



# Biotech Daily

Friday October 28, 2011

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: OPTISCAN UP 25%; MESOBLAST DOWN 10%**
- \* **BENITEC'S PAIN DRUG REDUCES MORPHINE TOLERANCE IN RATS**
- \* **MESOBLAST PLEADS SCHULTZ TO ASX 19% FALL QUERY**
- \* **CBIO'S XTOLL PREVENTS CUTANEOUS LUPUS IN MICE; TRADING HALT**
- \* **MRCF INVESTS \$500k IN VERA**
- \* **NOVOGEN'S MARSHALL EDWARDS LICENCES EQUOL TO AUSIO**
- \* **HEARTWARE Q3 REVENUE UP 54%; CFO DAVID MCINTYRE TO RETIRE**
- \* **CONSEGNA: VIBROVEIN SHOWS PROOF-OF-CONCEPT**
- \* **ALLIED AGM TO CONFIRM PLACEMENTS, ELECT DIRECTORS**
- \* **DIRECTORS FIGHT LOOMS AT NUSEP AGM**

## MARKET REPORT

The Australian stock market edged up 0.12 percent on Friday October 28, 2011, with the S&P ASX 200 up 5.1 points to 4,353.3 points. Twenty-one of the Biotech Daily Top 40 stocks were up, nine fell, four traded unchanged and six were untraded.

Optiscan was the best, up 1.5 cents or 25 percent to 7.5 cents with 150,000 shares traded, followed by Benitec up 11.1 percent to two cents with nine million shares traded and Impedimed up 11 percent to 55.5 cents with 23,459 shares traded.

Allied climbed 8.3 percent; Genera and QRX were up more than seven percent; Phosphagenics was up 5.6 percent; Heartware was up 4.2 percent; Genetic Technologies, Pharmaxis, Phylogica, Prana, Tissue Therapies and Uscom were up more than three percent; Circadian and Resmed rose more than two percent; with Acrux, Anteo, Biota, Psivida, Sirtex and Starpharma up more than one percent.

Mesoblast led the falls, down 95 cents or 10.1 percent to \$8.45 with 2.6 million shares traded.

Living Cell lost 9.2 percent; Prima fell five percent; CSL, Viralytics and Universal Biosensors shed more than two percent; with Alchemia, Bionomics, Nanosonics and Reva down by more than one percent.

## BENITEC

Benitec says that independent researchers have shown that, in addition to reducing pain, its gene silencing technology significantly reduces morphine tolerance in a rat model.

Benitec said that morphine was among the most prescribed opioid pain relievers for severe and chronic pain, but despite its prevalence, tolerance to morphine and its side effects were a major clinical side effect and roadblock to its chronic use.

The company said that tolerance was the progressive decline in the effectiveness of morphine that arose with continued use and resulted in the need to increase the dose to achieve the same level of pain relief.

Benitec said that continually increasing the dose resulted in well-known side effects of nausea, vomiting, constipation, abdominal pain and respiratory depression, limiting morphine use and compromising pain management.

Benitec said that China-based researchers using its technology demonstrated successful reduction of morphine tolerance using the same ddRNAi construct that they showed to be effective in overcoming neuropathic pain in the pre-clinical rat model.

The research, entitled 'Gene knockdown with lentiviral vector-mediated intrathecal RNA interference of protein kinase C gamma reverses chronic morphine tolerance in rats' was published in the Journal of Gene Medicine in 2010 and an abstract is available at:

<http://onlinelibrary.wiley.com/doi/10.1002/jgm.1514/full>.

Benitec said the discovery had the potential to significantly extend the market for the same construct used by Benitec in its pain program directed to silencing a key gene involved in neuropathic pain.

The company said this would allow continued use of morphine as part of a more complete pain management program and at the same time the potential of this multi-benefit approach could open a faster regulatory pathway and a broadened base for the commercialization of Benitec's pain technology.

Benitec's chief executive officer Dr Peter French said the result was "further support for Benitec's focus on developing our technology as a new class of molecule for chronic pain relief".

"From a single injection, this approach has the potential to achieve long term pain relief and be a transformational approach to the field," Dr French said.

"The attractions of this double headed approach, regulatory advantages and heightened commercial value are very exciting," Dr French said.

Benitec said it would meet the China-based researchers in Changsha in early November 2011 to explore a collaboration on the development of this exciting product.

Benitec was up 0.2 cents or 11.1 percent to two cents with nine million shares traded.

## MESOBLAST

Mesoblast has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price fell from \$9.70 on October 27, 2011 to \$7.90 during trading today, an 18.6 percent fall and noted an increase in trading volume.

Mesoblast fell as low as \$7.67 between 1.04pm and 1.08pm today.

On Wednesday October 26, 2011 Macquarie Private Wealth published a research note recommending a target price of \$5.80.

The note is at odds with other research notes from Lodge Partners (\$11.75), Bell Potter (\$16.00) and Nomura (\$10.15).

