



Biotech Daily

Tuesday February 24, 2009

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: IMPEDIMED UP 20%, PSIVIDA DOWN 17%**
- * **PHOSPHAGENICS' TPM-DICLOFENAC '7-FOLD BETTER THAN VOLTAREN'**
- * **FDA POINTS BONE IN RIGHT ORAL PARATHYROID HORMONE DIRECTION**
- * **POLARTECHNICS 11¢ SHARE PLAN TO RAISE UP TO \$8m**
- * **METABOLIC APPOINTS PAUL LAPPIN CHAIR; LOSES BELINDA SHAVE**
- * **BIO-MELBOURNE: GETTING THE BEST FROM BIO-PARTNER MEETINGS**
- * **XCEED H1 REVENUE DROP, LOSS REDUCED; BORON PROFIT UP 67%**

MARKET REPORT

The Australian stock market fell 0.6 percent on Tuesday February 24, 2009 with the S&P ASX 200 down 19.65 points to 3,331.6 points.

Three of the Biotech Daily Top 40 stocks were up, 16 fell, seven traded unchanged and 14 were untraded.

Impedimed was best, up 12 cents or 20 percent to 72 cents with 3,000 shares traded, followed by Clinuvel up two cents or 6.1 percent to 35 cents.

CSL climbed two percent and Heartware was up 0.45 percent.

Psivida led the falls, down 17 cents or 16.7 percent to 85 cents with 16,625 shares traded, followed by Labtech down 9.09 percent to 10 cents.

Peplin lost 8.4 percent; Polartechonics fell 7.7 percent; Cathrx was down 6.25 percent; Cellestis and Viralytics fell five percent; Genera fell 4.55 percent; Arana, Circadian, Clinuvel, Prana and Progen shed more than two percent; with Avexa and Cochlear down more than one percent.

PHOSPHAGENICS

Phosphagenics says its phase I diclofenac study demonstrates that its drug delivery is seven times stronger than Voltaren (1% diclofenac) at the same dose.

Phosphagenics said its tocopheryl phosphate mixture or TPM with the non steroid anti-inflammatory drug (NSAID) diclofenac formulation was safe and well tolerated in humans. The results also indicate that Phosphagenics' formulation can deliver significant amounts of diclofenac deep into the area of application.

Phosphagenics said diclofenac was one of the leading non-steroid anti-inflammatory drugs with global sales exceeding \$US1.2 billion and was used to reduce inflammation and pain associated with inflammation of tendons or joints and acute injuries.

The company said that as well as evaluating the safety, pharmacokinetics and tolerability of the formulation, the study compared the Phosphagenics TPM-diclofenac formulation with the leading commercial product, Voltaren, which also contains diclofenac.

Absorption of diclofenac was assessed by tape stripping and by measuring diclofenac concentrations in blood.

Tape stripping is a standard, non-invasive procedure used to measure the amount of a diclofenac or other drugs in the various layers of the stratum corneum, the outer layer of the skin.

The concentration of the drug in the systemic circulation was also measured to determine the amount of diclofenac that had penetrated deeply through the skin to reach the blood, as tape stripping does not measure the amount of diclofenac in the deeper layers of the skin or muscle.

Within 30 minutes of the application of Phosphagenics' patented formulation, diclofenac was detected in the blood of subjects, indicating both rapid absorption and deep penetration.

In contrast, measurable diclofenac was not detected in any subjects given Voltaren until two hours after application.

At that time, the average plasma concentration of diclofenac in subjects administered the Phosphagenics formulation was seven times greater than those subjects given Voltaren. Phosphagenics chief operations officer Dr Esra Ogru told Biotech Daily the trial compared Voltaren at the same concentration and dose as TPM-diclofenac.

Dr Ogru said Voltaren gel was 1% diclofenec and amounts of 250mg were used in both arms of the trial.

"TPM is a very powerful penetration enhancer," Dr Ogru said.

"And this is the fifth or sixth compound which we have shown we can delivery efficiently with TPM," Dr Ogru said.

In the media release to the ASX, Phosphagenics said that not until four hours after application did the average plasma concentration of diclofenac delivered by Voltaren reach the same concentration as that delivered by TPM.

There were no significant differences between the concentrations of diclofenac within the stratum corneum in subjects receiving TPM-diclofenac formulation and in subjects receiving Voltaren.

In the media release Dr Ogru said the plasma results provided "real encouragement that our TPM technology delivered diclofenac substantially deeper into the target tissue than Voltaren".

"As a consequence of the very promising results, Phosphagenics will now conduct a further, more definitive trial that will directly measure the amount of diclofenac in the deeper layers of the skin and perhaps the muscle, which are the appropriate sites to deliver diclofenac in order to reduce inflammation and therefore pain," Dr Ogru said.

Phosphagenics was untraded at 10.5 cents.

BONE MEDICAL

Bone Medical says it has had talks with the US Food and Drug Administration about clinical trials for its oral parathyroid hormone, Caphymone for osteoporosis.

Bone's chairman Leif Helth Jensen said the company "largely had our plans for product development and regulatory strategy for Caphymone confirmed".

