Biotech Daily

Tuesday August 8, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: BENITEC UP 7%, ATCOR DOWN 26%**

*** WESTMEAD TRIALS CAR-T-CELLS FOR LEUKAEMIA, LYMPHOMA**

*** MAYNE EXPECTS REVENUE, PROFIT UP; CEO SCOTT RICHARDS TO US**

*** ATCOR RAISES $825k**

*** BENITEC COMBINES GENE SILENCING, REPLACEMENT FOR OPMD**

*** LBT, CENTRAL ADELAIDE TRIAL WOUNDVUE FOR FOOT ULCERS**

*** IMPEDIMED ENROLS 1st SOZO HEART FAILURE PATIENT**

*** BARD1 ORIGINAL STUDY SHOWS LUNG CANCER TEST 86% ACCURATE**

*** UNISUPER TAKES 5% OF VIRALYTICS, AGAIN**

*** PROLOG REDUCES TO 6.7% OF AIRXPANDERS**

*** MICHAEL SORENSEN, VIG TAKE 18% OF BIOXYNE**

MARKET REPORT

The Australian stock market fell 0.52 percent on Tuesday August 8, 2017 with the ASX200 down 29.8 points to 5,743.8 points. Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, nine traded unchanged and two were untraded. All three Big Caps fell.

Benitec was the best, up one cent or 7.4 percent to 14.5 cents with 232,652 shares traded. Compumedics climbed 4.65 percent; Airxpanders was up 3.3 percent; Bionomics, Clinuvel and ITL rose more than two percent; Avita and Nanosonics were up more than one percent; with Sirtex, Starpharma and Viralytics up by less than one percent.

Atcor led the falls, down 1.3 cents or 26.0 percent to 3.7 cents with 1.3 million shares traded, followed by Prima down 15.4 percent to 2.2 cents with 17.6 million shares traded. Genetic Signatures lost seven percent; Polynovo and Reva fell five percent or more; Admedus shed 4.1 percent; Actinogen, Cellmid and Universal Biosensors were down more than three percent; Acrux, Cochlear, Impedimed, Mesoblast, Oncosil, Orthocell, Pro Medicus and Psivida shed more than one percent; with CSL, Medical Developments, Opthea and Resmed down by less than one percent.

WESTMEAD INSTITUTE FOR MEDICAL RESEARCH

The Westmead Institute says its staff will begin a phase I trial of genetically modified immune cells as a treatment for leukaemia and lymphoma, this month.

The Institute said that researchers and clinicians from WIMR and Westmead Hospital led by Prof David Gottlieb would use a Westmead-designed gene-altering leukaemia and lymphoma treatment, enabling immune cells that have been genetically engineered to attack tumors.

Last week, the private Sydney-based Haemalogix said it was working with Prof Gottlieb on an immuno-oncology agent for multiple myeloma using chimeric antigen receptor T-cells (BD: Jul 31, 2017).

Today, the Westmead Institute researcher Dr Kenneth Micklethwaite said he hoped the treatment would benefit patients with otherwise incurable blood cancers and offer them access to effective treatments, currently unavailable in Australia.

“This new approach to cell and gene therapy for cancer is exciting because it harnesses the power of the immune system to fight the cancer,” Dr Micklethwaite said.

“It really offers an alternative for patients who are no longer responding to chemotherapy,” Dr Micklethwaite said.

“We hope this approach will significantly increase the number of people we treat and cure, without using chemotherapy,” Dr Micklethwaite said.

The Institute said that the treatment involved collecting T-cells from a blood sample and genetically engineering them in a laboratory to produce special receptors on their surface called chimeric antigen receptors (CARs), and the CAR-T-cells were then infused into the patient to recognise and kill cancer cells that carry the antigen on their surfaces.

Prof Gottlieb said he hoped the new trials would give Australians access to this kind of treatment at a fraction of the cost of similar treatments being developed internationally.

“While initial trials conducted in the US have been highly encouraging, these trials are inaccessible to Australian patients, except those willing to travel overseas and pay up to $1 million,” Prof Gottlieb said.

“The long term goal of our research is to make CAR-T-cells affordable and widely accessible to Australian patients as quickly as we can,” Prof Gottlieb said.

MAYNE PHARMA

Mayne Pharma says it expects revenue for the 12 months to June 30, 2016 up 117.4 percent to $581 million with a net profit after tax up 150.3 percent to $92-$95 million.

