Biotech Daily

Tuesday March 31, 2020

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: GENETIC SIGS UP 24%; OPTISCAN DOWN 17%**

*** PROTEOMICS, JANSSEN EXPAND DIABETIC KIDNEY STUDY**

*** IMPEDIMED 1st US CANCER CENTRE SOZO ORDER**

*** MEDADVISOR LAUNCHES TELEHEALTH SERVICE**

*** BYE-BYE BENITEC**

*** AUSCANN STARTS THC-CBD DOSE STUDY**

*** NUHEARA: 'COVID-19 CUTS STAFF, EXECUTIVE SALARIES 50%'**

*** PHARMAUST: 'COVID-19 HALTS 3 DOG TRIAL SITES'**

*** G MEDICAL 'PRODUCT REGISTRATION' HALT, REPORT SUSPENSION**

*** ELIXINOL 'REBRANDS, REFRESHES' PRODUCTS**

*** MGC 5th MARIJUANA COVID-19 J-V SUSPENSION EXTENSION**

*** CLARITY APPOINTS CLINICAL DEVELOPMENT GROUP**

MARKET REPORT

The Australian stock market was up for much of Tuesday March 31, but the ASX200 closed down two percent or 104.6 points to 5,076.8 points. Twenty-four of the Biotech Daily Top 40 stocks were up, 11 fell, four traded unchanged and one was untraded.

Genetic Signatures was the best for the second day in a row, on its Sars-Cov-2 test news, up 39 cents or 28.7 percent to $1.75, with 2.2 million shares traded. Osprey climbed 25 percent; Dimerix was up 16.7 percent; Alterity was up 14.3 percent; Opthea rose 13.3 percent; Pharmaxis was up 12.2 percent; Imugene improved 11.1 percent; Universal Biosensors and Volpara were up more than 10 percent; Immutep, Patrys and Telix were up more than eight percent; LBT and Resonance climbed more than seven percent; Next Science rose 6.6 percent; Compumedics, Medical Developments, Orthocell and Proteomics improved more than four percent; Oncosil was up 3.85 percent; Antisense, Cochlear and Resmed rose more than two percent; Amplia and Paradigm were up more than one percent; with Clinuvel up 0.21 percent.

Optiscan led the falls, down 0.4 cents or 16.7 percent to two cents with 94,618 shares traded. Actinogen lost 9.1 percent; CSL was down 5.1 percent; Cynata and Polynovo fell more than four percent; Ellex shed 2.8 percent; Avita and Neuren were down one percent; with Mesoblast, Nanosonics, Pro Medicus and Starpharma down less than one percent.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it will expand its diabetic kidney disease research collaboration with Johnson & Johnson's Janssen Research and Development LLC.

In 2018, Proteomics said it had a six to 12 month research agreement with Janssen, with Janssen to provide samples from its clinical trials of a gliflozin, or SGLT-2 inhibitor, that helped lower blood sugar in adults with diabetes, and Proteomics would perform sample testing using its Promarkerd diabetic kidney disease software (BD: Nov 26, 2018).

Today, the company said that initial findings would be presented at the American Diabetes Association meeting and would be embargoed until June 13, 2020.

Proteomics said the expansion of the collaboration would examine the Promarkerd score in patient samples after treatment to assess if the patients display an improved prognosis.

The company said the collaboration would continue until November 2020, with both parties to continue to bear their own costs.

Proteomics said the samples would be tested using the higher throughput Promarkerd immunoassay instead of the mass spectrometry platform which could provide results to support the Promarkerd immunoassay in future US Food and Drug Administration applications.

Proteomics was up one cent or 4.2 percent to 25 cents.

IMPEDIMED

Impedimed says it has received its first order from an unnamed US cancer care network for 16 Sozo bio-impedance spectroscopy units for lymphoedema prevention.

Last week, Impedimed said it had a confidential purchasing agreement with an unnamed US oncology care network, which would provide access to Sozo to 1,200 physicians at 470 cancer treatment locations in the US (BD: Mar 23, 2020).

Today, Impedimed managing-director Richard Carreon said that "the initial order of 16 Sozo units will establish a comprehensive lymphoedema prevention program in key centres from this national recognized oncology care network".

Impedimed was untraded at four cents.

MEDADVISOR

Medadvisor says it will launch a telehealth service, following a Federal Government announcement extending Medicare rebates to bulk-billed telehealth consultations.

Medadvisor said its "telehealth service would help to protect Australians from the widespread impact of the coronavirus pandemic", expected to be online "in April".

