Biotech Daily

Monday July 19, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: LBT UP 4.55%; ANTISENSE DOWN 5%**

*** COMPUMEDICS: REVENUE UP 1.4% TO $36m; VACCINES THE KEY**

*** MESOBLAST: 'REMESTEMCEL-L CUTS UNDER 65s ARDS MORTALITY 48%'**

*** RECCE: R327 KILLS 'FLESH-EATING' BACTERIA, IN-VITRO**

*** MACH7 LICENCES EUNITY TO ADVOCATE AURORA FOR $4.3m**

*** VOLPARA DISTRIBUTES INVITAE GENETIC BREAST CANCER TEST**

*** GENETIC TECHNOLOGIES BUYS EASYDNA FOR $5.4m**

*** DIMERIX: FDA CONFIRMS PHASE III DMX-200 FSGS TRIAL DESIGN**

*** ADALTA CLOSES PHASE I TRIAL, TO TAKE INHALED AD-214 TO PHASE II**

*** ANTEO: AUSTRALIA, SE ASIA EUGENI SARS-COV-2 DISTRIBUTORS**

*** HERAMED: OBSTETRIX HERACARE FOETAL HEART PILOT STUDY**

*** MEDLAB: WEP TO RUN UK MARIJUANA DISTRIBUTION PROGRAMS**

*** RESPIRI: ADHERIUM OFFER LAPSES**

*** TOTAL BRAIN REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** RAIN MAKER REDUCES TO 9% IN OSTEOPORE**

MARKET REPORT

The Australian stock market fell 0.85 percent on Monday July 19, 2021, with the ASX200 down 62.1 points to 7,286.0 points. Eight of the Biotech Daily Top 40 stocks were up, 22 fell, nine traded unchanged and one was untraded. All three Big Caps were up.

LBT was the best, up 0.5 cents or 4.55 percent to 11.5 cents, with 347,192 shares traded. Cyclopharm and Polynovo climbed more than three percent; Resmed rose 2.4 percent; Compumedics, CSL, Medical Developments and Volpara were up more than one percent; with Avita, Clinuvel and Cochlear up by less than one percent.

Antisense led the falls, down one cent or 4.9 percent to 19.5 cents, with 1.2 million shares traded. Actinogen, Proteomics and Starpharma fell four percent or more; Imugene, Oncosil, Osprey and Patrys were down three percent or more; Alterity, Cynata, Kazia, Neuren, Orthocell, Pharmaxis, Telix and Universal Biosensors shed two percent or more; Mesoblast, Nanosonics and Opthea were down more than one percent; with Genetic Signatures, Paradigm and Pro Medicus down by less than one percent.

COMPUMEDICS

Compumedics says it expects revenue for the year to June 30, 2021 to be up 1.4 percent to $35.6 million compared to the previous corresponding period.
Compumedics said it expected “improved” earnings before interest, taxation, depreciation and amortization (Ebitda) from revenue stability, ongoing expense mitigation, and government Covid-19 assistance in the six months to December 31, 2020.
The company said revenue was up in France, Germany and other parts of Europe, offset by declines in Asia, with the US and Australia consistent with the prior year, and its cash improved to $6.1 million at June 30, 2021 with borrowings up $500,000 to $4.2 million.
The company said that the US and Europe either increased or performed in line with the prior year, despite the impact of the pandemic through the northern hemisphere winter.
Compumedics said that Asia, and China in particular, were “problematic from a pandemic and geopolitical point of view” with its China-based sleep and neurological business “significantly behind pre-pandemic levels”, while brain research and DWL business increased to pre-pandemic levels in China.
Compumedics said business in Japan fell 27 percent due to the pandemic.
The company said the unavoidable disruption caused by the pandemic and measures to control it “continue to abate as vaccine rollouts progress satisfactorily in our key markets”.
Compumedics was up half a cent or 1.3 percent to 38.5 cents.

