# Biotech Daily

Tuesday October 8, 2013

*Daily news on ASX-listed biotechnology companies*

*** ASX DOWN, BIOTECH UP: NEUREN UP 18%, OPTISCAN DOWN 11%**

*** PROF ALAN COWMAN, PROF LLOYD HOLLENBERG WIN VICTORIA PRIZES**

*** REGENEUS: 'HIQCELL EFFECTIVE, SAFE FOR OSTEOARTHRITIS'**

*** TGA ALLOWS 8 MORE SURGEONS TO USE ALLIED'S CARDIOCEL PATCH**

*** CLINICAL GENOMICS BUYS ENTERIX FOR BLOOD BOWEL CANCER TEST**

*** US POLITICS COULD DELAY BENITEC ON-TRACK HEPATITIS C TRIAL**

*** BROAD EURO PATENT FOR CELLMID'S MIDKINE**

*** BIONOMICS $17m OFF-SHORE R&D ELIGIBLE FOR 45% REBATE**

*** BIONICHE UROCIDIN CANADA FILING DELAYED 6 MONTHS**

*** AGENIX QUITS CHINA, THROMBOVIEW CHINA PATENT**

*** NUSEP RECEIVES $1.65m R&D TAX REFUND**

*** DAVID ADAMS TO REPLACE IMPEDIMED DIRECTOR DR MEL BRIDGES**

## MARKET REPORT

The Australian stock market fell 0.23 percent on Tuesday October 8, 2013 with the S&P ASX 200 down 11.7 points to 5,149.4 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, seven traded unchanged and four were untraded.

Neuren was the best, up two cents or 18.2 percent to 13 cents, with 9.5 million shares traded. Alchemia and Allied Health climbed more than six percent; Ellex, IDT and Psivida were up five percent or more; Avita and Medical Developments were up more than four percent; Cellmid climbed 3.6 percent; Bionomics, CSL and Prima rose more than two percent; Benitec, Mesoblast, Phosphagenics, Prana and Viralytics were up more than one percent; with Resmed up 0.35 percent.

Optiscan led the falls, down 0.8 cents or 11.4 percent to 6.2 cents with 57,095 shares traded. Universal Biosensors lost 9.9 percent; Living Cell fell 4.8 percent; QRX was down 3.4 percent; Atcor shed 2.8 percent; Anteo, Genetic Technologies, Nanosonics and Osprey fell more than one percent; with Clinuvel, Reva, Sirtex and Starpharma down by less than one percent.

VICTORIA GOVERNMENT

The Walter and Eliza Hall Institute's Prof Alan Cowman and the University of Melbourne's Prof Lloyd Hollenberg have been awarded Victoria Prizes for Science and Innovation.

Victoria's Minister for Innovation Louise Asher presented the $50,000 life sciences award to Prof Cowman for his work on how the malaria parasite causes the disease and how it circumvents many of the anti-malarial drugs used to control and treat the disease.

Ms Asher presented the $50,000 Victoria Prize for physical sciences to Prof Hollenberg for his discovery and application of a quantum-sensing technology with sensitivities and resolution one million times greater than conventional magnetic resonance imaging.

Ms Asher said the Prize recognized and honored Victoria's leading researchers and celebrated their contribution to the community through research and innovation.

"As world leaders in their respective fields, both researchers have established collaborative relationships and networks in the Victorian and international research communities," Ms Asher said.

Ms Asher awarded 12 Victoria Fellowships, each worth up to $18,000, to enable researchers in the early stages of their careers to undertake international study missions.

"Victoria Fellowships provides researchers with a once-in-a-lifetime opportunity to gain a valuable insight into the research community abroad, bringing knowledge, new insights and expertise back to Victoria," Ms Asher said.

The Victoria Government said the Prize and Fellowships were established by the Kennett Coalition Government in 1998, to support and celebrate the work of the people who drive Victoria's science and innovation capabilities.

