Biotech Daily

Monday June 24, 2019

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: KAZIA UP 16%; COMPUMEDICS DOWN 8%**

*** FDA ORPHAN STATUS FOR MESOBLAST'S REVASCOR**

*** LBT APAS INDEPENDENCE '100% ACCURATE FOR UTIs IN 13 SECONDS'**

*** OVENTUS SIGNS 2 CANADIAN SLEEP GROUPS FOR $1m O2VENT**

*** DIMERIX LICENCES RECEPTOR-HIT TO EXCELLERATE BIOSCIENCE**

*** SHAREROOT RIGHTS ISSUE FOR $1m**

*** 501-IMPLANT STUDY BACKS ADMEDUS CARDIOCEL**

*** MICRO-X, ALLORA SETTLE $1.8m INVOICE DISPUTE**

*** BIONOMICS REQUESTS 'TRIAL RESULTS' TRADING HALT**

*** CREDIT SUISSE TAKES 5% OF ADALTA**

*** DR JOHN LAMBERT REPLACES AMPLIA CEO SIMON WILKINSON**

MARKET REPORT

The Australian stock market was up 0.22 percent on Monday June 24, 2019, with the ASX200 up 14.6 points to 6,665.4 points.

Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and four were untraded.

Kazia was the best, up five cents or 15.6 percent to 37 cents, with 260,473 shares traded. Dimerix climbed 14.9 percent; Orthocell was up 9.7 percent; Mesoblast, Polynovo and Prescient improved more than five percent; both Optiscan and Pharmaxis climbed 4.2 percent; Starpharma was up 3.4 percent; Nanosonics rose 2.1 percent; Immutep was up 1.9 percent; with Cochlear, CSL and Pro Medicus up by less than one percent.

Compumedics led the falls, down five cents or 7.7 percent to 60 cents, with 91,010 shares traded. Antisense lost six percent; Ellex fell 5.2 percent; LBT and Paradigm were down more than three percent; Avita, Clinuvel and Neuren shed more than two percent; Genetic Signatures, Medical Developments, Oncosil, Osprey, Proteomics, Resmed and Volpara were down more than one percent; with Cynata, Opthea and Telix down by less than one percent.

MESOBLAST

Mesoblast says the US Food and Drug Administration has granted orphan drug designation to Revascor for bleeding associated with end-stage heart failure.

Last year, Mesoblast said a 159-patient, phase II trial of mesenchymal precursor cells for heart failure at New York's Mt Sinai Hospital did not meet its primary endpoint, but showed benefit for gastrointestinal bleeding (BD: Nov 12, 2018).

In March, the company said it would begin a trial of Revascor for gastrointestinal bleeding, and believed that a reduction in gastrointestinal bleeding would improve the quality of life for the 20 to 40 percent of left ventricular assist device implants patients with life threatening gastrointestinal bleeding episodes (BD: Mar 27, 2019).

Today, the company said that Revascor, which was originally known as MPC-150-IM and was now being referred to by the company as "rexlemestrocel-L" comprised 150 million allogeneic, or off-the-shelf, mesenchymal precursor cells.

Mesoblast said that Revascor was intended to prevent "post-implantation mucosal and gastrointestinal bleeding in end-stage chronic heart failure patients who require a left ventricular assist device", or heart pump.

Mesoblast chief executive officer Dr Silviu Itescu said the company would meet the FDA "to discuss a potential approval pathway under the product's existing regenerative medicine advanced therapy designation for this life-threatening condition".

The company said the FDA orphan drug designation program entitled it to incentives, including eligibility for seven years of market exclusivity, exemption from application fees, tax credits for trials and other potential assistance in the drug development process.

Mesoblast was up seven cents or 5.1 percent to $1.44 with 1.8 million shares traded.

LBT INNOVATIONS

LBT says a study of its automated plate assessment system (APAS) Independence on 720 samples shows 100 percent accuracy for urinary tract infections (UTIs) in 13 seconds.

LBT said the sensitivity of screening positive urine cultures or significant growth was 100 percent and APAS detected all of the common pathogens expected in the microbiology laboratory.

