# Biotech Daily

Thursday October 10, 2013

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: ANTISENSE UP 8%, MEDICAL DEVELOP DOWN 10%**

*** CALZADA POLYNOVO: 'NOVOSORB SAFE, EFFECTIVE IN DEEP WOUNDS'**

*** LITTLE IMPACT FROM US GOVERNMENT SHUT-DOWN, SO FAR**

*** CLARIFICATION: BURNET'S HEPSEEVAX**

*** WEHI'S PROF DAVID TARLINTON WINS $1m US LUPUS PRIZE**

*** NANOSONICS TROPHON 'SUPERIOR FOR CLEANING VAGINAL PROBES'**

*** NANOSONICS AGM FOR UP TO $900k, 1.6m 'PERFORMANCE RIGHTS'**

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*** DR ANTON UVAROV REPLACES ACUVAX DIRECTOR ALISTAIR JOBLING**

## MARKET REPORT

The Australian stock market slipped 0.11 percent on Thursday October 10, 2013 with the S&P ASX 200 down 5.9 points to 5,147.1 points. Eight of the Biotech Daily Top 40 stocks were up, 21 fell, seven traded unchanged and four were untraded.

Antisense was the best, up 0.1 cents or 8.3 percent to 1.3 cents, with 1,000,000 shares traded. Benitec and Prana climbed more than six percent; Neuren was up 4.35 percent; Atcor was up three percent; Resmed rose 2.65 percent; Cochlear, Ellex and IDT were up more than one percent; with Sirtex up 0.2 percent.

Yesterday's best, Medical Developments, led the falls, down 14 cents or 9.9 percent to $1.28 with 19,827 shares traded.

Patrys lost 7.1 percent; Psivida and Viralytics were down more than six percent; Avita, Clinuvel, Pharmaxis, QRX and Starpharma fell more than four percent; Anteo, Living Cell and Tissue Therapies were down more than three percent; Allied and Reva shed more than two percent; Acrux, Compumedics, Genetic Technologies, GI Dynamics, and Universal Biosensors fell more than one percent; with CSL and Mesoblast down by less than one percent.

CALZADA, POLYNOVO BIOMATERIALS

Calzada says its 10-patient trial of Novosorb biodegradable temporising matrix dermal scaffold for full thickness surgical wounds shows the product is safe and effective.

Calzada said the trial was conducted by its wholly-owned subsidiary Polynovo and was led by Royal Adelaide Hospital surgeon and principal investigator Prof John Greenwood.

The company said that the trial was designed to verify the safety and effectiveness of Novosorb biodegradable temporising matrix (BTM) in free flap donor sites, that is, deep full-thickness surgical wounds, by monitoring the patient and wound for any symptom or sign to suggest a reaction to the matrix.

Calzada said the secondary aim was to test the ability of the Novosorb BTM to be implanted into a controlled surgically created wound and create a new dermal tissue.

The company said the results were significant for BTM's potential use in applications, including deep second and third degree burns, surgical and trauma wounds and ulcers.

Calzada said that findings regarding the implantation process demonstrated the ease of material handling, implantation and fixation, progress of material integration into the wound, seal bond strength, identification of complete integration and timing for graft application and the ability of the integrated material to support skin graft application.

The company said that 12 months observations would determine final scar size or degree of contraction, functional and cosmetic outcome and patient satisfaction.

Calzada said that from a surgical perspective, implantation was straightforward and fixation rapid with surgical staples and in all cases, the matrix was well tolerated with no symptom or sign of adverse reaction.

The company said that in all cases, despite the depth and complexity of the free flap donor sites, the healed wound with a skin graft over the integrated matrix was flush with the surrounding skin, leaving no contour defect and allowed movement of underlying structures without impairment.

Calzada said that Novosorb BTM demonstrated efficiency of integration to allow successful skin grafting; was robust in the presence of infection; the quality of the free flap donor reconstruction was superior to current management with skin grafting alone; there was minimal wound contraction; demonstrated ability to resist infection and where infection occurred continued to integrate while the infection was being treated; and with minimal spontaneous seal delamination.

