Biotech Daily

Wednesday May 20, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ALTERITY UP 11%; AMPLIA DOWN 16%**

*** FEDERAL $400m FOR 267 MEDICAL RESEARCH PROJECTS**

*** INVEX: 'EXANATIDE SIGNIFICANT REDUCTION IN ICP'**

*** CLARITY: 64CU-SARTATE FOR NEUROBLASTOMA FDA ORPHAN STATUS**

*** G MEDICAL ECG PATCH WINS FDA COVID-19 'EMERGENCY USE STATUS'**

*** IMAGION, SIEMENS WORK ON NANOPARTICLE MRI CONTRAST**

*** MACH7: QATAR'S HAMAD MEDICAL $4.2m IMAGING RENEWAL**

*** SUDA: JAPAN PATENT FOR ANAGRELIDE FOR CANCER**

*** OPYL: 'COVID-19 PUTS FOCUS ON DIGITAL DATA'; TRADING HALT**

*** HERAMED, FREEMAN ROAD, PHI PILOT FOETAL HEART MONITOR STUDIES**

*** ANTISENSE REQUESTS 'ATL1102 DMD TRIAL RESULTS' TRADING HALT**

*** CANN GLOBAL TAKES 'RESEARCH INITIATIVES' HALT TO SUSPENSION**

*** REGAL FUNDS BELOW 5% OF ONCOSIL**

*** RACE LOSES FOUNDER, CEO DR PETER MOLLOY**

MARKET REPORT

The Australian stock market was up 0.24 percent on Wednesday May 20, 2020, with the ASX200 up 13.5 points to 5,573.0 points. Twenty-two of the Biotech Daily Top 40 stocks were up, eight fell, nine traded unchanged and one was untraded.

Alterity was the best, up 0.2 cents or 11.1 percent to two cents, with 141,795 shares traded. Immutep climbed 9.7 percent; Paradigm and Polynovo were up more than eight percent; LBT, Patrys, Starpharma and Uscom improved seven percent or more; Actinogen, Compumedics and Medical Developments were up five percent or more; Clinuvel climbed 4.4 percent; Opthea was up 3.15 percent; Volpara rose 2.55 percent; Avita, Cochlear, Cynata, Genetic Signatures, Nanosonics and Neuren were up one percent or more; with Mesoblast, Next Science and Pro Medicus up less than one percent.

Yesterday's 86.75 percent best, Amplia, led the falls, down 2.5 cents or 16.1 percent to 13 cents, with 2.6 million shares traded. Oncosil, Optiscan and Pharmaxis fell more than four percent; Imugene, Kazia, Resmed and Resonance shed more than one percent; Ellex was down one percent; with CSL down 0.7 percent.

FEDERAL GOVERNMENT

The Federal Government says it will provide $400 million to 267 health and medical research projects to prevent illness and improve healthcare delivery.
A media release from Federal Health Minister Greg Hunt said that 237 projects would receive funding from the National Health and Medical Research Council and 30 grants would be provided from the Medical Research Future Fund priority round.
The Government said that $87.1 million would support cancer research, $46.5 million would go to cardiovascular disease, $54.0 million for mental health, $19.4 million for indigenous research and $84.7 million would support 61 infectious disease projects.
The media release said it was in the process of awarding $42 million for Covid-19.
A list of grant recipients is available at: www.nhmrc.gov.au.

INVEX THERAPEUTICS

Invex says its 16-patient, phase II trial of Exanatide for idiopathic intracranial hypertension shows a statistically significant reduction in intracranial pressure (ICP).
Invex said the double-blind, placebo controlled, randomized trial was a first-in-human study of Exanatide and aimed to reduce intracranial pressure, as its primary endpoint, at 2.5 hours, 24 hours and 12 weeks as measured by a surgically implanted telemetric intracranial pressure monitor.
The company said secondary endpoints were to reduce headache frequency, improve visual acuity and reduce body mass index.
Invex said it Exanatide administered twice per day reduced intracranial pressure by between 18.7 percent and 21.0 percent and was statistically significant at all three time points compared to a placebo, including at 2.5 hours ($p = 0.048$), at 24 hours ($p = 0.03$) and at 12 weeks ($p = 0.058$).
The company said the study statistician and clinical trial investigators determined the appropriate level of significance was $p < 0.10$.
Invex said secondary endpoints showed a trend towards benefit, including a reduction in monthly headaches and an improvement in visual acuity at 12 weeks.
The company said that body mass index did not change significantly throughout the study and no serious adverse events were observed, with those observed being relatively low, including nausea in 38 percent of patients.
Invex said the phase II data supported progress to a phase III trial for registration in the US and Europe under orphan drug designation status beginning in 2021.
Invex was in a trading halt for a placement and last traded at $1.495.