The Government said the awards formed the centre-piece of awards and fellowships that include the Premier's Award for Health and Medical Research, the Victorian Postdoctoral Research Fellowships and the Veski Innovation Fellowships.

The Government said that in the 2012 State Budget, it doubled the number of Prizes and Fellowships.

The Victoria Government said the 2013 Fellows in life sciences were Dr Amil Kumar Asthana who was developing an intestinal ultrasound scan service for inflammatory bowel disease; Dr Ross Clark who was investigating technologies to identify those amongst the elderly most at risk of falling, and to implement falls-prevention programs in Victoria; Dr Natasha Holmes who was investigating the immune system response in patients who have developed Staphylococcus aureus, with the aim of being able to predict which individuals could benefit from a more-tailored treatment; Dr Simon James who would attend workshops and conferences supporting the use of the Australian Synchrotron to inform approaches to tackling Alzheimer's disease; Dr Arthur Nasis to inspect the cardiac magnetic resonance imaging technique called equilibrium-contrast imaging to detect and quantify heart fibrosis; and Dr Jennifer Pilgrim to take advantage of the similarities between Australia and Sweden's nation-wide coronial case databases, to establish the world's first evidence-based resource for toxic concentrations of drugs in humans.

The Government said that the Victoria Fellows for physical sciences were Dr Nishar Hameed who was developing highly sensitive medical imaging agents to diagnose and distinguish diseased tissue from normal tissue and provide information on a disease state and monitor the effect of a treatment; Dr Meenakshi Arora developing water service infrastructure; Prof Bradley Ladewig who was developing and commercializing technology to deliver water more efficiently; Dr Xiangping Li to investigate a new approach to nanophotonics-enabled super-resolution all-optical magnetic recording; Prof Timothy Rawling to visit developers of three-dimensional geological models; and Dr Jin Zhang to study wild silkworms to develop lightweight materials for personal protection, load bearing and energy absorbing purposes.

REGENEUS

Regeneus says its fat-based Hiqcell stabilizes levels of the cartilage break-down marker CTX-II and reduced macrophage migration inhibitory factor in osteoarthritis patients.

Regeneus said the 40-patient, double-blind, placebo-controlled clinical study of Hiqcell for knee osteoarthritis showed that Hiqcell was safe and clinically feasible.

The company said 20 participants received Hiqcell, which involved harvesting a small amount of adipose tissue using a mini-liposuction procedure, isolation of the regenerative cells from the adipose tissue and injection of these cells into the patient's arthritic knee.

Regeneus said the cells were a mixture of fat-derived stem cells, stromal vascular fraction cells and adipocytes.

The company said that the 20 participants in the surgical placebo group underwent the liposuction but received an intra-articular injection of saline rather than their cells.

Regeneus said assessment of cartilage degradation by magnetic resonance imaging mapping was performed at baseline and 24 weeks post-treatment.

The company said it also measured CTX-II in urine, an important cartilage breakdown molecule that increased in patients with osteoarthritis as the disease progressed and patients receiving placebo showed an increase in CTX-II compared with active patients showing no increase.

Regeneus said that macrophage migration inhibitory factor (MIF) was a second important biomarker of inflammation and osteoarthritis and it increased in the placebo group and decreased in the treatment group.

Regeneus chief executive officer Prof Graham Vesey said the biomarker results were important "as they provide medical specialists with a molecular basis that explains how Hiqcell slows cartilage degradation".

"CTX-II is well recognized as a key measurement in trials to determine whether a treatment is slowing the progression of osteoarthritis," Prof Vesey said. "While MIF is recognized as an important inflammatory marker, to our knowledge this is the first time that it has been demonstrated that you can use MIF to measure the anti-inflammatory effects of cell therapy."

Prof Vesey said the company had sought patent protection on the use of biomarker measurements, including MIF, for determining when to administer stem cell therapies.

