

# Biotech Daily

Friday February 13, 2009

Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH UP: PHOSPHAGENICS UP 11%, ANTISENSE DOWN 12.5%
- \* AGENIX RESULTS REVIVE THROMBOVIEW FOR EMBOLISM IMAGING
- \* BIOTECH DAILY BLACKBERRY EDITION
- \* NOVOGEN FOCUS ON CANCER; MODEST BELT-TIGHTENING
- \* GSK UPS DECEMBER QUARTER RELENZA SALES 30%; BIOTA ROYALTY
- \* HEARTWARE REQUESTS 'TRANSACTION' TRADING HALT
- \* CHINESE NEEDLEFREE PATENT FOR NORWOOD ABBEY
- \* OPTISCAN APPOINTS ANGUS HOLT DIRECTOR

#### MARKET REPORT

The Australian stock market climbed 1.3 percent on Friday February 13, 2009 with the S&P ASX 200 up 44.8 points to 3,559.1 points.

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

Phosphagenics was best, up one cent or 11.11 percent to 10 cents with 10,000 shares traded, followed by Cochlear up \$2.85 or 5.41 percent to \$55.55.

Cellestis climbed 4.12 percent; Arana and Avexa were up more than three percent; Acrux, Biota, Optiscan, Sirtex and Viralytics rose two percent or more; with Circadian, CSL, Pharmaxis and Resmed up more than one percent.

Antisense led the falls, down 0.5 cents or 12.5 percent to 3.5 cents with 90,000 shares traded, followed by Genera down two cents or 9.09 percent to 20 cents.

Peplin lost 3.23 percent; Living Cell shed 2.06 percent; with Progen down 1.18 percent and Mesoblast down 0.64 percent.

### **AGENIX**

Agenix says a phase II pulmonary embolism study of Thromboview has show overall accuracy of 83 percent and will progress to its final development.

Agenix previously sidelined Thromboview as it concentrated on the acquisition of two Shanghai pharmaceutical companies. Agenix made no mention of the Shanghai acquisition in today's Thromboview announcement.

Agenix chief executive officer Dr Stephen Phua said in March 2008 the company would "sell or otherwise divest Thromboview" (BD: Mar 25, 2008).

Agenix said it would continue the phase II Thromboview clinical trials "with a view to completion" but "future expenditure on Thromboview, its operations and business will be limited to \$2.5 million and on completion of the phase II clinical trials on Thromboview Agenix will endeavor to sell or otherwise divest Thromboview".

Today, Agenix said the US Food and Drug Administration had provided regulatory feedback on the design of pivotal pulmonary embolism studies.

"This news, together with the background that the agency has approved four new imaging products in the last eight months, leads management to believe that Thromboview has a greater chance to secure funds for the final phase of development and commercialization amidst a challenging capital market," Agenix told the ASX.

Agenix said it had added a new US patent to its expanding intellectual property portfolio. Agenix said the phase II pulmonary embolism study demonstrated that Thromboview "achieved a specificity of 91 percent and a sensitivity of 76 percent in a cohort of 42 patients for an overall accuracy of 83 percent, measured against computed tomographic pulmonary angiography as the reference.

These figures are comparable to computed tomographic pulmonary angiography (CTPA) itself when it was measured against an independent standard in the study, where it achieved 96 percent and 83 percent specificity and sensitivity respectively.

The company said it was the first time a pulmonary embolism accuracy study had been undertaken with Thromboview and results would improve with experience and training in reading images, as well as an alternate design that did not rely on a CTPA standard alone. Agenix said CTPA was an anatomical imaging technique while Thromboview was a functional technique that detects active clots.

