Biotech Daily

Monday November 14, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NEUREN UP 7%, BENITEC DOWN 13%**

*** MONASH BIOMEDICINE DISCOVERY INSTITUTE OPENS**

*** EMA COMMITTEE BACKS CSL AFSTYLA FOR HAEMOPHILIA A**

*** CORRECTION: UNIVERSAL BIOSENSORS**

*** MESOBLAST MSC-100- IV FOR GVHD PASSES 'FUTILITY TEST'**

*** NEUREN RECRUITS RETT TRIAL, LANG WALKER FUNDING EGM**

*** EARLY CAPRA TRIAL DATA BACKS VIRALYTICS CAVATAK FOR TUMORS**

*** MEDICAL DEVELOPMENTS APPOINTS MCKESSON US DISTRIBUTOR**

*** VOLPARA TEST IN BREAST CANCER RISK TOOL; H1 REVENUE UP 5% TO $1.2m**

*** UP TO 23% DISSENT AGAINST IMPEDIMED AGM RESOLUTIONS**

*** ATCOR REQUESTS CAPITAL RAISING TRADING HALT**

*** MACH7 REQUESTS CAPITAL RAISING TRADING HALT**

*** ITL TO RELEASE 6.7m ESCROW SHARES**

*** ANTEO LOSES CHAIRMAN MARK BOURIS BEFORE AGM**

*** IMPEDIMED EURO BIO-IMPEDANCE HEART FAILURE ADVISORY BOARD**

MARKET REPORT

The Australian stock market fell 0.47 percent on Monday November 14, 2016 with the ASX200 down 25.0 points to 5,345.7 points. Eight of the Biotech Daily Top 40 stocks were up, 20 fell, five traded unchanged and seven were untraded.

Neuren was the best up 0.4 cents or 7.4 percent to 5.8 cents with 880,903 shares traded. Mesoblast climbed 6.4 percent; Ellex and Prana improved more than five percent; Cellmid and Viralytics were up more than three percent; Impedimed rose two percent; Compumedics was up 1.2 percent; with CSL up 0.7 percent.

Benitec led the falls, down 1.5 cents or 13.0 percent to 10 cents with 76,719 shares traded. Clinuvel and Opthea fell more than five percent; IDT and Oncosil lost more than four percent; Bionomics and Living Cell were down more than three percent; Acrux, Nanosonics and Starpharma shed more than two percent; Admedus, Anteo, Cochlear, Factor Therapeutics, Orthocell, Osprey, Polynovo and Pro Medicus were down more than one percent; with Airxpanders, Medical Developments, Resmed and Sirtex down by less than one percent.

MONASH BIOMEDICINE DISCOVERY INSTITUTE

Monash University says its Biomedicine Discovery Institute at its Clayton, Melbourne campus was officially opened today by Prime Minister Malcolm Turnbull.

Monash University said the Institute brought together 120 research teams, 700 on-site researchers, clinical partners and industry working together.

The Institute's director Prof John Carroll said that its remit was "to undertake great discovery research and decrease the time it takes to get these findings to the clinic".

"We do this by bringing our researchers together with industry partners and clinicians as early as possible," Prof Carroll said.

The Institute said it was part of the Faculty of Medicine, Nursing and Health Sciences, which was ranked 35 in the world and top three in Australia "one of the largest … biomedical research institutes in Australia with strong international networks and partnerships with researchers, health precincts and industry, together with access to research infrastructure" and it hosted the Australian Research Council's Centre of Excellence for Advanced Molecular Imaging as well as the Directorate of European Molecular Biology Laboratory Australia.

CSL

CSL says the European Medicines Agency Committee for Medicinal Products for Human Use has recommended approval for Afstyla for haemophilia A.

CSL said Afstyla was a US-approved recombinant, human coagulation factor VIII, single chain compound designed for greater molecular stability and longer duration of action.

