Biotech Daily

Wednesday September 30, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 26%; DIMERIX DOWN 16%**

*** ANTISENSE WINS FDA RARE PAEDIATRIC DISEASE STATUS**

*** STARPHARMA PLACEMENT RAISES $45m, PLAN FOR $5m MORE**

*** MICRO-X: W.H.O. $1.4m ROVER X-RAY ORDER FOR PACIFIC ISLANDS**

*** ASTRAZENECA $2m TO LEASE 175 IMPEDIMED SOZOS FOR TRIAL**

*** TGA APPROVES 4D LUNG VENTILATION ANALYSIS SOFTWARE**

*** ADALTA: STUDY BACKS AD-214 FOR LUNG FIBROSIS**

*** EMYRIA, ZELIRA DEAL FOR ZENIVOL (ZLT-101) INSOMNIA STUDY**

*** RECCE, MURDOCH CHILDREN'S TEST RECCE-435 FOR HELICOBACTER**

*** KAZIA REQUESTS 'ENTITLEMENT OFFER' TRADING HALT**

*** FMR BELOW 5% IN SOMNOMED**

*** LITTLE GREEN RELEASES 1.4m ASX ESCROW SHARES**

*** DR RITA LAEUFLE REPLACES IMUGENE CMO DR MARK MARINO**

MARKET REPORT

The Australian stock market fell 2.29 percent on Wednesday September 30, 2020, with the ASX200 down 136.2 points to 5,815.9 points. Eleven Biotech Daily Top 40 stocks were up, 25 fell, three traded unchanged and one was untraded. All three Big Caps fell.

Antisense was the best, up three cents or 26.1 percent to 14.5 cents, with 19.5 million shares traded. Impedimed improved 7.9 percent; Cyclopharm climbed 6.6 percent; Actinogen and Resonance were up more than three percent; Alterity, Immutep, Imugene and Proteomics rose two percent or more; Compumedics was up 1.2 percent; with Next Science up 0.4 percent.

Yesterday's 49 percent best, Dimerix, led the falls, down six cents or 16.4 percent to 30.5 cents, with 20.3 million shares traded. Osprey lost 7.1 percent; Starpharma shed 6.5 percent; Amplia and Universal Biosensors were down more than five percent; Clinuvel, Genetic Signatures and Paradigm fell four percent or more; Avita, Cynata, Optiscan and Polynovo were down three percent or more; Cochlear, CSL, Mesoblast, Nanosonics, Neuren, Opthea, Orthocell, Pharmaxis and Uscom shed two percent or more; Medical Developments, Nova Eye, Prescient, Pro Medicus, Resmed and Volpara were down more than one percent; with Telix down 0.6 percent.

ANTISENSE THERAPEUTICS

Antisense says the US Food and Drug Administration has granted rare paediatric disease designation for ATL1102 for Duchenne muscular dystrophy.
Antisense said that the designation made the company eligible for rare paediatric disease priority review voucher, pending FDA approval by September 30, 2022, unless extended by US Congress.
The company said that the vouchers have sold from U68 million to $US350 million and could reduce the FDA review process by as much as six months, shortening the time it takes for the drug to reach the market.
Antisense said that Duchenne muscular dystrophy was a rare and fatal muscle wasting disease, leading to fibrosis and death of muscle tissue.
The company said it applied for the rare paediatric disease designation as part of its application for orphan drug designation for which it applied in the US and EU in August following submission of data from its phase II trial (BD: Dec 17, 2019; Aug 3, 31, 2020).
Antisense managing-director Mark Diamond said the designation "recognizes a great need for new and improved therapies for boys with [Duchenne muscular dystrophy]".
"We look forward to future interactions with [the] FDA as we refine our strategy for development of ATL1102 in [Duchenne muscular dystrophy] in the US," Mr Diamond said.
Antisense said a rare paediatric disease was a serious or life-threatening disease, which primarily affected fewer than 200,000 individuals aged from birth to 18 years in the US.
Antisense was up three cents or 26.1 percent to 14.5 cents with 19.5 million shares traded.

STARPHARMA HOLDINGS

Starpharma says it has raised $45 million through an oversubscribed placement and hopes to raise a further $5 million through a share purchase plan at $1.50 a share.
Starpharma said the price was at a 6.5 percent discount to the last closing price of $1.605.
The company said that eligible shareholders at the record date of September 29, 2020 would be able to subscribe for up to $30,000 of shares each.
Starpharma said the funds would be used for development, regulatory, commercialization activities and launch of SPL7013 nasal spray for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) the virus that causes Covid-19, expedite development of new dendrimer enhanced product (DEP) candidates, accelerate clinical combinations and expand the commercial opportunity for its three phase II DEP assets and working capital.
Starpharma said Bell Potter Securities was the lead manager to the placement.
Starpharma fell 10.5 cents or 6.5 percent to $1.50 with three million shares traded.

