imugene and Medical Developments were down more than five percent; Nanosonics and Pro Medicus fell four percent or more; Cochlear, CSL, Cyclopharm, Immutep, Oncosil, Paradigm and Resonance were down more than three percent; Avita, Clinuvel and Next Science shed more than two percent; Impedimed, Proteomics and Resmed were down more than one percent; with Cynata, Neuren, Nova Eye (Ellex) and Volpara down by less than one percent.

GREENLIGHT CLINICAL

Greenlight Clinical says that despite the coronavirus pandemic “Australia is already showing signs of recovery from the perspective of studies on clinical therapeutics”.
The Sydney based clinical research organization said that 360 clinical trials were expected to begin in the six months to June 30, 2020, 18.2 percent below the 440 studies in Australia for the six months to June 30, 2019.
Greenlight quoted figures provided by London’s Globaldata showing that Australia had returned to the monthly count of study initiations of January, before most sites, clinical research organization and sponsors were aware of what was to come.
The company said that the Covid-19 pandemic “provided several core challenges to conducting studies around the world” and enrolling patients to studies, even for vaccines, was difficult in the UK and Europe.
Greenlight said that patient safety and allocation of research staff had slowed progress.
The company said that the challenge “promoted improvements in the use of telemedicine and flexibility with assessment location and visit timelines” and regions that recovered quicker from the pandemic were “great opportunities for conducting studies”.
Greenlight said the timing of the financial year and the impact of global markets on foreign investment “would temper the recovery, but the early signs were promising”.
Greenlight head of medical affairs Dr Sam Adamson said that the data showed “that Australia remains an excellent location for clinical trials, from not only a execution standpoint but also a financial one in these rapidly changing times”.
“Australia’s proactive management of the Covid-19 crisis has allowed a swift return to close-to-normal clinical research operations across the country, giving sponsors confidence in enrolment projections and the ability of local [clinical research organizations] to meet their projected timelines,” Dr Adamson said.
“With attractive tax incentives, skilled research staff and well-defined patient pools, there has never been a better time to conduct research ‘Down Under’,” Dr Adamson said.
Greenlight is a private company.

TELIX PHARMACEUTICALS

Telix says it will collaborate with the Hayward, California-based Reflexion Medical “to improve treatment for high-risk or recurrent prostate and aggressive kidney cancers”.
Telix said it would evaluate its positron emission tomography (PET) tracers, 61-gallium-prostate-specific membrane antigen-11 (68Ga-PSMA-11) for prostate cancer and 89-zirconium-Girentuximab (89Zr-Girentuximab) for kidney cancer, to guide Reflexion’s biology-guided radiotherapy to treat disease.
The company said its tracers showed “considerable potential for detecting metastatic disease … [and] combining them with Reflexion’s [biology-guided radiotherapy which was] designed to treat metastatic disease, could bring us a step closer to improving outcomes for these cancer types”.
Telix said that Reflexion’s technology used biological emissions from a patient’s cancer cells evoked by injecting a small amount of a targeting molecule carrying a positron-emitting radio-isotope, or PET tracer, to guide external-beam radiotherapy.
The company said the tracer bound to tumor cells and produced biological emissions to signal the location of the cancer.
Telix said Reflexion’s X1 machine detected these emissions and responded in real time to direct the biology-guided radiotherapy to each tumor and destroy it, and it would use its prostate and kidney cancer PET tracers with Reflexion’s system to target specific cancers.
Telix was up three cents or two percent to $1.56 with 742,066 shares traded.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has provided clarifying information for to refine the design of its phase III, Prostact trial of TLX591 for prostate cancer.
Telix said the FDA was “broadly supportive” of its use of TLX591-CDx imaging to select patients, by identifying patients with prostate-specific membrane antigen (PSMA) expressing metastatic castration-resistant prostate cancer.
The company the FDA provided detailed feedback on the intended treatment population and on study design elements, statistical considerations, dosing strategy and safety monitoring.
Telix said it intended to include the FDA’s recommendations in the final trial design in order to file a phase III investigational new drug application by the end of 2020.

4D MEDICAL (FORMERLY 4DX)

4D says it expects to raise up to $55.79 million at 73 cents a share to list on the ASX and commercialize its non-invasive respiratory imaging platform, XV Technology.
4D said the XV technology was a four-dimensional lung imaging technology that used mathematic models and algorithms to convert X-ray scans into quantitative data to help physicians manage patients with respiratory diseases.
The company said it was designed to be fully compatible with existing hospital equipment and was delivered through an internet cloud-based ‘software-as-a-service’ model for hospitals and clinics on a pay per use basis.
4D said its XV Technology had US Food and Drug Administration 510(k) approval and was currently sold in the US.
The company said it had 43 patents and applications, included 15 granted patents in the US, Australia, the European Union and Asia.
4D said its customers included the Los Angeles-based Cedars-Sinai Medical Center, the Ohio’s Cleveland Clinic and the Adelaide-based South Australian Health and Medical Research Institute.
The company said it currently had 264,762,406 shares and 20,666,069 options on issue and the fully underwritten $55.79 million capital raising would value the company at $193.28 million.
4D said proceeds from the offer would be used for marketing through clinical trials and trade shows, for operating expenditure, product research and development, platform development, US sales and distribution, intellectual property and trademarks, and to pay selling shareholders and selling holders.
The company said the offer would open on July 14, 2020, with minimum investments of $2,000 and would close on August 10.
4D said its board comprised chairman Bruce Rathie, managing director Dr Andreas Fouras, non-executive directors Li Bianchi, Dr Robert Figlin, Lusia Guthrie, John Livingston and Julian Sutton, and executive director Heath Lee.
The company said its management team included chief executive officer and founder Dr Fouras, chief financial officer Mr Lee, company secretary Charlene Stahr, head of engineering Aidan Jamison and head of sales and marketing Paul Cooke.
4D said Bell Potter Securities and E&P Corporate Advisory were joint lead managers to the offer and it expected to list on the ASX under the ticker code 4DX on August 14, 2020.
The prospectus is at: https://4dmedical.com/prospectus/.
4D is a public unlisted company.

