Biotech Daily

Wednesday December 21, 2016

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: BENITEC UP 16%, IDT DOWN 8%**

*** CLINICAL GENOMICS, CSIRO US BOWEL CANCER TEST LAUNCH**

*** BENITEC BB-102, BB-103, COMBINATION REDUCE HEPATITIS B IN MICE**

*** US PILOT STUDY BACKS MEDIBIO HEART TEST FOR DEPRESSION**

*** OPTISCAN RAISES $1.9m**

*** REDHILL RESUMES CAPITAL RAISING**

*** APPLE APPROVES NUHEARA IQBUDS APPLICATION**

*** UP TO 30% OF ATCOR AGM OPPOSE SHARE ISSUE**

MARKET REPORT

The Australian stock market climbed 0.4 percent on Wednesday December 21, 2016 with the ASX200 up 22.4 points to 5,613.5 points.

Nineteen of the Biotech Daily Top 40 stocks were up, 14 fell, five traded unchanged and two were untraded.

Benitec was the best, up 1.5 cents or 15.8 percent to 11 cents with 897,577 shares traded.

Prima climbed 5.7 percent; Avita, Compumedics, Mesoblast and Osprey improved four percent or more; Medical Developments and Pharmaxis were up more than three percent; Clinuvel, Psivida and Viralytics rose more than two percent; Bionomics, Cyclopharm, Neuren, Opthea and Polynovo were up more than one percent; with Cochlear, CSL, Ellex, Nanosonics and Pro Medicus up by less than one percent.

IDT led the falls, down 1.5 cents or 7.7 percent to 18 cents with 198,775 shares traded.

Living Cell and Universal Biosensors lost more than five percent; Factor Therapeutics, Oncosil and Orthocell fell more than four percent; Starpharma was down 3.5 percent; Anteo shed 2.4 percent; Acrux, Admedus, Reva and Sirtex lost more than one percent; with Airxpanders and Impedimed down by less than one percent.

CLINICAL GENOMICS
COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

Clinical Genomics says its Colvera bowel cancer test, developed with the Commonwealth Scientific and Industrial Research Organisation, has been launched in the US.

A CSIRO media release said it had partnered with Clinical Genomics since 2003 and in 2012, Clinical Genomics said that with scientists from CSIRO and Adelaide's Flinders University it had identified genes that showed identifiable changes in the blood of people with bowel cancer (BD: May 23, 2012).

Today, Clinical Genomics director and Oneventures partner Dr Paul Kelly told Biotech Daily that the Colvera test was approved last week by the US Centers for Medicare & Medicaid Services under the Clinical Laboratory Improvement Amendments (CLIA) system and was launched in the US yesterday.

In March, with Oneventures, Clinical Genomics raised $US15 million ($A19.7 million) to launch the colorectal cancer diagnostic (BD: Mar 23, 2016).

Clinical Genomics said that the blood-based test was "2.5 times more accuracy than the current blood monitoring method and an opportunity to explore a blood-based DNA screening test for [colorectal cancer]".

Dr Kelly said that the laboratory-based test gad been specifically designed to monitor cancer recurrence in bowel cancer patients.

In March, Dr Kelly said that Clinical Genomics was "also uniquely positioned to transform colorectal cancer screening in the general population".

Clinical Genomics chief executive officer Dr Lawrence LaPointe said that part of the standard of care for post-surgical monitoring for colorectal cancer recurrence, three-monthly or six-monthly blood-based testing to measure carcino-embryonic antigen levels had poor sensitivity and specificity.

"Clinical Genomics has developed a new blood test to detect tumor-specific methylated DNA biomarkers that leak from active lesions into the circulatory system," Dr LaPointe said.

"Current data suggest that a genomic test specific for these biomarkers is more sensitive than [carcino-embryonic antigen] testing and highly specific," Dr LaPointe said.

A CSIRO media release said that bowel cancer, or colorectal cancer, accounted for more than 600,000 deaths a year, with about 15,000 new cases diagnosed in Australia each year.

The CSIRO said that in 30 to 50 percent of cases the disease would recur, usually in the first two to three years following initial diagnosis and treatment.

CSIRO scientist Dr Trevor Lockett said that by providing clinicians with a new blood test that was more sensitive for recurrence, "Colvera increases the likelihood of detecting curable recurrences of [colorectal cancer], with the ultimate aim of saving lives".

Dr LaPointe said the test could indicate early molecular changes associated with cancer development.

"It is intended to provide physicians with actionable information that can trigger further clinical assessment, which may lead to improved outcomes," Dr LaPointe said.

The CSIRO media release said that Colvera was "significantly more sensitive for bowel cancer" than the existing tests and provided an improved, simple test that increased the likelihood of detecting curable recurrence.