Agenix chief executive officer Dr Stephen Phua said the "excellent results reported here adds to the wealth of clinical data accumulated from a total of five phase I and II studies". "We have now shown that Thromboview images clots in the legs and lungs, and the product is safe," Dr Phua said. "Thromboview avoids the use of contrast dyes which can cause kidney health problems, especially if a patient has renal impairment, and can be safely used in a wide patient group due to the low dose in radiation-sensitive organs." Agenix said a proposed phase III clinical trial design was submitted to the FDA last year. Agenix said it received feedback and in a departure from previous communications and subject to provision of clinical and chemical data, the concept of a composite standard was accepted as a possible reference standard. The use of threshold values was accepted to assess test performance rather than a non-inferior comparison to the reference standard.

Agenix said it was "extremely pleased" with the FDA feedback and there was a clear path to approval and that after no imaging approvals in three years, the new imaging administration had approved four imaging products in the last eight months. "We are excited by this news," said Dr Stephen Phua. "We believe recent FDA history and the feedback we have received creates fertile ground for conducting a cost-effective and approvable phase III program".

Agenix is in a voluntary suspension and last traded at 1.7 cents.

## **BIOTECH DAILY BLACKBERRY EDITION**

The Biotech Daily Blackberry Edition has proven popular and format teething problems are being sorted out.

Any subscribers wanting to be added to the list have until the end of February to do so at no cost.

From March, a small charge will be levied to cover production costs.

## NOVOGEN

Novogen said the current economic climate was "making capital raising for extended programs difficult [and it would] rely on its internal resources to concentrate on the expanding oncology portfolio".

Novogen said it would outsource the scale-up manufacturing of clinical stage compounds; put on hold the cardiovascular and anti-inflammatory programs; reduce staff from 62 to 51; and implement fee and income reductions of 20 percent for the board and executive management.

Novogen said the group cash balance at December 31, 2008 was about \$44 million which it considers appropriate to ensure the viability of the company.

The company said that as it proceeded closer to commercialization of its oncology research and development and when financial market conditions became more favorable, it would be in a better position to fund work on the remainder of its intellectual property which is derived from its isoflavonoid technology platform.

Novogen said its most advanced anti-cancer compound, phenoxodiol, was in advanced clinical trials and was licensed to its 71 percent subsidiary, Marshall Edwards. Novogen said it maintained its commitments to its US based wound management subsidiary Glycotex and continued to earn revenue from sales of consumer healthcare products in Australia, Canada and the UK and from 13 licensees worldwide. Novogen was unchanged at 80 cents.

#### **BIOTA**

Glaxosmithkline has upgraded Relenza sales for the December 2008 quarter from \$20.8 million to \$27.1 million.

Biota said indicative royalties would be \$1.9 million instead of the \$1.46 million previously announced (BD: Feb 6, 2009).

The royalty payment follows the previous quarter indicative royalty of \$1.9 million and compares to indicative royalties of \$12 million for three months to December 31, 2007. Biota's best quarter for indicative royalties was \$16.0 million in the three months to March 31, 2007.

Biota was up one cent or 2.2 percent to 46.5 cents.

#### **HEARTWARE**

Heartware has requested a trading halt pending an announcement on "a material corporate transaction".

Trading will resume on February 17, 2009 or on an earlier announcement. Heartware last traded at 66.5 cents.

## NORWOOD ABBEY

Norwood Abbey says the Chinese Patent office has granted an additional patent to the Massachusetts Institute of Technology entitled 'Needleless Injector'.

Norwood Abbey said the patent flowed from its research at Massachusetts Institute of Technology in Cambridge, Massachusetts and the company had "an exclusive world wide licence over this patent and all intellectual property flowing from its sponsored research" at Massachusetts Institute of Technology.

Norwood Abbey was up half a cent or 83.33 percent to 1.1 cents.

# **OPTISCAN IMAGING**

Optiscan has appointed Angus Holt as a director, effective from February 12, 2009. Optiscan said Mr Holt had "extensive experience as a director and secretary of small listed companies".

He has worked on early stage medical technology ventures in Australia and in the US. Optiscan climbed 0.1 cents or 2.22 percent to 4.6 cents.