



# Biotech Daily

Tuesday November 25, 2008

*Daily news on ASX-listed biotechnology companies*

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## MARKET REPORT

The Australian stock market rebounded 5.5 percent on Tuesday November 25, 2008 with the All Ordinaries up 186.6 points to 3,575.4 points. Seventeen of the Biotech Daily Top 40 stocks were up, nine fell, eight traded unchanged and six were untraded.

Living Cell was best on no news, up four cents or 36.36 percent to 15 cents with 20,000 shares traded, followed by Polartechncs up 2.5 cents or 35.71 percent to 9.5 cents and Sunshine Heart up 20 percent to six cents.

Impedimed climbed 18.18 percent; Labtech and Pharmaxis were up more than 14 percent; Circadian and Universal Biosensors rose more than 11 percent; Clinuvel rose 9.09 percent; Benitec improved 7.14 percent; Cochlear was up 6.6 percent; Avexa was up five percent; Ventracor climbed 3.9 percent; CSL and Resmed rose more than two percent; with Acrux, Biota, Chemgenex and Novogen up more than one percent.

Cytopia led the falls, down 1.5 cents or 9.09 percent to 15 cents with 3,500 shares traded.

Genetic Technologies and Optiscan lost more than seven percent, Progen was down 5.63 percent, Starpharma fell 4.65 percent; Alchemia and Psivida were down more than three percent; with Prana down 1.64 percent.

## MARC SINATRA'S BIOGUIDE: CLINUVEL

**Overview:** The journey of Clinuvel's afamelanotide has been a long one since its discovery as a potential skin cancer preventative in the 1980s.

But its potential cosmetic use has become a main focus for investors, helped by a previous CEO often referring to the \$US5 billion US tanning market. Under current chief executive officer, Dr Philippe Wolgen, the cosmetic focus has been shelved and the potential clinical indications for afamelanotide have been expanded.

The one question most investors ask is: "Which market is Clinuvel really targeting?"

**Financials:** Market cap: \$67 million; cash: \$46 million; last quarter burn: \$2.8 million.

**Directors:** Non-executive chair, Brenda Shanahan; CEO, Dr Philippe Wolgen; chief scientific officer, Dr Helmer Agersborg; non-executive directors Dr Roger Aston, Stanley McLiesh and Jack Wood.

Clinuvel has a quality board with experience covering each of the required areas.

### **Products in Development:**

Afamelanotide is an analogue of alpha-melanocyte stimulating hormone. It stimulates production of photo-protectant melanin by melanocytes in the skin and is being developed to treat the following five indications:

- 1) Polymorphic light eruption (PLE) - a common rash affecting some individuals' skin upon sun exposure. A phase II study showed a significant reduction in the use of rescue medications in the test group, but not a reduction in symptoms. A European phase III PLE study should report next year.
- 2) Erythropoietic protoporphyria (EPP) - a disease where protoporphyrin accumulates in the skin causing severe, long-term, photosensitivity to strong light sources. Significantly increased time to photo-provocation in EPP patients on afamelanotide has been shown. The drug has orphan status for EPP in Europe and the US. A European phase III study should report in mid 2009.
- 3) Photodynamic therapy (PDT) side effects – In some PDT procedures the photo-sensitizers used cause photosensitivity in the same way EPP does for up to 90 days. A phase II study in PDT patients on afamelanotide, which also has European orphan status for this indication, is due to report in early 2009.
- 4) Actinic keratoses (AK) - are precancerous skin lesions which develop due to sun exposure. Transplant patients are 100 times more likely to develop skin cancer and their actinic keratoses are three times more likely to develop into cancer than for normal individuals. A European phase II AK prevention trial of afamelanotide in transplant patients should report in 2010.
- 5) Solar urticaria (SU) - is a form of hives that appears rapidly after sun exposure and often dissipates quickly. Afamelanotide is currently in a European pilot trial of 10 patients, with results expected in 2009.

Sunscreens are of no real use to EPP patients and those who have undergone PDT. They are of somewhat limited use to patients with PLE and SU. Clinuvel's previous regime submitted an IND for afamelanotide to the US FDA for sunburn prevention and PLE. After feedback from the agency, it was withdrawn.