MESOBLAST

Mesoblast says at 90 days the under 65-year-olds in its remestemcel-L for Covid-19-related acute respiratory distress syndrome trial had mortality reduced by 48 percent.
Last December, Mesoblast said the data safety monitoring board had recommended halting the trial of remestemcel-L for Covid-19-related acute respiratory distress syndrome (Ards) following a third interim analysis of 180 patients which found that the trial was “not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment” (BD: Dec 18, 2020).
In April, Mesoblast said that the subgroup of 123 patients under the age of 65 years had a 46 percent reduced mortality (BD: Apr 30, 2021).
Today, Mesoblast said “that two doses of remestemcel-L at days three to five conferred durable survival benefit through at least 90 days in … patients under age 65” ($p = 0.048$).
The company said that remestemcel-L reduced 90-day mortality by 77 percent in patients on dexamethasone as part of their standard of care, compared to controls under 65 years who received dexamethasone ($p = 0.0037$).
“Despite a treatment-related improvement in respiratory function at day-7, there was no mortality reduction in the 97 treated patients over [65 years], suggesting the need for more prolonged or higher dosing of anti-inflammatory therapy in these patients who may have a more exuberant inflammatory response associated with defective immune-mediated viral clearance mechanisms,” the company said.
Mesoblast said that US Food and Drug Administration guidance recommended “demonstration of mortality benefit for at least 60 days in critically ill patients”.
The company said it would meet the FDA to discuss the mortality reduction in patients under 65 years old and the regulatory pathway.
Mesoblast said it had a licence agreement with Novartis for remestemcel-L, initially for Ards, subject to conditions, including time to analyze the results from this trial.
Last year, the company said it had a potential up-to $US1,355 million ($A1,858.3 million) deal with Novartis for its remestemcel-L for Ards (BD Nov 20, Dec 2, 2020).
Mesoblast fell two cents or 1.05 percent to $1.885 with 3.4 million shares traded.

RECCE PHARMACEUTICALS

Recce says its synthetic anti-microbial R327 kills Clostridium perfringens in 30 minutes and Streptococcus pyogenes in 24 hours, in-vitro.

Recce said that Clostridium perfringens and Streptococcus pyogenes were “two main strains of bacteria associated with necrotizing fasciitis, also known as flesh-eating disease - a life-threatening bacterial infection with a mortality rate of up to 80 percent”.

The company said that the in-vitro study, conducted by a contract research organization, showed that the high dose 4,000 parts per million (ppm) reduced Clostridium perfringens to undetectable in 30 minutes, with lower doses of 2,000ppm taking one hour, 1,000pm three hours, 500ppm 24 hours and 250ppm similarly ineffective to vehicle control.

Recce said that 4,000ppm dose of R327 reduced susceptible Streptococcus pyogenes to undetectable in 24 hours, and similar activity with 2,400ppm, but less so at 1,200ppm, 600ppm and 300ppm.

The company said that R327 at 2,400ppm reduced erythromycin-resistant Streptococcus pyogenes to undetectable in 24 hours, with similar activity with 1,200ppm and 600ppm, but less so at 300ppm and 150ppm.

Recce said that Streptococcus was a Gram-positive bacterium that could cause life-threatening infections such as scarlet fever, bacteremia, pneumonia, necrotizing fasciitis, myonecrosis and streptococcal toxic shock syndrome.

The company said that Clostridium perfringens was a Gram-positive pathogen that was a leading cause of myonecrosis and a species that thrives in nil or low oxygen environments, which can cause infections in diabetic wounds and ulcers, a common characteristic of bacterial anaerobes.

Recce chief scientific officer Michele Diliza said that necrotizing fasciitis was “a rare and extremely challenging disease for physicians to manage, [but] it is highly traumatizing for patients and their families, often leading to serious complications and even death”.

“A broad spectrum anti-infective with rapid efficacy has the potential to significantly change the treatment paradigm and save lives,” Ms Diliza said.

“We have been thoroughly impressed with the efficacy that R327 has demonstrated thus far, as it reinforces our belief in the potential of this compound against such aggressive, life-threatening bacteria,” Ms Diliza said.

Recce was up five cents or 5.5 percent to 96 cents.

MACH7 TECHNOLOGIES

Mach7 says it has a $4.3 million contract to licence its Eunity universal medical imaging viewing platform to the Milwaukee, Wisconsin-based Advocate Aurora Health.

Mach7 said the fee included a software licence fee, professional services fee and an initial five-year support term fee, with $1.5 million to $1.7 million to be included in its 2021-’22 revenue and the remainder from 2022-’23 to 2026-‘27.

The company said Advocate Aurora Health was an integrated healthcare network with 10 large not-for-profit integrated health systems, including 28 hospitals, 500 outpatient locations and 68 clinics in Wisconsin and Illinois in the US, and currently used the Mach7 vendor neutral archive (VNA) system.

Mach7 chief executive officer Mike Lampron said that “with the Mach7 VNA already installed, the Eunity viewing solution will give [Advocate Aurora Health] the ability to access and view any image, anywhere, and serves as another great example of the additional value Mach7 can bring to our customers through the acquisition of Client Outlook.”

