Biotech Daily

Wednesday August 3, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTEO UP 16%, BENITEC DOWN 12%**

*** ANTEO LAUNCHES ZIKA, VITAMIN D TESTS; THREE COUPLING KITS**

*** CLINUVEL COMPLETES FDA SCENESSE VITILIGO SAFETY STUDY**

*** MACH7: '$1m CLIENT IS VIRGINIA COMMONWEALTH UNI HEALTH'**

*** REVA SUBMITS FANTOM STENT CE MARK APPLICATION**

*** MMJ, COWICHAN LAND LEASE FOR 26t MARIJUANA PER YEAR**

*** CHINA GRANTS ANALYTICA PERICOACH PATENT**

*** PHARMAUST, UNI OF NSW SWAP MONEPANTEL, MUCIN RIGHTS**

*** MAYNE COMPLETES TEVA ASSET ACQUISITION**

*** ORTHOCELL TO RELEASE 27m ESCROW SHARES, 4m OPTIONS**

*** FACTOR THERAPEUTICS APPOINTS MEDICAL ADVISORY BOARD**

*** OPTISCAN APPOINTS ANDREW FROUDE FOR PRECLINICAL PRODUCTS**

MARKET REPORT

The Australian stock market fell 1.35 percent on Wednesday August 3, 2016 with the ASX200 down 74.8 points to 5,465.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 21 fell, seven traded unchanged and one was untraded. All three Big Caps fell.

Anteo was the best, up 0.7 cents or 15.6 percent to 5.2 cents with 7.2 million shares traded. Cellmid climbed 6.25 percent; Genetic Technologies was up 5.6 percent; Acrux, Biotron, Ellex and Universal Biosensors were up more than three percent; Factor Therapeutics and IDT rose more than two percent; with Airxpanders and Pro Medicus up one percent or more.

Benitec led the falls, down 1.5 cents or 12.0 percent to 11 cents with 784,604 shares traded. Oncosil lost 9.1 percent; Admedus, Opthea and Uscom fell more than four percent; Atcor, Neuren and Prana were down more than three percent; Avita, Clinuvel, Living Cell and Starpharma shed more than two percent; Actinogen, Medical Developments, Mesoblast, Orthocell, Psivida, Resmed, Sirtex and Viralytics lost more than one percent; with Cochlear, CSL, Impedimed and Reva down less than one percent.

ANTEO DIAGNOSTICS

Anteo says it has launched a Zika virus assay, a free-25 hydroxy vitamin D assay and three application kits for the in-vitro diagnostics and life sciences markets

Anteo said that the kits were launched at the American Association for Clinical Chemistry in Philadelphia, Pennsylvania August 2 to 4, 2016.

The company said that its wholly-owned Louvain-La-Neuve, Belgium-based Diasource Immunoassays SA subsidiary launched the Zika virus and free-25 hydroxy vitamin D enzyme-linked immune-sorbent assay (Elisa) diagnostics.

Anteo said that the free-25OH vitamin D Elisa diagnostic was the "world's first commercially available assay measuring free-25OH, protein-unbound, vitamin D for the [in-vitro diagnostics] market" and Diasource manufactured the only commercially available assay to measure this free fraction of 25 hydroxy vitamin D.

Anteo said that the market for measuring 25OH vitamin D was estimated at $US1.2 billion in 2016 and recent studies suggested that measuring the free fraction of 25OH vitamin D rather than the total 25OH vitamin D as other assays do could be more diagnostically relevant for conditions including pregnancy, chronic kidney disease, liver failure, bladder and pancreatic cancer, and for haemodialysis patients.

The company said the World Health Organisation had declared the Zika virus a public health emergency, with as many as four million people being infected by the end of 2016.

Anteo said the Diasource Zika virus Elisa diagnostic would distributed in the most affected areas in South America.

The company said that its three new coupling kits included a lateral flow coupling kit, antibody coupling kit and a magnetic separation coupling kit.

Anteo said that the lateral flow coupling kit for magnetic and latex particles enabled the use of alternative particles to traditional gold, giving users more flexibility in the choice of assay components, allowing improved compatibility with the newer detection technologies in the point-of-care market.

