



Biotech Daily

Wednesday January 25, 2017

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: ELLEX UP 6%; DIMERIX DOWN 12.5%**
- * **DIMERIX PLACEMENT TO RAISE \$2m**
- * **MEDIBIO, EMORY EXPAND HEART RATE TEST TO PTSD**
- * **ANTEO \$2m EU GRANT FOR VITAMIN D TEST**
- * **ATCOR SPHYGMOCOR SHOWS BP-COGNITION RELATIONSHIP**
- * **PARADIGM RECRUITS PHASE IIa PPS HAY-FEVER TRIAL**
- * **MGC TO TRIAL SKINCARE CANNIBINOIDS ON SLOVENIAN VOLUNTEERS**
- * **BANK OF NEW YORK MELLON TAKES 5% OF COCHLEAR**
- * **AIRXPANDERS TAKES CAPITAL RAISING HALT TO SUSPENSION**
- * **JAPAN PATENT FOR OBJ MAGNETIC MICROARRAY TECHNOLOGY**
- * **SIRTEX APPOINTS RUEBEN TEO ASIA-PACIFIC CEO**

MARKET REPORT

The Australian stock market climbed 0.38 percent on Wednesday January 25, 2017 with the ASX200 up 21.4 points to 5,671.5 points. Ten of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and four were untraded.

Ellex was the best, up seven cents or 6.0 percent to \$1.24 with 157,495 shares traded. Bionomics and Neuren climbed more than four percent; Cellmid and Resmed were up more than three percent; Compumedics and Prima rose more than two percent; Genetic Signatures and Mesoblast were up more than one percent; with Clinuvel and Pro Medicus up by less than one percent.

Dimerix led the falls, down 0.1 cents or 12.5 percent to 0.7 cents with 5.9 million shares traded. Uscom lost 9.3 percent; Avita, Oncosil, Osprey and Viralytics fell more than four percent; Benitec, Impedimed, Reva and Starpharma were down more than three percent; Admedus, Living Cell and Sirtex shed more than two percent; Actinogen, Atcor, Cochlear, Medical Developments and Polynovo were down one percent or more; with CSL and Opthea down by less than one percent.

DIMERIX

Dimerix says it has commitments for a placement to raise \$2,000,000 at 0.6 cents a share. Dimerix said that the funds would be used for the continued development of DMX-200 for chronic kidney disease and Westar Capital was lead manager for the placement. Dimerix fell 0.1 cents or 12.5 percent to 0.7 cents with 5.9 million shares traded.

MEDIBIO

Medibio says Emory University will expand the study of its heart-rate technology from diagnosing depression to classifying post-traumatic stress disorder (PTSD).

Medibio said that the agreement with the Atlanta, Georgia-based Emory University was “a significant opportunity ... to open a large market for its ... technology”.

The company has previously said that by measuring the circadian heart rate it could diagnose major depressive disorder and distinguish between different types of depression (BD: May 11, 2015).

In May 2015, Medibio said it would begin a pivotal 80-patient study, conducted by the University of New South Wales and the Black Dog Institute, to differentiate melancholy depression from non-melancholy depression.

Today, Medibio chief executive officer Kris Knauer told Biotech Daily today that the trial was discontinued having enrolled 25 patients and the announcement was contained in the company's annual report.

In November 2015, Medibio announced a 100-patient trial at the Baltimore, Maryland-based Johns Hopkins University to differentiate between depressed and non-depressed people (BD: Nov 24, 2015).

The company published early results from the 26-subject pilot phase of the study claiming 81 percent accuracy and 82 percent sensitivity (BD: Dec 21, 2016).

Mr Knauer said the trial was continuing with 40 of 60 further patients enrolled.

Last year, Medibio said a University of Ottawa study of 98 patients to diagnose depression showed an 83 percent accuracy which compared favourably with 70 percent for psychiatrists, and later said that a separate University of Ottawa assessment of 259 patients using its technology was 86 percent accurate (BD: Aug 8, Nov 2, 2016).