Mesoblast said its clinical and commercial programs remained on-track.

Mesoblast closed down 95 cents or 10.1 percent to \$8.45 with 2.6 million shares traded.

## CBIO

CBio says a mouse trial of XToll entirely prevented cutaneous lupus and significantly suppressed nephritis in kidneys and significantly prolonged life span.

CBio said the study, entitled 'Recombinant chaperonin10 suppresses cutaneous lupus and lupus nephritis in MRL-(Fas)lpr mice' also showed that XToll reduced the levels of pro-inflammatory cytokines such as IL-6 and TNF-alpha, a finding consistent with data from the company's phase IIa rheumatoid arthritis clinical trial.

The study was published in Nephrology Dialysis Transplantation and an abstract is at: <http://ndt.oxfordjournals.org/content/early/2011/10/10/ndt.gfr544.short?rss=1>.

CBio said that in humans, nephritis in the kidneys was a major cause of mortality and shortened life span of patients with lupus.

The company said the research indicated that in addition to rheumatoid arthritis, XToll could have utility in the treatment of human lupus, either alone or as part of a drug combination therapy.

CBio said the lupus market was estimated to be worth \$2.5 billion a year by 2017.

CBio chairman Stephen Jones said the data was corroboration for developing XToll.

Separately CBio requested a trading halt until November 1, 2011 for a capital raising.

CBio last traded at 20 cents.

## VERVA PHARMACEUTICALS, MEDICAL RESEARCH COMMERCIALISATION FUND

Verva says the Medical Research Commercialisation Fund has invested \$500,000 in the company.

The Medical Research Commercialisation Fund (MRCF) is managed by Brandon Capital Partners and in June received \$20 million from the Federal Government's Innovation Investment Fund (BD: Jun 9, 2011).

Verva said the financing was an extension of the \$2 million approved by shareholders at its annual general meeting in April 2011.

Verva said the Fund would be issued dividend-bearing Class A preference shares with associated redemption rights and liquidation preferences.

Verva chief executive officer Vince Wachter said the additional financing would "significantly advance the identification of Verva's next-generation diabetes medicines".

"The addition of MRCF to Verva's shareholder register provides additional validation of our portfolio of assets," Mr Wachter said.

Medical Research Commercialisation Fund principal executive Dr Chris Nave said that Verva was developing "an extremely promising new therapy for the management of type 2 diabetes and provides another great example of the world class medical research being conducted by MRCF members".

"It is particularly pleasing that this technology, developed within the laboratories of the Institute of Biotechnology ... at Deakin University in Victoria, has been able to progress through early stage development and testing, to now be in a significant study in patients also in Victoria," Dr Nave said.

Verva said the funds would be invested in two milestone-based tranches to advance the discovery and preclinical development of novel diabetes therapies, known as VVP100X in partnership with the Metabolic Research Unit of Deakin University.

Verva said it was developing therapies to treat diabetes and to prevent and treat obesity.

The company said that its lead product VVP808 was a non-thiazolidinedione, non-PPAR-modulating insulin sensitizer in phase IIa clinical proof-of-concept testing in type 2 diabetes.

Verva is a public unlisted company.

## NOVOGEN

Novogen's 57 percent subsidiary Marshall Edwards has licenced the isoflavone metabolite known as equol for non-oncology applications to Ausio Pharmaceuticals.

Novogen said that the licence covered the development, manufacture and sale of products to Ausio in exchange for royalty payments on sales of any potential Ausio products that contain equol.

The company said the agreement gave Marshall Edwards a royalty-free licence to certain issued manufacturing-related intellectual property owned by Ausio.

Novogen said that detailed terms of the agreement were not disclosed.

Marshall Edwards chief executive officer Dr Daniel Gold the licencing agreement with Ausio was "our first since completing the acquisition of our isoflavone-based intellectual property portfolio [from Novogen] earlier this year".

"This agreement demonstrates our commitment to maximizing the value of these assets while maintaining our focus on the clinical development of our two current lead oncology drug candidates, ME-143 and ME-344," Dr Gold said.

Ausio chief executive officer Dr Richard Jackson said the licence to Marshall Edward's patents claiming the composition and therapeutic uses of equol "further strengthens our global patent portfolio for S and R-equol".

"S-equol, the S enantiomer of equol, is a first-in-class, non-hormonal, non-steroidal estrogen receptor beta agonist that is in phase II clinical development for the treatment of vasomotor symptoms in postmenopausal women and benign prostatic hyperplasia in men, and for various topical uses," Dr Jackson said.

Novogen said that Ausio was a private biotechnology development company focused on the advancement of safe and effective medicines for the aging population, was founded in 2006 by Dr Jackson and was based on technologies licensed from the Australian Health and Nutrition Association and Cincinnati Children's Hospital Medical Center and had "a strong patent position for its lead compound, AUS 131 also referred to as S-equol".

Novogen was up half a cent or 4.2 cents to 12.5 cents.

