Biotech Daily

Wednesday March 11, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 19%; MESOBLAST DOWN 17%**

*** RESAPP: FDA REFUSES RESAPPDX-US DE NOVO APPROVAL**

*** ORTHOCELL: CELGRO, IMPLANT REGENERATE BONE IN DOGS**

*** ADMEDUS: BELGIUM APPROVES 1st HUMAN STUDY OF …**

*** OSTEOPORE TO RELEASE 5m ASX ESCROW SHARES**

*** MACH7 COMPLETES SENTARA PACS INSTALLATION**

*** NEUROSCIENTIFIC: 'POTENTIAL EMTINB GLAUCOMA EFFECT IN PIGS'**

*** CHINA 'REQUESTS RESPIRI WHEEZOS FOR COVID-19'**

*** CYNATA RECEIVES EXTRA $619k R&D TAX PAYMENT; MSCs FOR COVID-19**

*** MEDLAB: MARIJUANA NANABIS CANCER PAIN REDUCTION 'SIGNIFICANT'**

*** G MEDICAL PRIZMA PHONE CASE BLOOD GLUCOSE MODULE**

*** RACE DIRECTOR DR WILLIAM GARNER REDUCES TO 13%**

*** MERCHANT FUNDS TAKES 7% OF RACE**

*** MEDADVISOR APPOINTS STEVE WATT CHIEF REVENUE OFFICER**

*** CRESO APPOINTS JACK YU, ISAAC ALLEN TO SUBSIDIARY MERNOVA**

MARKET REPORT

The Australian stock market fell 3.6 percent on Wednesday March 11, 2020, with the ASX200 down 213.7 points to 5,725.9 points. Thirteen of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and two were untraded. All three Big Caps fell.

Impedimed was the best, up 1.2 cents or 18.75 percent to 7.6 cents with 3.6 million shares traded. Oncosil improved 14.6 percent; Compumedics climbed 9.1 percent; Cynata was up 7.5 percent; Antisense, Dimerix, Orthocell and Patrys were up more than six percent; Amplia was up 5.6 percent; Pharmaxis rose 2.5 percent; Immutep was up 1.5 percent; with Nanosonics and Starpharma up by less than one percent.

Mesoblast led the falls, down 38 cents or 17.35 percent to $1.81, with 10.15 million shares traded. LBT lost 15.4 percent; Avita, Optiscan and Uscom fell more than nine percent; Proteomics retreated 8.8 percent; Polynovo and Pro Medicus were down more than seven percent; Clinuvel and Next Science shed more than six percent; Neuren fell 5.2 percent; Cochlear, Kazia and Paradigm retreated more than four percent; Telix and Volpara were down more than three percent; Cyclopharm, Genetic Signatures and Opthea shed more than two percent; with CSL, Ellex, Medical Developments and Resmed down more than one percent.

RESAPP HEALTH

Resapp says the US Food and Drug Administration has refused class III de novo classification for its Resappdx-US respiratory diagnostic.

Resapp said that “additional information is required to demonstrate that the probable benefits of the device outweigh its probable risks”.

Last year, Resapp said it had applied to the FDA for the de-novo classification of its Resappdx-US mobile telephone software application for the diagnosis of paediatric respiratory disease using cough sounds (BD: April 15, 2019).

Resapp has conducted several trials of its algorithm-based respiratory diagnostic including a 979-patient Australian Breathe Easy study which it said showed the diagnostic had more than 86 percent agreement with clinical diagnoses for lower respiratory tract disease and pneumonia (BD: Aug 23, 2019).

In 2017, the company’s share price fell as much as 82.3 percent on news that its 1,245-patient US Smartcough-C trial failed to meet its endpoints (BD: Aug 9, 2017).

The company said at that time that “contrary to instructions and training, a high number of patients were treated before clinical research staff recorded their cough sounds [and] a high number of recordings were also found to contain a second person’s cough sounds or an unacceptable amount of background noise and interference”.