Today, Medibio said that there was a PTSD prevalence rate of 3.5 percent in the US and up to 30 percent among returning US service members, with the annual cost of treating a US veteran with PTSD of \$US8,300 and 18.8 million veterans in the US.

Medibio said that Emory would test and develop its algorithms for the diagnosis of PTSD using data from an on-going study using archival and prospective data from a study of military veterans being conducted at Emory University.

The company said the data collected included 562 sets of twins (one with PTSD and one without) which had undergone evaluation of psychological, cardiovascular and other tests, with prospective data collected from the twins at a follow-up visit.

Medibio said that the collection of prospective data from the first 48 participants, of which 23 had current or remitted PTSD, and 25 controls with no history of PTSD, had been completed with initial findings submitted for peer review.

The company said the study would evaluate the influence of depression and PTSD on the circadian pattern of heart rate, skin conductance, and actigraphy to measure rest and activity cycles, to better examine the role of autonomic function, physical activity, and sleep quality/duration as mediators of progression in depression and PTSD.

The study will also incorporate a wrist-based wearable diagnostic to collect actigraphy, skin conductance, photoplethysmography data for heart rate, and temperature.

Medibio fell 1.5 cents or 3.8 percent to 38 cents.

ANTEO DIAGNOSTICS

Anteo says its Diasource Immunoassays subsidiary and Future Diagnostics have been awarded EUR1.4 million (\$A1.98 million) for a free-25-hydroxy vitamin D assay.

Anteo said that the research-use-only assay was developed and manufactured by the Wijchen, Netherlands-based Future Diagnostics Solutions using Diasource monoclonal antibodies and Diasource received exclusive worldwide distribution rights.

The company said the project aimed to develop a Conformité Européenne (CE) mark in-vitro diagnostic immunoassay for the quantification of free vitamin D to enable an optimized treatment of patients with vitamin D insufficiency, "improving quality of life and generating significant cost-savings for society".

Anteo chief executive officer Dr Jef Vangenechten said the grant meant "we can obtain CE marking and commercialize this unique assay in the clinical diagnostic testing market".

Anteo said that Diasource currently sold the assay to measure free vitamin D as a research-use-only assay to the research community, but studies suggested the assay could be diagnostically more relevant in conditions like pregnancy, chronic kidney disease, liver failure, bladder and pancreatic cancer than measuring the total 25 hydroxy vitamin D, as all other vitamin D assays do.

Anteo was unchanged at 3.9 cents with 10.4 million shares traded.

ATCOR MEDICAL

Atcor says its Sphygmocor system was used to show a relationship between central blood pressures, pulse pressure amplification and mild cognitive decline.

Atcor said that the University of Alberta study, funded by a Canadian Institute of Health Research student award and the University of Alberta Hospital Foundation, entitled 'Association between central blood pressure, arterial stiffness, and mild cognitive impairment' was published in the journal Clinical Hypertension and is available at:

<https://clinicalhypertension.biomedcentral.com/articles/10.1186/s40885-016-0058-5>.

The company said the 50-patient study aimed to determine the relationship between central blood pressure and mild cognitive impairment in adults over the age of 50.

Atcor said that "there was no significant association found between brachial blood pressure and cognition ... [but] a significant relationship was observed between central blood pressures, specifically augmentation index and pulse pressure amplification, and mild cognitive decline.

Atcor quoted the authors saying that "although blood pressure is typically measured peripherally over the brachial artery, central blood pressure measurements, including aortic blood pressure, have shown stronger associations with end-organ damage and may be of greater clinical use".

The article concluded that central blood pressure indices were "markers of vascular stiffness wave dynamics and augmentation pressure are associated with possible poor executive function and language cognitive domain deficits".

These [central blood pressure] indices may be sensitive indicators of cognitive decline," the article concluded.

"Future large studies are needed to clarify the effect of [central blood pressure] indices on cognitive aging," the research article concluded.

Atcor chief executive officer Duncan Ross said that a number of studies had "established a relationship between central aortic blood pressures, arterial stiffness and cognitive decline and we are pleased to see continued research in this important new clinical application".

