Biotech Daily

Thursday June 22, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: COMPUMEDICS UP 17%, POLYNOVO DOWN 9%**

*** RESAPP AUSTRALIAN TRIAL DELIVERS 70-97% ACCURACY**

*** IMAGION FALLS 20% ON $12m NANO-MAGNETIC CANCER TEST IPO**

*** OVENTUS RAISES $6.5m; EXPECTS $2.5m MORE**

*** RESONANCE BONE MARROW R2-MRI IN EU, AUSTRALIA, NZ**

*** RECCE BUILDS AUTOMATED ANTIBIOTIC PRODUCTION FACILITY**

*** ACTINOGEN ENROLS US PATIENTS IN XANAMEM ALZHEIMER'S TRIAL**

*** FIL TAKES 9% OF RESAPP**

*** CRYSTAL AMBER TAKES 44% OF GI DYNAMICS**

*** BANK OF NEW YORK MELLON TAKES 5% OF COCHLEAR, AGAIN**

MARKET REPORT

The Australian stock market recovered 0.71 percent on Thursday June 22, 2017 with the ASX200 up 40.3 points to 5,706.0 points. Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, 12 traded unchanged and one was untraded.

Compumedics was the best, up nine cents or 16.7 percent to 63 cents with 274,698 shares traded.

Osprey climbed 14.7 percent; Ellex was up 13.1 percent; Impedimed improved 10 percent; Universal Biosensors was up 9.3 percent; Benitec was up 7.7 percent; Factor Therapeutics and ITL were up more than six percent; Actinogen and Neuren climbed more than three percent; Mesoblast and Pro Medicus rose more than two percent; Admedus, Avita, CSL, Cyclopharm and Viralytics were up more than one percent; with Sirtex up 0.9 percent.

Polynovo led the falls, down two cents or 9.3 percent to 19.5 cents with 504,061 shares traded.

Acrux lost 8.3 percent; Opthea fell five percent; Oncosil and Psivida shed more than two percent; Bionomics, Cochlear, Orthocell and Reva were down more than one percent; with Clinuvel, Nanosonics and Resmed down by less than one percent.

RESAPP HEALTH

Resapp says results from its 1,127 patient paediatric trial of its Resappdx respiratory disease diagnostic showed accuracy ranging from 70 percent to 97 percent.

Last year, Resapp said that 524 subject results in the paediatric dataset improved its respiratory tract disease detection from 80 percent to 97 percent (BD: Mar 31, 2016).

Resapp said the study at the Perth, Western Australia-based Joondalup Health Campus and Princess Margaret Hospital had increased the dataset from 338 subjects and the analysis by the University of Queensland's Prof Udantha Abeyratne's team "reaffirmed the high level of accuracy of Resapp's diagnostic algorithms for the identification of lower respiratory tract disease".

Resapp said last year that the algorithms were able to correctly detect lower respiratory tract disease in 97 percent of patients initially diagnosed as clear by experienced clinicians using stethoscopes but the patients were finally diagnosed as having a lower respiratory tract disease after additional clinical testing.

Today, Resapp chief executive officer Dr Tony Keating told Biotech Daily that the company was using US Food and Drug Administration terminology of "positive, negative and overall percent agreement" instead of sensitivity, specificity and accuracy because the test was compared to a non-reference standard such as a clinical diagnosis, instead of a "gold standard" reference standard.

Dr Keating said the changes were to bring the Australian trial in line with the US-based Smartcough-C study, which completed enrolment with a total of 1,245 patients earlier this week (BD: Jun 19, 2017).

Today Resapp said that the Resappdx achieved between 90 percent and 100 percent positive percent agreement and between 89 percent and 96 percent negative percent agreement with clinical diagnosis of primary upper respiratory tract infection, with no comorbidities, croup, lower respiratory tract involvement, asthma or reactive airways disease and bronchiolitis.

The company said that for pneumonia, Resappdx demonstrated 89 percent positive percent agreement and 79 percent negative percent agreement with clinical diagnosis.

Resapp said that the lower negative percent agreement reflected "the higher uncertainty in the current method of clinical diagnosis of pneumonia and in particular the clinical overlap between pneumonia, bronchiolitis and asthma [or reactive airways disease], which can occur at the same time".

"In many of these cases Resappdx provides a diagnosis of both pneumonia and the other condition which accurately reflects the clinical situation," the company said.