The company said the APAS result correlated with the routine laboratory reporting mechanisms resulted in a 100 percent specificity or negative predictive value.

LBT said the study was presented at the American Society of Microbiology meeting in San Francisco on June 22, 2019 by the Minneapolis, Minnesota-based Hennepin Medical Centre's Dr Glen Hansen.

The company said APAS Independence was able to report and finalize negative urine culture findings within 13 seconds and that "removing negative and non-significant cultures from the work flow reduces hands-on time".

Dr Hansen said the study results "demonstrate the speed and reliability of the APAS Independence to facilitate and hasten the decision-making process for the diagnosis for UTIs, which represent a large percent of samples encountered in the microbiology laboratory".

"The ability to detect all routine pathogens, combined with a high [negative predictive value], confirms the APAS Independence is a safe and effective device to use within the laboratory," Dr Hansen said.

LBT chief executive officer Brent Barnes said that following US Food and Drug Administration clearance it was "very important to have US clinical data presented by a highly credentialed US clinician at the largest industry meeting in the US".

LBT fell half a cent or 3.7 percent to 13 cents with 2.1 million shares traded.

OVENTUS MEDICAL

Oventus says it has signed a contract with two unnamed Canadian sleep medicine groups to launch its O2Vent platform for sleep apnoea in July 2019.
Oventus said the two groups had seven sites and each would be required to deliver a minimum of 20 devices each month.
Biotech Daily calculates that at about $600 per vented mouth-guard, the 140 devices per month or 1,680 a year would generate more than $1 million in revenue.
The company said the O2Vent sleep treatment platform encompassed the O2Vent oral therapeutic device and the valve accessories, Exvent and O2Vent One Pap.
Oventus chief executive officer Dr Chris Hart told Biotech Daily that the laboratory inside a laboratory, or lab-in-lab, “uses a scanner to measure the patient’s mouth size for a custom-fit for the O2Vent”.
Dr Hart said the company had been working “to educate sleep clinicians and dentists on the benefits of our sleep treatment platform, which is delivering therapeutic outcomes similar to [continuous positive airway pressure] for the majority of [obstructive sleep apnoea] patients”.
“These first contracts are representative of a significant pipeline of interest in our technology and strong validation that our lab-in-lab model can make commercial sense,” Dr Hart said.
Oventus was up three cents or 14.6 percent to 23.5 cents.

DIMERIX

Dimerix says it has licenced its Receptor-HIT drug discovery platform to England’s Excellerate Bioscience, a pharmacological assay service provider.
Dimerix said that under the non-exclusive agreement the Nottingham, UK-based Excellerate would “offer Receptor-HIT to leading pharmaceutical and biotechnology companies … [and] academic institutes”.
The company said Receptor-HIT, or receptor-heteromer investigation technology, was a cell-based assay which could “be applied to a number of stages of the drug development process and has previously been used under licence by leading … pharmaceutical companies to profile a wide range of receptor targets”.
Dimerix said it would receive an undisclosed royalty on gross revenues of the service fee.
The company said the marketing for the Receptor-HIT service would begin this week at the Society for Laboratory Automation and Screening Europe conference in Barcelona.
Dimerix was up 1.1 cents or 14.9 percent to 8.5 cents.

SHAREROOT

Shareroot says it hopes to raise $954,342 through a non-renounceable, pro-rata two-for-three entitlement offer at 0.1 cents a share.
Shareroot said the funds raised would support building its business of marketing communications and strategic platforms for the digital healthcare industry and strengthen its balance sheet.
The company said the record date was June 27, the offer would open on July 21 and close on July 15, 2019.
Shareroot was unchanged at 0.1 cents with 55.2 million shares traded.

ADMEDUS

Admedus says that an independent study of 501 Cardiocel implants shows the Adapt-treated bovine cardiac patch is durable with no calcification.

Admedus said that the study, titled 'Multi-centre experience with 500 Cardiocel implants used for the repair of congenital heart defects' examined 501 implants in 377 patients at three sites in Australia and the UK and found 96 percent "freedom from reintervention at a median follow-up of three years… no evidence of bioscaffold calcification via echocardiography or radiology … good durability and performs comparably on the systemic and pulmonary circulations …[and] Cardiocel reduced re-operations, increased quality of life and offered cost savings to alternative implants".