The media release said that Colvera was available in the US through Clinical Genomics' Bridgewater, New Jersey laboratory and it was hoped that Colvera would be available in Australia in 2017.

Clinical Genomics is a private company.

BENITEC BIOPHARMA

Benitec says BB-102 and BB-103 with the standard of care reduce serum hepatitis B DNA, surface antigen (HBsAg) and envelope antigen HBeAg levels in mice.

Benitec said the fall in DNA and antigen levels was “significant and sustained”.

The company said that using a single administration of the DNA-directed RNA interference (ddRNAi) agents BB-101, BB-102 or BB-103 with the current standard-of-care agents demonstrated “a robust and sustained suppression of [hepatitis B virus] in an in-vivo model”.

Benitec said that the lead candidates were comprised of an adeno associated virus capsid (AAV8) and a recombinant DNA cassette engineered to express steady state levels of three short hairpin RNA (shRNA) that inhibited hepatitis B viral RNA at three regions well-conserved across all major genotypes.

The company said the study assessed the activity of BB-101, BB-102 and BB-103 in the Phoenixbio mouse model, in which a substantial portion of the mouse liver cells had been replaced with human hepatocytes making the animals susceptible to hepatitis B infection.

Benitec said that BB-101 was a single-stranded recombinant DNA vector expressing three anti- hepatitis B shRNA, BB-102 was similar to BB-101, with the recombinant genome packaged as a self-complementary, double stranded DNA and BB-103 was a next generation vector in which the anti- hepatitis B shRNA had been modelled into micro-RNA backbones for expression from wild-type polymerase III promoters.

The company said that the ddRNAi components were administered only once, at the beginning of treatment and anti- hepatitis B activity was monitored over 13 weeks by following serum hepatitis B DNA, surface antigen and envelope antigen on a weekly basis, with intracellular hepatitis B DNA as well as covalently closed circular DNA quantified at the conclusion of the study.

Benitec said that in the combination studies, a single dose of ddRNAi vectors was administered with daily entecavir, a nucleoside reverse transcriptase inhibitor, or a pegylated interferon agent administered twice a week for the duration of the study.

Benitec's chief scientific officer Dr David Suhy said it was “remarkable that these ddRNAi treatments, administered as a single infusion on top of an existing treatment regimen have this magnitude of impact on the viral burden in this model of [hepatitis B] infection”.

“With a high degree of confidence in our efficacy studies, we look forward to take the next steps of being able to move these compounds towards human clinical testing [and] … anticipate meeting with a number of regulatory agencies in early 2017,” Dr Suhy said.

Benitec said that in the absence of other anti-viral drugs, BB-103 and BB-102 showed a maximum drop of serum hepatitis DNA, 2.17 log (an order of magnitude, a 1.0 log increase is 10-fold) and 1.87 log, respectively, with a small rebound after 56 days of treatment, while daily entecavir alone resulted in a 2.63 log drop.

The company said that in combination with daily entecavir, a single dose of BB-103 and BB-102 dropped the serum hepatitis B DNA levels below 3.72 log, the lowest value that could result in accurate quantification of hepatitis B DNA levels, and the reduction in viral burden continued to diminish until the end of the 91-day experiment.

The company said that BB-103 with entecavir and BB-102 with entecavir dropped the surface antigen levels, a known contributor to immune-suppression and hepatitis B chronicity, by 2.14 log and 1.86 log, respectively.

The company said that treatment with entecavir only dropped HBsAg levels by 0.46 log.

Benitec said that BB-103 with entecavir and BB-102 with entecavir dropped the envelope antigen by 1.90 log and 1.42 log, respectively, compared to entecavir alone reducing HBsAg levels by 0.37 log.

Benitec was up 1.5 cents or 15.8 percent to 11 cents.

MEDIBIO

Medibio says early results from the 26-subject pilot phase of its US study of its cardiac rhythm depression test shows 81 percent accuracy and 82 percent sensitivity.

Medibio said that the prospective study enrolled 11 subjects with major depressive disorder and 15 healthy controls and the results delineated those with major depressive disorder from non-depressed individuals, including those on medication for their illness.

The company said the study led by principal investigators from the Baltimore, Maryland-based Johns Hopkins Medicines Dr Naresh Punjabi and Dr Francis Mondimore, was intended to support US Food and Drug Administration clearance for its depression algorithm, which it claimed "significantly outperforms [the] existing standard-of-care diagnosis in US primary care setting of 33 to 50 percent accuracy" and the 70 percent agreement rate among psychiatrists.

Medibio said that to measure circadian heart rate, subjects were monitored by electro-cardiogram for "one day's sleep cycle".