MICRO-X

Micro-X says the $1.4 million World Health Organisation order for Rover x-ray units for several Pacific Island nations is its first Rover order.
Micro-X said its full-performance, digital, mobile medical Rover x-ray imager was for deployed or temporary medical facilities, developed under a contract with the Australian Department of Defence, and would be delivered in the next four weeks.
Micro-X managing-director Peter Rowland said that "achieving this first deal for the Rover product less than two months after receiving [US Food and Drug Administration] clearance is a significant step for Micro-X as we further grow revenue and become a commercially focused technology business".
Micro-X was up 2.5 cents or 11.9 percent to 23.5 cents with 2.7 million shares traded.

IMPEDIMED

Impedimed says Astrazeneca will lease 175 bioimpedance spectroscopy Sozo devices for an 18-month, phase II trial for heart failure patients with chronic kidney disease.
Impedimed said Astrazeneca would use the Sozo monitor in 20 countries for the trial, to track fluid volume and evaluate the efficacy, safety and tolerability of two Astrazeneca drugs, with the trial scheduled to begin in November 2020.
The company said that each device would attract a monthly licence fee and the study was expected to generate $2 million in revenue.
Impedimed head of research, development and technology Dennis Schlaht said that by using the Sozo, Astrazeneca would "be able to achieve the fluid measurement accuracy of gold standard dilution methods in a test that takes 30 seconds instead of up to 24 hours".
"Add in the fact that it offers real-time data review globally, and it's clear why the Sozo digital health platform was chosen for this new research," Mr Schlaht said.
"Astrazeneca has used Impedimed's … technology for a number of years to measure subjects' fluid volumes in their clinical studies," Mr Schlaht said.
Impedimed said that its Sozo was cleared by the US Food and Drug Administration for heart failure and had Conformité Européenne (CE) mark for heart failure and renal failure.
The company said that the trial would "provide a significant number of cardiologists … first-hand experience with Sozo and coincides with [its] launch into the cardiology market".
Impedimed chief executive officer Richard Carreon said that heart failure and chronic kidney disease were "two of our three strategic focus areas and this agreement provides further validation of the applicability of our technology in both patient populations".
"This endorsement of our technology is timely as the company begins the launch of Sozo into the cardiology market," Mr Carreon said.
Impedimed was up half a cent or 7.9 percent to 6.8 cents with 14.4 million shares traded.

4D MEDICAL

4D Medical says the Australian Therapeutic Goods Administration has approved the commercial sale of its x-ray velocimetry lung ventilation analysis software (XV LVAS).
4D said the software converted sequences of x-ray images into four-dimensional quantitative data, or three-dimensional over time, allowing physicians to better diagnose and treat patients with respiratory diseases.
The company said the XV technology sought "to improve the capacity of physicians to diagnose and treat patients with respiratory diseases, by providing objective measurements of regional lung motion and airflow" using a non-invasive method to understand regional lung motion and airflow.
The company said that the technology was designed to be compatible with existing hospital and clinic equipment, not requiring any capital expenditure and delivered through an internet cloud-based software as a service to deliver the technology more quickly and at a lower cost than existing procedures.
4D said that with TGA approval it would develop a software as a service for departments of health, laboratories, medical practitioners and health care professionals in Australia.
The company said that the TGA approval followed US Food and Drug Administration 510(k) clearance for the XV LVAS in May (BD: May 21, 2020).
4D chief executive officer Dr Andreas Fouras said the approval was "ahead of schedule, allowing us to offer our world-class technology to our own backyard in Australia".
"We are now establishing a sales and marketing team to deliver customers in 2021," Dr Fouras said.
4D was up 17.5 cents or 11.5 percent to $1.70 with 2.15 million shares traded.

ADALTA

Adalta says AD-214 target, the CXC chemokine receptor type 4 (CXCR4), is increased in idiopathic pulmonary fibrosis and fibrotic interstitial lung disease tissue.

Adalta said that CXCR4 was a member of the G-protein coupled receptor (GPCR) family of drug targets and a study with Melbourne's Monash University and Alfred Hospital found that expression of CXCR4 receptors was "substantially increased in fibrotic tissue" and agents that blocked CXCR4 slowed or halted progression of fibrosis in animal models.

The company said the research showed that increased CXCR4 expression was "due to increased expression on epithelial cells that line blood vessels and the surface of airways in the lungs as well as in the sites of fibrotic injury".