Mach7 fell 1.5 cents or 1.5 percent to 96 cents with 1.1 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it will distribute the San Francisco-based Invitae Corporation's genetic breast cancer testing services to its customers in the US.
Volpara said it would integrate Invitae's services into its breast cancer risk assessment software to create "additional access for women to comprehensive genetic testing services in different clinical settings".
Volpara chief executive officer Dr Ralph Highnam said the company was "proud of its major role in driving the adoption of personalized breast screening in the US".
"Our relationship with Invitae adds a prominent partner to our breast health platform and will allow us to offer increased value to our customers," Dr Highnam said.
Volpara was up two cents or 1.75 percent to $1.16.

GENETIC TECHNOLOGIES

Genetic Technologies says it has acquired the electronic-commerce business and distribution rights of Easydna for $US4.0 million ($A5.4 million) in cash and scrip.
Genetic Technologies said it bought Easydna from the Fort Lauderdale, Florida-based Belhealth Investment Fund for $US2 million in cash, $US1.5 million in American depositary receipts and $US500,000 in cash payable on the first anniversary of closing.
The company said in the year to December 31, 2020 Easydna had an unaudited revenue of $US4.63 million through online, retail sales of its at-home DNA tests.
Genetic Technologies said the deal included the acquisition of Easydna brands, websites and reseller agreements, including more than 70 websites in 40 countries and six brands with revenue mostly from Australia, UK, France, Canada and the US, and was subject to satisfying customary closing conditions expected by July 31, 2021.
Genetic Techno rose 0.1 cents or 12.5 percent to 0.9 cents with 5.7 million shares traded.

DIMERIX

Dimerix says the US Food and Drug Administration has confirmed the design of its phase III study of DMX-200 for focal segmental glomerulo-sclerosis (FSGS).
In June, Dimerix said the European Medicines Agency confirmed the design of its phase III study of DMX-200 for FSGS kidney disease (BD: Jun 3, 2021).
Last year, the company said s 10-patient, phase IIa trial of DMX-200 for FSGS met its primary and secondary endpoints, reducing proteinuria (BD: Jul 29, 2020).
Today, Dimerix said the FDA confirmed that improvement in proteinuria was an "acceptable surrogate endpoint for accelerated approval" if sufficient relationship to kidney function could be shown.
The company said it had appointed the Danbury, Connecticut-based Iqvia as lead contract research organization for the trial.
Dimerix managing-director Dr Nina Webster said the feedback from the FDA aligned the that received from the EMA in June, providing "further clarity and confidence that the planned FSGS phase III study meets US and European regulatory expectations for marketing approval, including the potential for accelerated marketing approval".
"The positive phase II clinical data reported in 2020 suggests that treatment with DMX-200 may indeed result in clinically meaningful improvements in kidney function when added to the standard of care in patients with FSGS," Dr Webster said.
The company said that study sites had been selected with initiation planned for August 2021, pending ethics approvals.
Dimerix was unchanged at 24 cents.

ADALTA

Adalta says it has closed its phase I trial of AD-214 for idiopathic pulmonary fibrosis and other interstitial lung diseases and will progress to efficacy studies of inhaled AD-214.
In March, Adalta said that its 34-participant phase I, part A study showed that intra-venous AD-214 was “very well-tolerated in single doses up to 20mg/kg” (BD: Mar 10, 2021).
Today, the company said it completed the phase I intra-venous multi-dose cohort at 5mg/kg with no dose limiting safety issues identified and had approval for 10mg/kg.
Adalta said it could develop an inhaled formulation of AD-214 within the current budget and without delaying efficacy studies planned for 2023.
The company said it had developed a radio-labelled version, RL-AD-214, to inform dose levels and optimal routes of administration for various fibrotic indications.
Adalta said that pre-clinical imaging studies identified that rapid liver distribution following intravenous administration was likely to significantly increase the dose of AD-214 required for therapeutic effect by this delivery route.
The company said that while no liver toxicity was observed in any pre-clinical or clinical studies to date, delivery of AD-214 by inhalation was expected to reduce the required dose, deliver greater patient and clinician convenience, enhance cost effectiveness and diversify Adalta’s partnering options.
Adalta chief executive officer Dr Tim Oldham said that AD-214 “behaved as expected across all safety measures”.
“We are pleased to be able to respond quickly to these results and progress a preferred, inhaled formulation of AD-214 for [idiopathic pulmonary fibrosis] without delaying the next clinical trials in patients,” Dr Oldham said.
“Currently, [idiopathic pulmonary fibrosis] patients routinely inhale salbutamol and steroids for symptom relief and we are aware of clinician and patient interest in current clinical trials for inhaled pirfenidone, one of the two marketed drugs for [idiopathic pulmonary fibrosis],” Dr Oldham said.
Adalta was unchanged at 13.5 cents.