Sydney Sportsmed Specialists' Dr Diana Robinson said the "lack of disease progression and the biomarker results indicate that Hiqcell treatment may have a disease modifying effect" which correlated with post-treatment magnetic resonance imaging she had observed, which meant "that I can now use the measurement of biomarkers, such as MIF, to monitor Hiqcell treatments and importantly to determine when additional injections of stem cell treatments should be administered".

Regeneus said Hiqcell was effective at reducing pain, well tolerated and there were no major safety concerns and no joint infections during the course of the study.

Regeneus said both treatment and placebo groups experienced a large and statistically significant decrease in total pain score from baseline, which was not unexpected "as it is well known that placebo treatment can decrease pain in osteoarthritis trials".

Regeneus said that magnetic resonance imaging (MRI) T2 mapping, which showed that the loss of cartilage was slower than expected at the six-month post-treatment time point.

The company said that Qmetrics Technologies conducted the imaging and found that both groups had a greater proportion of participants remaining stable than those progressing.

Regeneus said that MRI analysis showed that prior to treatment there were significantly more patients with advanced cartilage damage in the treatment group, tending to predispose that group toward an accelerated progression, which was not observed.

Regeneus fell half a cent or 1.85 percent to 26.5 cents.

## ALLIED HEALTHCARE GROUP

Allied Health says that an additional eight surgeons at Brisbane's Prince Charles Hospital have been allowed to use Cardiocel for adult heart defects.

Allied said the treated bovine cardiac tissue patch was permitted under the Australian Therapeutic Goods Administration Authorised Prescriber Scheme for access to medicines or medical devices that have not been approved.

The company received Conformité Européenne (CE) mark approval for adults and children in August and has filed for US Food and Drug Administration 510k pre-market approval as well as Therapeutic Goods Administration approval (BD: Aug 26, 2013).

Allied chief executive officer Lee Rodne said the approval was important for Allied "as it represents the first department-wide team of cardiac heart surgeons to gain early access to use Cardiocel for treating and repairing heart defects in adult patients".

"The adult market has the potential to significantly expand the market and revenue for the company considerably," Mr Rodne said.

Allied said there were 14 surgeons in Australia authorized to use Cardiocel for the repair of heart defects with more than 60 patients having received the tissue implant since the initial procedure was performed.

"We are extremely encouraged by the growing support for Cardiocel from Australian and international surgeons and these early access approvals further validates the importance of Cardiocel in the future treatment of heart defects," Mr Rodne said.

Allied said that the adult market was significant with more than 30,000 cardiac surgery procedures a year in the UK alone.

Allied was up half a cent or 6.4 percent to 8.3 cents with 11.0 million shares traded.

## CLINICAL GENOMICS

The Sydney based Clinical Genomics says it has acquired cancer screening company Enterix Inc to launch blood-based colorectal cancer screening tests in 2014.

Clinical Genomics chief executive officer Dr Lawrence LaPointe told Biotech Daily that his company acquired Enterix from the Madison, New Jersey-based Quest Diagnostics for an undisclosed "up-front cash payment".

Dr LaPointe said that Clinical Genomics was "currently conducting clinical trials to prepare for the launch in 2014".

In a media release, Clinical Genomics said its team had developed the first commercially available blood test for bowel cancer and Enterix was Australia's largest private cancer screening company.

Clinical Genomics said that the acquisition included Enterix's Sydney-based subsidiary and provided licenced manufacturing facilities in the US and Australia, as well as access to a specialty pathology laboratory in Australia for selling bowel cancer screening services to be used as the platform to launch its blood test for colorectal cancer in Australia.

Clinical Genomics said that the Enterix acquisition also provided ownership of the Insure fecal immunochemical test product line, which would be combined with the blood plasma test to deliver a portfolio of colorectal cancer screening products.

Dr LaPointe said the acquisition was "an exciting milestone for the company".

"This is a key step in our transition from a biotech company focused primarily on research and development into a commercial entity with a portfolio of cancer screening products and an exciting pipeline," Dr LaPointe said.

