Biotech Daily

Monday April 6, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: OPTISCAN UP 83%, MESOBLAST 35%; OSPREY DOWN 14%**

*** FDA CLEARS MESOBLAST REMESTEMCEL-L FOR COVID-19 ARDS**

*** FDA CLEARS ADMEDUS ADAPT CARDIAC EXPANSION**

*** GENETIC TECHNOLOGIES RAISES $3m**

*** RESONANCE FILES FDA 510(k) FOR HEPAFAT-AI**

*** AVITA: TREATMENTS CONTINUE DESPITE COVID-19; Q3 REVENUE UP**

*** RHINOMED EXPANDS US PRODUCTS, DISTRIBUTION**

*** MEDLAB, RANDALL FOOD ADDITIVES DEAL**

*** FDA TELLS PARADIGM: '2 PHASE III TRIALS', CAPITAL RAISING**

*** CHINA BANS TBG UNREGISTERED COVID-19 TEST EXPORT**

*** RHYTHM PASSES ISO13485 AUDIT**

*** G MEDICAL PRIZMA ITALIAN REGISTRATION, TAIWAN PERMIT**

*** CELLMID TAKES CAPITAL RAISING TRADING HALT TO SUSPENSION**

*** PERENNIAL TAKES 9% OF GENETIC SIGNATURES**

*** REGAL FUNDS TAKES 8% OF MEDADVISOR**

*** ELIXINOL: BENHAIM CHAIR; HORN IN; DUFF, ELLERY OUT**

*** RESAPP APPOINTS DR MICHAEL STEIN DIRECTOR**

*** MGC REDUCES SALARIES UP-TO 50%**

MARKET REPORT

The Australian stock market was up 4.33 percent on Monday April 6, 2020, with the ASX200 up 219.3 points to 5,286.8 points. Twenty-nine Biotech Daily Top 40 stocks were up, two fell, seven traded unchanged and two were untraded. All three Big Caps rose.

Optiscan was the best on no news, up 1.9 cents or 82.6 percent to 4.2 cents, with 4.3 million shares traded, followed by Mesoblast up 34.9 percent to $1.815 with 13.8 million shares traded. Prescient and Uscom were up more than 13 percent; Avita was up 12.6 percent; Telix rose 11.9 percent; Clinuvel, Cynata and Imugene were up more than 10 percent; Actinogen, Orthocell, Starpharma and Universal Biosensors climbed more than nine percent; Immutep and Resmed improved more than eight percent; Compumedics and Patrys were up more than seven percent; Medical Developments rose 6.15 percent; Cochlear, CSL, Ellex and Genetic Signatures were up five percent or more; LBT, Neuren, Oncosil, Resonance and Volpara improved four percent or more; Cyclopharm, Nanosonics, Next Science and Pro Medicus were up more than three percent; with Opthea up 2.5 percent.

Osprey fell 0.2 cents or 14.3 percent to 1.2 cents, with 1.8 million shares traded; with Proteomics down 4.2 percent.

MESOBLAST

Mesoblast says that the US Food and Drug Administration has cleared remestemcel-L to treat for use acute respiratory distress syndrome caused by coronavirus infection.
Mesoblast said that the FDA cleared an investigational new drug application to use intravenous infusions of the allogeneic mesenchymal stem cell formulation to treat patients with acute respiratory distress syndrome (ARDS) caused by Covdi-19.
Mesoblast chief medical officer Dr Fred Grossman said “the FDA clearance provides a pathway in the United States for use of remestemcel-L in patients with Covid-19 ARDS, where the prognosis is very dismal, under both expanded access compassionate use and in a planned randomized controlled trial”.
The company said that remestemcel-L was being developed for inflammatory conditions and was believed to counteract the inflammatory processes implicated in these diseases by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues.
A number of companies have said they were working to develop treatments for what is described as “a cytokine storm”.
Mesoblast said that remestemcel-L safety and efficacy had been evaluated in more than 1,100 patients in clinical trials, including its phase III trial for steroid-refractory acute graft versus host disease in children, a potentially fatal inflammatory condition due to a similar cytokine storm process as is seen in Covid-19 acute respiratory distress syndrome.
The company said that a post-hoc analysis of a randomized, placebo-controlled study in 60 patients with chronic obstructive pulmonary disease showed that remestemcel-L “significantly improved respiratory function in patients with the same elevated inflammatory biomarkers that are also observed in patients with Covid-19 [acute respiratory distress syndrome],” Mesoblast said.
The company said the outcomes provided the rationale for evaluating remestemcel-L in patients with COVID-19 acute respiratory distress syndrome.
Mesoblast was up 47 cents or 34.9 percent to $1.815 with 13.8 million shares traded.

