Biotech Daily

Wednesday June 21, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 14%, ITL DOWN 9%**

*** ST VINCENT'S TRIALS LBT APAS INDEPENDENCE**

*** CE MARK FOR IMPEDIMED'S SOZO**

*** THALASSAEMIA FEDERATION BACKS RESONANCE LIVER IRON TEST**

*** AGC PAYS REGENEUS $1.3m PROGENZA MILESTONE**

*** BLUECHIIP SHIPS FIRST VALIDATION STOCK TO LABCON; US PATENT**

*** CYNATA FILES STEM CELLS FOR CANCER AUSTRALIAN PATENT**

*** FDA CLEARS INNATE MS416 TRIAL IND APPLICATION**

*** GOLDMAN SACHS INVESTS $5m IN REVA NOTES**

*** IMMURON ANASTASIOU, PATTISON, BIDDICKS DILUTED IN NASDAQ IPO**

MARKET REPORT

The Australian stock market fell 1.59 percent on Wednesday June 21, 2017 with the ASX200 down 91.6 points to 5,665.7 points.

Six of the Biotech Daily Top 40 stocks were up, 19 fell, 12 traded unchanged and three were untraded. All three Big Caps were up.

Impedimed was the best, up 8.5 cents or 13.8 percent to 70 cents with 1.4 million shares traded.

Prana climbed 8.7 percent; Cochlear improved 3.2 percent; Bionomics, LBT and Polynovo rose more than two percent; Compumedics was up 1.9 percent; with CSL and Resmed up by less than one percent.

ITL led the falls, down 4.5 cents or 8.7 percent to 47 cents with 156,711 shares traded.

Viralytics lost six percent; Living Cell, Psivida and Starpharma fell more than four percent; Actinogen, Admedus, Mesoblast and Neuren were down more than three percent; Airxpanders, Cyclopharm, Orthocell, Reva and Uscom shed more than two percent; Avita, Medical Developments, Nanosonics and Pro Medicus lost more than one percent; with Ellex down half a percent.

LBT INNOVATIONS

LBT says that Melbourne's St Vincent's Hospital will be the first pathology laboratory to trial its automated plate assessment system (APAS) Independence instrument.
LBT said that APAS was "a breakthrough artificial intelligence technology for the automated imaging, image analysis, interpretation and reporting of growth on microbiology culture plates after incubation" developed through the Switzerland-based Hettich AG joint venture company Clever Culture Systems AG.
The company said that APAS Independence improved the clinical efficiency of microbiology labs and enabled faster diagnosis and reporting of infectious diseases.
LBT said that the APAS Independence was cleared by the US Food and Drug Administration.
LBT chief executive officer Brent Barnes said the company had instruments "undergoing advanced reliability and performance testing that will be finalized over the coming months ahead of the first placement at St Vincent's in September".
"We look forward to seeing the independent results of APAS Independence used in a clinical laboratory setting for the first time as part of our global commercialisation milestones," Mr Barnes said.
"This is a precursor to selling product in Australia and globally which we still expect to occur at the very end of 2017," Mr Barnes said.
LBT said that microbiologists individually reviewed Agar plates of which up to 95 percent were negative.
The company said that APAS Independence automatically reviewed and sorted plates into neat stacks of negatives, positives and those to be reviewed, could read and interpret 200 plates an hour and in clinical trials demonstrated greater accuracy than microbiologists.
LBT was up half a cent or two percent to 25 cents.

IMPEDIMED

Impedimed says it has been granted Conformité Européenne (CE) mark for its Sozo body fluid composition diagnostic.
Impedimed said the bio-impedance spectroscopy Sozo approval covered indications including fluid status monitoring for heart failure, the L-Dex for lymphoedema monitoring, hydration monitoring and body composition.
The company said that the device was designed for use in hospitals, clinics and in patient's homes under a clinician's direction.
Impedimed said that the Sozo was intended for monitoring patients with heart failure, take diuretic medication, live with fluid management problems, end-stage renal disease, recovering from a coronary artery disease related event or suffered from recurrent dehydration.
Impedimed chief executive officer Richard Carreon said that CE Mark was "a pivotal regulatory and commercial milestone for Impedimed, enabling us to now make Sozo commercially available to physicians and patients throughout Europe and Australia".
"The Sozo platform is a sophisticated connected medical device that offers significant advantages over our previous [bio-impedance spectroscopy] products," Mr Carreon said.
"Testing time has been reduced to mere seconds versus tens of minutes, testing no longer requires an exam room, gel backed electrodes, or the need for a highly-trained clinician to administer the test," Mr Carreon said.
"Data can be integrated straight into a patient's electronic health records and our [internet] cloud-based system allows us to analysis data streams in real-time," Mr Carreon said.
Impedimed was up 8.5 cents or 13.8 percent to 70 cents with 1.4 million shares traded.

