Biotech Daily

Thursday August 11, 2016

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: MESOBLAST UP 14%, ANTISENSE DOWN 11%**

*** RESONANCE HEPAFAT-SCAN 'ACCURATE, REPEATABLE, EQUALS BIOPSY'**

*** BELGIUM $1.4m FOR CLARITY'S PLATEVIEW PLAQUE RUPTURE TEST**

*** IMPEDIMED'S SOZO BODY COMPOSITION TEST READY FOR PRE-ORDER**

*** ATOMO RAISES $4.5m FOR DIAGNOSTIC PLATFORM**

*** NOVOGEN FILES FDA CANTRIXIL FOR OVARIAN CANCER IND**

*** TAIPEI HOSPITAL OKAYS IMUGENE HER-VAXX GASTRIC CANCER TRIAL**

*** BLUECHIIP REQUESTS CAPITAL RAISING TRADING HALT**

*** MGC SELLS ERIN MINING DATA FOR $500k**

*** CEO DR PHILIPPE WOLGEN TAKES 5% OF CLINUVEL**

*** CEO DR GRAHAM KELLY, FAMILY TAKE 32% OF NOXOPHARM**

*** DRH, DAVID HANNON TAKE 10% OF NOXOPHARM**

*** ADAM BLUMENTHAL, ANGLO MENDA TAKE 7% OF NOXOPHARM**

*** NANOSONICS APPOINTS DR STEVEN FARRUGIA FOR DESIGN, DEVELOPMENT**

*** MMJ LOSES DIRECTOR ROSS MCKAY**

MARKET REPORT

The Australian stock market was down 0.64 percent on Thursday August 11, 2016 with the ASX200 down 35.7 points to 5,508.0 points. Fourteen of the Biotech Daily Top 40 stocks were up, 11 fell, 13 traded unchanged and two were untraded.

Mesoblast was the best, up 18 cents or 14.2 percent to $1.445 with 2.5 million shares traded. Impedimed climbed 10.1 percent; Genetic Technologies and Orthocell were up more than five percent; IDT and Medical Developments improved more than four percent; Anteo, Bionomics, Biotron and Uscom were up more than three percent; Starpharma rose 2.2 percent; Cochlear and Polynovo were up more than one percent; with Clinuvel, CSL and Sirtex up by less than one percent.

Antisense led the falls, down half a cent or 10.9 percent to 4.1 cents with 111,562 shares traded. Prana lost 8.3 percent; Atcor and Neuren fell more than seven percent; Osprey was down three percent; Prima shed 2.5 percent; with Avita, Ellex, Nanosonics, Pro Medicus and Universal Biosensors down by more than one percent.

RESONANCE HEALTH

Resonance says that a pivotal 59-patient clinical study has confirmed the accuracy and repeatability of its Hepafat-Scan technology as “directly comparable to liver biopsy”.

Resonance said the research, entitled ‘Stereological Analysis of Liver Biopsy Histology Sections as a Reference Standard for Validating Non-Invasive Liver Fat Fraction Measurements by MRI’ was published in the US Public Library of Science and is at: http://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0160789.

The research, co-authored by Resonance staff, “aimed to assess a stereological method of measuring volumetric liver fat fraction (VLFF) in liver biopsies and to use the method to validate a magnetic resonance imaging method for measurement of VLFF”.

The paper said that research measured 59 subjects by three independent analysts using a stereological point counting technique combined with the Delesse principle on liver biopsy histological sections and three independent analysts using the Hepafat-Scan technique on magnetic resonance images of the liver.

The research paper concluded that “Repeatability of the stereological method is superior to the previously reported performance of assessment of hepatic steatosis by histo-pathologists and is a suitable reference standard for validating non-invasive methods of measurement of VLFF”.

In a media release, Resonance said the study was “an important milestone for Hepafat-Scan since it provides direct evidence of the performance and reliability of the technology and lays a solid foundation for uptake of Hepafat-Scan in the clinical community”.

The company said that the Hepafat-Scan enabled the measurement of volumetric liver fat fraction from magnetic resonance images, without the need for an invasive liver biopsy, the current standard.

Resonance said that the study showed that Hepafat-Scan had a very high degree of accuracy and repeatability, it was directly comparable to liver biopsy and was the only magnetic resonance imaging technique for measuring volumetric liver fat fraction that could be directly compared to biopsy, giving “a significant competitive advantage over alternative techniques”.

The company said its participation in the studies aimed to collect supporting data and evidence on the effectiveness of Hepafat-Scan in a range of indications.

Resonance said that Hepafat-Scan was being used in both adult and paediatric populations to diagnose and monitor fatty liver disease and was being trialled in pre-surgical assessments for patients with colorectal metastatic liver cancer, diabetic patients and in monitoring the results of bariatric surgery.

The company said it was in discussions with pharmaceutical companies who were developing therapeutic compounds to target fatty liver disease and it had experience in the provision of imaging core laboratory services to pharmaceutical companies and was positioned to provide Hepafat-Scan to them, as well as in the wider clinical community for routine patient diagnosis, monitoring and management.