Mayne said that “to oversee the next stage of growth” chief executive officer Scott Richards would relocate to the US, which was its “most strategically important market representing 94 percent of group revenue”.

Mayne fell 8.5 cents or 9.55 percent to 80.5 cents with 42.1 million shares traded.

ATCOR MEDICAL

Atcor says it has raised $825,000 in a placement to sophisticated and institutional shareholders at 2.5 cents a share.

Atcor said that the funds would be used to provide additional working capital to its strategic review, including securing new sales, restructuring operations to maximize profitability and developing a wearable version of the Sphygmocor central blood pressure diagnostic technology.

The company said that Taylor Collison was the lead manager for the placement.

Atcor fell 1.3 cents or 26.0 percent to 3.7 cents with 1.3 million shares traded.

BENITEC BIOPHARMA

Benitec says it has combined gene silencing and gene replacement to target a mutant gene associated with oculo-pharyngeal muscular dystrophy (OPMD).

Benitec said that its DNA-directed RNA-interference (ddRNAi) technology simultaneously silenced the mutant gene and added back a copy of the normal version of the same gene to restore gene function.

In April, Benitec said that pre-clinical mouse data shows that DNA-directed RNA-interference could correct oculo-pharyngeal-muscular dystrophy and a was begun at the Royal Holloway had shown that the combination of two recombinant adeno associated virus vectors, one allowing the inhibition of mutated PABPN1 by ddRNAi, and the other expressing a functional PABPN1, “significantly reduces the amount of PABPN1 nuclear aggregates, decreases muscle fibrosis, reverts muscle strength to the level of healthy muscles and normalizes the expression of RNA” (BD: Apr 3, 2017).

Today, Benitec chief clinical and development operations officer Georgina Kilfoil told Biotech Daily that the two separate technologies in two separate vectors were now in one vector and the result was “as good as if not better than” the two vector technology.

The company said that the BB-301 single vector system was the clinical candidate it intended to take to human clinical trials by the end of 2018.

Benitec said that by combining both silence and replace functions into a single recombinant adeno-associated virus vector, it could focus its manufacturing efforts for the program on a single product, “which vastly simplifies the regulatory process and reduces the complexity of the clinical strategy”.

The company said that the vector design which integrated both silence and replace modalities into a single vector was not readily achievable with other gene therapy and gene editing technologies.

Benitec chief executive officer Greg West said the single vector system “shows the same excellent activity as the earlier generation dual vector system where the silence and replace constructs were delivered in separate vectors”

“Similar application of the single vector technology may allow development of novel therapeutics to treat other orphan diseases,” Mr West said.

Benitec was up one cent or 7.4 percent to 14.5 cents.

LBT INNOVATIONS

LBT says it will collaborate with the Central Adelaide Local Health Network on a trial of its Woundvue prototype device to predict diabetic foot ulcer treatments.

LBT said that the trial would use the Woundvue hand-held device that takes two and three dimensional images of chronic wounds to monitor wound healing.

The company said the technology behind Woundvue originated from its automated plate assessment system (APAS) platform, with the core machine learning algorithms adapted to interpret tissue types and provide surface area, volume and depth measurements.

The Central Adelaide Local Health Network head of vascular surgery Prof Rob Fitridge said that Woundvue would provide “reliable and objective data that will feed into our predictive model for amputations resulting from diabetic foot ulcers”.

“Accurate and reproducible measurements are required for any clinical decision support system, especially in the context of this trial where these data will be used to predict the likelihood of surgical intervention,” Prof Fitridge said.

LBT chief executive officer Brent Barnes said the collaboration was “the logical next step having recently completed the proof-of-principle work developing our core algorithms”..

LBT was unchanged at 29 cents.

IMPEDIMED

Impedimed says it has enrolled the first patient of up to 30 congestive heart failure patients in a trial of its Sozo fluid detection system at Scripps Health.

Impedimed said that the initial study at the San Diego, California-based Scripps Health would monitor up to 30 patients in a clinical setting for 30 days and was expected to be completed by the end of 2017 (BD: Nov 17, 2016; Mar 7, 2017).

The company said that the data would be used "to form the basis for the design of the larger scale trial expected to be initiated by late … 2017".