Curtin University Joondalup Health Campus clinical lead Prof Paul Porter said that "the ability to diagnose individual diseases among a cohort of patients experiencing a variety of different respiratory diseases is impressive".

"These levels of accuracy will give clinicians significantly more confidence in their treatment decisions, especially in emergency department and telehealth settings," Prof Porter said.

"Previous studies have used Resappdx to diagnose one disease from another," Dr Keating said.

"This is the first study where Resappdx has been used to diagnose a full range of respiratory diseases among a group of patients with a variety of ailments, which is a much greater challenge than previously reported," Dr Keating said.

"The excellent results achieved reaffirm the performance of Resappdx and give us a great deal of confidence as we enter the analysis phase of Smartcough-C and prepare our de novo submission to the US FDA," Dr Keating said.

Resapp fell half a cent or 1.5 percent to 32 cents with 2.3 million shares traded.

IMAGION BIOSYSTEMS

Imagion opened down 10 percent at 18 cents following its $12 million initial public offer to list on the ASX under the code IBX to develop its Magsense cancer diagnostic tests.
Imagion said it raised the full amount in “a heavily supported” offer at 20 cents a share, but the stock fell as much as 25 percent tor trade 15 cents
Earlier this month, the Albuquerque, New Mexico-based Imagion said it hoped to raise up to $12 million at 20 cents share to list on the ASX (BD: Jun 7, 2017).
Imagion said it was founded by Dr Ed Flynn, with Robert Proulx as executive chairman.
The company said that there was an unmet medical need for non-invasive detection of specific cancerous tumors and the Magsense “super-para-magnetic relaxometry technology has broad applicability in the diagnosis and staging of cancers and other diseases and provides a platform to commercialize a wide range of products and applications”.
The company said it had spent directly and through grants about $US18 million in developing the Magsense technology and initial end-use applications.
Imagion said the technology used nanoparticles labelled with cell-specific targeting antibodies which could be injected intravenously or by other routes of administration.
The company said that the nanoparticles could then be magnetized by a low-field magnetic pulse and their location detected by superconducting quantum interference device detectors in its Magsense instrument.
Imagion said that Magsense nanoparticles attached to bio-marked cancer cells lost their induced magnetization more slowly than an unattached particle, so only those particles attached to their target tumor were measured, with unattached nanoparticles not detected.
The company said that the Magsense system did not expose the patient to ionizing radiation or radioactive tracers.
Imagion said the technology had not been tested in humans.
Imagion closed down four cents or 20 percent at 16 cents with 2.2 million shares traded.

OVENTUS MEDICAL

Oventus says it has raised about $6.5 million in a placement at 36 cents a share, expects to place a further $500,000 and raise $2 million more in a share plan.
Oventus said it had completed the first tranche of the placement of about 18 million shares to institutional and sophisticated investors and the second tranche for $500,000 was subject to shareholder approval at an August 2017 meeting of shareholders.
The company said it would offer a share plan capped at $2 million and providing up to $15,000 in shares to each shareholder at the record date of June 21, 2017.
Oventus said the share plan opened today and would close on July 19, 2017.
The company said that chairman Dr Mel Bridges, founder Dr Chris Hart and managing-director Neil Anderson would participate in the second tranche placement to an aggregate value of $420,000, subject to shareholder approval.
Oventus said that the funds will be used for working capital and to build sales by co-marketing with distributors, including Modern Dental, as well as complete research and development and regulatory approvals for products in development and complete current clinical trials (BD: Jun 20, 2016).
The company said the fund would also use the funds for to engage with clinicians and scale production in collaboration with manufacturing partners where required.
Oventus said the placement was managed by Bell Potter Securities.
Oventus was up two cents or 5.3 percent to 40 cents.

RESONANCE HEALTH

Resonance says it will launch its Bone Marrow R2-MRI for the assessment of iron levels in bone marrow for clinical use in Europe, Australia, and New Zealand.

Resonance general-manager Sander Bangma told Biotech Daily that the Bone Marrow R2 magnetic resonance imaging (MRI) technology fell under the scope of the Australian Therapeutic Goods Administration approval for its existing Ferriscan technology and had reciprocal recognition by the European Union.

Resonance said the Bone Marrow R2 MRI would be launched at the European Haematology Association meeting in Madrid, Spain from June 22 to 25, 2017.