The company said that Afstyla used a covalent bond that formed one structural entity, a single polypeptide-chain, to improve the stability of factor VIII and provide extended factor VIII activity with the option of twice weekly dosing.

CSL said that as well as the European Union, regulatory agencies, including Switzerland and Australia, were reviewing CSL Behring's marketing applications for Afstyla.

CSL chief scientific officer and research and development director Dr Andrew Cuthbertson said that "for 100 years, CSL has focused on researching and developing innovative therapies that meet the treatment challenges patients face".

"CHMP's positive opinion for Afstyla moves us one step closer to bringing this novel treatment option to haemophilia A patients in the European Union," Dr Cuthbertson said.

"Once approved, Afstyla will provide adults and children with a therapy that delivers on our promise to develop and bring to market innovative specialty biotherapies that help patients live full lives," Dr Cuthbertson said.

CSL said that haemophilia A was a congenital bleeding disorder primarily affecting males and characterized by deficient or defective factor VIII with patients experiencing prolonged or spontaneous bleeding, especially into the muscles, joints or internal organs.

CSL was up 69 cents or 0.7 percent to $103.92 with 722,541 shares traded.

UNIVERSAL BIOSENSORS

Friday's Market Report headline incorrectly said Universal Biosensors led the falls, down 16 percent, which was a typographical error.

The Market Report correctly said that Universal Biosensors led the falls, down two cents or 6.25 percent to 30 cents with 3,759 shares traded.

Biotech Daily apologizes unreservedly to Universal Biosensors.

The Friday typographical sub-editor has been sacked.

Universal Biosensors was untraded at 30 cents.

MESOBLAST

Mesoblast says an interim analysis of its paediatric phase III trial of MSC-100- IV for steroid-resistant acute graft versus host disease met a pre-specified futility analysis.
Mesoblast said the independent data safety monitoring board assessing the trial of the intravenous MSC-100-IV as front-line therapy in the 60-patient open-label trial determined that the Bayesian futility rule to determine the probability of success using the primary endpoint of day-28 overall response had been passed.
The company said the analysis determined the likelihood of a statistically significant treatment effect at study completion, based on the data observed at this interim time point.
Mesoblast said that more than half the patients had been treated, it expected to complete the trial by July 2017 and commercial launch activities were underway.
The company said that there were no US-approved products for graft versus host disease and Japan was the only jurisdiction where the therapy was available, through its licencee JCR Pharmaceuticals.
Mesoblast said that based on guidance from the US Food and Drug Administration it believed that positive data from the phase III trial might be sufficient for filing for accelerated approval of MSC-100-IV in the US.
The company said that it planned to broaden its use in adult patients with high-risk steroid-refractory acute graft versus host disease.
Mesoblast said that the successful outcome of the interim analysis was consistent with previously reported results in a paediatric expanded access program which evaluated MSC-100-IV in 241 children (BD: Feb 22, 2016).
Mesoblast was up 7.5 cents or 6.4 percent to $1.25 with 1.2 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has recruited 82 girls in its phase II trial of trofinetide for Rett syndrome in girls and the company will vote to issue Langley Walker 100 million shares.
Neuren said that the last subjects would conclude the randomized, double-blind, placebo-controlled trial in January 2017, with top-line results in March 2017.
The company said that 62 subjects were randomized into one of four treatment groups of 50mg/kg, 100mg/kg, 200mg/kg or placebo.
Neuren said that a further 20 subjects were randomized into one of two treatment groups of 200mg/kg or placebo.
The company said that the total duration of a subject's participation in the trial, from screening through to follow-up was 11 weeks and to date, 55 subjects had completed the trial, with one subject withdrawn before completion.
Neuren previously said that to provide "funding flexibility" it would seek shareholder approval to allow major shareholder Lang Walker to increase his holding beyond the current 19 percent (BD: Aug 25, 2016).
Today, the company proposed two resolutions for an extraordinary general meeting, the first to make allotments to Walker Group Holdings, an entity associated with Langley Walker, of up to 100 million shares up to June 30, 2017 at the 10-day volume-weighted average price to each allotment and to amend the constitution to allow electronic meetings and voting.
Neuren said that following the allotment of 100 million shares, Walker Group and associates would hold 465,342,357 shares or 23.96 percent of the company.
The meeting will be held at Chartered Accountants Australia and New Zealand, Level 18, 600 Bourke Street, Melbourne on December 6, 2016 at 3pm (AEDT).
Neuren was up 0.4 cents or 7.4 percent to 5.8 cents.