Impedimed chief executive officer Richard Carreon said the trial "together with the other planned initial trials, will form the foundation of our marketing of Sozo in the heart failure indication in the US and other select international markets".

"This initial trial is designed to use Sozo to measure fluid levels in class III [congestive heart failure] patients," Mr Carreon said. "If successful, Sozo may provide an early warning system for cardiac decompensation with the potential to optimise patient care and significantly reduce hospital readmissions."

Impedimed fell one cent or 1.5 percent to 65 cents.

BARD1 LIFE SCIENCES

Bard1 says its original proof-of-concept study shows that its lung cancer test is 86 percent accurate and could be developed as a screening test or diagnostic aid for lung cancer.

Bard1 said that the study achieved an "area under the curve" of 96 percent and 86 percent in independent validation sets

The article, entitled 'Bard1 serum autoantibodies for the detection of lung cancer' was co-written by Bard1 executive director and chief scientific officer Dr Irmgard Irminger-Finger, was published in the US Public Library of Science, PLOS1 and was available at: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0182356.

Bard1 chief executive officer Dr Leearne Hinch told Biotech Daily that the proof of concept study conducted at the University of Geneva achieved sensitivity of 90 percent and specificity of 85 percent in the "best fitted model" and sensitivity of 80 percent and specificity of 77.5 percent in the test sets.

The study authors said that enzyme-linked immunosorbent assays (Elisa) were performed with a panel of Bard1 epitopes to detect serum levels of antibodies against Bard1 epitopes, with 194 blood samples from healthy donors and lung cancer patients tested with a panel of 40 Bard1 antigens.

The authors said that the area under the curve, or accuracy was 0.86, or 86 percent, with identical results for combined stages 1 to 3 and late stage 4 lung cancers.

The study authors said that the Bard1 antibody test was "highly specific for lung cancer and not breast or ovarian cancer".

The study concluded that the Bard1 test "shows higher sensitivity and specificity than previously published blood tests for lung cancer detection and/or diagnosis or [computed tomography] scans and it could detect all types and all stages of lung cancer".

"This Bard1 lung cancer test could therefore be further developed as [a] screening test for early detection of lung cancers in high-risk groups and [a] diagnostic aid in complementing [computed tomography] scan," the study concluded.

Dr Hinch said Bard1 congratulated Dr Irminger-Finger and her team for the milestone.

"Dr Irminger-Finger has now published over 40 papers on the Bard1 biology and science that underpins the intellectual property of the company, including the Bard1 lung cancer test," Dr Hinch said.

Bard1 was up 0.1 cents or 10 percent to 1.1 cents with 3.3 million shares traded.

VIRALYTICS

The Melbourne-based Unisuper says it has become a substantial shareholder in Viralytics, again, with 13,126,257 shares or 5.46 percent.
In March, Unisuper became a substantial shareholder in Viralytics, reducing below the five percent threshold in May (BD: Mar 6, May 23, 2017).
Unisuper said that on May 19 it sold 2,634,070 shares for $3,022,516 or $1.15 a share and on June 27 and July 31, 2017 it bought 2,697,540 shares for $2,302,855 or 85.4 cents a share.
Unisuper said the shares were held by the Sydney-based Quest Asset Partners Pty Ltd and Sydney's BNP Paribas Nominees as its custodian and that "various fund managers hold the shares as investment manager for Unisuper".
Viralytics was up half a cent or 0.6 percent to 85.5 cents.

AIRXPANDERS

Prolog Capital says it has reduced its holding in Airxpanders from 20,334,507 Chess depository instruments (CDIs) (7.70%) to 19,213,465 CDIs (6.68%).
The St Louis, Missouri-based Prolog said that between February 14 and August 7 2017, it sold 1,121,042 CDIs but failed to disclose the cost of shares as required of substantial shareholders in Australian-based companies under the Corporations Act 2001.
Airxpanders is a US-based company.
Airxpanders was up 2.5 cents or 3.3 percent to 79 cents.

BIOXYNE

Michael Sorensen and Vig Limited say they have increased their substantial holding in Bioxyne from 85,188,117 shares (16.78%) to 93,380,193 shares (18.37%).
The Auckland, New Zealand-based Mr Sorensen said that between June 23 and August 4, 2017 he and Vig bought 8,192,076 shares for $149,869 or 1.8 cents a share.
Bioxyne was untraded at 1.8 cents.