Biotech Daily

Tuesday June 9, 2015

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: VIRALYTICS UP 19%, TISSUE THERAPIES DOWN 10%**

*** MESOBLAST CLAIMS MPC KIDNEY FAILURE EFFICACY, SAFETY**

*** PROTEOMICS: '1st DIABETIC KIDNEY DISEASE TEST', JUMPS 278%**

*** VIRALYTICS: 'EARLY CAVATAK EFFECT IN BLADDER CANCER TRIAL'**

*** HEARTWARE ISSUES 'URGENT CORRECTION' FOR PUMP USE**

*** 3D, GENESIS CARE COLLABORATE ON PERSONALIZED RADIATION**

*** AUSTRALIAN PATENT FOR SUN, DIMERIX DMX-200 FOR KIDNEY DISEASE**

*** LBT BEGINS US APAS TRIAL**

*** GI DYNAMICS 19% OPPOSE DIRECTORS STOCK**

*** BVF PARTNERS, MARK LAMPERT TAKE 6.4% OF PHARMAXIS**

*** PHOSPHAGENICS APPOINTS DR STEVE MELLER TO PARTNER TPM**

MARKET REPORT

The Australian stock market fell 0.49 percent on Tuesday June 9, 2015 with the S&P ASX 200 down 27.2 points to 5,471.3 points.

Ten of the Biotech Daily Top 40 stocks were up, 17 fell, 11 traded unchanged and two were untraded. All three Big Caps fell.

Viralytics was the best for the second trading day in a row, up 14 cents or 18.7 percent to 89 cents with 4.0 million shares traded. GI Dynamics climbed 7.7 percent; Compumedics and Prima were up four percent or more; Living Cell was up 3.3 percent; Bionomics and Psivida rose more than two percent; Benitec and Medical Developments were up more than one percent; with Sirtex up 0.55 percent.

Tissue Therapies led the falls, down 0.4 cents or 10.3 percent to 3.5 cents with 2.4 million shares traded. Atcor lost 10 percent; Universal Biosensors fell 8.8 percent; Acrux was down five percent; Admedus and Antisense fell more than four percent; Circadian, Ellex and Mesoblast were down more than three percent; IDT, Neuren and Prana shed more than two percent; Actinogen, Clinuvel, Impedimed and Resmed were down more than one percent; with Cochlear, CSL, Nanosonics and Osprey down by less than one percent.

MESOBLAST

Mesoblast says that its 30-patient trial of mesenchymal precursor stem cells has shown safety and efficacy for diabetic nephropathy at two dose levels.

The study, entitled 'Mesenchymal Precursor Cell Therapy for Diabetic Nephropathy: A Phase 2 Randomized Controlled Trial', co-authored by Mesoblast chief executive Prof Silviu Itescu, concluded that "efficacy testing showed preservation or improvement in [the kidney disease measure, glomerular filtration rate] at 12 weeks, persisting for at least 24 weeks, in [mesenchymal precursor cell] treated subjects relative to placebo".

The abstract, presented at the American Diabetes Association meeting in Boston, Massachusetts, concluded that "no treatment-related safety issues were identified during the 12 week study period following a single [mesenchymal precursor cell] infusion … [and] benefit was similar with both … doses".

In a media release, Mesoblast said the trial showed that a single infusion of its intravenous allogeneic mesenchymal precursor cell (MPC) MPC-300-IV was safe, reduced inflammation and preserved or improved renal function over 24 weeks.

The trial's lead investigator, the University of Melbourne's Prof David Packham said the results "show that Mesoblast's allogeneic cell therapy was safe and may be particularly useful in patients with moderate to severe diabetic nephropathy, a disease which, despite all existing therapies, continues to have a high rate of progression to dialysis or transplantation, and to portend a high risk of death from cardiovascular disease."

Mesoblast said that diabetic nephropathy affected up to 50 percent of patients with type 2 diabetes and about 40 percent of all patients with end-stage renal disease and was thought to be caused by on-going monocyte inflammation and endothelial dysfunction, or abnormal blood vessels, in the kidneys.