**Significant Product Markets:** In Europe and the US, EPP and SU are rare affecting 5,000 to 15,000 and 30,000 individuals, respectively. PLE is common, affecting one hundred million people in these locations. IMS Health has put the markets for EPP, SU and PLE in 2006 at \$US25 million, \$US12 million and \$US40 million, respectively.

At the end of 2005, there were 164,000 living transplant patients in the US. IMS put the market size for transplant patients at \$US240 million.

It is difficult to derive solid figures for PDT. A common photo-sensitizer, Photofrin, generated \$US5.9 million dollars in 2007, enough sales to treat about 1200 patients.

There is little product development in these markets.

**Opinion:** It is clear that Clinuvel is focused on the clinical benefits of afamelanotide, which are likely to be greatest for EPP and PDT side-effects.

The photosensitivity suffered by such patients is and can be extreme. Small improvements in quality of life would be significant and it is for these groups that I believe Clinuvel will submit an investigational new drug application to the US Food and Drug Administration.

Submission of the application has been continually pushed back, almost certainly as a result of the previous aborted application attempt which may have raised some red flags with regulators.

Clinuvel must be certain this time. The good news is given the photodynamic therapy side effects indication requires only short term therapy; the delay in submission is likely to be off-set by shorter clinical trial requirements.

Afamelanotide's likely impact on the other indications is less clear, as the inability to significantly reduce symptoms in the phase II polymorphic light eruption study showed. With the actinic keratoses study, the drug seems unlikely to obviate the need for aggressive sun protection for, and skin cancer screening of, transplant patients.

To be a blockbuster, afamelanotide must make inroads into some combination of the combined polymorphic light eruption, actinic keratoses and off-label areas. Off-label use may occur in skin cancer survivors to more peripheral use in areas such as patients allergic to sunscreens.

The cosmetic use of afamelanotide is problematic since doctors will need to balance all of the risks relative to only a cosmetic benefit before prescribing it, but significant sales could occur in this area.

I have arrived at a discounted cash flow valuation for Clinuvel of 54 cents a share, but I have only factored in low penetrations into the PLE, AK and off-label markets. Should any or all of these three take-off, the company could benefit considerably.

Clinuvel climbed two cents or 9.09 percent to 24 cents.

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## POLARTECHNICS

Polartechncs says the supply of its Truscreen cervical cancer test and Cerviscreen sexually transmitted diseases test to China will increase revenue 10-fold in the next year. In a series of media releases and notices to the ASX related to the company's annual general meeting, chairman Robert Hunter projected sales growth by the company from \$6.8 million in 2009 to \$67 million in 2010 and \$151 million in 2011.

"Directors expect Polartechncs will become profitable in 2010 on the basis of contracts we have entered into with subsidiaries of a Top 200 company in China, Unisplendour Group", Mr Hunter said.

Polartechncs said shareholders approved the issue to Unisplendour of shares priced at up to 11.5 cents a share to raise \$2 million, which with other private placements of up to 15 percent of the current issued shares would "provide adequate capital to take the company through to profitability".

"Over the last two years, our new management team and board have laid the foundations for the company's new stage of growth, securing long term, scalable supply contracts in Malaysia, China and Poland to satisfy the demand we are now seeing for our state of the art products," Mr Hunter said.

Polartechncs said its "flagship product", Truscreen, would deliver 77 per cent of the company's revenue in 2009 and lead the group to profitability with its signed contract for the supply of 500 Truscreen screening units in a range of hospitals across China in 2009. The company said the China contracts alone were expected to generate sales of \$88 million over the next three years and would make Polartechncs cash flow positive.

This revenue is expected to be matched by other markets under development, including India, Korea and Eastern Europe, the company said.

Polartechncs said Truscreen was a cervical cancer detection product that supplies point of care testing and real time results, with medical staff only requiring minimal training to operate the units.

Unlike the traditional Pap smear test, Truscreen uses optical and electrical sensors to measure the response of cervical tissue to light and electrical currents, delivering more accurate results at the time of screening rather than Pap test results which may take weeks to be reported, Polartechncs said.

Mr Hunter said private medical clinics in Europe and Asia were seeking "real time point of care screening and triage for cervical cancer, which we can deliver through Truscreen".

The company said it had also developed and was marketing Cerviscreen, a low cost, sample collection device that can be used at home by women to obtain samples for testing of a range of sexually transmitted diseases.