Resapp repeated the trial and in 2018, said it was “very pleased” with the mixed results of its US Smartcough-C-2 trial, which included missing its first primary endpoint for pneumonia, with accuracy rates ranging from 73 percent to 86 percent for three diseases, and lower rates for other respiratory diseases (BD: Oct 30, Oct 31, 2018).

Resapp chief executive officer Dr Tony Keating said at that time the company was “very pleased with these positive results as they allow us to submit to the [US Food and Drug Administration] for approval for at least three indications, lower respiratory tract disease, upper respiratory tract disease and asthma/reactive airway disease”.

“We will very likely add croup to this list for approval as well, considering our previous results for croup,” Dr Keating said.

Last year, the company said its Resappdx-EU diagnostic for acute paediatric respiratory disease had Conformité Européenne (CE) mark certification as a class IIa medical device, the second software-only version also had CE mark approval and Australia’s Therapeutic Goods Administration had approved the Resappdx-EU (BD: Aug 23, Sep 26, Oct 2, 2019).

Today, Resapp said that with its regulatory consultants, Experien Group, it would request “an in-person meeting with the FDA review team to determine our next steps in the US, which may include a resubmission”.

Dr Keating said the company was “understandably disappointed by the FDA’s decision, especially after recently receiving European CE mark and Australian TGA … approvals”.

“Following positive discussions during the review process last year with the FDA and submitting a detailed response to the FDA’s request for additional information in December, we were anticipating either approval of the de novo [application] or further dialogue as the next steps in the process,” Dr Keating said.

“We will now work closely with the FDA and Experien Group to plan our next steps in pursuing regulatory approval in the US,” Dr Keating said.

“In parallel, we will also continue to focus our commercialization efforts in Europe and Asia-Pacific, where we have the appropriate regulatory approvals and a growing list of commercial opportunities,” Dr Keating said.

Dr Keating told Biotech Daily the de novo application was as a class III device as there was no predicate diagnostic and said: “We hope to meet with the FDA within months and resubmit after that.”

Resapp fell 8.9 cents or 52.35 percent to 8.1 cents with 59.3 million shares traded.

ORTHOCELL

Orthocell says an 18-dog US study shows that its collagen Celgro platform is effective for bone regeneration when combined with bone substitute and a dental implant.
Last year, Orthocell said all 10 patients in a dental implant Celgro treatment marketing study regenerated high quality bone in about four months, “almost half the time of the usual two-stage, eight-months, dental implant treatment” (BD: Jun 19, 2019).
Today, the company said it administered dental guided bone regeneration treatments and a titanium dental implant was fixed into the empty socket after a tooth extraction and were covered with either Celgro or no membrane, to 18 animals.
Orthocell said treatment sites were examined at four, eight and 12 weeks to measure bone growth with micro-computed tomography to identify adverse responses and to monitor resorption of the collagen devices.
The company said Celgro treated animals showed “almost 60 percent more bone growth following dental implant treatment compared to bone growth without a collagen membrane”, Celgro was biocompatible, showed no adverse tissue reactions and was completely resorbed by week-12.
Orthocell said the study was a collaboration with Texas A&M University’s Prof Lynne Opperman and the University of Western Australia’s Prof Ming Hao Zheng.
The company said that the study would support a 510(k) application to the US Food and Drug Administration for Celgro for guided bone regeneration procedures, which it planned to submit by April 2020.
Orthocell was up two cents or 6.6 percent to 32.5 cents with 3.9 million shares traded.

ADMEDUS

Admedus says it has been granted the final step to approve a first-in-human study beginning this month, but did not specify directly what the study would study.
Admedus said the approval was through Belgium’s Federal Agency for Medicines and Health Products and provided a link for additional information to an article on transcatheter aortic valve replacement in a medical device magazine.
A spokesperson told Biotech Daily that the approval was for a study of its Adapt-treated bovine tissue process for surgical aortic valve replacement.
Admedus chief executive officer Wayne Paterson said that with “final approval to commence the study, we can move forward according to our plan with Prof Bart Meuris and his team at the University Hospitals Leuven, Belgium to perform this important study”.
“The study will give us valuable information that will help progress our path to market,” Mr Paterson said.
Admedus has completed a 100-to-one stock consolidation taking the then share price of about 7.0 cents a share to about $7.00 a share, following a previous 10-to-one stock consolidation which took the then 6.7 cents a share to 67 cents a share (BD: Nov 16, 2015; Feb 26, 2020)
Admedus was untraded at $4.09, equivalent to a pre-consolidation 4.1 cents.