CLARITY PHARMACEUTICALS

Clarity says the US Food and Drug Administration has granted orphan drug designation for 64-copper Sartate as a diagnostic agent for neuroblastoma.
Last month, Clarity said the FDA had granted its 67-copper Sartate orphan drug designation as a therapy for neuroblastoma (BD: Apr 22, 2020).
Today, the company said orphan drug designation would qualify it for seven years of market exclusivity on approval, potential tax credits on US clinical costs, exemptions from certain FDA costs and eligibility for grants for future clinical work.
Clarity said neuroblastoma most often occurred in children under five years of age and accounted for around 15 percent of paediatric cancer mortality.
Clarity is a public unlisted company.

G (GEVA) MEDICAL INNOVATIONS

G Medical says it has US Food and Drug Administration emergency use authorization for its vital signs monitoring system (VSMS) electrocardiogram patch for Covid-19 patients.
G Medical said the electrocardiogram (ECG) patch would monitor the QT interval of the heart rhythm, which when prolonged, indicated arrhythmias.
The company said the patch would monitor patients for up to 14 days and would record and transmit ECG data to its diagnostic call centers for analysis, which would then be sent to a prescribing physician at the hospital.
G Medical said the FDA concluded there was “no adequate, approved and available alternative to the emergency use of the VSMS patch for remote monitoring of the QT interval of an ECG in patients who are undergoing treatment in a hospital … for Covid-19 with drugs that can prolong QT intervals and may cause life-threatening arrhythmias”.
“Remote monitoring may reduce the [health care professionals] risk of exposure to Sars-CoV-2 during the Covid-19 pandemic,” the company quoted the FDA saying.
G Medical chief executive officer Dr Yacov Geva said the FDA authorization was “an outstanding development for G Medical and its value cannot be underestimated”.
“It is heartening to see that our technology has been recognized as being able to help ease the burden of Covid-19 on the US healthcare system”.
G Medical was up one cent or 13.9 percent to 8.2 cents with 63.3 million shares traded.

IMAGION BIOSYSTEMS

Imagion says it will work with Siemens Healthcare Pty Ltd to explore its Magsense nanoparticles as a magnetic resonance imaging (MRI) contrast agent.
Imagion said Siemens would provide expertise and technical support to clinical sites to identify optimal MRI scanning protocols for its Magsense human epidermal growth factor receptor-2 (HER-2) targeted nanoparticles.
Imagion executive chairman Bob Proulx said “the ability to use a targeted contrast agent like ours … could transform the way MRI is used to diagnose cancer and other diseases”.
Siemens Healthcare head of collaborations and research Dr Kieran O’Brien said that “Imagion’s targeted contrast technology Magsense could offer patients a more specific means to monitor cancer with MRI”.
Imagion was up 0.4 cents or 18.2 percent to 2.6 cents with 102.4 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says it has a five-year, $4.2 million renewal contract agreement with Qatar’s Hamad Medical Centre to continue support for its Enterprise imaging platform.
Mach7 said annual revenue would be recognized evenly throughout the year and cash would be received every six months in advance.
The company said the renewal was 25 percent more than the previous agreement.
Mach7 was up 6.5 cents or 10.2 percent to 70.5 cents with 4.6 million shares traded.

SUDA PHARMACEUTICALS

Suda says the Japan Patent Office has accepted a patent for its Anagrelide for cancer and for the treatment or prevention of metastatic disease in the bone or lung.
Suda said the patent, titled ‘Use of Anagrelide for Treating Cancer’ would protect its intellectual property until December 2035.
Suda was up 0.4 cents or 10.3 percent to 4.3 cents with 2.2 million shares traded.