The company said the results showed that Novosorb had advantages over existing treatments and could be applied in deep surgical wounds, with results implying success in its designed burn wound management as well as in complex skin reconstructive surgery.

Calzada said that Novosorb had advantages over collagen-based implants, which were expensive and prone to infection due to their biological composition, often resulting in loss of the implant.

Polynovo chief executive officer Laurent Fossaert said the study was "a significant clinical outcome that demonstrates the safety and performance of a Novosorb implantable device for potential use in many deep wound and tissue repair applications".

Calzada said that Polynovo intended to submit a 510(k) pre-market approval submission to the US Food and Drug Administration by April 2014 for the Novosorb BTM dermal scaffold in surgical wound applications.

The company said Dr Greenwood had approval for a trial of five patients with significant burn injuries to begin by the end of 2013.

Calzada said a Paris-based clinical research organization would define the requirements for regulatory submissions in the US and Europe and planned a 10-patient burns trial to begin in France by April, 2014.

Calzada was up 0.4 cents or 5.3 percent to eight cents with 1.8 million shares traded.

## US GOVERNMENT

Most Australian biotechnology companies with exposure to the US report they have not been affected by the US Government shut-down, so far.

This week, Biotech Daily reported that Benitec could have its phase II trial of TT-034 for hepatitis C delayed by the Tea-Party-enforced Shut-Down of US Government spending impacting the US Food and Drug Administration (BD: Oct 8, 2013).

A large number of Australian biotechnology companies have ongoing interactions with US Government agencies including the FDA, the National Institutes of Health and the US Army including related hospitals and research organizations, as well as the US Biomedical Advanced Research and Development Authority (BARDA).

One US-based executive told Biotech Daily that the FDA was funded by its users and it had not been overly affected, but that might not be the case for companies receiving funding from the NIH or other agencies.

The executive said that US Army personnel were still working, but their travel allowances had been restricted.

Biotech Daily asked about 40 companies with US interactions two questions:

1. Has the US Government shut-down had a direct impact of any sort on your company to date (i.e. has Barda/NIH/Army said halt a program - or has the FDA been unavailable)?
2. Can you envisage an impact of the shut-down on your company in the near future?

At the time of publication 10 companies replied “no and no”.

Psivida director Brian Leedman said his company had an FDA Prescription Drug User Fee Act (PDUFA) date of October 16 and there had been no indication of a change.

QRX chief executive officer Dr John Holaday told Biotech Daily that in his meeting with the FDA, “they confirmed that companies in review that have submitted their [new drug application] and paid their PDUFA fees will continue business as usual”.

Dr Holaday said that “if the shut-down continues for several weeks, these monies may be depleted … [and] in the meantime, they are not accepting any new NDAs until the shut down is over”.

Dr Holaday said that QRX was safe “for the near future”.

A Sydney chief executive officer told Biotech Daily “our US contacts are without email because of the shut down so we don't know the impact because we can't get in contact with them”.

“Some meetings set up outside the US with US NIH participants could be affected but, because of the contact difficulty, we don't know,” the executive said.

Biotech Daily understands that Biota bills BARDA on a monthly basis for its research, but Biota executives had not responded to the questions at the time of publication.

BARDA is part of the US Department of Health and Human Services.

One US-based executive noted that although his company had “zero impact” and he did not expect any impact in the future, unless the shutdown lingers for an extended period of time.

“However, if that happens we all have much larger issues than at a company-level,” the executive said.

## THE BURNET INSTITUTE

Last night’s edition reported The Burnet Institute’s wholly-owned subsidiary Hepseevax Pty Ltd hoping to raise $1.5 million for a phase I trial for its Delta3 hepatitis C vaccine.

Subsequently, the Burnet Institute has told Biotech Daily that it hopes to raise $3 million to $5 million to take Delta3 through to the end of the phase I clinical trial (BD: Oct 9, 2013).

## THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that Prof David Tarlinton has won the $US1 million ($A1.1 million) Lupus Research Institute distinguished innovator award.

The Institute said the four year funding would be used to investigate the immune cells at the root of lupus to further investigate the causes and develop new treatment approaches.

WEHI said that lupus was a potentially fatal autoimmune disease in which the body's immune system attacked itself, damaging tissues including kidneys, heart, skin, joints, blood vessels and lungs, affected more than 17,000 Australians, mostly women.

Prof Tarlinton said it was a great honor to receive the award and he could "expand enormously on our work into how lupus develops".

"Many symptoms of lupus are caused by abnormalities in antibody production, both the nature of the antibodies and amount that is made," Prof Tarlinton said.

"Antibodies are produced by specialized immune cells called plasma cells and normally these antibodies detect and remove foreign objects such as bacteria and viruses," Prof Tarlinton said. "In people with lupus, the production of plasma cells can go awry and they produce antibodies, known as auto-antibodies, which recognize the body's own tissues as foreign and attack and destroy them."

Prof Tarlinton said that the Lyn protein played an important role in plasma cell survival and if Lyn was not functioning properly, more plasma cells making harmful antibodies lived longer than they should, and lupus-like symptoms developed.

"By determining how Lyn is involved in plasma cell survival signaling, we aim to develop treatments that inhibit or reverse this build-up of plasma cells and thus either prevent the disease from developing or diminish the severity of established disease," Prof Tarlinton said.

## NANOSONICS

Nanosonics says a study of 306 vaginal ultrasound probes has shown its Trophon EPR is superior in safety and risk mitigation that manual disinfection with glutaraldehyde.

Nanosonics said that the conventional process did not disinfect the handle which was a potential vector for bacterial cross-contamination and 79.5 percent of 78 ultrasound probe handles showed signs of contamination following disinfection with glutaraldehyde.

Nanosonics chief financial officer McGregor Grant said the study investigated 75 probes treated with the Trophon EPR and 153 control samples.

The company said that the contaminants included Staphylococcus aureus from wound infections Staphylococcus saprophyticus from urinary tract infections and methicillin-resistant Staphylococcus aureus.

"None of these organisms were identified post processing with Trophon EPR," Nanosonics said.

The company said the study was conducted by the past president of the Australasian Society for Ultrasound in Medicine Dr Glenn McNally and the president of the International Society of Ultrasound in Obstetrics and Gynaecology Dr Andrew Ngu, with AMS Laboratories performing microbiological testing.

The company said that the study showed a key shortcoming of standard ultrasound probe disinfection methodology involving bulk-liquid disinfectants as manufacturer advice prevents the probe from being fully submerged, but its Trophon EPR encased and disinfected the entire probe, including the handle.

Nanosonics said that the study called for stricter disinfection standards requiring high-level disinfection of the whole probe, handle included.

Nanosonics was unchanged at 76 cents.

## NANOSONICS

Nanosonics will vote to issue up to $900,000 in performance rights over three years to chief executive officer Michael Kavanagh and head of development Dr Ron Weinberger.
Nanosonics said that with shareholder support at the annual general meeting, and pending hurdles, Mr Kavanagh could receive a short-term incentive of up to $200,000 a year, for three years, with half in cash and half in performance rights, exercisable at no cost for shares.
The company said Dr Weinberger could receive up to $100,000 a year on the same terms.
Nanosonics said that for 2013-'14, Mr Kavanagh's fixed remuneration was $427,775 and his maximum allowable short-term incentive would be a maximum of $136,530.
The company said that resolutions included the issue of 1,500,000 performance rights to Mr Kavanagh as a long-term incentive, with 134,818 long-term incentive performance rights for Dr Weinberger, as well as the approval of termination pay for Mr Kavanagh, chief financial officer McGregor Grant and chief operating officer Gerard Putt.
The company said it would also seek approval for the re-election of directors Maurice Stang and Dr Weinberger; the remuneration report; two share plans and two option plans.
The meeting will be held at the Marriott Hotel, 30 Pitt Street, Sydney on November 8, 2013 at 11am (AEDT).

