Biotech Daily

Tuesday January 28, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: RESONANCE UP 6%; CYCLOPHARM DOWN 9%**

*** TGA CANCELS NEUROTECH MENTE AUTISM**

*** IMUGENE READIES FOR 2020 PD1-VAXX LUNG CANCER TRIAL**

*** GI DYNAMICS ENROLS 1st PATIENT IN ENDOBARRIER US TRIAL**

*** POLYNOVO: 1st UK NOVOSORB PATIENTS**

*** SOMNOMED REVENUE UP 15% TO $33.3m**

*** ALCIDION REVENUE $15.4m, CUSTOMER RECEIPTS $9.2m**

*** IMMURON H1 TRAVELAN SALES UP 55% TO $1.7m**

*** LIFESPOT RAISES $330k**

*** ADMEDUS: 44m DIRECTOR OPTIONS, 62m LOAN SHARES, 100-TO-1 CONSOL EGM**

*** ZELIRA, PARKINSON'S FOUNDATION DEVELOP MARIJUANA SURVEY**

*** MGC: 5-YEAR DEAL WITH ANDEN FOR BOLIVIA, PERU MARIJUANA SALES**

*** CRESO SELLS MORE THAN 100,000 CANNAQIX PACKS**

*** JEREMY GREEN, REDMILE REDUCE TO 9.5% OF AVITA**

*** CRYSTAL AMBER TAKES 76% OF GI DYNAMICS**

*** RACE APPOINTS PROF BORJE ANDERSSON DIRECTOR**

*** IMAGION APPOINTS DR OLIVER STEINBACH CLINICAL HEAD**

MARKET REPORT

The Australian stock market lost 1.35 percent on Tuesday January 28, with the ASX200 down 96.0 points to 6,994.5 points. Eight of the Biotech Daily Top 40 stocks were up, 24 fell, and eight traded unchanged.

Resonance was the best, up 1.5 cents or 6.25 percent to 25.5 cents, with 1.4 million shares traded. Oncosil climbed three percent; Imugene, Polynovo and Volpara rose more than two percent; Resmed was up 1.3 percent; with CSL, Ellex, Medical Developments and Pro Medicus up by less than one percent.

Cyclopharm led the falls, down 11 cents or 8.7 percent to $1.15, with 57,343 shares traded. Optiscan lost 6.1 percent; Prescient and Universal Biosensors fell more than five percent; Antisense, Avita and Uscom were down more than four percent; Cynata, Dimerix, Immutep and Mesoblast lost more than three percent; Actinogen, Compumedics, Nanosonics, Orthocell and Telix shed two percent or more; Genetic Signatures, Kazia and Starpharma were down one percent or more; with Clinuvel, Cochlear, Neuren, Next Science, Opthea and Paradigm down by less than one percent.

NEUROTECH INTERNATIONAL

Neurotech says the Australian Therapeutic Goods Administration has revoked approval of the Mente Autism device, prohibiting its sale as a medical device.

Neurotech said it had supplied the TGA with extensive information following the Administration's review of products related to bio-resonance and bio-feedback, but said it had been unable to convince the TGA that its neuro-feedback device complied with all "essential principles" under the Therapeutic Goods Act 1989 and the Therapeutic Goods (Medical Devices) Regulations 2002.

The company said that, according to the TGA, the information and clinical evidence it supplied had not been sufficient to substantiate compliance with the regulations and so its device would be removed from entry on the Australian Register of Therapeutic Goods, effective February 24, 2020.

Neurotech said it did not consider its Mente Autism device unsafe to use, as the TGA did not warn of adverse effects, and it did not expect the cancellation to have "any material effect on [its] revenue and current operations" as it has only a few devices in Australia, although it would reconsider its marketing of the device.

The company said the cancellation would not affect the sale and marketing of the device in the European Union and it continues developing "market opportunity" in the US under US Food and Drug Administration registration as a biofeedback device.

Neurotech fell half a cent or 27.8 percent to 1.3 cents with 6.7 million shares traded.

IMUGENE

Imugene says it is planning a 32-patient, phase I trial of its PD1-Vaxx immunotherapy for non-small cell lung cancer this year, at six sites in North America and Australia.

Imugene said the US Food and Drug Administration investigational new drug application trial followed completion of pre-clinical studies, including non-human primate safety toxicology studies that indicated the three tested doses to have no adverse effects and generated high levels of programmed death-1 (PD-1) targeting polyclonal antibodies.