"Our next clinical step is to enter a phase IIb study where the primary end point will be lumbar spine bone mineral density and the secondary end point will be the bio-marker P1NP," Mr Jensen said.

Mr Jensen said the 150-patient study was likely to take six months.

"Assuming this trial meets its clinical endpoint, the next step will be a pivotal phase III non-inferiority study of 12 months duration, involving an estimated 400 patients, which will be sufficient for registration purposes under rule 505(b)(2)," Mr Jensen said.

Bone said the FDA wanted it to document that Caphymone's pharmacokinetics were similar to that of Lilly's injectable parathyroid hormone product Forteo, a benchmark the company said it was comfortable it could meet.

Bone's chief scientific officer Dr Roger New said it was the first time the company knew exactly what the FDA needed and was confident the requirements would be met.

"We are also pleased that the FDA has recognized the product development and regulatory strategy which Bone initiated two to three years ago," Dr New said.

"The challenges set by the FDA for Caphymone, in comparison with new chemical entity drugs, are in general less expensive and with the right level of funding can be finalized over the next few years," he said.

Bone was untraded at 25 cents.

POLARTECHNICS

Polartech is offering eligible shareholders up to \$5,000 worth of shares at 11 cents a share to raise up to \$7,983,552.

Polartech chairman Robert Hunter said the issue of up to 72,577,753 shares would fund continued expansion and "also offer existing shareholders the opportunity to enjoy the longer term benefit we expect Polartech shares will deliver".

The 11 cents price is a 19.94 percent discount to the 13.74 cents five-day, average traded market price to February 20, 2009.

The company said shareholders at the record date of February 20, 2009 would be eligible to participate in the plan and could buy shares in \$1,000 parcels up to \$5,000.

The share plan is not underwritten.

Application forms are expected to be mailed to shareholders on February 25, 2009 with a closing date of March 20, 2009.

Parcels of shares can be bought in a range from \$1,000 to \$5,000.

Polartech fell one cent or 7.69 percent to 12 cents.

METABOLIC

Metabolic has appointed non-executive director Paul Lappin as chairman replacing Rob Stewart who resigned on February 20, 2009.

The company said that to minimize staff, company secretary and financial controller Belinda Shave had left the company "effective immediately".

Metabolic's non-executive director Iain Kirkwood had been appointed company secretary.

Metabolic climbed 0.2 cents or 10 percent to 2.2 cents.

BIO-MELBOURNE NETWORK

A panel of experts will give Bio-Melbourne Network's March Bio-Breakfast advice on how to ensure the 2009 BIO International Convention is a valuable experience.

The Network said that BIO International Conventions were "both exhilarating and exhausting".

The Bio-Melbourne Network said the US BIO conventions were "the biggest biotechnology meeting in the world with more than 20,000 delegates, an exhibition hall the size of the [Melbourne Cricket Ground] and a packed program of events, speakers and sessions" along with the chance to meet with pharmaceutical and biotechnology giants.

"Without some forward planning for BIO, as well as other international meetings, attending these events can simply be exhausting," the Network said.

March's Bio-Breakfast is sponsored by Austrade and a panel of "seasoned biotechnology travelers" will discuss how to ensure delegates get value from major partnering meetings.

Speakers include the Victorian Department of Innovation, Industry and Regional Development's Dr Amanda Caples, Circadian Technologies' Dr Alex Szabo, Xenome chief executive officer Dr Ian Nisbet and Chemgenex's Dr James Campbell.

The 2009 BIO International Convention is in Atlanta, May 17-20, 2009.

Other meetings that the panel will discuss include: the Allicense Conference, Biopartnering Europe, JP Morgan Healthcare Conference, Biopartnering North America, C21 Bioventures, BIO-Asia, Medica and BIO-Europe.

The March 3, 2009 Bio-Breakfast will be held in the Supper Room, Melbourne Town Hall, Swanston St, Melbourne, with registration and breakfast from 7.15am and the presentation at 8am.

For further information go to www.biomelbourne.org; email npitcher@biomelbourne.org; or call Nicole Pitcher on +613 650 8800.

XCEED CAPITAL

Xceed's revenue for the six months to December 31, 2008 fell two percent to \$2,327,000 with the net loss after tax reduced by five percent to \$998,000.

Xceed's revenues were primarily derived from activities by subsidiaries Polynovo and Boron Molecular.

Xceed's share of Polynovo was diluted by the transaction with Metabolic, with Xceed and the Commonwealth Scientific and Industrial Research Organisation, retaining 25.5 percent and 14.5 percent of Polynovo, respectively (BD: Dec 18 and 19, 2008).

Polynovo had revenue of \$63,000 for the period July 1 – December 17, 2008 and an operating loss of \$1,296,000, with a net loss of \$48,000 for December 17-31, 2008.

Boron Molecular had total revenue up 1.1 percent to \$2,541,000 for the six months to December 31, 2008 and an operating profit up 67 percent to \$701,000.

Xceed's diluted earnings per share was a loss of 1.0 cents and the company had \$821,000 cash at December 31, 2008.

Xceed was untraded at 1.2 cents.