The company said its stem cells were "potent modulators of monocyte inflammation, and had been shown in preclinical studies to reduce monocyte infiltration in diabetic kidneys and to reverse endothelial dysfunction".

Mesoblast said that stage 3b-4 chronic kidney disease patients in the double-blind, randomized, placebo-controlled, dose escalating trial received a single infusion of 150 million MPCs, 300 million MPCs, or saline.

The company said the primary efficacy endpoint was to evaluate MPC treatment relative to placebo on renal functional decline at 12 weeks, as defined by change in glomerular filtration rate (GFR) with an additional 48 weeks of follow-up.

Mesoblast said the secondary analyses included GFR differences between MPC and placebo groups and effects on interleukin-6 (IL- 6), an inflammatory marker associated with renal failure progression and adverse cardiovascular outcomes.

The company said all three groups had similar mean GFRs at baseline, but at 12 weeks the placebo group showed a decline in GFR relative to the groups receiving either 150 million MPCs or 300 million MPCs, with a significant difference in creatinine-based GFR decline between placebo and the 150 million MPC group ($p = 0.05$), and a correlation between increased baseline IL-6 levels and improvement at 12 weeks in both serum creatinine and GFR ($r = 0.57$, $p = 0.008$) in MPC-treated patients, as well as a dose-dependent inhibition of IL-6 increase over 12 weeks.

Prof Itescu said the company was "very encouraged by the safety profile and the sustained efficacy signal that we have seen over 24 weeks … [and] the growing burden of diabetic nephropathy and its impact on healthcare made it an important disease target".

"We will specifically evaluate whether MPC-300-IV can alter the natural course of the disease in patients with rapid progression towards dialysis or renal transplantation and will focus on early access regulatory pathways for developing this product," Prof Itescu said.

Mesoblast fell 12 cents or 3.0 percent to $3.83 with 576,568 shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics climbed as much as 278 percent to 77.5 cents on news that it has produced and validated the world's first predictive test for the diagnosis of diabetic kidney disease.
Proteomics said that the test, Promarkerd, was the first proteomics-derived predictive, or prognostic, test for the diagnosis of diabetic kidney disease and was "a global breakthrough in the diagnosis and treatment of the disease".
The company said there were no tests for predicting diabetic kidney disease onset and the potential global medical benefits and cost savings from the predictive test were "huge".
Proteomics said that diabetes was "the fastest growing health issue in the world today and is the largest cause of kidney disease" with 35 percent of adults in the US with diabetes having chronic kidney disease.
The company said that the ability to predict accurately the onset of diabetic kidney disease via a simple blood test and then provide appropriate clinical treatment to prevent the onset of the disease had "the potential to save health care systems globally billions of dollars".
Proteomics said that the total cost to the Australian health system and in productivity loss attributed to diabetes was estimated at $10.3 billion a year and of the 1.7 million Australians who had chronic kidney disease, 1.5 million were not aware they had it.
The company said the potential for pharmaceutical companies to market Promarkerd to identify at-risk patient groups and then to provide drugs to manage patients more effectively could provide substantial returns from licencing fees and royalties.
Proteomics said that Promarkerd simultaneously measured a panel of two to six proteins to determine the patient's disease state and applying its mass spectrometry-based proteomics technology, it had developed a deeper understanding of diabetic kidney disease beyond classical pathology, by comparing the differences in the protein makeup of people with and without the disease.
The company said the test was developed and validated in a study of 576 patients with diabetes, followed between 2010 and 2014 in Western Australia, which showed that Promarkerd could predict which diabetic patients would progress to a significant decline in kidney function better than any other measure and which people with apparently healthy kidney function as measured by conventional tests were at risk of kidney problems.
The company said that the ongoing study found that 10 percent of the patients had a significant and rapid decline in kidney function over the four year study period and that Promarkerd correctly predicted 67 percent of these individuals.
Proteomics said that the samples were cross-validated with an established antibody-based technique broadly accepted by the US Food and Drug Administration, which showed "there was excellent correlation between the two methods".
The company said that Promarkerd had a diagnostic component as well as its predictive application, which used the biomarker panel to diagnose the early onset in a patient, where current tests for kidney function fail to detect the disease.
Proteomics said that 382 million people had diabetes worldwide and that 25 million individuals of the 38 million at risk of significant and rapid decline in kidney function could be identified by Promarkerd, "a massive potential market for the technology owner/developer and any licencing partner(s)".
The company said that Promarkerd could be commercialized using standard pathology laboratory assay systems and it would attend BIO 2015 in Philadelphia, Pennsylvania, next week for discussions with major pharmaceutical companies and continue to engage with industry for partnering and licencing opportunities to commercialize Promarkerd as a ground-breaking predictive test for the diagnosis of diabetic kidney disease.
Proteomics closed up 50.5 cents or 246.3 percent to 71 cents with 12.7 million shares traded.

