# Biotech Daily

Tuesday November 8, 2011

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: STARPHARMA UP 8%; ANTISENSE DOWN 10%**

*** 12 OF 15 SUNSHINE HEART CARDIAC PATIENTS IMPROVE**

*** WEHI MALARIA VACCINE WINS $1m GATES FOUNDATION GRANT**

*** FDA ACCEPTS QRX APPLICATION; LIKELY PDUFA DATE SET**

*** US ATCC TO EVALUATE BLUECHIIP TRACKING DEVICE**

*** US FORMULATION PATENT FOR CLINUVEL MELANIN-ACTIVATING DRUG**

*** UNIVERSAL BIOSENSORS, LIFESCAN ONE TOUCH VERIO IN CANADA**

*** TROUBLE AT USCOM MILL; AGM ADJOURNED; CHAIRMAN ATTACK**

*** CBIO DIRECTORS 'REVIEW' RESIGNATION THREAT AND STAY**

*** CRYOSITE AGM DEFEATS REMUNERATION, CHAIR THEO ONISFOROU**

*** LANDON CLAY, EAST HILL TAKE 10% OF BIOTA**

*** DR CHERRELL HIRST REPLACES MEL BRIDGES AS IMPEDIMED CHAIR**

*** VIRALYTICS APPOINTS PROF JEFFREY WEISBERG TO SCIENTIFIC BOARD**

## MARKET REPORT

The Australian stock market climbed 0.48 percent on Tuesday November 8, 2011 with the S&P ASX 200 up 20.4 points to 4293.8 points. Ten Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and five were untraded. All three Big Caps were up.

Starpharma was the best, up eight cents or 7.6 percent to $1.135 with 449,831 shares traded. Prana climbed 6.7 percent; Prima was up 5.9 percent; Neuren was up 3.7 percent; Allied Health rose 2.8 percent; Acrux, Anteo and QRX were up more than one percent; with Biota, Cochlear, CSL, Mesoblast and Resmed up by less than one percent.

Antisense led the falls, down 0.1 cents or 10 percent to 0.9 cents, with 4.2 million shares traded. Cathrx lost 9.1 percent; Patrys was down 7.4 percent; Optiscan was down 6.25 percent; Avita fell 4.55 percent; Alchemia, Phylogica and Viralytics were down more than three percent; Pharmaxis, Phosphagenics and Nanosonics shed more than two percent; with Bionomics, Clinuvel, Impedimed, Psivida and Sirtex down more than one percent.

## SUNSHINE HEART

Sunshine Heart says that of 15 patients receiving its C-Pulse aorta cuff pump and reviewed at six months, 12 improved, with five reaching ‘class I’ status.

In September, Sunshine Heart provided ‘top-line’ results from the 20-patient pilot trial of its C-Pulse aorta cuff pump (BD: Sep 22, 27, 2011).

Today, the company presented the detailed results at the Transcatheter Cardiovascular Therapeutics Conference in San Francisco.

Sunshine Heart principal investigator and Ohio Medical Centre’s director of cardiovascular medicine Dr William Abraham presented the data, which showed that of 14 patients in New York Heart Association class III heart failure, four improved to class I, seven improved to class II and three remained in class III.

Dr Abraham told an investor presentation in Melbourne in September that remaining in the same New York Heart Association classification was a positive for the patients, whose health normally would continue to deteriorate.

Dr Abraham told the conference that the one patient with class IV heart failure improved to class II at six months and was assessed as class I at 12 months.

Sunshine Heart said that of the five patients not assessed at six months, three patients died of non-device related issues, one received a transplant and one had a left ventricular assist device implanted.

Dr Abraham said that two ‘super-responder’ patients were permanently discontinued from therapy dues to improvement, with two more patients who had improved to class I “likely to be permanently discontinued”.

Dr Abraham said 11 patients had their diuretic drug doses reduced or discontinued and all inotrope-dependent patients had their inotropic drugs, for cardiac muscular contraction force, discontinued.

A Sunshine Heart spokesperson told Biotech Daily that despite the small numbers in the trial, there was a clear trend demonstrating efficacy.