Last year, Clinical Genomics said that Quest Diagnostics had licenced its gene-based biomarkers for colon cancer detection tests in the US (BD: Nov 5, 2012).

Clinical Genomics is a private company.

## BENITEC BIOPHARMA

Benitec says it is finalizing its investigational new drug application to the US Food and Drug Administration for a trail of TT-034 for hepatitis C this year.

In Australian to meet investors and the media, Benitec's head of Tacere research and development Dr David Suhy told Biotech Daily that the company was "finalizing the IND to file to the FDA very, very soon".

Dr Suhy said that in theory the trial could begin shortly after filing pending FDA review.

Last year, Benitec re-acquired its US-based Tacere spin-out for $1.5 million in scrip from Pfizer, which had spent about $20 million in taking TT-034 from pre-clinical to phase I/II ready (BD: Oct 11, 2012).

Dr Suhy said that the FDA was "accepting INDs with reduced staff due to the US Government shutdown, but TT-034 could be in the clinic by the end of the year".

The US Government has been forced into a Government services shut-down by the Republican-dominated Congress opposing the US Budget and linking it to the Affordable Health Care Act, known as Obamacare.

Dr Suhy said that the open-label trial of 14 patients receiving a single infusion of TT-034 could have final results in 18 months if recruitment and dosing was optimal.

Dr Suhy said viral counts would be measured several times in the first week after dosing and then weekly for six weeks and then fortnightly until the 24-week review period was concluded.

Dr Suhy said he expected to see a reduction in viral count over the 24-week period, rather than a dramatic reduction in two weeks as has been reported with some of the most recently approved anti-hepatitis C combination therapies.

Benitec was up half a cent or 1.4 percent to 36 cents.

## CELLMID

Cellmid says the European Patent Office has granted a patent, entitled 'Antibody recognising Cdomain of midkine' protecting its intellectual property to 2027.

Cellmid said that the granted claims covered its cancer program for antibodies and antibody fragments which bind to the functional C-domain of growth factor midkine, and in particular, antibodies of any kind that bind to key midkine C-domain epitopes were covered by the patent.

The company said that the patent also granted composition of matter claims for midkine - specific antibodies, including its lead anti-cancer antibody, and the use of any such antibody for prevention and treatment of cancer, autoimmune disease, inflammatory disease, and any disease attributed to cell migration.

Cellmid said that in published studies, the midkine C-domain was shown to convey most of the disease promoting activities attributed to midkine and blocking the C-domain was a powerful potential treatment option in any MK-related disease (BD: Oct 3, 2013).

Cellmid chief executive officer Maria Halasz said that "having patents granted in Europe for our [midkine] antibodies across such a wide array of diseases is a tremendous commercial outcome for Cellmid".

"This patent gives Cellmid very clear exclusive rights to develop [midkine] antibodies un-encumbered by competition," Ms Halasz said. "Moreover, Cellmid's patent coverage for its therapeutic antibodies now extends across cancer, inflammatory and autoimmune diseases, multiple sclerosis and surgical adhesion," Ms Halasz said.

Cellmid said it held 78 patents in 20 patent families, covering the use of midkine and anti-midkine agents in a number of diseases, as well as a diagnostic marker.

Cellmid was up 0.1 cents or 3.6 percent to 2.9 cents with 6.9 million shares traded.