The company said the technology was trialled in a model human chorionic gonadotropin assay and found five times more sensitive lateral flow assays with less variation in their experiments than was achieved with covalent chemistry using magnetic particles.

Anteo said that its antibody coupling kit for magnetic, polystyrene and silica particles was a ready-to-use alternative to covalent chemistry.

"With this kit, antibodies assemble in the correct orientation greatly reducing the risk of antibody damage, leading to fewer antibodies required for the experiment, increased antibody functionality, reduced interference and increased uniformity between experiments," the company said.

Anteo said its magnetic separation coupling kit reduced labor costs and simplified reagent preparation times, enabling scientists "to achieve results even when testing with unknown proteins … [streamlining] the protein coupling screening process often required to select a compatible coupling method for novel proteins lacking complete characterisation".

Anteo chief executive officer Dr Jef Vangenechten said that the American Association for Clinical Chemistry was "a great event to promote Anteo and Diasource products to the market" with Anteo presenting new products with very targeted applications.

"We believe that these products are a new milestone for Anteo's technology as they prove that the chemistry can be applied across the diversity of surface materials used in the [in-vitro diagnostics point-of-care] industry," Dr Vangenechten said.

"The Diasource free-25OH vitamin D assay is a unique assay [and] with the launch at AACC we expect that more interest in this marker by reference laboratories may give a boost to its world-wide routine use," Dr Vangenechten said.

Anteo was up 0.7 cents or 15.6 percent to 5.2 cents with 7.2 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says it has completed an undefined “pre-clinical” safety study required by the US Food and Drug Administration for a combination trial of Scenesse for vitiligo.

Clinuvel said the FDA communicated that “prior to pursuing later stage clinical trials and seeking marketing authorisation for Scenesse in vitiligo in the US the company would need to demonstrate the safety of the drug in combination with [narrow-band ultraviolet B] light simulating the proposed human dose in a pre-clinical model”.

The company said the main purpose of the pre-clinical study was to evaluate the combination therapy of Scenesse, 16mg afamelanotide, administered at 28 days intervals and narrow-band ultraviolet B (NB-UV-B) light given three times a week for 24 weeks, but it also assessed Scenesse administered at 28 day intervals alone for 24 weeks.

The company said that the safety of the combination therapy was confirmed, with the “no observed adverse effect level” of Scenesse found to be higher than the current clinical dose level of 16mg per month.

Clinuvel said that the results supported Scenesse’s pre-clinical safety profile and during the past two decades, Scenesse had been “thoroughly evaluated in an extensive toxicology program to support EU and US marketing authorizations for … erythropoietic protoporphyria as a mono-therapy, administered every 60 days”.

The company said the safety evaluation included genetic toxicology at maximum concentrations and dose levels, reproductive and developmental toxicity studies at doses far higher than the human dose and single, repeat-dose and chronic toxicity studies.

Clinuvel said that safety data added to the new drug application package to be submitted to the FDA for erythropoietic protoporphyria and it would request a guidance meeting with the FDA to discuss the next clinical trial in vitiligo patients in North America.

The company said that results from its CUV102 trial and data from its CUV103 trial showed that Scenesse with NB-UV-B light administered twice or three times a week had a good safety profile with the optimal effectiveness of the combination identified in patients of darker skin complexion (BD: Sep 2, 2013; May, 2014; Dec 3, 2015).

Clinuvel said that vitiligo was a depigmentation disorder most conspicuous in patients of darker skin complexion and progression over large body surfaces was distressing and often led to patients reporting a loss of identity.

The company said that the current standard of care was NB-UVB light with often disappointing clinical results and no or incomplete repigmentation.

Clinuvel clinical affairs director Dr Emilie Rodenburger said that the “results of the repeated administration of Scenesse show its lack of toxicity when given alone at 28 day intervals over a 24-week period, but also that safety is upheld when the drug is combined with NB-UVB light dosed thrice weekly”.

“Safety of Scenesse supplied to our patients will always be our primary focus, and I am thrilled with these results,” Dr Rodenburger said. “Our team will now engage the FDA to establish the pathways forward for the upcoming vitiligo trials.”