VIRALYTICS

Viralytics says that “promising early data” from its trial of Cavatak for bladder cancer and other studies will be presented at the Oncolytic Virus Therapeutics meeting.

Viralytics said that it would deliver a total of five oral and poster presentations at the meeting in Boston, Massachusetts, to be held from June 13 to 16, 2015.

The company said that preliminary data from the first three patients in its phase I/II ‘Canon’ trial of Cavatak in non-muscle invasive bladder cancer shows that administration via catheter directly into the bladder, or intravesicular treatment, was well-tolerated with widespread virus replication within the tumor and viral-induced cancer cell death.

Viralytics said that serial photography identified possible evidence of viral-induced surface haemorrhage and inflation of the tumor micro-environment, with potential multi-cycle virus replication within tumors highlighted by detection of secondary viral load peaks in the urine and tissue analysis displayed marked tumor-specific cytoplasmic viral protein expression and widespread evidence of viral-induced apoptotic cell death.

The abstracts of all of the oral and poster presentations are available at: http://ovcboston.com/wp-content/uploads/2015/02/Final_OVC_Program_5.29.15.pdf.

The University of Surrey’s Cancer Research Institute director and principal investigator Prof Hardev Pandha said that the trial was “seeing viral tumor targeting, virus replication and evidence of tumor cell death, notably mediated from the administration of the lowest planned dose of Cavatak”.

“To date the treatment has been well tolerated with no significant toxicity,” Prof Pandha said.

“We are proceeding with the study expecting increased levels of Cavatak activity in these tumors, not only with higher levels of viral dosing, but also when combined with mitomycin C,” Prof Pandha said.

“We are very optimistic that the observed tumor targeting and viral replication is likely to provide a strong signal in generating both a strong local and systemic anti-tumor immune response,” Prof Pandha said.

Viralytics said that the two-part, open-label, dose-escalation study expected to enrol up to 40 patients to evaluate the safety and tolerability of Cavatak administered alone, as well as in combination with a sub-therapeutic dose of the standard chemotherapy, mitomycin C and would assess the pharmacodynamics of CAVATAK and document evidence of anti-tumor activity.

Viralytics managing-director Dr Malcolm McColl said that there was “a real need for new therapies for bladder cancer that will improve the durability of response and reduce toxicities compared to current treatments”.

“These positive initial results from the Canon trial suggest that Cavatak is an oncolytic virus highly suited for application in [non-muscle invasive bladder cancer],” Dr McColl said.

The company said that other presentations included ‘Phase I/II STORM study: Intravenous delivery of a novel oncolytic immunotherapy agent, CAVATAK, in advanced cancer patients’; ‘Characterisation of the oncolytic kinetics of the immunotherapeutic agent, CAVATAK, delivered intratumorally in patients with advanced malignant melanoma’; ‘Combination of a novel oncolytic immunotherapeutic agent, CAVATAK (Coxsackievirus A21) and immune-checkpoint blockade significantly reduces tumor growth and improves survival in an immune competent mouse melanoma model’; ‘Oncolytic Virotherapy for the Treatment of Non-Hodgkin Lymphoma’; and ‘Investigation of Coxsackievirus A21 as a Potential Treatment for Pancreatic Cancer’.

