



Biotech Daily

Thursday February 5, 2009

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH FLAT: AVEXA UP 25%, CLINUVEL DOWN 12%**
- * **AUSBIOTECH: FEDERAL \$4.2bn PACKAGE ‘OVERLOOKS BIOTECH’**
- * **BIONOMICS OPTIONS RAISE \$4m**
- * **PROGEN, AVEXA BACK MERGER, OPPOSE CYTOPIA, ANNOUNCE EGM**
- * **AVEXA: ‘APRICITABINE WORTH \$226m’**
- * **CYTOPIA DETERMINES ORAL CYT997 DOSE FOR CANCER**
- * **POLARTECHNICS SIGNS ASEAN DISTRIBUTION AGREEMENTS**
- * **BIODIEM CEO DR ANDREW O'BRIEN RESIGNS**

MARKET REPORT

The Australian stock market fell 0.27 percent on Thursday February 5, 2009 with the S&P ASX 200 down 9.3 points to 3,428.6 points.

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

Avexa was best, up 1.6 cents or 25 percent to eight cents with 2.4 million shares traded, followed by Novogen up 12 cents or 16.44 percent to 85 cents.

Progen climbed 6.55 percent; Phosphagenics was up 5.26 percent; Cellestis improved 4.76 percent; CSL, Sirtex and Viralytics rose more than two percent; with Cochlear and Mesoblast up more than one percent.

Clinuvel led the falls, down three cents or 12.24 percent to 21.5 cents with 311,867 shares traded.

Bionomics and Pharmaxis lost more than five percent; Acrux and Starpharma fell more than four percent; Alchemia and Optiscan were down more than three percent; Biota shed 2.2 percent; with Arana down 1.85.

AUSBIOTECH

Ausbiotech chief executive officer Dr Anna Lavelle has called on the Federal Government to pay attention to biotechnology as an industry of the future.

"Governments around the world are responding to the economic crisis by bolstering industries of the future and Australia must do the same," Dr Lavelle said.

In response to the Federal Government's stimulus package announced yesterday, Dr Lavelle says the biotechnology sector, which offers long-term job prospects, has been overlooked for support (BD: Feb 4, 2009).

"The Rudd Government must throw its support behind the industries of the future that will help lead us out of the current crisis and drive the next wave of growth," she said.

"The package has attractive features but the backing of globally-competitive innovation is key to providing sustainable employment in this country," Dr Lavelle said.

"The financial crisis has put at risk a generation of small biotech companies, which are in a precarious position, and we risk losing life-saving discoveries and therapies that will ultimately improve our economic situation," she said.

"All of our global trading partners see the sense in supporting biotechnology and are doing this," she said.

"Governments in the developed world are stepping forward to buttress industries of the future that will lead their economies out of this crisis," Dr Lavelle said.

Ausbiotech said the Norwegian government moved quickly with a multi-million dollar stimulus package for life sciences and innovation research.

In Britain, Prime Minister Gordon Brown has placed pharmaceuticals and biotechnology at the heart of his government's economic agenda, the industry organization said.

In Canada, Japan and Germany governments have unveiled national stimulus packages of tax cuts and new spending initiatives to both stimulate its economy and promote long-term growth in innovative future industries like biotechnology.

Ausbiotech said China had announced an investment equivalent to \$8 billion into biotechnology over the next two years and Taiwan said its research and development capability was essential to economic recovery and promised to increase the country's research and development budget to three percent of the gross domestic product.

Ausbiotech said one quarter of Australian biotechnology companies did not have funds beyond June 2009 and half lack the resources to operate beyond 12 months.

The industry organization said the sector needed refundable tax credits, competitive matched grants and an increased pool of venture capital to support companies in clinical trials for new drugs and devices.

"Despite the current recession, populations in the developed and developing world are still growing and ageing, driving demand for therapies and medicines," Dr Lavelle said.

"Many other countries see the need to preserve sustainable industries offering long-term employment," she said.

BIONOMICS

Bionomics says the exercise of the BNOOB listed options has raised \$4,004,000.

Bionomics said Phillip Capital, the corporate advisory arm of Intersuisse, was the underwriter for the options exercise and 18,200,000 shares would be issued.

