Biotech Daily

Wednesday March 2, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MESOBLAST UP 28%, PRANA DOWN 7%**

*** WUXI'S IMP321 DOSED IN PRIMA EUROPEAN BREAST CANCER TRIAL**

*** AVITA LAUNCHES REGENERCELL, RENOVACELL IN EUROPE**

*** RESAPP: 'DIAGNOSTIC FINDS DISEASE MISSED BY AUSCULTATION'**

*** SOUTHERN ORTHOPAEDICS JOINS PARADIGM BONE BRUISING TRIAL**

*** BIO-MELBOURNE 'WIRELESS AND WEARABLE TECHNOLOGY' LAB**

*** UNIVERSAL BIOSENSORS APPOINTS DAVID HOEY DIRECTOR**

*** BRAIN APPOINTS DR STEPHEN KOSLOW, MATT MORGAN DIRECTORS**

*** MEDICAL DEVELOPMENTS DAVID WILLIAMS SELLS 1m MORE SHARES**

MARKET REPORT

The Australian stock market climbed 2.01 percent on Wednesday March 2, 2016 with the ASX200 up 98.9 points to 5,021.2 points. Twenty-one of the Biotech Daily Top 40 stocks were up, nine fell, seven traded unchanged and three were untraded.

Mesoblast was the best for the second day in a row, apparently on the back of three announcements in the past fortnight, up 62 cents or 28.2 percent to $2.82 with 4.4 million shares traded, breaking back through the $1 billion market capitalization level.

Oncosil climbed 14.3 percent; Atcor, Pharmaxis and Tissue Therapies were up more than 10 percent; Benitec and Biotron rose more than eight percent; Uscom was up 6.25 percent; Actinogen and Genetic Technologies were up more than five percent; Ellex climbed 4.7 percent; Compumedics and Polynovo were up more than three percent; Nanosonics, Prima and Sirtex rose more than two percent; Admedus, Cochlear, CSL and IDT were up than one percent; with Acrux, Clinuvel and Pro Medicus up less than one percent.

Prana led the falls, down 0.6 cents or 6.8 percent to 8.2 cents with 9,130 shares traded.

Universal Biosensors fell 5.1 percent; Avira shed 4.8 percent; Antisense was down 3.5 percent; Medical Developments and Viralytics lost more than two percent; Resmed and Starpharma were down more than one percent; with Impedimed down 0.6 percent.

PRIMA BIOMED

Prima says its IMP321, or LAG-3 immunoglobulin fusion protein, manufactured at Wuxi Biologic's China facility, has been dosed in a phase IIb clinical trial in Belgium.
Prima said the dosing represented "two significant milestones".
The company said it was the first time a biologic manufactured in China had been released for use in a clinical trial within countries in the European Union and also marked the first patient being dosed in its phase II active immunotherapy paslitaxel (Aipac) trial for metastatic breast cancer.
Prima said that Wuxi was supplying IMP321 for the trial as well as its phase I melanoma trial currently recruiting in Australia.
The company said that Belgium's Federal Agency for Medicines and Health Products approved the trial in October 2015, the application had been approved in the Netherlands and was pending in several other EU countries.
Prima chief executive officer Marc Voigt said that the company had "benefited greatly from the considerable expertise of the scientists and staff at Wuxi in producing the material we need for our Aipac clinical trial".
"The quality of the product Wuxi produced and their high operating standards have been most impressive and we are honored to be the first company to conduct a clinical trial in Europe with material produced in China," Mr Voigt said.
Prima was up 0.1 cents or 2.6 percent to 3.9 cents.

AVITA MEDICAL

Avita says it has launched two new treatments for wounds and skin defects in Europe Regenercell for chronic wounds and Renovacell for re-pigmentation.
Avita said that along with the original Recell for burns, last year Regenercell and Renovacell were granted the Conformité Européenne (CE) mark, allowing distribution throughout the European Union and countries recognizing the mark (BD: Oct 7, 2016).
The company said that Regenercell for chronic wounds was targeted at diabetic foot ulcers and venous leg ulcers, with Renovacell for re-pigmentation and aesthetic applications including scar revision.
Avita said that Regenercell and Renovacell used the regenerative technology first developed for Recell of harvesting skin from the patients to prepare a spray-on skin or epithelial suspension at the point of care in about 30 minutes.
Avita Asia Pacific general manager Lorraine Glover told Biotech Daily that Recell provided up 1,920 square centimetre (sqcm) of coverage, Renovocell covered 640sqcm and Regenercell covered 320sqcm.
The company said Regenercell was targeted at chronic wounds which affected patients' quality of life which were "a leading cause of burgeoning healthcare costs worldwide".
Avita said Renovacell restored natural pigmentation where it was absent as a result of vitiligo or skin damage to the skin and Renovacell could be used in patients where other treatment options have failed, including for hyper and hypopigmentation and regenerating damaged skin.
Avita chief executive officer Adam Kelliher said the launch of Regenercell and Renovacell would "offer hope to a wider base of patients and new treatment options to medical professionals".
"These new products demonstrate Avita Medical's commitment to further pioneering the developing field of regenerative medicine, bringing to the market here-and-now solutions that can deliver benefit to patients today," Mr Kelliher said.
Avita fell half a cent or 4.8 percent to 10 cents.