The company said it would extend its mobile telephone application general practitioner link (GP Link) technology to "enable patients to undertake telehealth consultations with their GP or one of Medadvisor's on-demand GPs".

Medadvisor said the extended service would be offered "through a convenient integration link between Medadvisor's GP link and the GP's own clinical system patient record to ensure compliance with clinical governance standards for GP accreditation".

The company said the platform would provide a "Carer mode" to allow a nominated carer to monitor a patient's medication management and request repeat scripts.

Medadvisor said that following the consultation, the patient would receive a digital script and could have it home delivered through no-contact Medadvisor's delivery service announced last week (BD: Mar 26, 2020).

Medadvisor was up 4.5 cents or 11.25 percent to 44.5 cents with 1.8 million shares traded.

BENITEC BIOPHARMA

Benitec says the Foreign Investment Review Board has confirmed that changes to foreign investment "do not apply to agreements prior to 10.30pm on March 29, 2020.
Benitec said its move to the US was agreed on January 30, 2020.
Yesterday, the company said that the Supreme Court of Queensland approved the scheme of arrangement for the company to move to the US (BD: Mar 30, 2020).
Last year, Benitec said that if the scheme was approved, shareholders would receive one share in Benitec Biopharma or Holdco for every 300 Benitec shares held at the April 6, 2020 record date (BD: Nov 27, 2019).
In February, the company said that if the Supreme Court approved the scheme, Benitec would be suspended from trading on the ASX, a share sale facility would be held on April 6 and shares would be implemented to shareholders and trading would commence on the Nasdaq (BD: Feb 7, 2020).
Benitec had been attempting to develop DNA-directed-RNA-interference (dd-RNA-i) drugs for more than 15 years, but sustained a series of drug failures over the period.
On Christmas Eve 2018 the company said BB-401 for head and neck cancer did not meet the objective response rate to continue enrollment in the phase II study, but said that BB-401 was "fundamentally different" from its other DNA-directed-RNA-interference drugs, but later faced an ASX query (BD: Jan 20, Jul 23, 2019).
In June last year, Axovant terminated a then $945 million deal for BB-301 for oculo-pharyngeal muscular dystrophy (BD: Jun 7, 2019).
In 2016, Benitec said its first-in-human phase I/IIa trial of the DNA-directed interference TT-034 for hepatitis C failed to show any efficacy (BD: Mar 22, 2013; Sep 16, 2016).
In 2011, Benitec worked with the Duarte, California-based City of Hope hospital on a dd-RNA-i treatment of HIV positive lymphoma patients eventually licencing the technology to Calimmune (BD: Feb 9, 2009; Mar 21, 2011; Mar 5, 2012).
Benitec last traded at 2.6 cents.

AUSCANN

Auscann says it hopes to start a 28 subject, phase I study of two dose strengths of its tetrahydrocannabinol (THC) and cannabidiol (CBD) capsules on April 20, 2020.
Auscann said the randomized, open-label, cross-over bioavailability study would examine the pharmaco-kinetics of the two doses of the "balanced THC:CBD formulations" to inform dose selection.
The company said the trial would be held at Melbourne's Nucleus Network and it was committed to starting recruitment on April 20 but would monitor developments around Covid-19 and adjust the study timelines accordingly.
Auscann chief executive officer Ido Kanyon told Biotech Daily that he expected "to have results within the current calendar year, [but] we recognize the impact Covid-19 may have on our plans".
The company said that concurrently with the clinical study it had made the dose-controlled hard-shell capsules commercially available for prescription to patients through the Australian Therapeutic Goods Administration's special access scheme and authorized prescribers.
Auscann said it had all appropriate notifications from the TGA, commercial inventory of the hard-shell capsules was shipped to distribution partner CH2 and it was authorized for distribution in Australia.
Auscann was up three cents or 18.75 percent to 19 cents with 5.7 million shares traded.

NUHEARA

Nuheara says it will temporarily stand down “non-essential” employees and reduce senior executive pay by 50 percent due to the Covid-19 pandemic.
Nuheara said its Malaysia-based hardware manufacturing had been constrained, but it was monitoring the situation to re-commence production and delivery of products.
The company said it had secured its supply chain for the first 6,000 units of its Iqbuds Max hearing and sound filtering earbuds, which had surpassed $1 million pre-orders since the January launch (BD: Feb 28, 2020).
Nuheara said that pre-orders for Iqbuds Max “remained strong”, the company had more than 2,500 units ordered and due to its online direct-to-customer sales platform, it did not expect Covid-19 related restrictions to interfere with deliveries.
The company said it would review the Covid-19 measures at June 30, 2020.
Nuheara chief executive officer Justin Miller said that “globally and in Australia we have seen businesses respond swiftly to the Covid-19 situation”.
“We don’t take this decision lightly,” Mr Miller said.
Nuheara was unchanged at 1.3 cents with 2.1 million shares traded.