IB Australian Bioscience Fund 1 acquired 5.0 million shares and holds more than the 13.6 million shares.

The company said the funds would support the anti-cancer compound BNC105 phase II trial "and assist the company in securing an additional major partnership".

Bionomics fell one cent or 5.26 percent to 18 cents.

PROGEN AVEXA CYTOPIA

In a series of media releases to the ASX, Progen and Avexa supported their proposed merger and questioned the alternative Cytopia proposal to merge with Progen.

Progen has about \$70 million in cash following the demise of the company's phase III trial of PI-88 for liver cancer.

It has subsequently defeated a minority shareholder group coup, proposed a merger with Avexa and opposed a hostile merger from Cytopia (BD: Nov 14, 21; Dec 1, 22, 2008; Jan 16, 28, 2009).

Avexa has insufficient funds to complete its phase III trial of apricitabine for HIV and has been unable to partner the drug despite showing benefit over existing drugs (BD: Mar 12; Nov 24, 2008).

In media releases today Progen questioned the validity of the five percent Cytopia shareholder group requisition, along with the merits and execution of the Cytopia group's proposals - including the share buyback - and restated support for the Avexa merger.

Progen directors confirmed their recommendation for the merger with Avexa and described the Cytopia group's call for a meeting as "a purported requisition" to consider an alternative share buy-back proposal and a spill of the board.

Progen said the three directors proposed by Cytopia were all Cytopia shareholders.

Cytopia chief executive officer Andrew Macdonald confirmed the three held small holdings in his company with Rob Collins having the largest shareholding with 138,000 shares.

Progen said the group asked for resolutions to spill the board to be included on the agenda for the meeting which will consider the Avexa merger, but questioned "several legal issues regarding the validity of this group's requisition".

"Even without these issues, if the resolutions had been included on the March 11, 2009 meeting agenda, the resolutions to appoint new directors could not have been validly passed under the constitution because the required 35 business day notice period for new director candidates' consents and nominations to be received would not have expired," Progen said.

Progen said the legal issue and the practicality of preparing complex information meant that any requisitioned meeting would need to be held at a later date.

The company said if all the issues were resolved, it would announce a shareholders meeting in response to the requisition.

Progen said implementation of the Cytopia buy-back proposal was "highly questionable" and the cap would be set at a level which leaves Progen a going concern but there was "no information surrounding what is meant by going concern".

Approving the resolution provides no certainty to shareholders that the resolution will be implemented, Progen said.

Progen said the valuation of the merged entity shares in the independent expert report provided by BDO Kendalls Corporate Finance (Queensland), had "the potential to deliver value of \$2.03 to \$3.18 per share to Progen shareholders based on a discounted cash flow valuation of [apricitabine] alone".

Cytopia's Andrew Macdonald told Biotech Daily he was reviewing the material and would respond in due course.

"We still strongly believe shareholders should have a full choice on how the funds are distributed," Mr Macdonald said.

The Progen meeting will be held at Level 6, 320 Adelaide Street, Brisbane on March 11, 2009 at 10am.

Progen climbed 5.5 cents or 6.55 percent to 89.5 cents.

Cytopia was untraded at 11 cents.

Biotech Daily editor David Langsam holds Cytopia shares.

AVEXA

Avexa says an independent expert's report by Lonergan Edwards & Associates assessed apricitabine between \$151.4 million to \$225.8 million.

Avexa said the Lonergan Edwards report said completion of the transaction and the resulting removal of short-term funding requirements was likely to result in the merged entity's share price being re-rated, assuming comparable share market conditions, post completion of the merger.

On the basis of the findings in the report, Avexa's directors reiterated their unanimous support for the merger.

The Independent Expert believes that the merged entity's share price, expressed in Avexa terms was "likely to trade at a higher price than the Avexa share price prior to the announcement of the scheme" and completion of the week 24 phase III milestone was likely to lead to a further material increase in the value of Avexa shares and as an indication of the upside potential of Avexa shares, the independent expert assessed the theoretical control value of Avexa shares in the range of 44.4 cents to 58.6 cents prior to taking into account financing risks, dilution and "in the money" options.