VIRALYTICS

Viralytics says that early data from its phase Ib trial of Cavatak with Keytruda shows a disease control rate of 100 percent and an objective response rate of 70 percent.
Viralytics said its 30-patient, phase Ib Cavatak and pembrolizumab in advanced melanoma (Capra) trial was designed to evaluate the safety and tolerability of the established dose of intra-tumoral Cavatak in combination with Keytruda for advanced melanoma where Keytruda would be considered standard-of-care.
The company said that preliminary data from the first 10 patients evaluable for best overall tumor response assessment showed a disease control rate of 100 percent including seven patients with an objective tumor response and three patients with stable disease.
Viralytics said that the response rates exceeded the published rates for either agent used alone, with responses observed in injected lesions, non-injected non-visceral lesions and in distant non-injected visceral lesions, including lung and liver metastases.
The company said that the best overall response rate in six patients with advanced disease with liver, lung or other visceral metastases was 100 percent, with objective responses in six of seven patients and a disease control rate of 100 percent in seven patients with non-injected visceral and non-visceral target lesions.
The poster, entitled 'Interim results of the Capra clinical trial: Cavatak and pembrolizumab in advanced melanoma' was presented at the Society for the Immunotherapy of Cancer meeting in National Harbor, Maryland, November 9 to 13, 2016 and was at: http://www.viralytics.com/our-pipeline/scientificpresentations/.
Principal investigator Dr Howard Kaufman said that "although the number of patients treated is small, I am impressed with these early results demonstrating very promising response rates, in patients with advanced metastatic disease".
"The low incidence and grade of adverse events are also encouraging," Dr Kaufman said.
"The response rates and side event profile of this novel immunotherapy combination compare favourably with other combination clinical trials in melanoma," Dr Kaufman said.
Viralytics was up four cents or 3.3 percent to $1.24.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has appointed McKesson Corp as its US distributor for its Space Chamber anti-static respiratory devices.
Medical Developments said that the San Francisco, California-based McKesson had placed its first order which would be delivered by the end of December 2016.
Medical Developments chief executive officer John Sharman said the agreement with McKesson "complements our agreements with Amerisourcebergen and Cardinal Health".
"Through these three companies we now have the relationships to wholesale into virtually every pharmacy and hospital in the US," Mr Sharman said.
"Having established an excellent wholesale infrastructure for our respiratory products, our focus is now firmly on getting deals done with the large retail pharmacy chains across the US," Mr Sharman said.
Medical Developments chairman David Williams said the company expected "business as usual' … in the US post the election".
"We do not expect [President-elect Donald] Trump's election will have any negative impact for [Medical Developments] and like US equity analysts, we expect the new Congress will focus less on drug pricing which will be good for biotech companies," Mr Williams said.
"In this environment we are excited about the prospects for our respiratory devices and our pain drug, Penthrox," Mr Williams.
Medical Developments fell two cents or 0.4 percent to $4.83.

VOLPARA HEALTH TECHNOLOGIES

Volpara says that breast density measurements generated by its software have been incorporated into the Tyrer-Cuzick breast cancer risk assessment tool.

The London-based Queen Mary University's Prof Jack Cuzick said that multiple studies "have demonstrated that mammographic density is a strong breast cancer risk factor".