Resonance said that there was an “epidemic of fatty liver disease worldwide, with an estimated 20 to 30 percent of the population of the United States having fatty liver disease, with similar prevalence estimates for Europe, Asia and Australia”.

The company said that a significant fraction of people with fatty liver would develop the serious liver condition non-alcoholic steato-hepatitis (NASH).

Resonance said that the Hepafat-Scan was “a new tool for the medical community who are seeking to understand and manage fatty liver disease in patients worldwide … [and] it is expected to make a positive global contribution to the management of the fatty liver disease epidemic and associated conditions”.

Resonance was up 0.2 cents or 8.3 percent to 2.6 cents.

CLARITY PHARMACEUTICALS

Clarity says it has been awarded a Belgium government grant of EUR950,000 ($A1,376,820) for its Plateview rupture-prone plaque diagnostic.

Clarity said that the grant was funded by the European Union and the Directorate General for Economy, Employment and Research, Belgium and would fund the development of its Plateview diagnostic for the detection of rupture-prone vulnerable plaque and support expansion to Europe.

The company said that Plateview had been licenced from Melbourne's Baker IDI Heart and Diabetes Institute and had the ability "to detect and visualize unstable, rupture-prone plaque".

Clarity said that there were more than 17.5 million people globally who died each year from cardiovascular disease, about 31 percent of all deaths worldwide, with four of five deaths are caused by cardiac arrests and strokes with the majority of cardiac arrests due to rupture of unstable plaques, subsequent formation of clots in the coronary arteries and ultimately loss in cardiac function.

The company said that majority of this population had no prior symptoms.

Clarity said that the Belgium Government grant would assist progressing Plateview to human clinical trials and to commercialize the technology to help diagnose and prevent cardiac arrests caused by rupture of unstable plaque.

The company said that partners in the Wallonia region had "a strong track record in the life sciences field with substantial experience in radiation technologies".

Clarity executive chairman Dr Alan Taylor said the grant "presents a unique opportunity for Clarity to expand its partnerships, further leveraging our collaborations and grow expertise in the radiopharmaceutical field outside of our cancer program, which we are developing in Australia".

"We see the development of Plateview as an opportunity to commercialize the work of Australian researchers and scientists as well as pioneer the vulnerable plaque segment of the [positron emission tomography] cardiology nuclear medicine segment and tap into the large [cardio-vascular disease] diagnostics market," Dr Taylor said.

"We believe that translating this research from the lab into the clinic will lead to significant value creation for Clarity and our academic collaborators," Dr Taylor said. "We aim to generate better patient outcomes for people around the world through the diagnosis and prophylactic treatment of vulnerable plaque and sudden heart attack."

Clarity is a private company.

IMPEDIMED

Impedimed says its Sozo bio-impedance spectroscopy diagnostic for body composition, fluid status and hydration was available for on-line pre-order.

Impedimed said that Sozo device and "wellness platform that [combined] bio-impedance spectroscopy technology with artificial intelligence to create a rapid, non-invasive scan of a person's body providing a precise and repeatable snapshot of a person's body composition, fluid status and hydration".

The company said that the diagnostic weighed under one kilogram and included eight body sensors and four weight sensors and could run applications on a user's mobile device or tablet.

Impedimed said the suite of Sozo products would be sold direct to consumers through its digital marketing channels, with first customer orders expected by the end of 2016.

Impedimed was up 15.5 cents or 10.1 percent to $1.695 with 963,916 shares traded.

ATOMO DIAGNOSTICS

Atomo says it has raised $4.5 million from a professional investors including New York's Global Health Investment Fund and a company associated Allan Moss.
Atomo said that Mr Moss was the former managing-director of Macquarie Group.
Atomo chief executive officer John Kelly told Biotech Daily that the capital raising valued that company at about $30 million post-transaction.
The company said that the investment followed a $US6 million ($A7.8 million) loan from the Global Health Investment Fund in January this year.
Atomo said that the Fund's managing-partner Dr Curt LaBelle had been appointed as a director.
Dr LaBelle said that Atomo had developed "a unique platform enabling quick, accurate and affordable point-of-care and consumer diagnostics".
Mr Moss said that Atomo had developed a "user-friendly and accurate testing device which has the potential to assist greatly in detecting HIV and other diseases in Africa and globally".
Atomo said that in the past 12 months it had secured grant funding from the New South Wales Medical Devices Fund for a digital HIV self-test and a Federal Government grant for a range of tropical fever tests.
In June, Anteo Diagnostics said it would partner with Atomo to develop a clinical prototype of a point-of-care test for the diagnosis of cardiac arrests (BD: Jun 15, 2016).
Anteo said at that time that Atomo had won the $100,000 medical device sector of the Advance Queensland Johnson & Johnson Innovation Quickfire Challenge.
Mr Kelly said in June that the funding would "allow us to evaluate the feasibility of an easy-to-use test for the early detection of heart attacks away from laboratory and hospital settings".
Atomo is a public unlisted company.