Viralytics was up 14 cents or 18.7 percent to 89 cents with 4.0 million shares traded.

HEARTWARE INTERNATIONAL

Heartware says it has issued a voluntary Urgent Medical Device Correction, describing five different complaints reviewed as part of its product performance monitoring.
Heartware said that the notice provided information to reinforce proper performance and safe use of the Heartware ventricular assist system to help reduce the potential occurrence of avoidable patient injury, as per the patient manual and to be aware of certain signs of wear.
The company said that patients should never to disconnect the Heartware ventricular assist device (HVAD) pump from both power sources at the same time and to be aware that alignment guides in the controller's power supply connector ports might wear down over time.
Heartware said that in certain situations, it was possible that a temporary loss of communication between the controller and the batteries could result in premature battery switching or false battery alarms and while they did not increase risk to patients, they might result in an increase in alarms or the need for more frequent battery changes.
The company said it was developing a software upgrade to improve how the controller manages a transient loss of communication between the controller and HVAD system batteries, expected to become available later in 2015.
Heartware said the driveline outer sheath might become discolored or display small cracks over time as it contained a plastic material that might degrade if exposed to excessive ultraviolet light, while the internal driveline conductors remain protected and intact.
The company said that discolored or cracked outer sheaths had not shown an elevated safety risk, but could contribute to the risk of infection at the exit site.
Heartware said that patients should take care when managing their drivelines to avoid accidental snagging or pulling, which could cause damage to the driveline or a disconnection, which could lead to serious injury or death.
The company said that patients who experienced these issues should contact their physician or HVAD coordinator at their hospital and clinicians should contact their Heartware representative.
On the Nasdaq last night Heartware was unchanged at $US76.38 ($A99.43, equivalent to $2.84 per CDI prior to the company departing the ASX).

3D MEDICAL

3D Medical says it will collaborate with radiation oncology company Genesis Cancer Care to evaluate 3D printing and workflow processes for personalized treatment plans.
3D said that the parties would undertake joint testing and evaluation of 3D printing and workflow processes for the purpose of manufacturing patient-specific electron beam shields personalized to the specific requirements of each patient’s radiotherapy treatment.
The company said that if successful they would enter a manufacture and supply relationship on commercial terms.
3D said that if successful, the collaboration would provide Genesis Cancer Care with enhanced workflows that would reduce the time to deliver radiotherapy treatments and deliver a personalized medical approach with improved patient outcomes.
3D executive officer Max Ghobrial said that the projects to be completed during the investigative phase of the agreement involved a novel application of 3D printing technology.
“If successful this will reduce the cost to deliver patient care and increase the quality of patient outcomes,” Mr Ghobrial said.
3D Medical fell half a cent or 4.55 percent to 10.5 cents with 2.4 million shares traded.

DIMERIX BIOSCIENCE, SUN BIOMEDICAL

Sun Biomedical says that acquisition target Dimerix Bioscience has been granted an Australian patent for DMX-200 for chronic kidney disease (BD: May 13, 2015).
Sun said that Dimerix had advised it that the patent entitled 'Combination Therapy' provided protection until January 11, 2032.
The company said that an application for examination under the US Patent Prosecution Highway had been filed in relation to the US equivalent application.
Sun was up 0.1 cents or 10 percent to 1.1 cents with 6.4 million shares traded.
Dimerix Bioscience a public unlisted company

LBT INNOVATIONS

LBT says it has begun the US phase of the clinical trial program for its automated plate assessment system (APAS) culture-plate image analysis technology.
LBT said that the trial underway at the Albuquerque, New Mexico-based Tricore Reference Laboratories was in support of its US Food and Drug Administration 510(k) de novo submission.
The company said that the trial would test the efficacy of APAS in screening for the presence of disease-causing pathogens in urine samples from about 5,700 patients.
LBT said that about 55 percent of all the samples analysed in microbiology laboratories worldwide were urine samples and modules for other specimen types were being developed.
The company said that APAS was being incorporated into new laboratory instruments under the supervision of LBT's joint venture partner Hettich AG Switzerland, including an automated culture plate reader and an automated-incubator, to automatically generate laboratory reports and sort culture plates for the next step in the workflow.
LBT was untraded at 6.2 cents.