"After extensive independent testing on multiple data sets, we are pleased to now incorporate volumetric breast density percentages from Volpara Density as one method of adding breast density into our risk assessment tool," Prof Cuzick said.

"Volpara Density has strong predictive value, which we believe will help identify high-risk women and guide clinical decisions about adjunctive screening options based on their specific risk factors," Prof Cuzick said.

Volpara said that revenue for the six months to September 30, 2016 was up 4.8 percent to $1,228,000 with net loss after tax up 126.0 percent to $4,675,000.

Volpara was up half a cent or 0.7 percent to 75.5 cents.

IMPEDIMED

Impedimed's annual general meeting passed all resolutions, but with up to 22.8 percent opposition to options for chief executive officer Richard Carreon.

Impedimed said that the remuneration report escaped a second strike and was passed with 30,796,006 votes (15.22%) against, with 171,597,900 votes (84.78%) in favor.

Last year, Impedimed earned a remuneration report first strike with the annual general meeting voting 30,760,032 votes (25.1%) against the report and 91,846,039 votes (74.9%) in favor (BD: Oct 29, 2015).

Today, a resolution to amend the terms of options granted to Mr Carreon was opposed by 51,844,948 votes (22.78%) and supported by 175,710,664 votes (77.22%), with the grant of 872,000 options to Mr Carreon passed by a larger margin, as was the grant of options to director David Adams (BD: Oct 13, 2016).

Impedimed said that directors Scott Ward, Elizabeth Gaines and Gary Goetze were re-elected overwhelmingly.

The company's most recent Appendix 3B said that Impedimed had 374,357,788 shares on issue meaning that the opposition to Mr Carreon's option terms amounted to 13.85 percent of the company's total shares on issue, sufficient to requisition extraordinary general meetings.

Impedimed was up three cents or two percent to $1.53 with 1.1 million shares traded.

ATCOR MEDICAL

Atcor has requested a trading halt pending "an announcement to the market in relation to a potential capital raising".

Trading will resume on November 16, 2016 or on an earlier announcement.

Atcor last traded at 10 cents.

MACH7 TECHNOLOGIES (FORMERLY 3D MEDICAL)

Mach7 has requested a trading halt pending "a material announcement to the market in relation to a proposed capital raising".

Trading will resume on November 16, 2016 or on an earlier announcement.

Mach7 last traded at four cents.

ITL

ITL says that 6,723,870 shares related to the Myhealthtest transaction will be released from escrow on December 1, 2016 (BD: Apr 29, 2015).
Last year, ITL said it would acquire the Myhealthtest consumer pathology test provider for up to $3,350,000 through a series of milestone-based call options, with ITL executive chairman Bill Mobbs owning 67 percent of Myhealthtest 38.63 percent of ITL.
Following the release of the escrow shares, ITL will have 95,928,314 shares available for trading, with no further shares held in escrow.
ITL was untraded at 24 cents.

ANTEO DIAGNOSTICS

Anteo says that chairman Mark Bouris did “not seek re-election to the board at today’s annual general meeting” resigning immediately prior to the meeting.
Mr Bouris said that his commitments with Yellow Brick Road Group and TZ had “broadened in recent weeks and relinquishing my role with Anteo Diagnostics allows me [to] invest more time into these companies”.
Anteo fell 0.1 cents or 1.9 percent to 5.2 cents.

IMPEDIMED

Impedimed says it will establish a European medical advisory board to advise on the clinical use of bio-impedance spectroscopy in fluid detection for chronic heart failure.
Impedimed said that the European medical advisory board would include Germany’s University Medicine Göttingen professor of innovative clinical trials Prof Stefan Anker; Greece’s Athens University Hospital head of the heart failure Prof Gerasimos Filippatos; the University of Brescia, Italy professor of cardiology Prof Marco Metra; and Poland’s Medical University Wroclaw heart disease department head Prof Piotr Ponikowski.