ADMEDUS

Admedus says the US Food and Drug Administration has cleared an indication expansion for its Adapt tissue treatment through the “Special” 510(k) pathway.
Admedus said the change extended its Adapt tissue approval for use in cardiac defects including intra-cardiac defects, septal defects and valve and annulus repairs.
Admedus chief executive officer Wayne Patterson said that the approval was “an important distinction from previous approvals and clears the way for future approval of Adapt based material for our aortic valve products”.
Admedus was up $1.59 or 33.0 percent to $6.41.

GENETIC TECHNOLOGIES

Genetic Technologies says it has raised $US 1.8 million ($A2,991,649) in a placement at $US1.75 per American depositary share (ADS) (BD: Apr 2, 2020).
Genetic Technologies said each ADS represented 600 ASX shares at 0.48 cents each.
Genetic Technologies managing-director Dr George Muchnicki said that the capital raising showed “the institutional interest in the United States in [Genetic Technologies] as we continue our product commercialization”.
Genetic Technologies was unchanged at 0.5 cents with 7.2 million shares traded.

RESONANCE HEALTH

Resonance says it has filed a US Food and Drug Administration 510(k) application for its Hepafat artificial intelligence (AI) liver fat measuring software.
Resonance said Hepafat-AI was a “fully automated artificial intelligence software tool that measures a patient’s volumetric liver fat fraction” that could be integrated directly into existing radiology workflows or into the digital cloud.
The company said the software could be used to monitor liver-fat contents in weight loss patients, to assess and screen living liver donors and manage conditions including fatty liver disease.
Resonance said it would continue with the work required for the Australian Therapeutic Goods Administration and Conformité Européenne (CE) mark regulatory clearances.
The company said that further work was in progress to apply artificial intelligence to other organs and disease conditions.
Resonance was up half a cent or 4.2 percent to 12.5 cents.

AVITA MEDICAL

Avita says that it will continue to treat patients under Covid-19 restrictions as “burn procedures are not elective and cannot be deferred”.
Avita said that it would continue to operate through the Covid-19 crisis with employees working from home and implementing social distancing.
The company said it would continue to manufacture its Recell system for acute thermal burns and did not expect any disruptions to its supply chain for distribution network, as it had enough raw material and access to service providers to support demand into 2021.
Avita said that for the three months to March 31, 2020 its total revenue was up 21 percent or $1 million to $6 million compared to the three months to December 31, 2019.
Avita was up 5.5 cents or 12.6 percent to 49 cents with 25.0 million shares traded.

RHINOMED

Rhinomed says it has initial orders from US pharmacy chain Consumer Value Stores (CVS) to distribute its Pronto Sleep nasal decongestant in 1,930 US shops.
Rhinomed said CVS already stocked the company’s Mute nasal dilator and its Pronto range was also stocked by the US Walgreen pharmacies (BD: Jul 15, 2019).
The company said that Pronto Sleep was a vapor release, non-drug sleep aid containing lavender, eucalyptus, valerian and tea tree essential oils.
Rhinomed said that it had products stocked on “close to 15,000 shelves globally”.
Rhinomed was up 0.6 cents or 8.2 percent to 7.9 cents.