RESONANCE HEALTH

Resonance says the Nicosia, Cyprus-based Thalassaemia International Federation supports its low cost liver iron concentration diagnostic.

Last week, Resonance said it had developed a machine-learned artificial intelligence prototype for a low-cost test to measure liver iron concentration, following a study that showed a need for an affordable product to measure liver iron concentration in developing nations, where a widely-available but unvalidated magnetic resonance imaging transverse relaxation time technique known as T2* was potentially endangering patients' lives (BD: Jun 14, 2017).

Today, the company said that the Thalassaemia International Federation was a leading patient organisation in the field of iron overload and fully supported the diagnostic.

The Federation said it was "urging all hospitals and centres using non-regulated or non-calibrated [magnetic resonance imaging] methods to measure [liver iron concentration], to review their techniques and re-call patients, at least those whose clinical status mandates the need for accurate measurement of liver iron content, to proceed to the measurement by a validated method".

The Federation said "the issue of iron monitoring by MRI should be given immediate and serious attention and priority by all involved in the care of these patients so that patients' rights for access to quality healthcare services cease to be violated".

"We urge all centres and health care professionals to ensure that they are using only validated techniques," the Federation said.

"[The Federation] is seeking collaboration with all governments, other involved stakeholders, the industry, and in particular Resonance Health, who at the moment are providing the only validated tool to date, so as to identify ways to expand to the maximum access of its patients for [liver iron concentration] measurements globally," the Federation said.

The Federation said that Resonance had developed a prototype for a new affordable magnetic resonance imaging test and it was "within our scope to partner with Resonance Health to expedite the development and access pathways for this new test".

Resonance said that the Federation was hosting a meeting at the European Haematology Association congress this week to escalate the warnings against the unvalidated T2* technique and to progress its product.

Resonance was up 0.1 cents or 3.7 percent to 2.8 cents with 1.3 million shares traded.

REGENEUS

Regeneus says AGC Asahi Glass will pay a $US1 million ($A1.3 million) milestone for meeting the primary endpoints of its phase I trial of Progenza for knee osteoarthritis.

Last month, Regeneus said its 20-patient phase I trial for mild or moderate knee osteoarthritis showed that a single knee injection of either 3.9 million or 6.7 million allogeneic, fat-derived Progenza stem cells were safe, well-tolerated and "showed durable and clinically meaningful pain relief" (BD: May 22, 2017).

The company said that the milestone payment was part of the agreement with the Tokyo-based AGC for the licence of the rights to manufacture Progenza for all clinical indications in Japan (BD: Jan 23, 2017).

Regeneus said there were two further milestones relating to the development and approval of Progenza in Japan for payments totalling $US10 million.

Regeneus was up one cent or 7.7 percent to 14 cents.

BLUECHIIP

Bluechiip says it has shipped its first order of cryo-buttons, cryo-boxes and readers to the San Francisco-based Labcon North America (BD: Apr 10, 2017).
Bluechiip chief executive officer Andrew McLellan told Biotech Daily that the company had shipped “thousands of cryo-buttons, enough for the first validations site”.
The company said that Labcon had begun tooling for manufacture of Bluechiip-enabled cryo-vials to service the 2ml vial market, valued at $US40 million a year.
Labcon president Jim Happ said his company was “delighted with the progress and see a large market opportunity for Bluechiip-enabled Labcon cryogenic equipment”.
“We have customers already interested in the technology,” Mr Happ said.
“The Bluechiip technology enables us to differentiate our range of cyrogenic vials and we have already commenced tooling for manufacture,” Mr Happ said.
Bluechiip said that further sites would be established across Europe and US.
The company said the US Patent and Trademark Office had allowed a patent, entitled ‘Temperature Sensing and Heating Device’ which would provide coverage until 2031.
Bluechiip was up 0.1 cents or 3.6 percent to 2.9 cents.