In a media release the company said that after six months follow-up, its C–Pulse therapy produced statistically significant improvements in New York Heart Association (NYHA) class reduction (3.1 ± 0.3 to 2.2 ± 0.8, p = 0.0001); quality of life (64 ± 17 to 49 ± 26, p = 0.001) and left ventricular ejection fraction (28 ± 5 to 31 ± 7, p = 0.04) which measured cardiac pumping ability.

Sunshine Heart said that primary safety measurements included device related death, neurological dysfunction including strokes, aortic disruption, myocardial infarction or heart attack, major infection and any other device-related serious adverse event through six months.

The company said that one patient died from complications of mediastinitis which was related to a sternal wound infection resulting from the sternotomy at implant, but there were no strokes, heart attacks or device related bleeding events.

Sunshine Heart chief executive officer Dave Rosa said the feasibility trial showed that the C-Pulse device had “the potential to help the millions of moderate to severe heart failure patients who have limited, if any, therapeutic interventions available to them”.

“With this important milestone behind us, we will look to work with the FDA to gain permission to initiate a pivotal trial in the US next year,” Mr Rosa said.

Sunshine Heart was unchanged at four cents.

## WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says a project to develop the first carbohydrate-based malaria vaccine has won a $1 million Bill and Melinda Gates Foundation grant.

The Institute said that the vaccine, developed by Prof Louis Schofield targeted an essential Plasmodium parasite carbohydrate, glycolsylphosphatidylinositol (GPI).

The Institute said that GPI was also a toxin produced by the Plasmodium parasite that had been identified as a major determinant in the severity and fatality of disease.

Prof Schofield said the $US1 million grant would allow the team to advance development and preclinical trials to test the ability of the vaccine to interrupt transmission of the parasite, and decrease the severity of the disease.

“The anti-GPI vaccine is novel in that it is the first potential anti-malarial vaccine that targets a parasite carbohydrate, rather than a protein,” Prof Schofield said.

“Malaria parasites invest considerable effort in evading the immune system, continuously modifying its proteins to avoid detection, which is why a malaria vaccine has continued to be elusive,” Prof Schofield said. “A vaccine that targets a highly conserved carbohydrate target could be especially effective in treating malaria.”

Prof Schofield said that a vaccine with anti-toxic properties could also be a highly effective public health tool.

“Vaccines against pathogen-derived toxins have been successful against tetanus, diptheria and pertussis [whooping cough], but have not been developed for treating malaria,” Prof Schofield said.

“The use of a vaccine with anti-toxin properties could help to diminish the disease burden in countries where malaria is endemic, particularly if used in combination with other prevention and treatment strategies.”

Prof Schofield said the $US1 million phase II followed a one-year I funding project also supported by the Gates Foundation’s Grand Challenges Explorations program.

The Institute said Grand Challenges Explorations enabled researchers to test unorthodox ideas that address persistent health and development challenges.

## QRX PHARMA

QRX says the US Food and Drug Administration has accepted for formal review, its new drug application for Moxduo immediate release (IR).

QRX said the FDA set June 25, 2012 as the Prescription Drug User Fee Act (PDUFA) target date for a decision on the approval of Moxduo IR.

QRX chief executive officer Dr John Holaday said the company was “extremely pleased with this important milestone from the FDA and, subject to approval, making plans to launch Moxduo IR in the second half of 2012 for the treatment [for] moderate to severe acute pain”.

QRX said the FDA had completed its filing review of the Moxduo IR application submitted on August 24, 2011 and determined the application was sufficiently complete to permit a substantive review.

QRX said the FDA notification included useful technical information on chemistry, manufacturing and controls (CMC), as well as the pediatric program to be conducted after drug approval that would enable further marketing exclusivity.

The application was submitted under 505(b)(2) regulations in which approval for a new drug could be expedited by citing historical published evidence supporting each of Moxduo’s already approved components to supplement the data derived from its development program.

QRX was up three cents or 1.9 percent to $1.63.