The study was published in the Annals of Thoracic Surgery, with an abstract available at: https://www.ncbi.nlm.nih.gov/pubmed/31207244.

"Cardiocel has good durability when used for the repair of congenital heart defects. It performs comparably in the systemic and pulmonary circulations in neonates, infants and older children," the abstract concluded.

Admedus said that "performance was consistent across the three patient groups [of] babies 28 days and younger, infants aged from one month to one year and children older than one year".

The company said the study was "the largest series of data collected on the use of Cardiocel in humans" and the primary endpoint was freedom from implant related reintervention, either transcatheter or surgical, with secondary endpoints including interoperative and perioperative mortality, calcification, infection and thrombosis.

Admedus said that the secondary endpoints "demonstrated an excellent safety and durability profile, with one case of thrombosis and one case of patch dehiscence [or separation] recorded across the entire patient population.

The company said that Cardiocel was a cost-effective product compared with other bio-scaffolds, given the reduced need for repeat surgery and improved quality of life.

Admedus chief medical officer Dr Kiran Bhirangi said the study showed that Cardiocel had "few complications and minimal chance of required intervention … [which was] relevant for paediatric patients who need to lead healthy and active lives".

Admedus chief executive officer Wayne Paterson said the data would "support further market adoption not only for Cardiocel but our entire Adapt portfolio".

Admedus was in an extended suspension and last traded at six cents.

MICRO-X

Micro-X says it has settled its $1.8 million disputed invoices legal action against Allora Services Pty Ltd "with no admissions as to liability or wrongdoing".

In March, Micro-X said it had begun a $13.7 million proceedings against Allora Services and its managing-director Mark Brydon for breach of contract and misleading and deceptive conduct (BD: Mar 29, 2019).

Micro-X said at that time that proceedings at the Federal Court related to a contract with Hydrix Services, now Allora Services, in 2015 for $19 million in engineering design services for its DRX Revolution Nano.

The company said it withheld $1.8 million in invoices in 2016, following disputes over overcharging, project cost overruns and design defect costs and said it expected Allora to lodge a cross claim for unpaid invoices in the proceedings.

Today, the company said that the dispute had been settled with no admissions on liability or wrongdoing and the proceedings have been dismissed with no order on costs.

Micro-X was up two cents or 9.1 percent to 24 cents.

BIONOMICS

Bionomics has requested a trading halt “pending an announcement regarding the results of its BNC210 clinical trial to treat agitation in elderly patients”.
Trading will resume on June 26, 2019 or on an earlier announcement.
Bionomics last traded at 5.6 cents.

ADALTA

Credit Suisse says it has become a substantial shareholder in Adalta with 7,744,735 shares or 5.14 percent.
The Sydney-based Credit Suisse said that it acquired the shares between May 29 and June 18 with the single largest purchase 4,989,013 shares for $748,352 or 15 cents a share.
Last month, Adalta said it had raised $5 million in a placement and would raise a further $2 million in a rights offer at 15 cents a share (BD: May 23, Jun 14, 2019).
Adalta fell half a cent or 3.3 percent to 14.5 cents.

AMPLIA THERAPEUTICS

Amplia says operations manager Dr John Lambert will replace Simon Wilkinson as chief executive officer, starting on $197,000 a year.
Amplia said that Mr Wilkinson would continue as a non-executive director.
The company said Dr Lambert had been its operations manager since August 2018, and had more than 20 years’ experience in drug discovery and development, including as Biota’s head of drug development and later with Medicines Development for Global Health.
Amplia said Dr Lambert held a Bachelor of Science and a Doctor of Philosophy from the University of Melbourne.
Amplia said that after three months as chief executive officer Dr Lambert would receive 1.2 million options, vesting over four years, exercisable at 16.5 cents a share by June 24, 2024.
The company said that Dr Lambert would be entitled to a short-term incentive of up to 25 percent of his base salary, along with eligibility for long-term incentives.
Amplia was up one cent or 10 percent to 11 cents.