ANTEOTECH

Anteo says it has distribution agreements with Biomed Global and Abacus Dx to distribute its Eugeni reader and Sars-Cov-2 tests in Asia and Australia, respectively.
In April, Anteo said it had Conformité Européenne (CE) approval for the Eugeni severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) antigen rapid test, a single use, disposable, immuno-chromatographic test (BD: Apr 12, 28, 2021).
Today, the company said it has a one-year binding agreement with Kuala Lumpur’s Biomed Global to distribute its products in Malaysia, Singapore, Indonesia, Vietnam, Thailand, and Myanmar with an option to extend by an additional two years.
Anteo said it had a five-year exclusive agreement with the Meadowbrook, Queensland-based Abacus starting on October 1, 2021 to distribute its products in Australia, New Zealand and the Pacific Islands with an option to extend by three years.
The company said Biomed would be responsible for acquiring the required registration to the local device authorities for product sales while Anteotech would support Biomed with relevant documentation and data.
Anteo chief executive officer Derek Thomson said “this is a significant milestone for the rollout of the Eugeni platform signing our first multi-territory agreement.”
“This agreement will provide us access to six major south-east Asian territories, covering a total population of around 340 million people,” Mr Thomson said.
Anteo fell one cent or 4.2 percent to 23 cents with 19.3 million shares traded.

HERAMED

Heramed says Obstetrix Medical Group has begun a paid pilot program to evaluate the functionality and suitability of its Heracare foetal heart rate platform.
In May, Heramed said the San Jose, California-based Obstetrix Medical Group would supply its Herabeat and Heracare at-home foetal heart-rate monitor platform to 100 pregnant women (BD: May 13, 2021).
Today, the company said Obstetrix would licence the hardware and software on a "software as a service" per user per month basis.
Heramed said both companies had worked on configuring and optimizing the platform to accommodate Obstetrix's requirements and providing training to the project's staff.
Heramed co-founder David Groberman said that the launch of the pilot program was "a significant achievement" and the two companies were discussing extensions to the pilot program.
Heramed was up 1.5 cents or 6.8 percent to 23.5 cents.

MEDLAB CLINICAL

Medlab says London's WEP Clinical will develop and distribute named patient programs for its unlicenced supply of its marijuana-based products in the UK.
Medlab said the agreement with WEP was the "first partnership" to supply its cannabinoid-based medications Nanabis and Nanocbd in UK and Europe.
The company said it would work with WEP over the next three months to prepare for the launch of its products.
Medlab said the agreement was its first partnership to supply the products beyond the Australian special access scheme, which chief executive officer Dr Sean Hall said was "a major milestone".
The company said that WEP Clinical managed pre-approval expanded access and post-approval named patient programs for pharmaceutical companies and healthcare providers, including regulatory expertise, data collection, drug warehousing and distribution services to help patients with an unmet medical need receive unapproved medicines in a timely manner.
Medlab was unchanged at 16 cents.

ADHERIUM, RESPIRI

Respiri says that its takeover bid for Adherium has lapsed with one or more of the defeating conditions not waived or satisfied by July 16, 2021.
In April, Respiri offered to exchange one Respiri share for seven Adherium shares valuing Adherium at 2.25 cents a share or $19.14 million, was based on its 30-day volume-weighted average price to April 28, which was 15.77 cents (BD: Apr 30, 2021).
In March, Adherium said it had raised $18 million at 1.5 cents (BD: Mar 18, 2021).
Today, Respiri said that Adherium shareholders who accepted the offer would have their acceptances cancelled and would be free to deal with their shares as they saw fit.
Respiri did not disclose how many investors had accepted the offer, nor the number of shares, they held, if any, but in its April becoming a substantial shareholder notice, Respiri said it held no Adherium shares and today, in its ceasing substantial shareholder notice, Respiri said it held 2,792,771 shares, which Biotech Daily calculates to be 0.13 percent.
Adherium was unchanged at 1.8 cents.
Respiri was up 0.2 cents or 4.8 percent to 4.4 cents with 1.2 million shares traded.

TOTAL BRAIN

Total Brain has requested a trading halt “pending an announcement in relation to a capital raising”.
Trading will resume on July 21, 2021 or on an earlier announcement.
Total Brain last traded at 29 cents.

OSTEOPORE

Rain Maker Management and says it has reduced its substantial share-holding in Osteopore from 13,300,927 shares (11.34%) to 10,268,345 shares (8.76%).
In a substantial shareholder notice signed by director Benny Chua Kok Meng, the Kuala Lumpur-based Rain Maker said that between June 3 and July 15, 2021 it sold 2,847,555 shares for $1,354,528 or at an average price of 47.56 cents a share.
Osteopore fell one cent or 2.3 percent to 43 cents.