Clinuvel fell 11 cents or 2.2 percent to $4.98.

MACH7 TECHNOLOGIES

Mach7 says its five-year $US800,000 ($A1,059,974) enterprise imaging software agreement is with Virginia Commonwealth University Health System Authority.

Yesterday, Mach7 announced the contract but was unable to name the customer due to a confidentiality agreement but today that the Richmond, Virginia-based Commonwealth University Health System Authority was the client (BD: Aug 2, 2016).

Mach7 was up 0.2 cents or 5.3 percent to 4.0 cents.

REVA MEDICAL

Reva says it has submitted its Conformité Européenne (CE) mark application for its Fantom coronary scaffold.
Reva said that it had completed the clinical data analyses and required testing for the application and the regulatory approval process generally spanned several months including evaluation of the clinical, pre-clinical and bench test data, as well as audits of the company's quality assurance system and related processes, with CE mark approval, or notice of any issues, expected by December 31, 2016.
The company said that approval would allow commercial sales in Europe and countries that recognized the CE mark.
Reva said that the data used in the application was from the 117 patients in cohort A of the Fantom II trial, which was being conducted in 28 hospitals in eight countries outside the US (BD: May 18, 2016).
The company said it would continue to follow and evaluate patients in the trial for five years.
Reva said that the 123 patients enrolled in cohort B would undergo clinical safety evaluations at six months and invasive imaging assessments at nine months and as the patients completed enrolment in March 2016, the imaging evaluations were expected to be completed by April 2017.
The company said the available data from both cohorts was expected to be reported at the Transcatheter Cardiovascular Therapeutics conference In Washington DC, October 29 to November 2, 2016.
Reva fell one cent or 0.8 percent to $1.29.

MMJ PHYTOTECH

MMJ Phytotech says its wholly-owned subsidiary United Greeneries expects to lease 13 acres of land adjacent to its marijuana facility from Canada's Cowichan Tribes.
MMJ said that the land had the capacity to support up to 10 acres of greenhouse production space yielding about 25 tonnes a year of cannabis, making the company "one of the leading large-scale cannabis producers" and able to supply the medical marijuana market and the "soon to be legalized" $C5 billion Canadian recreational market.
The company said the land was owned by the Cowichan Tribes as private commercial property, was clear, flat and had been vacant for several years, previously used for commercial greenhouse growing operations and would require little preparation.
MMJ said that with the existing production capacity, the expanded Duncan, British Columbia facility could produce up to 26 tonnes of cannabis a year and as one of 29 companies licenced to produce medical cannabis in Canada, it expected "to be well positioned as a first mover in this emerging recreational market".
The company said the agreement gave it an option to lease 13 acres (5.3ha) until June 1, 2017 and allowed MMJ to increase the acreage, if needed, on exercise of the option.
MMJ said that the lease terms would be subject to further negotiation and it would pay Cowichan Tribes $C1,000 per month until the earlier of the expiry of the option agreement on June 1, 2017, or the entry into a lease agreement and it would work with a Cowichan Tribes employment liaison to identify employment opportunities for community members.
MMJ managing-director Andreas Gedeon said that the company was "pleased to have entered this strategic land expansion agreement for our Duncan facility, which provides the land access which would be required for the requisite scale for MMJ to become one of the largest commercial producers of cannabis globally".
MMJ was unchanged at 27 cents with 1.4 million shares traded.

ANALYTICA

Analytica says the People's Republic of China has granted a patent covering its Pericoach intra-vaginal pelvic floor force sensing technology.

Analytica said that the patent, entitled 'An intra vaginal device to aid in training and determining muscle strength' provided coverage until January 9, 2032.

The company said that there were nearly 227 million women with urinary incontinence in China and this was the first Pericoach patent to be granted in a major market.

Analytica chief executive officer Geoff Daly said that patent protection was "critical in licencing negotiations as it affords the licencing partner freedom to operate in the market".

"China and other emerging markets are a major part of our global strategy for the Pericoach system," Mr Daly said.