After the dilutionary impact of assumed future capital raising to fund apricitabine development costs up to the week 24 milestone, the independent expert assessed the control value of Avexa shares in the range of 21 cents to 41 cents.

Avexa said it expected to dispatch the scheme book containing the independent expert's report to shareholders in mid-February 2009 with the shareholder meeting to consider the merger scheduled to be held on March 20, 2009.

Avexa was up 1.6 cents or 25 percent to eight cents with 2.4 million shares traded.

CYTOPIA

Cytopia has concluded dose-escalation in its oral phase I study for its anticancer vascular-disrupting agent CYT997.

Cytopia said the primary objectives of the safety and tolerability study to determine the maximum tolerated dose and the dose-limiting toxicities were achieved.

The company said CYT997 was administered orally in capsule form every two weeks to patients with a diverse range of solid tumors.

Cytopia said the safety and tolerability data from the study augmented data from the first phase I study where CYT997 was administered intravenously.

"Together, these studies suggest that the CYT997 is a potent and selective [vascular-disrupting agent] which is well-tolerated at biologically efficacious doses and is worthy of further investigation as a novel anticancer agent," Cytopia said.

Cytopia chief executive officer Andrew Macdonald said CYT997 had demonstrated broad clinical potential in both intravenous and oral forms.

"The oral activity of CYT997 is a key advantage over most other vascular disrupting agents which are administered intravenously," Mr Macdonald said.

"The oral activity of the agent should markedly improve its clinical and commercial value," he said.

The company has begun phase II studies for the intravenous form of CYT997 and intends to undertake similar efficacy studies for the oral presentation.

Investigating the safety and efficacy of metronomic dosing, frequent oral administration at a comparatively low, but biologically effective dose, is of particular interest.

Cytopia said CYT997 was generally well tolerated in this study with a maximum tolerated dose in cancer patients of about 165 mg/m².

This dose resulted in maximal plasma concentrations some two-fold higher than those observed in the phase I intravenous infusion study at a comparable dose, indicating favorable oral absorption, the company said.

Three dose-limiting toxicities were observed, namely two cases of significant drug-induced fatigue and one case of hypoxia.

Importantly, no significant prolongation of the corrected QT interval (a measure of cardiac conduction) was observed.

Patients in the trial had advanced cancer that failed to respond to other therapies or for which no other therapy exists. Each was eligible to receive up to six cycles of CYT997, subject to clinical status. One patient continued to receive the drug beyond their initial six cycles due to prolonged disease stabilization. No patients remain on study.

Secondary objectives of the study included the determination of a recommended dose for phase II studies and pharmacokinetic assessment and a preliminary investigation of the anti-tumor properties of CYT997.

The company expects a finalized trial report within three months.

POLARTECHNICS

Polartechnics has signed distribution agreements with companies in Thailand, Philippines, Indonesia and Sri Lanka for its Truscreen and Cerviscreen tests.

Polartechnics said the Association of South East Asian Nations distributors were Pacific Healthcare Holdings for Thailand and the Philippines, PT Mega Utama Medica for Indonesia and Mega Pharma for Sri Lanka.

The company said the distributors supplied more than 2,300 pharmacies in the region with extensive distribution networks across pharmacies, hospitals and private clinics.

Polartechnics has secured distribution of Truscreen and Cerviscreen in China.

The company said the World Health Organisation estimated that infection rates across South East Asia were significantly higher than other parts of the world with more than 150 million cases of curable sexually transmitted infections each year.

Polartechnics chairman Robert Hunter said the agreements covering the ASEAN market "highlight the continued roll out of our products globally".

To meet anticipated demand, Polartechnics said it had high volume supply contracts from Europe and Malaysia for production of Truscreen and Cerviscreen consumable products. Polartechnics was unchanged at 12 cents.

BIODIEM

Biodiem says Dr Andrew O'Brien will resign as chief executive officer and managing director, effective on February 24, 2009.

Biodiem said Dr O'Brien would "further pursue his growing interests in his corporate finance practice Grannus Securities".

Chairman Hugh Morgan will extend his duties to overseeing the day to day activities of the company, while an executive search is conducted for a new chief executive officer.

Biodiem fell half a cent or 7.14 percent to 6.5 cents.