Atcor fell 0.1 cents or 1.45 percent to 6.8 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says all 40 clinical trial subjects have been recruited to its phase IIa allergen challenge of pentosan polysulfate sodium (PPS) for allergic rhinitis or hay fever.

Paradigm said that the trial in Lund, Sweden-based Skane University Hospital was a double-blind, placebo controlled, cross-over trial design.

The company said that the first group of 15 subjects would finish treatment in two weeks, the second group of 15 subjects would finish treatment by mid-March, and the third group of 10 subjects would finish treatment by end of March 2017.

Paradigm said that a read-out of results was expected about July 2017.

The company said that the market for allergic rhinitis was about \$US11 billion and was dominated by anti-histamines and corticosteroids with market surveys highlighting patient dissatisfaction and the need for effective therapy.

Paradigm said that its Rhinosul pentosan polysulfate sodium nasal spray had “unique properties consisting of both histamine stabilizing and non-steroidal anti-inflammatory properties without the known side effects of anti-histamines and steroids ... [and] the company believes its product can meet market needs that are not effectively managed by current nasal sprays”.

Paradigm was up half a cent or 1.1 percent to 46 cents.

MGC (MEDICAL GRADE CANNABIS) PHARMACEUTICALS

MGC says it will begin three months of clinical tests of its cannabinoid products for skin conditions on a 30 healthy volunteers in Slovenia.

MGC said that the study would determine the efficacy of its dermatological skin care products for the relief of redness, dryness, flaky and oily indications for skin prone to acne, seborrhea and psoriasis and on completion it planned to begin commercial sales by October 2017.

MGC said its three cannabinoid-based skin care products would be trialed “at the largest Slovenian private dermatological institution in the country”.

MGC fell 0.1 cents or 2.4 percent to four cents with 6.0 million shares traded.

COCHLEAR

The Bank of New York Mellon says it has become a substantial shareholder in Cochlear with 2,873,003 shares or 5.0029 percent.

The Bank of New York Mellon said it bought and sold shares between September 22 2016 and January 23, 2017 at prices ranging from \$115.70 to \$141.35, as well as a number of acquisitions and disposals described as “transfer in” and “transfer out” at no cost.

In 2013, The Bank of New York Mellon says it has ceased its substantial shareholding in Cochlear selling 2,689,622 shares at an average price of \$63.49 (BD: Jun 3, 2013).

Cochlear fell \$1.27 or 1.0 percent to \$127.39

AIRXPANDERS

Airxpanders has requested a voluntary suspension to follow the January 23, trading halt for a proposed capital raising (BD: Jan 23, 2017).

Airxpanders last traded at \$1.075.

OBJ

OBJ says that the Japan Patent Office has granted a patent for its magnetic microarray technology.

OBJ said that the patent, entitled 'Delivery of Skincare Products' provided protection in Japan for its magnetic microarray technology in skin delivery applications until June 17, 2031.

OBJ fell 0.1 cents or 1.35 percent to 7.3 cents.

SIRTEX MEDICAL

Sirtex says that Rueben Teo has been appointed as Asia-Pacific chief executive officer, based in Singapore, effective from March 27, 2017.

Sirtex said that Mr Teo was previously RTI Surgical's Asia senior commercial director and before that was a director at Perceptus Consulting and spent 10 years with Stryker Corp in senior roles.

On January 13, Sirtex said it had "terminated [chief executive officer Gilman] Wong's employment ... with immediate effect" (BD: Jan 22, 2017).

Sirtex said the investigation into the trading of shares by Mr Wong in October 2016 had been conducted by its legal advisers Watson Mangioni and investigation had been completed, but the report was "privileged and confidential".

The company said it had appointed chief operating officer Nigel Lange as acting chief executive officer and Anthony Dixon as chief executive officer for Europe, the Middle East and Africa, with immediate effect.

Sirtex fell 43 cents or 2.85 percent to \$14.68 with 692,025 shares traded.