Analytica said it had Pericoach patents pending in the US, India, Brazil, Australia, Europe and Japan, with many jurisdictions allowing patent protection to 2032.

Analytica was up 0.2 cents or 25 percent to one cent with 1.3 million shares traded.

PHARMAUST

Pharmaust says it has concluded an intellectual property exchange with the University of New South Wales commercialization arm, Newsouth Innovations.

Pharmaust said that it would own additional rights to monepantel and related compounds that were previously held by the University and Newsouth Innovations would receive intellectual property relating to the mucin project that it provided to Pharmaust in the "easy access scheme" in 2014 and 2015.

The company said that the mucin project entailed the use of enzymes and other agents in cancers such as Pseudomyxoma peritonei, caused by cancerous cells, known as mucinous adenocarcinoma, that produce abundant mucin and or gelatinous ascites.

Pharmaust said that if Newsouth Innovations partnered the mucin project, it would receive a royalty stream.

Pharmaust chairman Dr Roger Aston said the agreement was "an important milestone".

"With continued progress and investment in [monepantel] and related compounds and the prospects of both human and veterinary phase II trials beginning, it is important that Pharmaust can establish an [intellectual property] position where it is as far as possible free to operate and commercialize its lead amino-acetonitrile MPL-related product [or products]," Dr Aston said.

"At the same time, Pharmaust will retain an on-going interest in the mucin project through a royalty stream based on what is received by [Newsouth Innovations]," Dr Aston said.

"This strategy is also in line with Pharmaust's strategy to list on [the] Nasdaq."

Pharmaust was up 0.8 cents or 9.2 percent to 9.5 cents.

MAYNE PHARMA GROUP

Mayne Pharma says it has completed the acquisition of the US generic product portfolio from Teva Pharmaceutical Industries and Allergan Plc.

In June, Mayne said it would acquire 37 approved products and five US Food and Drug Administration-filed products for $US652 million ($A880.7 million) funded by an underwritten equity raising and an increase in debt facilities (BD: Jun 28, 2016).

Mayne chief executive officer Scott Richards said the company was "very pleased to have completed this acquisition that establishes Mayne Pharma as a key player in the US generic pharmaceutical market".

Mayne was unchanged at $1.995 with 4.5 million shares traded.

ORTHOCELL

Orthocell says that 27,185,515 shares and 4,250,000 options held in ASX escrow will be released on August 12, 2016.
Orthocell said company secretary Simon Robertson told Biotech Daily that following the release of the shares, the company would have 91,479,437 shares available for trading.
Orthocell fell half a cent or 1.35 percent to 36.5 cents.

FACTOR THERAPEUTICS

Factor Therapeutics says it has appointed Dr Robert Kirsner, Prof David Margolis, Dr Keith Harding and Ronald Shannon as its medical advisory board.
Factor Therapeutics said that the board would advise the company on the development of its VF-001 lead program for venous leg ulcers, as well as future indication expansion of the wound care platform technology.
The company said that Dr Kirsner was the chair of dermatology at the University of Miami, Prof Margolis was the professor of dermatology at the University of Pennsylvania, Dr Keith Harding was the head of the wound healing research unit at Cardiff University in Wales and Mr Shannon was an epidemiologist and pharmaco-economist with the Clifton Park, New York-based Global Health Economic Projects LLC
Factor Therapeutics said that the initial tenure of the board was for two years and its members were retained on a consultancy basis in compliance with their institutional policies for external advisory activity.
Factor Therapeutics was up 0.1 cents or 2.4 percent to 4.3 cents.

OPTISCAN

Optiscan says that Andrew Froude has been appointed as preclinical research products general manager, effective from August 8, 2016.
Optiscan said that Mr Froude had 25 years' experience with technology-based organizations "shaping and driving product direction, take-to-market strategies and delivering bottom-line profitability" and previously was an executive with Fuji Xerox Asia Pacific, Hewlett-Packard Australia, Upstream Solutions and the City Of Melbourne.
The company said that the appointment was part its strategy to promote sales of its confocal microscope for pre-clinical research.
Optiscan was untraded at two cents.