## BIONOMICS

Bionomics says that Innovation Australia has confirmed that off-shore research and development work is eligible for the 45 percent Federal Government Tax Incentive.
Innovation Australia is a statutory body administering Federal Government innovation and investment programs including the Research and Development Tax Incentive.
Earlier this year, Bionomics received $4.2 million from the Federal Government for previous research and development expenditure (BD: Jan 20, 2013).
Today, the company said it expected to receive a Research and Development Tax Incentive refund of $7 million for the year to June 30, 2013.
Bionomics said that Innovation Australia confirmed that certain overseas expenditure totaling $17.42 million was eligible for the 45 percent Tax Incentive for the three years beginning on July 1, 2012 and cover its cancer stem cell targeting antibody BNC101 and other programs within Bionomics' pipeline.
Bionomics acquired BNC101, then known as ET101, when it bought Eclipse Therapeutics, last year (BD: Sep 17, 2012).
The company said the eligible expenditure was in addition to those announced in January for BNC105 and BNC375, totaling $8.9 million over three years from July 1, 2011.
Bionomics chief executive officer Dr Deborah Rathjen said that "with BNC101 on target to enter clinical trials in 2014, the … Tax Incentive provides important funding".
Bionomics was up 1.5 cents or two percent to 76 cents.

## BIONICHE LIFE SCIENCES

Bioniche says its Canadian filing of a new drug submission for Urocidin for bladder cancer has been delayed by about six months to June 2014.
Bioniche said that in June, it met with Health Canada, which advised that the data from the first phase III trial might be sufficient to qualify for filing, but the regulator had asked for a clinical assessment package addressing clinical questions.
The company said it believed the materials could be submitted before the end of 2013 but it "now believes that it will have these materials ready for submission by June 30, 2014".
Bioniche said that an early registration in Canada would generate revenues from sales to offset the cost of additional trials that could be required for the US and other jurisdictions.
The company said it would seek a meeting with the US Food and Drug Administration.
Bioniche was untraded at 38 cents.

## AGENIX

Agenix says that executive chairman Nicholas Weston has replaced Tang Wen Sen as chairman and legal representative of Agenix Biopharmaceuticals Shanghai Co.
Agenix said that Mr Weston would oversee the exit of the company from China operations to follow the divestment of its AGX-1009 project, a tenofovir pro-drug for hepatitis B.
Agenix originally developed Thromboview for pulmonary embolism and deep vein thrombosis imaging, and prior to Mr Weston's involvement, invested in two Chinese companies, resulting in a failed acquisition, followed by exposure of fraud by previous chief executive officer Neil Leggett (BD: May 28, 2008; Feb 18, 2010; Dec 11, 2012).
Last year, Agenix licenced Tyrian Diagnostics point-of-care Diagnostiq technology for human use (BD: Oct 25, 2012).
Agenix said China had granted a patent entitled 'Humanised antibodies derived from DD-3B6/22, specific for the D-Dimer fragment of Fibrin' the basis of Thromboview.
Agenix was unchanged at 1.9 cents.

## NUSEP

Nusep says it has received $1,647,903 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Nusep said the rebate related to research and development expenditure on its Prime Biologics project and other technologies in 2012-'13.
The company said the funds would be used to reduce its current commitment and advance its product development programs.
Nusep was untraded at 4.5 cents.

## IMPEDIMED

Impedimed says the US-based David Adams will be appointed a director when founding chairman Dr Mel Bridges retires on November 11, 2013.
Impedimed said that Mr Adams would be the company's second US director.
The company said that Mr Adams was previously Medtronic's vice-president of integration and divestitures, focused on acquisitions and integrations and had experience in legal, tax, mergere and acquisition ventures and strategic planning.
Impedimed said that Mr Adams was previously Medtronic's cardiovascular business development vice-president vascular business development and ventures vice-president and held management roles in financial planning and analysis.
The company said that Mr Adams held a Bachelor of Science in accountancy from the University of Illinois and a Juris Doctorate from the St Paul, Minnesota-based William Mitchell College of Law.
Impedimed chair Dr Cherrell Hirst said that Impedimed paid tribute to Dr Bridges "for his long involvement and commitment to Impedimed and especially for his services as chairman of the board for many years".
"As founder and a significant investor, Mel will always be part of Impedimed and can be counted on to continue his strong support for the company and its health and business goals," Dr Hirst said.
Impedimed was unchanged at 17.5 cents.