"This product is delivering a low cost, do-it-yourself device that is expected to be in huge demand across major overseas markets, with more than 50 percent of our sales expected to come from China and other ASEAN countries over the next three years", Mr Hunter said.

Polartechncs has been developing cancer detection and screening technologies for women's health and skin cancer since 1987.

"We have emerged from being a single operational business to one with a global commercialization strategy, being involved in product research and development, manufacturing and promotion of innovative low-cost and accurate detection products for cervical cancer and sexually transmitted infections", said Mr Hunter.

Polartechncs said it had offices in Sydney, Shanghai, London; production facilities in Australia and China; and long term supply contracts in Malaysia, Italy and Poland.

Biotech Daily editor David Langsam holds Polartechncs shares.

Polartechncs climbed 2.5 cents or 35.71 percent to 9.5 cents.

### BIOPROSPECT

Bioprospect says that chairman Stephen Morrow and non-executive director Peter Landau resigned from the company yesterday.

Mr Morrow and Mr Landau said they were very pleased with the progress of the company in developing the natural termiticide, Termilone and early stage development of Solagran's Bioeffectives range of products for use in the animal health sector.

Had Mr Morrow remained on the board, he would have faced a resolution proposed by 6.64 percent shareholder Solagran, that he be removed at tomorrow's annual general meeting to be held in Melbourne (see Biotech Daily; October 24, 2008).

With the departure of Mr Morrow and Mr Landau, the company will be run by Solagran directors Charles Pellegrino and Peter Stedwell and Snr Sgt Anthony Langdon, who is under investigation by the Victoria Police.

Bioprospect fell 0.2 cents or 10.53 percent to 1.7 cents.

Solagran climbed three cents or 17.65 percent to 20 cents.

### STEM CELL SCIENCES

Stem Cell Sciences has requested a trading halt pending an announcement on "a review of the company's financial position and strategic options".

Stem Cell said it was "in discussions with ... third parties about various options, including possible refinancing, divestiture of certain operations and/or merger opportunities".

Trading will resume on November 27, 2008 or on an earlier announcement.

Stem Cell last traded at 15 cents.

### AVEXA

Avexa's remuneration report faced significant opposition at the company's annual general meeting, with all other resolutions passed overwhelmingly.

A total of 12,297,855 proxy votes opposed the remuneration report, with 32,955,666 proxy votes in favor.

The election of directors Nathan Drona, David Bottomley and Alan Boyd were carried overwhelmingly, as were the ratification of a prior share issue and approval of deeds of access, indemnity and insurance.

Avexa climbed 0.5 cents or five percent to 10.5 cents with 1.0 million shares traded.

### COMPUMEDICS

Director Alan Anderson was re-elected to the board of Compumedics with 2,318,050 proxy votes in favor and 1,111,786 proxy votes against.

All other resolutions were passed overwhelmingly.

Compumedics was unchanged at 13 cents.

### ARANA

Lim Sen Yap and associates have increased their substantial shareholding in Arana from 32,181,701 shares (13.7%) to 34,540,682 shares (14.7%).

Lim Sen Yap is associated with Rockwell Securities of the British Virgin Islands, Alana Siew Ypa of Vaucluse Sydney, Biofusion Capital of Sydney and Siew Chin Yap and Jek Nan Yap of Malaysia.

Arana was up half a cent or 0.63 percent to 79.5 cents.

### OPTISCAN

Optiscan says non-executive director Keith Daniel retired at the conclusion of yesterday's annual general meeting.

Optiscan chairman Grant Latta told the meeting that Mr Daniel had been a director since August 2001.

All resolutions to the meeting were passed overwhelmingly.

Optiscan fell half a cent or 7.58 percent to 6.1 cents.

### BIOLAYER, ANTEO DIAGNOSTICS

Biolayer has been removed from the ASX to be replaced by its holding company Anteo Diagnostics Limited.

Anteo is trading with the ASX code of ADO.

Prior to the change of name, supported at the company's annual general meeting last week, Biolayer said the rebranding and repositioning exercise reflected an expanded field of operation including fast track assay development and commercialization of diagnostics, test components and diagnostic data.

The board said the previous name did not reflect its underlying operations.

The company said Anteo was a latin root for "anticipate, prevent, precede" which was consistent with the underlying diagnostic element to its operations.

Anteo was unchanged at three cents.