PHARMAUST

Pharmaust says that Covid-19 pandemic has closed new enrolments at three of five sites in its trial of monepantel in dogs with treatment-naïve B-cell lymphoma.
Pharmaust said that enrolments at Sydney’s Animal Referral Hospital Homebush, the Sydney University Veterinary Teaching Hospital and Melbourne’s U-Vet Werribee had ceased due to Covid-19-related State Government shutdown measures, but currently enrolled dogs at these sites would continue to receive treatment.
The company said the Brisbane-based Animal Referral Hospital and Perth’s Western Australian Veterinary Emergency and Specialty would continue enrolment.
Pharmaust said that “a number” of dogs were being treated at different centres and “some” had completed the 28-day course of treatment.
The company previously said the trial intended to enrol 15 to 20 dogs (BD: Sep 20, 2019).
Pharmaust was up 0.6 cents or 9.7 percent to 6.8 cents.

G MEDICAL INNOVATIONS

G Medical has requested a voluntary suspension “pending lodgement of its audited annual report” and to follow the trading halt requested on March 27, 2020.
Last week, G Medical requested a halt pending “an announcement regarding an update on the registration status of the company’s products” (BD: Mar 27, 2020).
Trading will resume on April 17, 2020 or on an earlier announcement.
G Medical last traded at 4.5 cents.

ELIXINOL GLOBAL

Elixinol says it will “rebrand and … refresh” its products to “build on its existing customer trust and knowledge about hemp derived [cannabidiol]”.
Elixinol said it had launched “eight new high quality [stock keeping units],” or scannable barcodes, on its website and in 2,600 location in the US as a “rededication to the customer-oriented principles and research-backed approach the brand as always had”.
Elixinol was up three cents or 11.3 percent to 29.5 cents.

MGC (MEDICAL GRADE PHARMACEUTICALS) PHARMACEUTICALS

MGC has requested a fifth extension to its voluntary suspension following the trading halt requested on March 19, 2020 for a Covid-19-related joint venture.
On March 19, MGC requested a trading halt pending an announcement on "a material agreement regarding a strategic joint venture with a Swiss company in relation to Covid-19" (BD: Mar 19, 2020).
Last week, the company requested its first voluntary suspension, followed by daily extensions to the suspension (BD: Mar 23, 24, 25, 26, 27, 2020).
Today, MGC said it expected the suspension to last until April 2, 2020.
MGC last traded at 1.7 cents.

CLARITY PHARMACEUTICALS

Clarity says Dr Gillies O'Bryan-Tear will chair its "clinical development group" which includes Clarity chief medical officer Dr Robert Miller and Dr Anne-Kirsti Aksnes.
Clarity said that Dr O'Bryan-Tear joined the pharmaceutical industry in 1986 and had 30 years' experience in clinical development, management and commercial roles.
The company said that in 2009, Dr O'Bryan-Tear was appointed chief medical officer of the Oslo, Norway-based Algeta ASA, which developed the Xofigo radiopharmaceutical for prostate cancer, with Bayer AG acquiring Algeta in 2014 for $US2.9 billion.
Clarity said that Dr Miller and Dr Aksnes were also former Algeta staff.
The company said that Dr Miller worked in medical management and clinical development for more than 30 years and Dr Aksnes had more than 20 years' experience in clinical research and development in the pharmaceutical and biotechnology industry and 10 years' experience in clinical physiology.
Clarity said the clinical development group would "fast-track" the development of diagnostic and therapeutic radio-pharmaceuticals based on copper-64 for diagnosis and copper-67 for therapy in combination with Clarity's chelator for copper.
The company said the group would "optimize the development pathway to market by using the combined clinical development experience of the group, together with key opinion leaders and [its] scientific advisory board".
Clarity said that the group's "specific experience in the successful development of prostate cancer therapeutics [was] extremely relevant to the clinical development of Clarity's prostate specific membrane antigen asset using our sarcophagine chelator which has blockbuster potential as both a stand-alone diagnostic and as a combined therapy".
Clarity executive chairman Dr Alan Taylor said that "by structuring the development pathway correctly, we avoid issues of taking products to market based on the back of studies where therapeutic dosing may not be optimized."
Clarity is a public unlisted company.