Imugene chief executive officer Leslie Chong said the company was "pleased to reach both the toxicology and [good manufacturing process] drug product manufacturing milestones with such positive results, enabling us to progress PD1-Vaxx into phase I trials in 2020 as an important next step in bring a much-needed new therapeutic option to cancer patients".

Imugene was up 0.1 cents or 2.9 percent to 3.5 cents with 18.4 million shares traded.

GI DYNAMICS

GI Dynamics says it has enrolled the first of 67 patients in the first stage of its pivotal, randomized, controlled, US trial of Endobarrier for type 2 diabetes and obesity.

GI Dynamics said the patient had been enrolled at the Ann Arbor-based Michigan Medicine, one of the trial's five clinical study sites with full enrolment expected this year.

Michigan Medicine principal investigator Dr Alison Schulman said the trial was "the first of its kind to measure the primary endpoint of type 2 diabetes combined with reductions in weight, cardiovascular risk, non-alcoholic fatty liver disease, non-alcoholic steatohepatitis and chronic kidney disease".

In 2015, GI Dynamics closed a planned 500-patient trial with 325 patients enrolled, following seven cases of hepatic abscess, and later said the trial failed to meet its primary safety and efficacy endpoints (BD: Jul 30, 31, 2015; Mar 15, 2016).

GI Dynamics was unchanged at 1.5 cents with 1.2 million shares traded.

POLYNOVO

Polynovo says Novosorb has been used to treat its first two UK patients, one with necrotizing fasciitis, or flesh-eating disease, and the other with a scalp defect.
Polynovo said that additional surgeries using its Novosorb biodegradable temporizing matrix (BTM), had been completed in Switzerland and Germany, following its launch on January 22, 2020.
Polynovo chief executive officer Paul Brennan said that Novosorb had been used in its "first surgeries in England, Germany and Switzerland".
"Last week I visited several surgeons with our UK sales manager and I was impressed by the excitement that Novosorb has generated," Mr Brennan said.
"The first surgeries in England so soon after registration are a reflection of doctor enthusiasm," Mr Brennan said.
Polynovo climbed seven cents or 2.5 percent to $2.90 with 4.5 million shares traded.

SOMNOMED

Somnomed says revenue for the six months to December 31, 2019 was up 15 percent to $33,256,000, compared to $28,814,680 in the previous corresponding period.
Somnomed said its previous year's comparative included revenues from its Renew Sleep Solutions business, which was closed in December 2019.
Somnomed was up nine cents or 3.1 percent to $3.00.

ALCIDION GROUP

Alcidion says revenue for the six months to December 31, 2019 was $15,400,000, compared to $16,900,000 for the year to June 30, 2019.
Alcidion said receipts from customers for the six months to December 31, 2019 was $9,206,000, compared to $9,194,000 for the year to December 31, 2018.
The company said it launched its Miya mobile electronic medical record in November 2019 and signed a three-year $500,000 deal with Taunton and Somerset National Health Service Foundation Trust for its Patientrack software in December 2019.
Alcidion fell half a cent or 2.3 percent to 21.5 cents with 5.3 million shares traded.

IMMURON

Immuron says Travelan sales were up 55 percent to $1.68 million for the six months to December 31, 2019, compared to the previous corresponding period.
Immuron said Australian sales of its cow colostrum-derived anti-diarrhoea compound Travelan were up 33 percent to $954,000, with US sales up 39 percent to $514,000.
The company said North American sales were up 98 percent.
Immuron fell half a cent or 3.6 percent to 13.5 cents.

LIFESPOT HEALTH

Lifespot says it has raised $330,000 in a placement at 3.3 cents a share to sophisticated and professional investors.
Lifespot said the funds would go towards medical sales and partnership opportunities with pharmaceutical companies and potential merger and acquisition activities.
The company said its chairman Rod Hannington subscribed for $5,000 worth of shares.
Lifespot was untraded at 3.4 cents.

ADMEDUS

Admedus will vote on a 100-to-one consolidation, to issue 61,969,857 loan shares to Sio and 43.5 million options to directors exercisable at 11.5 cents within five years.
Admedus said it proposed to issue chief executive officer Wayne Paterson 35,000,000 options, director John Seaberg 6,000,000 options and director Stephen Denaro 2,500,000 options.
The company said that the 61,969,857 shares to be issued to Sio Partners were valued at 2.0 cents each and related to the repayment of the accrued loan balance of a loan of $1,000,000 for which the company agreed to pay a $125,000 facility fee, along with 12 percent interest compounding monthly (BD: May 9, 2019).
The meeting will be held at the office of Jones Day, Level 31, Riverside Centre, 123 Eagle Street, Brisbane on February 26, 2020 at 10am (AEST).
Admedus fell 2.1 cents or 19.1 percent to 8.9 cents with 4.9 million shares traded.