RESAPP HEALTH

Resapp says a preliminary analysis of its respiratory diagnostic trial has detected lower respiratory tract disease in 80 percent of paediatric patients cleared by stethoscope.

Resapp said that the patients at the Joondalup Health Campus and Princess Margaret Hospital in Perth, Western Australia, were later diagnosed as having a lower respiratory tract disease after additional clinical testing.

The company said that the trial had enrolled 598 subjects, 481 with a confirmed respiratory disease and 117 control cases.

Resapp said the diagnostic correctly detected 99 percent accuracy for distinguishing patients with lower respiratory tract disease from subjects with no discernible respiratory disease and 91 percent accuracy for differential diagnosis of patients with lower respiratory tract disease, compared to patients with upper respiratory tract infections with no lower respiratory tract involvement and subjects with no discernible respiratory tract disease.

The company said the preliminary analysis by the research team, led by Prof Udantha Abeyratne showed the “high level of accuracy of Resapp’s diagnostic algorithms for the identification of lower respiratory tract disease”.

In November, Resapp said the diagnostic had accuracy ranging from 87 percent to 99 percent in differentiating respiratory illnesses in children (BD: Nov 10, 2015).

Today, the company said that the algorithm used in its diagnostic when used with cough sound alone had 91 percent sensitivity, 91 percent specificity and 91 percent accuracy.

Resapp said that detecting lower respiratory disease form normal patients using cough sound with the patient’s age resulted in 93 percent sensitivity, 93 percent specificity and 93 percent accuracy, and when cough sound was combined with the patent’s age plus the presence of fever and runny nose resulted in 99 percent sensitivity, 100 percent specificity and 99 percent accuracy.

The company said that lower respiratory diseases, such as bronchiolitis and pneumonia, were often more severe than upper respiratory tract infections, and the ability to differentiate between them was critical for effective treatment.

Resapp said that traditional diagnostic techniques relied on chest auscultation, listening with a stethoscope, followed by additional observations such as oxygen saturation and tests including chest x-ray, blood tests and sputum tests.

Resapp said its dataset of 218 lower respiratory tract disease cases included 24 cases where auscultation by experienced paediatric clinical teams was clear, but after further observations and tests the 24 cases were correctly diagnosed with lower respiratory tract disease.

The company said that its algorithms were able to correctly identify 19 cases of the 24 with lower respiratory tract involvement without the use of additional clinical observations or additional tests.

Resapp chief executive officer Dr Tony Keating said that the results “clearly demonstrate that Resapp’s diagnostic tool outperforms experienced clinicians using stethoscopes and can match the results provided by an entire suite of expensive, time-consuming clinical tests”.

“We are confident that Resapp’s accuracy will improve even further as we enrol more patients,” Dr Keating said.

Resapp said that algorithm was evaluated using the method of leave-one-out cross-validation against the medical team’s final clinical diagnosis based on clinical presentations, auscultation findings and imaging as well as laboratory test results.