Last year, the company said it had filed applications to regulators and expected approvals during the course of this year (BD: Sep 23, 2017.)

Today, Resonance said the technology had application in bone marrow transplants, where quantitative assessment of bone marrow iron levels prior to transplant was thought to assist with the prediction of complications and the prognosis of patients post-transplant.

The company said that elevated iron levels were associated with a range of poorer health outcomes, including an increased likelihood of death and knowledge of bone marrow iron levels allowed interventions to improve patient outcomes.

Resonance said that more than 50,000 bone marrow transplants were performed each year and the current gold standard for assessing bone marrow iron was from bone marrow biopsy, which was subjective, non-standardized, and subject to large error between pathologists.

The company said that the Bone Marrow R2-MRI was non-invasive, standardized and correlated significantly with iron in bone marrow, positioning it favorably as an affordable, safe and pain-free alternative to biopsy.

London's Imperial College paediatric blood and marrow transplant program director Dr Josu de la Fuente said that "a non-invasive, standardized method for assessing bone marrow iron may provide important additional clinical information to assist in managing patients being considered for bone marrow transplant, as severe complications such as graft versus host disease can, in some cases, become more severe and costly to manage than the original disease of the patient".

Resonance said the company expected US Food and Drug Administration clearance for the Bone Marrow R2-MRI by the end of 2017.

Resonance was up 0.2 cents or 7.1 percent to three cents with 1.1 million shares traded.

RECCE

Recce says it has completed construction of an automated production facility in Sydney's Macquarie Park to supply the Recce 327 antibiotic in its clinical trials.

Recce said the construction of the facility, procurement and equipment testing was a "critical milestone" for producing product in line with US Food and Drug Administration good laboratory practice guidelines.

The company said the facility was able to produce one litre a day of Recce 327 with yields in the order of 99 to 100 percent, with a connected sterile packaging unit, and would produce sufficient antibiotic for both phase I and phase II clinical trials.

Recce executive chairman Dr Graham Melrose said the company "has a world-class manufacturing facility designed to supply FDA-standard batches of our synthetic antibiotic, Recce 327, for anticipated clinical trials".

"Automating the manufacturing process is cost-efficient and ensures product of the highest quality," Dr Melrose said.

Recce was up one cent or 4.35 percent to 24 cents.

ACTINOGEN MEDICAL

Actinogen says it has enrolled the first two US-based patients in 174-patient Xanadu phase II trial of Xanamem for Alzheimer's disease.
In May, Actinogen said it treated the first patient in the trial at the East Gosford, New South Wales–based Central Coast Neurosciences Research site (BD: May 16, 2017).
The company said that the first US patients were enrolled at the Atlanta Centre for Medical Research in Atlanta, Georgia, with additional sites in the US open for recruitment and more patients expected to be recruited over the next few weeks.
Actinogen said the trial expected to enrol patients at 20 sites in Australia, the US and UK, with top-line results expected by April 2019.
Actinogen was up 0.2 cents or 3.3 percent to 6.3 cents.

RESAPP

FIL Limited says it has increased its substantial holding in Resapp from 54,156,098 shares (8.22%) to 60,848,856 shares (9.23%).
The Hong Kong, London and Sydney-based FIL said it bought shares and on one occasion had a "transition in" of shares between March 27 and June 19, 2017, at prices ranging from 30 cents and 37 cents.

GI DYNAMICS

The Crystal Amber Fund says it has increased its substantial shareholding in GI Dynamics from 239,357,636 shares (42.91%) to 246,504,725 shares (44.19%).
The London and Guernsey Island-based Crystal Amber Fund said that between May 31 and June 20, 2017 it bought 7,147,089 shares for $426,346 or 5.97 cents a share.
GI Dynamics was untraded at 6.5 cents.

COCHLEAR

The Bank of New York Mellon says it has become a substantial shareholder, again, Cochlear with 2,874,587 shares or 5.0057 percent.
The Bank previously became and ceased substantial on a number of occasions, with the most recent in January this year and ceasing in February (BD: Jan 25, 2017).
The Bank of New York Mellon said it bought and sold shares between February 17 and June 20, 2017 at prices ranging from $129.63 to $154.59, as well as a number of acquisitions and disposals described as "transfer in" and "transfer out" at no cost.
Cochlear fell $1.69 or 1.1 percent to $157.75 with 227,356 shares traded.