## BLUECHIIP

Bluechiip says it has signed an evaluation agreement with the Manassas, Virginia-based ATCC to evaluate its tracking technology.
Bluechiip said the ATCC, formerly known as the American Type Culture Collection, “was established in 1925 when a committee of scientists recognized a need for a central collection of microorganisms that would serve scientists all over the world”.
The company said the agreement allowed ATCC to evaluate its tracking technology and following the evaluation and trial period ATCC could exercise an option to deploy the technology in its cold-storage logistics workflow.
Bluechiip said ATCC stored about 10 million biological samples of different forms, with a repository containing 200 freezers to store biomaterials, including vapor-phase liquid nitrogen freezers, mechanical freezers and cold rooms.
Bluechiip said it expected the evaluation and pilot trial would verify that the tracking technology could enhance ATCC’s bio-specimen management.
The company said the technology enabled data to be read at temperatures as low as those reached in liquid nitrogen, about minus 196 degrees Celsius and enabled data to be transmitted through frost.
Bluechiip chief executive officer Brett Schwartz said the “robustness of our technology provides significant advantages over traditional identification or tracking solutions”.
Bluechiip was untraded at 11.5 cents.

## CLINUVEL PHARMACEUTICALS

Clinuvel says the US Patent and Trademark Office has granted “pivotal patent protection for the delivery of melanocortins as photoprotective agents in transdermal formulations”.
Clinuvel said it had two melanocortin drugs in development, afamelanotide or Scenesse and CUV9900, both of which were analogues of the naturally occurring hormone alpha-melanocyte stimulating hormone (alpha-MSH).
The company said that US patent (number 20110263508) entitled ‘Compositions and methods for including melanogenesis in a subject’granted exclusive rights for compositions of alpha-MSH analogues and transdermal delivery systems and methods of inducing melanogenesis by topical administration.
Clinuvel chief scientific officer Dr Hank Agersborg said the patent was “a long time coming but our program has demonstrated the importance of melanocortins in inducing melanogenesis and thus protecting skin”.
“This patent will allow the company a further extension of the use of afamelanotide and CUV9900 in non-invasive formulations,” Dr Agersborg said.
Clinuvel fell two cents or 1.3 percent to $1.48.

## UNIVERSAL BIOSENSORS

Universal Biosensors says Johnson & Johnson’s Lifescan has begun marketing and promotional activities for its One Touch Verio glucose test in Canada.
Universal Biosensors said the system incorporated its disposable glucose test strips specifically designed and manufactured for Lifescan.
Universal Biosensors chief executive officer Paul Wright said that following the regulatory approvals of the One Touch Verio in North America, “it is very rewarding to see the continued global roll-out of [the] technology by Lifescan”.
The company manufactures the test strips in its Rowville, Melbourne facility.
Universal Biosensors was unchanged at 90 cents.

## USCOM

Uscom's annual general meeting has been adjourned, with a threat of internal legal action and the chairman's address attacking founder and former chairman Rob Phillips.
Uscom told the ASX that "allegations from investors … may lead to legal proceedings"
The company said that if Mr Phillips voted for the removal of executive chairman Philip Kiely and director Jochen Bonitz and they were removed investors supporting the two "would take legal action against the company to recover funds previously subscribed".
The only resolutions to the meeting were the election of Mr Kiely, Mr Bonitz, Mr Phillips and the remuneration report.
Last year Uscom said Mr Kiely would be appointed executive chairman on the finalization of a $3 million capital raising and Mr Phillips would stand down as chairman to be the director of medical services (BD: Dec 4, 2010; Jan 16 2011).
Part of the placement was to Mr Kiely and at that time Mr Phillips owned about 40 percent of the company but has been diluted to about 33 percent.
Uscom said the annual general meeting had been adjourned to November 22, 2011.
In an unusual chairman's address, Mr Kiely said the company previously did not have a commercialization strategy and the "previous state of play" included "no accountability, global travel, uncontrolled expenses, no strategic plan, no tactical implementation, sales team compromised [and] lip service to changes being established".
The address said the new board and new chief executive officer Joe Tryger were among a range of measures that were the "key to future success".
Uscom was untraded at 14.5 cents.