GI DYNAMICS

GI Dynamics says its annual general meeting saw up to 19.2 percent opposition to the grant of stock to five directors.
In its notice of meeting, GI Dynamics proposed the issue of stock and options equivalent to 50,000 Chess depositary interests and options to each of six directors Anne Keating, Michael Carusi, Timothy Barberich, Graham Bradley, Jack Myer and Daniel Moore as well as shares equivalent to 1,343,500 CDIs and 1,568,150 options to chief executive officer Michael Dale (BD: May 1, 2015).
In the notice, the company said that Mr Dale's options would be exercisable at $US5.38 per US share or 13.62 Australian cents per CDI, vesting over 48 months, while the director options would be exercisable at $US5.70 per US Share or 14.43 Australian cents per CDI.
Today, the company said 1,062,433 votes (19.2%) opposed the issue to Ms Keating, Mr Carusi, Mr Barberich, Mr Bradley and Mr Myer, with 4,475,437 votes (80.8%) in favor.
The company's most recent Appendix 3B new issue announcement said that GI Dynamics had the equivalent of 474,233,550 Chess depository instruments on issue, or 9,484,671 US shares, meaning that the votes against the directors' stock issue amounted to 11.2 percent of the company, sufficient to requisition extraordinary general meetings.
GI Dynamics said that other resolutions including the issue of stock to Mr Dale and Mr Moore were passed overwhelmingly, with the re-election of Ms Keating, Mr Carusi and Mr Moore passed without opposition.
GI Dynamics was up one cent or 7.7 percent to 14 cents.

PHARMAXIS

BVF Partners and Mark Lampert say they have increased their substantial holding in Pharmaxis from 15,841,327 shares (5.04%) to 20,000,000 shares (6.36%).
The San Francisco, California-based BVF Partners and Mr Lampert said they acquired the shares in 12 trades between June 2 and 4, 2015, with the single largest purchase 1,213,770 shares for $279,046 or 23 cents a share.
BVF Partners and Mr Lampert also hold 13.12 percent of Circadian and 13.55 percent of Viralytics (BD: Nov 25, 28, 2014).
Pharmaxis was unchanged at 23 cents with 1.9 million shares traded.

PHOSPHAGENICS

Phosphagenics says it has appointed Dr Steve Meller to help partner its tocopheryl phosphate mixture (TPM) technology with large companies selling to the mass market.
Phosphagenics said that Dr Meller had 20 years' experience in senior health, innovation and sustainability roles at Procter and Gamble and currently ran a specialty consulting company based in Silicon Valley, California with a focus on relationships with institutional and corporate venture capital investors.
The company said that Dr Meller would work closely with it to promote its technology to prospective partners, with a focus on the pharmaceutical and consumer health markets.
Phosphagenics chief executive officer Dr Ross Murdoch, said that Dr Meller's "track record speaks for itself".
"His deep personal global networks, his experience in building and negotiating deals, combined with our technology and the considerable data supporting it, make a strong combination when looking for partners in mass markets," Dr Murdoch said.
Dr Meller said that "the amount of data and information collected over more than a decade provides the TPM technology with a strong foundation upon which mass market licencing deals can be made".
"There is a wide range of potential partners who could be interested in a platform technology that enhances dermal and transdermal delivery of drugs and other molecules," Dr Meller said.
Phosphagenics has previously attempted to develop the phosphorylated vitamin E crème based technology for the transdermal application of insulin, diclofenac (Voltaren), opioids, an acne treatment, and as a cosmetic preparation, including with AOP9604 as a fat-removal treatment.
Phosphagenics said that Dr Meller held a Bachelor of Science and Doctorate of Philosophy from the University of Adelaide before continuing his career in neuroscience research at the University of Adelaide, the University of Iowa and the University of Cincinnati.
Phosphagenics was unchanged at 2.3 cents with 1.9 million shares traded.