RECCE PHARMACEUTICALS
THE PETER DOHERTY INSTITUTE FOR INFECTION AND IMMUNOLOGY
COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

Recce says its Recce-327 and Recce-529 have been selected by the CSIRO and the Doherty Institute as Covid-19 “priority 1 candidates”.

Recce said that priority 1 status was defined as “highest or strong likelihood of anti-viral or antiseptic efficacy [and] compounds in this grouping will be eligible for stage 1 laboratory screening trials”.

The company said that Recce-327 was a broad-spectrum synthetic antibiotic formulated using synthetic polymer technology to treat blood infections and sepsis, while Recce-529 was a synthetic polymer formulation and they were selected for their unique mechanism of actions against hyper-mutation, as indicated on bacteria and viruses, respectively, and the testing program would be conducted by the CSIRO and the Doherty Institute.

Recce said that the severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) Antiviral Screening Program would evaluate the compounds with in-vitro screening and testing, ex-vivo testing using an animal model of human epithelial lung cells at the Doherty Institute and testing in ferrets at the CSIRO’s Australian Centre for Disease Preparedness.

The company said that the Program was part of the Federal Government’s efforts to identify promising anti-viral candidates and fast-track research into potential treatments for Covid-19.

Recce said that it would retain intellectual property rights, the program was expected to take “some months”, with expenditure staged and the first stage to be about $35,000.

Recce chairman Dr John Prendergast said the company was “very pleased to have been selected by the CSIRO … to investigate the efficacy of two of our promising compounds against Sars-Cov-2”.

“The compounds’ unique, universal mechanisms of action indicate potential to attack a broad range of viruses and … overcome the threat of viruses’ typical hyper-mutation into new and deadly pathogens,” Dr Prendergast said.

Recce emerged from a suspension after the market closed, untraded at 68 cents.

MEDLAB CLINICAL

Medlab says it has raised $1.57 million through a share purchase plan at 15 cents a share, taking the total raised to $6.97 million.

Last month, Medlab said it had commitments to raise $5.4 million through a placement and hoped to raise $4 million through a share purchase plan (BD: Jun 15, 2020).

Today, the company said the funds would be used for the Nanabis program, reach catalysts, working capital and to cover any potential Covid-19-related regulatory delays.

Medlab was up half a cent or 3.3 percent to 15.5 cents.

ALLEGRA ORTHOPAEDICS

Allegra says it has detailed the 12 Australian, European, US and Asian strontium-hardystonite-Gahnite (Sr-HT-Gahnite) patents acquired from the University of Sydney.

On Monday, Allegra said it had issued the University of Sydney 4,806,000 shares to acquire patents and applications for Sr-HT-Gahnite (BD: Jul 6, 2020).

Today, the company said the patents, all entitled ‘Biocompatible material and uses thereof’, would protect its intellectual property until January 3, 2031 and July 15, 2032 in the US and to June 1, 2032 in all other jurisdictions.

Allegra fell 6.5 cents or 20.3 percent to 25.5 cents.

VISIONEERING TECHNOLOGIES

Visioneering 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 100 percent from 1.0 cent on June 26, 2020 to 2.0 cents yesterday, July 7, and noted a "significant increase" in the trading volume.
Visioneering was up 0.1 cents or 4.8 percent to 2.2 cents with 10.2 million shares traded.

ALTHEA GROUP

Althea says Australian patients will be able to order medical marijuana online through its Althea Concierge platform, eliminating the need for a doctor or pharmacy visit.
Althea said online sales through Althea Concierge would be used in conjunction with video telemedicine and would enable doctors to prescribe its medical marijuana, patients to pay for the prescription online and for products to be delivered directly to patients' doors.
The company said Concierge included a customizable interactive treatment plan, issued by doctors directly to patients and an assessment tool to collect real world evidence.
Althea said it planned to add online sales functionality to Althea Concierge in the UK.
Althea was up three cents or 8.7 percent to 37.5 cents with 1.2 million shares traded.

MGC PHARMACEUTICALS

MGC says the Australian Office of Drug Control has granted it an import licence for schedule 4 prescription only and schedule 8 controlled drugs for medical marijuana.
MGC was up 0.2 cents or 9.1 percent to 2.4 cents with 63.2 million shares traded.

UNIVERSAL BIOSENSORS

The Sydney-based CVC says it has sold all 23,820,765 Universal Biosensors shares (13.455%) it said that it held in March at 22.02 cents a share (BD: Mar 6, 2020).
Universal Biosensors was up 1.5 cents or 6.1 percent to 26 cents.

ESENSE-LAB

Esense says it has issued 10,00,000 Chess depositary interests or 2.0 percent of issued CDIs to the West Palm Beach, Florida-based Blue Science Solutions at one cent each.
Yesterday, Esense said Blue Science would distribute its terpenes-based sanitizer products in the US (BD: Jul 7, 2020).
Esense fell half a cent or 20.8 percent to 1.9 cents with 184.3 million shares traded.