ZELIRA THERAPEUTICS (FORMERLY ZELDA THERAPEUTICS)

Zelira says it will develop a survey with the Parkinson's Foundation for people with Parkinson's disease about their use of medical marijuana and cannabidiol products.
Zelira said it would review the results with the Miami, Florida-based Parkinson's Foundation, for a clinical trial on the safety and efficacy of medical marijuana use by people with Parkinson's disease.
The company said it would use the survey in future development of medical marijuana and hemp-derived cannabidiol products, as well as to provide guidance to people with Parkinson's disease regarding marijuana-based treatments.
Parkinson's Foundation chief executive officer John Lehr said "the volume and frequency of questions Parkinson's Foundation receive from people with Parkinson's regarding the safety and impact of medical cannabis and CBD has led us to examine this public health issue more fully, and to seek collaborations with leaders in the field from academia, government, advocacy groups and industry to provide the most accurate information possible".
Zelira fell 0.6 cents or 9.0 percent to 6.1 cents with 2.2 million shares traded.

MGC PHARMACEUTICALS

MGC say it has a five-year distribution deal with the Lima, Peru-based Anden Bio Naturals to sell its medical marijuana in Peru and Bolivia.
MGC said Anden would have exclusive rights to sell its products subject to meeting specified sales targets.
The company said it would produce an unbranded line of food additive products for Anden to sell in Peru and Bolivia, provided it did not compete with its existing products.
MGC was unchanged at 3.5 cents with 2.6 million shares traded.

CRESO PHARMA

Creso says it has sold more than 100,000 packs of its hemp-oil derived Cannqix lozenges since its launch in April 2018, with more than $1 million in revenue for 2019.
Creso said the Cannaqix line comprised lozenges designed to relieve stress and chronic pain and was sold in Australia, New Zealand, Brazil, Switzerland, the UK, the Netherlands and Germany, with upcoming product launches in South Africa and Latin America.
Creso fell half a cent or 2.9 percent to 17 cents with 1.3 million shares traded.

AVITA MEDICAL

Jeremy Green and Redmile Group say they have reduced their substantial holding in Avita from 225,659,260 shares (10.66%) to 200,178,760 shares (9.45%).
The San Francisco, California-based Redmile Group and Mr Green said that between December 9, 2019 and January 28, 2020 they sold the shared on-market with the single largest sale 4,239,660 shares for $2,594,952 or 61.2 cents a share.
Avita fell three cents or 4.35 percent to 66 cents with 11.9 million shares traded.

GI DYNAMICS

Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 1,305,918,587 shares (72.62%) to 1,567,504,005 shares (76.10%).
The Guernsey-based Crystal Amber said it received 340,325,575 shares for $8,749,568 or 2.57 cents a share through the conversion of warrants on November 5 and 20, 2019 and January 14, 2020.
In August, GI Dynamics said it had $US10 million ($A14,773,150) in convertible notes and warrants with Crystal Amber to fund trial enrolments and European approval and in October exercised $US2 million ($A2,962,200) in Chess depositary interests (CDIs) to Crystal Amber (BD: Aug 22, Oct 4, 2019).

RACE ONCOLOGY

Race says it has appointed Prof Borje Andersson as a non-executive director, effective from February 1, 2020.
Race said Prof Andersson was the inventor of IV Busulfan, a US-approved drug used in stem cell transplantation that had helped reduce the death rate in the first 100 days after transplant from between 30 and 40 percent to less than three percent.
The company said Professor Andersson would focus on the clinical strategy of both its planned phase I/II paediatric acute myeloid leukaemia (AML) and phase II AML residual disease in patients in remission, as well as other clinical trial programs in adult AML, breast cancer and ovarian cancer.
Race was up 3.5 cents or 15.6 percent to 26 cents.

IMAGION BIOSYSTEMS

Imagion says it has appointed Dr Oliver Steinbach head of clinical and regulatory affairs, for its first in-human study for HER2 breast cancer.
Imagion said Dr Steinbach had more than 20 years of experience in the pharmaceutical, diagnostics and medical device industries, with eight years at the Wesel, Germany-based Altana pharmaceutical company and 12 years at diagnostic company Philips.
Dr Steinbach's Linkedin profile said he held a Doctor of Philosophy from the University of Tübingen, Germany.
Imagion fell 0.2 cents or 6.25 percent to three cents with 3.6 million shares traded.