Adalta said that the research paper, titled 'CXCR4+ cells are increased in lung tissue of patients with idiopathic pulmonary fibrosis' was co-authored by chief scientific officer Prof Michael Foley, published in the journal Respiratory Research and available at: https://respiratory-research.biomedcentral.com/articles/10.1186/s12931-020-01467-0.

Adalta said agents that blocked CXCR4 had previously been shown to slow or halt the progression of fibrosis in animal models and was the target of AD-214, its lead "i-body", named from the "intermediate" of four groups of immunoglobulin and immunoglobulin-like domains, which was in phase I trials for idiopathic pulmonary fibrosis.

Prof Foley said the study suggested that CXCR4 had "a much broader role in fibrosis than merely stimulating the migration of inflammatory cells and fibroblasts from the circulation".

"This work also lends support to a role for AD-214 in [interstitial lung diseases other than idiopathic pulmonary fibrosis]," Prof Foley said."

Adalta was up two cents or 19.05 percent to 12.5 cents with 4.6 million shares traded.

ZELIRA THERAPEUTICS, EMYRIA (FORMERLY EMERALD CLINICS)

Zelira and Emyria say they have an initial 12-month agreement for an up to 100-patient study of Zelira's Zenivol for chronic insomnia using Emyria's network of clinics.

Zelira and Emyria said Zelira would pay Emyria up to $100,000, including $50,000 upfront and a subscription fee for each patient enrolled, to collect longitudinal data and monitor the safety and efficacy of the marijuana-derived Zenivol, formerly ZLT-101.

In April, Zelira said its 23-patient, phase Ib/IIa trial of ZLT-101 had shown safety and statistical significance for reduction of chronic insomnia (BD: Apr 7, 2020).

Today, the companies said the data would inform further clinical development and product registration.

Emyria was up 0.1 cents or 1.25 percent to 8.1 cents with 1.2 million shares traded.

Zelira was up 0.2 cents or 3.1 percent to 6.7 cents with 5.1 million shares traded.

RECCE PHARMACEUTICALS

Recce says Melbourne's Murdoch Children's Research Institute will conduct for in-vitro and mouse studies of Recce-435 for Helicobacter pylori.

Recce said the studies, conducted by the Institute's Mucosal Immunology Group at the Royal Children's Hospital, would evaluate the anti-microbial activity and optimal dosing of its oral antibiotic Recce-435 for Helicobacter pylori, including drug-resistant forms.

The company said the eradication rate of the standard triple therapy had fallen below 80 percent due to antibiotic resistant strains and there was currently no first-line therapy.

Recce said it expected to complete the study in 12 months, followed by a human clinical trial, but the agreement would be in place until December 31, 2022.

Recce was up four cents or 3.6 percent to $1.145 with 2.5 million shares traded.

KAZIA THERAPEUTICS

Kazia has requested a trading halt “pending the release of an announcement about an accelerated non-renounceable entitlement offer”.
Trading will resume on October 2, 2020 or on an earlier announcement.
Kazia last traded at 96 cents.

SOMNOMED

Fidelity Management & Research (FMR) says it has ceased to be a substantial shareholder in Somnomed but continues to hold 4,079,596 shares or 4.93 percent.
The Tokyo-based FMR said that between May 21 and June 24, 2019 it bought 623,100 shares for between $1.60 and $1.81 a share and between November 27, 2019 and September 25, 2020 it sold 1,028,842 shares for between $2.15 and $2.92 a share.
FMR said that on April 1, 2020 it acquired 1,194,871 shares and was diluted in an institutional entitlement offer.
In March, Somnomed said it raised $9,680,000 in the institutional component of a one-for-3.24 non-renounceable entitlement offer at 80 cents a share (BD: Mar 26, 2020).
Somnomed fell six cents or 2.6 percent to $2.28.

LITTLE GREEN PHARMA

Little Green Pharma says it will release 1,392,855 shares from ASX escrow on October 7, 2020.
According to Little Green’s most recent Appendix 2A, the company will have 78,763,324 shares on issue following the release of shares, with a further 55,596,339 shares remaining in ASX escrow.
Little Green was unchanged at 27.5 cents.

IMUGENE

Imugene says it has appointed Dr Rita Laeufle as chief medical officer, replacing Dr Mark Marino.
Imugene said Dr Laeufle was most recently the chief medical officer of the San Diego, California-based Oncolytics Biotech and previously worked in clinical development at Hoffman-La Roche AG and Novartis Pharmaceuticals Corp.
Imugene said Dr Laeufle held a Doctor of Medicine and Doctor of Philosophy from the Freiburg, Germany-based Albert Ludwig University.
Imugene was up 0.1 cents or 2.1 percent to 4.8 cents with 3.3 million shares traded.