MEDLAB CLINICAL

Medlab says it will expand its marijuana-based nutritional food additive business through a heads-of-agreement with Randall Communications Pty Ltd.
Medlab said Sydney’s Randall, trading as Fevermates, distributed fever management and prevention products including thermometers, hand sanitizers and medical face masks.
The company said Randall would distribute several of Medlab’s food additives to its customers in India and Eastern Europe.
Medlab said the companies were negotiating the financial and commercial terms, specifying products, territories and market channels.
Medlab was up 4.5 cents or 19.15 percent to 28 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says the US Food and Drug Administration requires two large phase III trials for pentosan polysulphate sodium and it has requested a capital raising suspension.
Paradigm said its pre-investigational new drug (IND) meeting for injectable pentosan poly-sulphate sodium (PPS) for osteoarthritis "was both positive and informative".
The company said it "presented its case to use the FDA 505(b)(2) pathway and conduct one phase III clinical study and use published literature to confirm efficacy".
Paradigm said that the FDA "advised that the literature would not serve as one of the two required efficacy studies".
The company said it would conduct two concurrent phase III trials: one with 750 patients spanning 18 to 20 months, and the other with 400 patients over 12 months.
Paradigm said the FDA required that the Bene Pharmachem PPS be used in all studies, as PPS from other manufactures could have different atomic and molecular structure.
The company said that data from special access scheme patients suggested that the PPS had a duration of up to 12 months before re-dosing was necessary, and the FDA requested clinical confirmation of this.
Paradigm said the dosing and durability would be addressed in its 18 to 20 month phase III trial.
Paradigm chief executive officer Paul Rennie said that the phase III trial clarity provided by the FDA was "a huge milestone for [the] company".
Separately, Paradigm said its phase III trials would have a primary endpoint of a reduced Western Ontario and McMaster Universities Osteoarthritis Index (Womac) pain score and a secondary endpoint of improved patient global impression of change (PGIC).
The company said these endpoints were derived from "real world data" collected from 34 special access scheme patients.
Paradigm said the data showed a mean Womac pain score reduction of 44.9 percent, which compared "favorably with analgesic products".
The company said that 30 out of 34 patients has reported PGIC of moderate to definite and noted "considerable improvement in their [osteoarthritis] condition".
Paradigm extended its suspension, originally called for the FDA regulatory update, to a suspension for a capital raising.
Paradigm last traded at $1.69.

TBG DIAGNOSTICS

TBG says China has banned the export of Covid-19 diagnostics kits without the required China medical device product registration.
Last month, TBG's share price climbed 938.5 percent rose from 2.6 cents to 27 cents on news that its 46.65 percent subsidiary TBG Biotechnology Xiamen Inc had Conformité Européenne (CE) mark approval for its Covid-19 nucleic acid diagnostics kit which would allow the sale of the kit in Europe (BD: Mar 18, 2020).
Today, the company said TBG Xiamen's Covid-19 diagnostic did not have the required registration and would not be exported until it received the certification for sale and export.
TBG said TBG Xiamen intended to apply for the relevant regulatory approvals to sell and distribute the Covid-19 Nucleic Acid diagnostic kits within Europe, Asia and the US, but it was not clear whether this would be to China regulators or others.
TBG chairman Jitto Arulampalam told Biotech Daily that TBG Xiamen would apply for Chinese approval and was also considering manufacturing the kits outside China.
TBG was in a suspended and last traded at 27 cents.

RHYTHM BIOSCIENCES

Rhythm says it has maintained its certification to the international standard for in-vitro diagnostics and medical devices, following a British Standards Institution audit.
Rhythm said that the certification as International Organization of Standardization (ISO): 13485: 2016 covered consistent design, development, production, installation and sale of medical devices that are safe for their intended purposes.
The company said that ISO: 13485 certification was “an important component in Rhythm’s aim to achieve compliance for the European market via a [Conformité Européenne (CE)] Mark and the Australian market via the Therapeutics Goods Administration”.
Rhythm was up half a cent or 4.55 percent to 11.5 cents with 1.2 million shares traded.