NOVOGEN

Novogen says it has submitted an investigational new drug application to the US Food and Drug Administration for a trial this year of Cantrixil for ovarian cancer.
Novogen said that the Cantrixil (TRX-E-002-1) submission included a package of data, encompassing pre-clinical pharmacology and toxicity, manufacturing, quality control and clinical development plans.
The company said that it would establish the clinical trials program 30 days after submission, unless FDA reviewers had questions or concerns which could not be resolved during that time.
Novogen director of clinical and regulatory affairs Dr Kimberley Lilischkis said that the company expected "to initiate the study swiftly in the last quarter of 2016, with participation from centres in the US and Australia".
The company said that Cantrixil would be administered directly into the abdominal cavity.
Novogen said that the pre-clinical data showed evidence of anti-tumor activity in mouse models of ovarian cancer and a toxicology program demonstrated a toxicity profile that appeared appropriate for use in humans at therapeutic doses.
Novogen chief executive officer Dr James Garner said the filing was "an important milestone".
"The team is working with Quintiles, our contract research organisation, to select and initiate the most appropriate trial sites and prepare for the phase I study," Dr Garner said.
Novogen was up 1.3 cents or 14.1 percent to 10.5 cents with 6.1 million shares traded.

IMUGENE

Imugene says it the Taipei Veterans General Hospital in Taiwan has approved its phase Ib/II study of HER-Vaxx immuno-oncology therapy for gastric cancer.
Imugene said that the ethics committee approval was “another major milestone”.
The company said that the study would be conducted in two parts with the phase Ib trial treating up to 18 patients with HER-Vaxx with chemotherapy at three dose levels, to provide safety data, immunogenicity data, evaluate the booster schedule and determine the optimal phase II dose.
Imugene said that the open-label phase II study would recruit about 68 patients randomized into either HER-Vaxx plus standard-of-care or standard-of-care alone.
Imugene chief operating officer Leslie Chong said that “with another milestone met, we are ever closer to providing much needed therapy to our patients and to obtaining valuable data for Imugene”.
Imugene was unchanged at 0.8 cents with 5.3 million shares traded.

BLUECHIIP

Bluechiip has requested a trading halt pending an announcement regarding “a proposed pro-rata non renounceable entitlement offer and associated placement”.
Trading will resume on August 15, 2016 or on an earlier announcement.
Bluechiip last traded at 2.6 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it has sold its interests in, and data relating to exploration work completed on its Senegal Bouroubourou and Lingokoto exploration permits for $500,000.
MGC said it inherited the interests from its backdoor listing into Erin Resources, retains interests in three other permits and was in discussions to divest them.
MGC fell 0.1 cents or 2.1 percent to 4.6 cents with 2.5 million shares traded.

CLINUVEL

Clinuvel chief executive officer Dr Phillipe Wolgen says he has become a substantial shareholder in his company with 2,579,724 shares (5.4%).
Dr Wolgen’s substantial shareholder notice aid he was based in Singapore and Melbourne and did not disclose a value for the shares.
Clinuvel was up three cents or 0.6 percent to $5.00.

NOXOPHARM

Noxopharm chief executive officer Dr Graham Kelly and associates say they have become substantial shareholders with 24,345,000 shares or 32.38 percent of the company.
The substantial shareholder notice said that the holders included Milligene Pty Ltd for the GE and PR Kelly Family Trust, Prue Kelly, Bende Holdings Pty Ltd, Phytose Corp and Boundaryone Superannuation Fund
Noxopharm was down one cent or 5.3 percent to 18 cents.

NOXOPHARM

The Sydney-based DRH Superannuation, RAH (STC) Pty Ltd and David Hannon say they have become substantial shareholders in Noxopharm with 7,566,429 shares (10.07%).

NOXOPHARM

The Sydney-based Anglo Menda Pty Ltd says it has become a substantial shareholder in Noxopharm with 5,089,286 shares (6.77%).
The substantial shareholder notice, signed by director Adam Blumenthal said that the shares were held by Anglo Menda as trustee for the Anglo Australasia Trust.

NANOSONICS

Nanosonics says it has appointed Dr Steven Farrugia as design and development senior vice president.
Nanosonics said that Dr Farrugia previously held executive roles in applied research, technology development and product development for more than 20 years at Resmed.
The company said that Dr Farrugia was an inventor of nearly 300 granted and pending patents and had been “identified as one of Australia’s top 10 inventors in the Australian medical device industry”.
Nanosonics said that Dr Farrugia held a Bachelor of Electrical Engineering and a Doctorate of Philosophy in Electrical Engineering from the University of Sydney and was currently an adjunct professor at the University of Sydney’s Faculty of Engineering and Information Technologies.
Nanosonics fell three cents or one percent to $2.85 with 437,268 shares traded.

MMJ PHYTOTECH

MMJ says that director Ross McKay has resigned effective immediately “due to increased workloads associated with other business interests in Canada”.
MMJ said that it was “in the process of canvassing replacement directors”.
MMJ fell half a cent or 1.9 percent to 25.5 cents with one million shares traded.