## HEARTWARE

Heartware says that in the three months to September 30, 2011 revenue was up 54 percent to \$21.3 million primarily from reimbursement for its ventricular assist device.

Separately Heartware announced that chief financial officer and chief operating officer David McIntyre would relocate with his family to Australia for personal reasons and would be replaced by the company's finance vice president Lauren Farrell.

The company said that Mr McIntyre would continue with his responsibilities for the remainder of this year and would be available throughout 2012 to assist with Australian operations and investor relations as needed.

Heartware chief executive officer Doug Godshall said that Mr McIntyre "played a key role in the growth of Heartware and his leadership has helped successfully position the company for expanded global commercialization of our devices".

"For more than five years Lauren Farrell ... has played an essential role in the management of the finance function and more broadly in ensuring the integrity of our financial analysis and reporting," Mr Godshall said.

Heartware was up seven cents or 4.2 percent to \$1.75.

### CONSEGNA GROUP (FORMERLY HELICON GROUP)

Consegna says that Invetech has completed a series of independent tests confirming a proof-of-concept that its Vibrovein technology reduces needle force by 60 percent. Consegna said the Invetech testing “clearly demonstrated that Vibrovein was able to produce up to a 60 percent reduction in the force required to cause a hypodermic needle to penetrate a membrane representative of human skin.

The company said that Vibrovein was a small vibrating device that attached to the barrel of any syringe to reduce penetration resistance and thereby reduce pain and tissue distortion and increase needle efficiency and patient comfort.

Consegna said it expected Vibrovein would be used in a wide variety of applications including paediatric vaccinations, blood-banking, insulin injections, cosmetic procedures and wherever a more comfortable patient experience is desired.

Consegna chief executive officer Fabio Pannuti said that Vibrovein resulted in a substantial reduction of the force required to cause a hypodermic needle to penetrate the skin in medical procedures.

“We now have now clear quantitative data to confirm the clinical observations,” Mr Pannuti said.

“The data from the Invetech study is consistent with earlier penetration forces studies conducted in the UK and provides Consegna with important information to assist the company in its licencing efforts and is the subject of a patent filing,” Mr Pannuti said.

“A further series of tests are now planned to correlate this important characteristic with a reduction in the pain produced during hypodermic-based procedures,” Mr Pannuti said.

Consegna or Helicon fell 0.1 cents or five percent to 1.9 cents.

### ALLIED HEALTHCARE GROUP

Allied Health says shareholders will vote to ratify prior placements, confirm earlier option issues and elect directors, including Avexa director and Bell Potter executive Jet Soedirdja.

Allied's notice of annual general meeting asked shareholders to ratify the Bell Potter placement of 38,478,571 shares at 2.8 cents a share to raise \$1,077,400, along with a private placement of 27,180,000 shares at the same price to “professional and sophisticated investors”.

Allied asked shareholders for approval to place 3,500,000 shares at 2.8 cents a share with director Robert Towner-related Mandolin Pty Ltd, 7,500,000 shares to Avexa, 1,964,286 shares to Graeme Rowley and 6,000,000 free options to Bell Potter for arranging the placement, exercisable at six cents by October 20, 2014.

The company asked shareholders to ratify the issue of 5,611,765 shares to Kodiak Capital, along with the 43,200,000 Biomed options and 8,500,000 transaction options. Earlier this month, Allied was notified by ASX Compliance that it breached the Listing Rules in relation to the issuance of options outside the time period prescribed by the ASX Listing Rules along with the late lodgment of Appendix 3Y change of directors interests notices and required a new vote (BD: Oct 19, 2011).

Allied did not allow retail shareholders to participate in the 2.8 cents a share raising.

Allied shareholders will also vote on the election of directors, including chief executive officer Lee Rodne, Christopher Catlow, Graeme Rowley, Handojo (Jet) Soerdirdja and Mr Towner.

The meeting will be held in the Wattle Room, Ambassador Hotel, 196 Adelaide terrace, Perth on November 29, 2011 at 10.30 (AWST).

Allied was up 0.3 cents or 8.3 percent to 3.9 cents with 1.8 million shares traded.

## NUSEP

Nusep says it opposes the requisitioned resolutions for the election of Dr Ian Nisbet and Terry O'Dwyer as directors at its annual general meeting.

In its notice of meeting Nusep said that the requisitioned resolutions came from shareholders Julien Renard and Andrew Doyle.

The board recommended voting against the two candidates.

Nusep said that Mr Doyle was a shareholder in the Metal Storm weapons company and Mr O'Dwyer was the chairman of the company.

Dr Nisbet is the former chief executive officer of Xenome and Meditech and is a director of Verva.

The company said shareholders would also vote on the election of directors John O'Connor, David Roffe and Ward Wescott, whom Nusep supports.

The meeting will be held at Level 18, 133 Castlereagh Street, Sydney, on November 29, 2011 at 10am (AEDT).

Nusep was unchanged at 10 cents.