CYNATA THERAPEUTICS

Cynata says it has filed a patent application with IP Australia for oncology-related therapeutic uses of its Cymerus mesenchymal stem cell technology.
IP, or intellectual property, Australia was formerly known as the Australian Patent Office.
Cynata said that the patent, entitled ‘Method’ would cover the application of Cymerus in immunotherapy treatments, including chimeric antigen receptor T cell and checkpoint inhibitor-based therapies and if granted would provide protection until June 2038.
The company said it had recently filed another patent application with IP Australia covering uses of Cymerus in oncology (BD: Apr 12, 2017).
Cynata chief executive officer Dr Ross Macdonald said that the patent application “would strengthen our intellectual property portfolio in the oncology field and expand commercial opportunities for Cymerus in immunotherapy”.
Cynata was up 0.25 cents or 0.4 percent to 63.75 cents.

INNATE IMMUNOTHERAPEUTICS

Innate says that it has US Food and Drug Administration clearance for its investigational new drug application for MIS416 for multiple sclerosis.
Innate said the clearance to begin clinical trials was an “important milestone”.
The company said that MIS416 recently completed a phase IIb safety and efficacy trial in patients suffering from secondary progressive multiple sclerosis, conducted at five sites in Australia and two sites in New Zealand, with results expected by October 2017.
Innate said that it had filed details on the composition of the drug, manufacture, results from pre-clinical safety studies and results from previous human clinical trials.
Innate chief executive officer Simon Wilkinson said that “opening an IND in the US at this time is particularly important for the company and the culmination of years of work”.
“It allows us to meet with the FDA following the release of our phase IIb data and discuss the design of a phase III study,” Mr Wilkinson said.
“We can also establish whether MIS416 would qualify for one of the FDA's expedited approval programs which exist to help drugs for serious conditions get to market faster,” Mr Wilkinson said.
Innate was up 1.5 cents or 2.3 percent to 67 cents.

REVA MEDICAL

The Goldman Sachs Group says it acquired 37 convertible notes for $US3,700,000 ($A4.9 million) in Reva's $US34,600,000 convertible notes issue (BD: Jun19, 2017).
Goldman Sachs said it acquired 166,500 stock options as well as the 8.0 percent convertible notes.
Reva's annual report published on February 28, 2017 said that Goldman Sachs held 4,375,000 US shares or 10.2 percent of the company.
Reva fell two cents or 2.3 percent to 84 cents.

IMMURON

Immuron's Peter Anastasiou, Ian Pattison, Kenneth Biddick and Catherine Biddick say they have been diluted in the recent capital raise to list on the Nasdaq.
Earlier this month Immuron said it had raised $US6.1 million ($A8.1 million) through the issue of 610,000 American depository shares (ADSs) at $US10 each along with 610,000 attaching warrants with each ADS equivalent to 40 Australian shares valued at 33.2 cents each (BD: Jun 9, 2017).
Immuron executive vice chairman Peter Anastasiou and Grandlodge Pty Ltd said they increased their holding and were diluted from 13,663,364 shares (12.93%) to 14,971,644 shares (11.51%).
Authentics Australia Pty Ltd, Kenneth Biddick and Catherine Biddick said they increased their holding and were diluted from 10,249,998 shares (10.11%) to 11,755,998 shares (9.04%).
Ian Pattison and Inverarey Pty Ltd of Collins Street, Melbourne said they had reduced below the five percent substantial level, primarily through the Nasdaq initial public offer dilution but also through the on-market sale of shares between December 5, 2016 and May 2, 2017, with the largest sale 60,243 shares for $23,688 or 39.3 cents a share.
Immuron said that the 610,000 ADSs were equivalent to 24,400,000 Australian shares, but no further substantial shareholder notices had been filed at the time of publication.
Immuron fell 2.5 cents or 7.6 percent to 30.5 cents.