OPYL

Opyl chief executive officer Michelle Gallaher says the Covid-19 pandemic has increased focus on digital channels and data optimization in healthcare.
“Each day we get more companies coming to us to help them with their clinical trial recruitment or market insights,” Ms Gallaher said.
“We are experiencing our busiest proposal period ever, as remote working and acceleration of social media use in healthcare highlights the benefits and importance of digital and social media outreach,” Ms Gallaher said.
Opyl said it had signed two new contracts and had several active additional proposals due to a two-year business development campaign in collaboration with the Bracknell, England-based Huumun (BD: Feb 11, 2020).
The company said it remained on track for a cash flow neutral quarter or better.
Opyl later requested a trading halt “pending an announcement regarding the commercial details of two contracts” and said trading would resume on May 22, 2020 or on an earlier announcement.
Opyl last traded up 2.8 cents or 38.9 percent to 10 cents.

HERAMED

Heramed says it will work with Perth’s Freeman Road Pty Ltd on pilot and clinical studies of its Herabeat and Heracare for telehealth and remote pregnancy monitoring.
Heramed said Freeman Road, in cooperation with Partnering in Health Innovations (PHI), would work with the company on studies of the foetal heart monitors at Western Australia’s Joondalup Health Campus.
The company said it was in the final stage of submitting study protocols, with a primary goal to examine the usability and acceptability, accuracy and reliability of Herabeat both at the ante-natal clinic and at home as a foetal heart rate monitor.
Heramed said it expected final ethics approvals in the coming weeks.
The company said that under the agreement and subject to shareholder approval, it would issue Freeman Road 5,500,000 options, exercisable at 15 cents a share within two years.
Heramed said the agreement would include opportunities to expand the cooperation through PHI’s international network of global consultants, including in Perth, Queensland, Singapore, Boston, Oxford, Helsinki and Israel.
Heramed was up 0.75 cents or 7.0 percent to 11.5 cents.

ANTISENSE THERAPEUTICS

Antisense has requested a trading halt pending an announcement “in relation to releasing the results of our phase II clinical trial of ATL1102 in Duchenne muscular dystrophy”.
Last year, Antisense said the nine-patient trial at Melbourne’s Royal Children’s Hospital showed safety, tolerability and efficacy and in March, its database was locked for final analysis, with results expected in April (BD: Dec 17, 2019, Mar 18, 2020).
Trading will resume on May 22, 2020 or on an earlier announcement.
Antisense last traded at 4.8 cents.

CANN GLOBAL

Cann Global has requested a voluntary suspension following a trading halt requested on Monday pending an announcement “regarding current research initiatives”.
Cann Global last traded at 0.7 cents.

ONCOSIL MEDICAL

Sydney's Regal Funds Management says it has ceased to be a substantial shareholder in Oncosil.

Last week Regal Funds said it had become substantial with 40,981,369 shares or 5.28 percent of the company (BD: May 13, 2020).

Earlier this month, Oncosil said it had commitments to raise $14 million through a placement at nine cents a share and would raise $5 million in a fully underwritten rights offer at the same price (BD: May 4, 2020).

Today, Regal Funds said that between May 11 and 15, 2020 it sold 3,500,000 shares for between 11.00 and 11.12 cents a share.

According to Oncosil's most recent Appendix 2A, the company had 775,685,388 shares on issue and Biotech Daily calculates that Regal Funds retains 37,481,369 or 4.83 percent of the company.

Oncosil fell half a cent or 4.35 percent to 11 cents with 2.1 million shares traded.

RACE ONCOLOGY

Race says that founder and chief executive officer Dr Peter Molloy has resigned to continue working with his company Firebrick Pharma.

Race said chairman Dr John Cullity and chief scientific officer Dr Daniel Tillet would act as interim executive chairman and interim chief operating officer, respectively.

The company said it would pay Dr Molloy in lieu of notice and he had until May 27, 2020 to repay a previous $800,000 limited recourse loan and if not repaid, it would implement a relinquishment and buy-back procedure in relation to loan shares.

In 2012, the former Biota chief executive officer and then Firebrick executive chairman Dr Molloy told Biotech Daily he hoped to cure the common cold with an off-patent microbicide, within five years (BD: Sep 25, 2012).

Today, Dr Molloy told Biotech Daily that he was credited as the inventor of the Betadine sore throat gargle and Firebrick was using the same active ingredient as a nasal spray to treat the common cold.

Dr Molloy said the Nasodine nasal spray had been shown to eliminate the infectivity of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) which caused Covid-19.

Race fell three cents or 7.9 percent to 35 cents.