G MEDICAL INNOVATIONS

G Medical says its Prizma smartphone case vital health sign monitor has Italian Health Ministry registration and a Taiwan Food and Drug Administration licence.
G Medical said the Italian registration allowed its Prizma to be distributed and used in Italy.
The company said it was “confident that the Prizma device may assist in alleviating pressure” on Italian healthcare systems in the current Covid-19 crisis.
G Medical said it would begin to fulfil orders to its Italian distributor, the Milan-based Meditel, which was appointed in February (BD: Feb 6, 2020).
In a separate announcement, the company said it had received a permit licence for Prizma use in Taiwan.
In January, G Medical said the Taiwan Food and Drug Administration had granted regulatory approval for Prizma and its partner, the British Virgin Islands-based First Channel Ltd had until April 4 to collect the permit licence (BD: Jan 20, 2020).
Today, the company said it was discussing commercial strategies for the Taiwanese market with First Channel.
G Medical said it was “exploring additional partnerships within Taiwan”.
G Medical was in a suspension and last traded at 4.5 cents.

CELLMID

Cellmid has requested a voluntary suspension to follow the trading halt “pending the release of an announcement regarding a capital raising” (BD: Apr 2, 2020).
Cellmid said it expected the suspension to last until April 7, 2020 or on an earlier announcement.
Cellmid last traded at 27 cents.

GENETIC SIGNATURES

Perennial Value Management says it has increased its substantial shareholding in Genetic Signatures from 11,909,422 shares (8.37%) to 13,399,698 shares (9.40%).
The Sydney-based Perennial said that between January 28 and March 31, 2020 it bought and sold shares with the single largest purchase and sale on March 24 buying and selling 2,419,599 shares for $2,563,807 or an average of $1.06 a share.
Genetic Signatures was up 10 cents or 5.7 percent to $1.85.

MEDADVISOR

Sydney's Regal Funds Management says it has increased substantial holding in Medadvisor from 15,366,837 shares (6.25%) to 20,580,476 shares (8.37%).
Regal said it sold 2,141,361 shares between March 25 and April 1, 2020 for prices ranging between 33.27 and 41.78 cents a share, and on April 1 bought 7,355,000 shares for 33 cents a share.
Medadvisor fell one cent or 2.6 percent to 38 cents.

ELIXINOL GLOBAL

Elixinol says founder and director Paul Benhaim will replace chairman Andrew Duff, and Oliver Horn will replace director Greg Ellery, effective immediately
Elixinol said Mr Benhaim would "take a more active role" within the company.
The company said Mr Horn was previously the chief executive officer of Swisse Wellness Australia and New Zealand and North America, and had worked in sales and marketing, as well as corporate finance.
Elixinol said Mr Duff and Mr Ellery had both resigned from the board.
Elixinol was up 6.5 cents or 23.6 percent to 34 cents with 2.6 million shares traded.

RESAPP HEALTH

Resapp says it has appointed Dr Michael Stein as a non-executive director, effective immediately.
Resapp said Dr Stein was acting chief executive officer of Valo Therapeutics, and was previously the chief executive officer of Oxstem, Doctor Care Anywhere, and the University College of London's Map of Medicine.
The company said Dr Stein held a Bachelor of Medicine and Bachelor of Surgery from South Africa's University of Cape Town and a Doctor of Philosophy from the University of Oxford.
Resapp was up one cent or 5.4 percent to 19.5 cents with 1.95 million shares traded.

MGC PHARMACEUTICALS

MGC says it will reduce staff salaries by up to 50 percent from March 1, 2020 amidst the Covid-19 pandemic "to minimize the company's operating cost".
MGC said that directors and executive management salaries would be reduced by a minimum of 50 percent, and senior management and most staff had agreed to take "significant cash salary reductions to be offset for shares in the company equating to between 40 to 50 percent of their salaries from March 1, 2020".
The company said that the issue price of the shares would be determined by the board based on end-of-month share prices and would be reviewed by July.
MGC was in an extended suspension for a Swiss marijuana Covid-19 joint venture announcement and last traded at 1.7 cents.