The company said that as "the gold standard comparator", subjects were classified as depressed or non-depressed by two independent psychiatrists, with agreement required for final classification and to be included in the analysis.

Medibio said that following "de-noising of the heart rate data" heart rate tracings were evaluated, with 81 percent accuracy, 82 percent sensitivity and 80 percent specificity.

The company said the results provided "a preliminary indication that Medibio's diagnostic is robust in the face of on-going pharmacological therapy for depression".

Medibio said that seven of the depressed subjects were on medication for the illness at the time of heart rate data gathering with five on multiple medications, and six of the seven were correctly identified as being depressed, giving an 86 percent accuracy, similar to the overall cohort.

The company said the results provided an indication that its diagnostic was "state dependent [that is] currently depressed or non-depressed".

Medibio said that two of the control subjects had a history of depression but were clinically judged to be non-depressed at the time of heart rate data gathering and both were correctly classified by Medibio's diagnostic as non-depressed.

Medibio chief executive officer Kris Knauer said that the results were "exactly what we were hoping to achieve and are well above what is required to support the claims we intend to make in our application to the [US Food and Drug Administration].

"The study cohort was also typical of the GP setting, with a range of comorbidities and a high prevalence of poly-pharmacy," Mr Knauer said.

"It's clear that our depression diagnostic, based on these results, should prove a valuable tool in the under-resourced [general practitioner] setting," Mr Knauer said.

Medibio was up 0.5 cents or 1.3 percent to 39.5 cents.

OPTISCAN IMAGING LIMITED

Optiscan says it has commitments to raise $1,932,500 in a placement of 38,650,000 shares at five cents a share to sophisticated, professional and other exempt investors.

Optiscan said that 33,542,880 shares would be issued under its 10 percent placement capacity, with the remaining 5,107,120 shares to be issued under the 15 percent capacity.

The company said that the funds would be used to meet firm and expected orders from partner Carl Ziess Meditech over the coming months as well as to meet the expected demand for the recently launched Viewnvivo microscope as well as working capital including payment of wages, operating costs, sales and marketing expenses.

Optiscan was up 0.9 cents or 17.7 percent to six cents.

REDHILL BIOPHARMA

Redhill says it intends to resume a capital raising through an offer of its American depositary shares and warrants in an underwritten placement and a direct offering.
In November, Redhill announced and withdrew a $US10 million underwritten American depositary share offer at $US11 a share “due to market conditions” (BD: Nov 2, 3, 2016).
The company said at that time that it was “not in the best interest of its stockholders to raise the equity capital in the current market environment” when a fall in global stock markets was related to the that Donald Trump could be elected US President.
Redhill said it held about $US40.5 million at September 30, 2016.
Today the company said it expected to grant the underwriters a 30-day option to purchase up to an additional 15 percent of the securities offered to the public in the offer.
Redhill said that both offers were subject to market conditions and there could be no assurance as to whether or when the offers might be completed, or the size or terms.
The company said the proceeds would fund clinical development programs, potential acquisitions, support commercial operations and general corporate purposes.
Redhill said that Roth Capital Partners was the sole book-running manager and placement agent in the registered direct offer and Echelon Wealth Partners was the Canadian manager for the underwritten public offer in Canada.
On the Nasdaq, Redhill was up nine US cents or 0.84 percent to $US10.80 ($A14.88) with 43,950 shares traded

NUHEARA

Nuheara says Apple has approved its Iqbuds sound filtering and device ear buds mobile telephone application to be released through the Apple application shop.
Nuheara said that the Iqbuds application was “the final major technical component to be developed and completed for the Iqbuds”.
The company said that the program provided “a simple and intuitive user interface that controls the Iqbuds’ hardware, earbuds and charging case, and the Iqbuds [software]”.
Nuheara said that the approval of the android version for other company mobile telephones was pending.
Nuheara was up 1.5 cents or 18.3 percent to 9.7 cents with 22.1 million shares traded.

ATCOR MEDICAL

The Atcor extraordinary general meeting to ratify a $1.9 million placement at 6.5 cents a share faced up to 30.3 percent opposition.
Atcor said that the ratification of the prior share issue was opposed by 21,389,309 votes (30.3%) with 48,616,772 votes (69.0%) in favor and 460,611 votes at the proxy’s discretion.
The company said that three resolutions allowing chairman Donal O’Dwyer and directors King Nelson and David Brookes’ superannuation fund were all opposed by 15,838,045 votes with more than 47.1 million votes in favor.
Atcor’s most recent Appendix 3B new issue announcement said it had 231,630,539 shares on issue, meaning that the votes against the placement amounted to 9.2 percent of the company, sufficient to requisition extraordinary general meetings.
Atcor was unchanged at 6.8 cents.