OSTEOPORE

Osteopore says it will release 5,439,213 shares from ASX escrow on March 18, 2020.
Following the release from escrow, the company will have 61,572,970 shares available for trading on the ASX, with a further 39,340,438 shares remaining in escrow until September 23, 2021 and 427,094 shares remaining in escrow until June 19, 2020.
Osteopore fell five cents or 9.1 percent to 50 cents.

MACH7 TECHNOLOGIES

Mach7 says it has completed the installation of a picture archiving and communication system (PACS) modernization project for Sentara Healthcare.

Mach7 said the PACS was powered by its vendor neutral archive (VNA) enterprise imaging platform and diagnostic studio, with Client Outlook's electronic unity diagnostic viewer, and would store imaging data for the Norfolk, Virginia-based Sentara's radiology and cardiology departments.

The company said the installation, or 'go-live', would trigger a new software subscription licence, which would generate $850,000 in recurring subscription revenue, of which 50 percent would be revenue and 50 percent would be conversion of a previous agreement.

Mach7 said that the project was "the first [internet] cloud-based deployment of the complete Mach7 [product suite] at a customer site".

Mach7 chief executive officer Mike Lampron said the system would "give Sentara unparalleled flexibility and cost savings".

Mach7 was up half a cent or 0.8 percent to 62 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says that Emtinb indicates a neuroprotective effect for glaucoma-like damage in pigs.

Neuroscientific said that Emtinb was injected into the right eye of pigs one hour prior to intraocular pressure (IOP) elevation, and preliminary data showed that it reversed changes caused by IOP, including changes in neurofilament, tubulin and microtubule-associated protein levels, compared to a left eye control.

The company said it was progressing a safety and toxicology program of Emtinb, to be concluded this year, and would begin human studies later this year.

Neuroscientific chief executive officer Matthew Liddelow said the results were "better than expected and unprecedented in this model".

"Given that we only had a six-hour window for Emtinb to demonstrate its neuroprotective effect at the molecular level and the severity of the IOP model that mimics the worst human pathology, we believe in the high potential of Emtinb as a disease modifying agent in future human studies of glaucoma," Mr Liddelow said.

Neuroscientific rose three cents or 21.4 percent to 17 cents with 2.7 million shares traded.

RESPIRI

Respiri says it has "agreed to a request" by three hospitals in China to trial Wheezos on patients with respiratory problems resulting from Covid-19 coronavirus infection.

Respiri said the three hospitals were under the supervision of the Chongqing Municipal Health Commission and "expressed their interest in using Respiri's Wheezo device to help monitor the lung function of patients who have been admitted with the Covid-19 virus".

The company said the hospitals were the People's Hospital of Dadukou District which requested three devices, the People's Hospital of Banan District (three devices), and the People's Hospital of Double River New Zone (four devices).

Respiri said that "for humanitarian reasons [it] has agreed to assist and deliver the requested devices accordingly".

The company said the supply was "not part of a formal trial nor does it represent any form of pivot in the company's strategy to focus on coronaviruses, but if the device can help with remote monitoring of affected asthma families … the company is happy to assist".

Respiri fell 0.3 cents or 4.05 percent to 7.1 cents.