## CBIO

In a media release to the ASX entitled 'CBio Addresses Shareholder Feedback' chairman Dr Michael Monsour said the five continuing directors withdrew their resignation threat.
Prior to last week's general meeting, then chairman Stephen Jones said that all existing directors would resign if any one of three shareholder action group proposed directors was elected (BD: Nov 4, 2011).
The action group wanted Mr Jones, Prof John Funder and James Greig removed and all resigned prior to the vote, with the three proposed directors elected, overwhelmingly.
The new board appointed two more directors and there was no mention of resignations.
After the market closed last night, CBio said Dr Monsour Dr Goran Ando, Dr Peter Corr, Dr Thomas Lonngren and Dr Terje Kalland had reconsidered their positions and would continue as directors.
Dr Monsour said that CBio was left with no management and "due to this tenuous situation, each individual director reviewed their respective positions in the context of the lack of management resources in the company".
"A big priority in the success of CBio and XToll is continuity in corporate knowledge and leadership," Dr Monsour said.
"This is especially important with the relationships built up over time with Novo Nordisk and other prospective CBio licence partners," Dr Monsour said.
"At this crucial point in the company's history where we are following the strategy agreed with shareholders and seeking to realise value by concluding a commercial transaction for XToll, in light of these resignations to leave the company would have been irresponsible and in neglect of obligations," Dr Monsour said.
"Each director named above took the view that their obligations to shareholders were best met by continuing to serve on the board for at least the immediate term," Dr Monsour said.
CBio was up half a cent or 2.2 percent to 23 cents.

## CRYOSITE

Cryosite says shareholders defeated both the remuneration report and the re-election of director Theo Onisforou with more than nine million votes against both resolutions.
Cryosite said the poll of votes showed 3,851,880 proxy votes in favor of the reelection of Mr Onisforou with 9,299,881 proxy votes against.
The cord blood storage company's remuneration report was supported by 2,269,701 proxy votes, with 9,423,809 votes against.
Cryosite said Mr Onisforou had been appointed a director to fill a casual vacancy.
Cryosite was up two cents or 19.05 percent to 12.5 cents.

## BIOTA HOLDINGS

Landon Clay, East Hill Holding Co and associates have increased their substantial shareholding in Biota from 16,782,735 shares (9.23%) to 18,625,357 shares (10.25%).
East Hill said the shares were bought at prices between 76 and 84 US cents between October 4 and November 7, 2011.
Biota was up half a cent or 0.7 percent to 76.5 cents.

## IMPEDIMED

Impedimed says Dr Cherrell Hirst will replace Mel Bridges as chairman at today's annual general meeting.
Impedimed said Mr Bridges would continue as a non-executive director.
The company said Mr Bridges was the founding chairman since the company's inception in September 1999.
Impedimed said Dr Hirst, a medical doctor and practitioner in breast cancer diagnosis, had been a non-executive director since 2005 and had served as deputy chairman.
Dr Hirst is also the deputy chair and chief executive officer of QIC Bioventures and is on other commercial boards including Medibank Private.
Impedimed fell one cent or 1.5 percent to 64 cents.

## VIRALYTICS

Viralytics says it has appointed Prof Jeffrey Weisberg to its scientific advisory board.
The company said Prof Weisberg was the head of therapeutic oncology for the Americas for drug development services company Pharmanet-i3 and was a p at the Florida-based Nova Southeastern University's College of Osteopathic Medicine.
Viralytics said Dr Weisberg had been with the company for two years and played a significant role in Viralytics obtaining US Food and Drug Administration allowance for its investigational new drug application for its Cavatak phase II melanoma trial.
The company said Prof Weisberg graduated from the Kansas City University of Medicine and Biosciences and completed a fellowship in haematology at Maimonides Medical Center in Brooklyn, New York.
Viralytics said Prof Weisberg was a medical director for Pfizer and had been involved in scores of clinical trials, serving as an investigator, lead and medical monitor.
Viralytics fell 1.5 cents or 3.3 percent to 43.5 cents.