## VICTORIA GOVERNMENT, SMALL TECHNOLOGIES CLUSTER

The Small Technologies Cluster says the Technology Implementation Voucher and 'Medtech's Got Talent' program applications close on October 22, 2013.
The Victorian Government voucher program provides up to $250,000 in competitive rounds and supports innovative projects.
The Cluster said that the Voucher program was open to Victorian businesses, requiring 25 percent matching funds and equal matching funds from non-Victorian businesses to work with a Victorian supplier to undertake commercial feasibility, test applications in new markets, undertake pilot scale trials or carry out applied development and testing of technologies that can improve productivity and/or profitability.
More information is at: http://business.vic.gov.au/tvp.
The Cluster said that 'Medtech's Got Talent' was an entrepreneurship support program for Victorian students, post-doctoral students and recent graduates to pitch new business or product concepts for one of five $20,000 awards and entry into a three-month technology program.
The Cluster said that the program was to support medical technology supported by enabling technology.
More details are at: http://www.stcaustralia.org/entrepreneur-challenge.

## GENETIC TECHNOLOGIES

A trial date for Genetic Technologies founder and major shareholder Dr Mervyn Jacobson is expected to be set when he returns to Victoria's Supreme Court on February 7, 2014.
The Commonwealth Director of Public Prosecutions has charged Dr Jacobson with 39 counts of market manipulation and two charges of conspiring to commit a Commonwealth offence, namely market manipulation (BD: Nov 27, 2012; Jun 28, 2013).
An officer of the Supreme Court told Biotech Daily that a procedural hearing yesterday set a further date of February 7, 2014.

## THE TRANSLATIONAL RESEARCH INSTITUTE

The Translational Research Institute was officially opened today by the Governor-General Quentin Bryce.

The Brisbane-based Translational Research Institute said it was “one of only a few facilities in the world to research, trial and manufacture breakthrough treatments” in one location.

The Institute said it brought together four leading research institutes and a co-located manufacturer to discover and develop new therapies and vaccines, including the University of Queensland’s Diamantina Institute and School of Medicine, Queensland University of Technology’s Institute of Health and Biomedical Innovation, Mater Research, the Princess Alexandra Hospital’s Centres for Health Research and DSM Biologics.

The Institute said it was supported by the Federal and State Governments, Atlantic Philanthropies, Queensland University of Technology and the University of Queensland.

The institute said it would be led by chief executive officer and director of research Prof Ian Frazer and focus on discovering therapies and vaccines to prevent and treat common and serious illnesses, including breast, prostate, blood, head and neck and skin cancers; diabetes and obesity; infectious diseases such as HIV and malaria, and bone and joint diseases such as rheumatoid arthritis.

## ACUVAX

Acuvax says that Dr Anton Uvarov has been appointed as a non-executive director replacing Alistair Jobling, effective from today.

Acuvax said that Dr Uvarov was a healthcare analyst with RM Research and previously was a healthcare research analyst with Citigroup Investment Research in New York.

The company said that at Citigroup Dr Uvarov was responsible for the coverage of small and mid-capitalization biotechnology stocks and the vetting of companies for the investment banking division.

Acuvax said that Dr Uvarov had a knowledge of the healthcare industry including intellectual property, US and European regulations, reimbursement coverage and clinical science.

The company said that prior to Citigroup, Dr Uvarov worked for the Calgary, Alberta, Canada-based Smart Technologies as a strategy analyst.

Dr Uvarov told Biotech Daily that his undergraduate degree from Moscow State University was a five year Specialist Degree in Biochemistry and Molecular Biology.

Acuvax said that Dr Uvarov held a Doctorate of Philosophy from the University of Manitoba and a Master of Business Administration from the University of Calgary.

The company said that Dr Uvarov had co-authored several peer reviewed publications on the mechanisms of intracellular protein degradation and its role in cancer and cardiovascular diseases.

Acuvax is suspended and last traded at 0.1 cents.