Resapp was up 5.5 cents or 40.7 percent to 19 cents with 36.1 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm says the Adelaide-based Southern Orthopaedics has joined its 40-patient, open-label trial of Zilosul for bone marrow oedema lesions, or bone bruising.
Last week, Paradigm said it had begun the trial at Melbourne's Box Hill Sportsmed Biologic medical clinic to investigate whether Zilosul, a formulation of pentosan polysulphate sodium, could resolve bone bruising from sporting or accidental injuries to the knee such as a ruptured anterior cruciate ligament (BD: Feb 23, 2016).
Paradigm was up half a cent or 1.8 percent to 28 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says Victoria's Parliamentary Secretary for Medical Research Frank McGuire will open its March 17 Devices and Diagnostics Laboratory.
The Network said the Victoria Government was the premier sponsor of the full day program which would showcase 'Wireless and Wearable Technology' and explore the product development lifecycle for wireless and wearable medical technology.
The Bio-Melbourne Network chief executive officer Dr Krystal Evans said that "wireless and wearable devices are the new frontier in medical technology".
"Data is key to the personalized medicine revolution and being able to track, monitor and analyze outputs on an individual basis in real-time is driving massive shifts in approaches to healthcare," Dr Evans said.
The Network said the Devices & Diagnostics Lab would be held at the Spring Street Conference Centre, 1 Spring Street, Melbourne on March 17, 2016, with registration from 8:30am with presentations from 9am to 5.15pm followed by networking drinks.
The Network said that the event was supported by the Commonwealth Scientific and Industrial Research Organisation, Davies Collison Cave and the Department of Industry, Innovation and Science.
To register go to: http://www.biomelbourne.org/events/view/404.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has appointed David Hoey as an independent non-executive director.
Universal Biosensors said that Mr Hoey had more than 25 years experience in technology financing and commercialization and would be a US-based director with expertize in business development, strategic planning, market development, corporate partnering and financing.
The company said that Mr Hoey was currently the chief executive officer and a director of the Brisbane-based Vaxxas, developing and commercializing the Nanopatch vaccine delivery technology and was also an advisor to the US-based Healthcare Ventures.
Universal Biosensors said that following the retirement of chief executive officer Paul Wright from March 10, 2016, Andrew Denver would assume the interim role of executive chairman and Denis Hanley, who previously intended to retire, would continue as a non-executive director.
Universal Biosensors fell two cents or 5.1 percent to 37 cents.

BRAIN RESOURCE

Brain Resource says it has appointed Dr Stephen Koslow and Matthew Morgan as directors, replacing Prof Arthur Toga and Nestor Hinzack.

Brain said that Dr Koslow and Mr Morgan would be appointed effective from yesterday, March 1, 2016, with Prof Toga retiring on the same day and Mr Hinzack retiring on June 30, 2016.

The company said that Prof Toga and Mr Hinzack were founding directors in 2001.

Brain said that Dr Koslow was most recently Otsuka America Pharmaceutical's director of central nervous system medical affairs and before that was the American Foundation for Suicide Prevention's research director.

The company said that in 1982, Dr Koslow was the inaugural director of the Neuroscience Research Branch at the US National Institute of Mental Health, responsible for initiating new research programs including human brain imaging using non-invasive methods.

Brain said that Dr Koslow created the NIMH report to Congress on research opportunities for neuroscience, articulating research opportunities.

The company said that in 1993, Dr Koslow initiated the multi-agency initiative on the Human Brain Project to establish a computer-based knowledge management system for the neuroscience community.

Brain said that Dr Koslow established an International Neuroinformatics Coordinating Facility at the Karolinska Institute in Sweden and was the director of external relations at the Seattle, Washington-based Allen Institute for Brain Science.

The company said that Dr Koslow had 90 publications in referred journals, 20 invited chapters in books and had edited 16 books, including 'Databasing the Brain' and had been part of its consortium since inception and a consultant since 2008.

Brain said that Dr Koslow held a Bachelor of Science and a Doctorate of Philosophy.

The company said that Mr Morgan was a co-founder of Diversa and the principal of advisory firm Millers Point and had been a venture capitalist at Queensland Investment Corporation, with more than 10 years executive management and had been a director of Leaf Resources, Bluechiip and 3D Medical.

Mr Morgan holds a Bachelor of Commerce, a Bachelor of Applied Science and a Masters of Business Administration.

Brain was up one cent or 6.7 percent to 16 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments chairman David Williams has sold 1,000,000 shares reducing his holding from 18,731,990 shares (32.45%) to 17,731,990 shares (30.66%).

Last September, Mr Williams sold 4,640,000 shares at $3.29 a shares and in May, Mr Williams said he sold 7,000,000 shares at $2.40 a share to mainly institutional investors "to increase liquidity in the company" (BD: May 12, Sep 30, 2015).

Today, Mr Williams said he sold the shares, held through Lawn Views Pty Ltd, Moggs Creek Pty Ltd, Pari Passu Pty Ltd, Kidder Peabody Pty Ltd, Ward Williams and Saul Williams, on March 1, 2016 for $4,600,000 or $4.60 a share.

Medical Developments fell 11 cents or 2.2 percent to $4.80 with 215,362 shares traded.