CYNATA THERAPEUTICS

Cynata says it has received a further $618,667 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Cynata said the rebated related to offshore expenditure on its planned phase II critical limb ischemia trial for the year to June 30, 2019.
In January, the company said it received a $1,891,795 Federal Research and Development Tax Incentive for spending in the year to June 30, 2019 (BD: Jan 19, 2020).
Today, Cynata said it was in discussions with pharmaceutical companies and other parties about the potential of its Cymerus mesenchymal stem cells "to be a useful adjunct in the management of patients with serious and ongoing issues related to Covid-19 infection".
The company said the potential of mesenchymal stem cells to treat the consequences of Covid-19 was shown by recent studies in China, which suggested that the stem cells might protect against serious outcomes of the infection, particular pneumonia.
Cynata climbed 6.5 cents or 7.5 percent to 93 cents.

MEDLAB CLINICAL

Medlab says that further to Monday's results, its 30-patient, phase IIa trial of Nanabis for cancer pain achieved statistical significance on two validated pain scoring systems.
Medlab said that its marijuana based Nanabis was superior to placebo on the Numerical Pain Rating Scales ($p = 0.046$) and on the Brief Pain Inventory ($p = 0.04$).
The company said the scoring systems were "in line with the World Health Organisation pain guidelines and are routinely used in pain management practices".
Medlab said "the total cohort had meaningful pain reduction, a specific patient subset being breast or prostate cancers with bone metastasis had an average of 40 percent improvement in pain scores from baseline".
On Monday, Medlab said the trial of Nanabis for cancer pain was safe, tolerable and showed efficacy, but did not provide statistical data (BD: Mar 9, 2020).
Medlab was unchanged at 21 cents.

G MEDICAL INNOVATIONS HOLDINGS

G Medical says it has integrated a blood glucose module for diabetes management into its Prizma Generation 3 medical device phone case.
G Medical said the test required 0.5µL of blood and had a five-second reaction time.
The company said the Prizma tests were automatically synced and stored in its existing mobile platform and recorded on the individual's personal electronic medical record, which could be shared with the patient's physician, health care provider or guardian.
G Medical said another five chemical tests were currently in further development.
G Medical was up half a cent or 10.2 percent to 5.4 cents with 1.2 million shares traded.

RACE ONCOLOGY

Race director Dr William Garner says he has reduced his substantial shareholding in Race from 16,414,927 shares (17.15%) to 13,930,078 shares (12.75%).
The San Juan, Puerto Rico-based Dr Garner said that in October 2019 he bought 1,515,151 shares for $100,000 or 6.6 cents a share in the placement that raised $1.45 million and on March 6, 2020, he sold 4,000,000 shares for $1,194,000 or 29.85 cents a share off-market "to [a] strategic investor". (BD: Aug 20, 2019).
Race fell half a cent or 1.4 percent to 35.5 cents.

RACE ONCOLOGY

Merchant Funds Management says it has become a substantial shareholder in Race with 8,533,334 shares or 7.40 percent of the company.
Last week, Race said it had commitments for a $1.8 million placement at 30 cents a share, corner-stoned by Merchant (BD: Mar 6, 2020).
Today, the Perth, Western Australia-based Merchant said that between March 6 and 13, 2020 it acquired the shares for $2,592,762 or an average of 30.4 cents a share.

MEDADVISOR

Medadvisor says it has appointed Steve Watt as its chief revenue officer.
Medadvisor said Mr Watt was previously the chief executive officer of taxi dispatch software company Raywood, the co-founder of Australian software company Invisic and was currently the chairman of transport technology business Belengo.
Medadvisor fell two cents or 4.55 percent to 42 cents.

CRESO PHARMA

Creso says it has appointed Jack Yu, replacing Bill Fleming as managing director and Isaac Allen as vice president of its subsidiary Mernova Medical, effective from today.
Creso said Mr Yu was previously production manager for Canada's Canopy Growth Corp, interim cultivation manager of Canopy's facilities, master grower for Medreleaf Corp and consulted for Health Canada.
The company said Mr Allen was previously national operations process improvement manager at Canopy and was the founder and chief executive officer of an insurance technology start-up company.
Creso was up 0.3 cents or 4.3 percent to 7.3 cents with two million shares traded.