



Biotech Daily

Wednesday January 27, 2010

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: PHYLOGICA UP 5%; LABTECH DOWN 10%**
- * **BIONOMICS BEGINS PHASE II BNC-105 RENAL CELL CANCER TRIAL**
- * **LIVING CELL WARNING ON FAKE SHARE CERTIFICATES**
- * **ACRUX SUBMITS US AXIRON TESTOSTERONE APPLICATION**
- * **HEARTWARE NASDAQ IPO TO RAISE ABOUT \$US50m**
- * **COGSTATE RECORD REVENUE UP 31%; 18 MONTHS OF PROFIT**
- * **ANTEO HAS TWO QUARTERS CASH; 1.2c OPTIONS RAISING FUNDS**
- * **AUSBIOTECH NOT HAPPY WITH NOTITIA ASIA PACIFIC CONFERENCE**

MARKET REPORT

The Australian stock market fell 1.55 percent on Wednesday January 27, 2010 with the S&P ASX 200 down 73.3 points to 4644.6 points.

Twelve of the Biotech Daily Top 40 stocks were up, 20 fell, four traded unchanged and four were untraded.

Phylogica was best, up 0.5 cents or 4.8 percent to 11 cents with 104,000 shares traded, followed by Patrys up four percent to 13 cents.

Cellmid climbed three percent with three million shares traded; Novogen and Uscom rose more than two percent; with Bionomics, Biota, Chemgenex, Mesoblast, QRX, Resmed and Sirtex up more than one percent.

Labtech led the falls, down one cent or 10 percent to nine cents with 25,000 shares traded, followed by Genetic Technologies down 8.9 percent to 4.1 cents.

Antisense, Compumedics and Viralytics lost more than seven percent; Prima was down six percent; Heartware, Living Cell, Phosphagenics and Tissue Therapies fell more than four percent; Avexa, Cochlear, Prana and Psivida were down more than three percent; Benitec, Clinuvel and Universal Biosensors shed more than two percent; with Acrux and Pharmaxis down more than one percent.

BIONOMICS

Bionomics says it has begun a US phase II clinical trial of its lead cancer drug BNC105 in patients with renal cell carcinoma.

Bionomics said the trial was being conducted by the Hoosier Oncology Group at the Baylor Sammons Cancer Centre in Dallas, Texas the Indiana University Melvin and Bren Simon Cancer Centre in Indianapolis and the Cancer Treatment and Research Centre, University of Texas in San Antonio.

The company said it expected to have 12 sites involved in the trial with 152 patients.

Bionomics said the trial would determine whether BNC105 was effective in the treatment of progressive metastatic renal cell carcinoma, either in combination with or following Afinitor (also known as Everolimus) treatment in patients who have disease progression following treatment with tyrosine kinase inhibitors such as Sutent or Nexavar.

Bionomics principal investigator for the trial Dr Thomas Hutson of the Baylor Sammons Cancer Centre said the "mechanism of action of BNC105 provides an innovative approach to the treatment of solid tumors, including metastatic renal carcinoma, by attacking established tumor vasculature".

"It is particularly exciting to be conducting a trial which has the potential of creating a new paradigm for the treatment of renal cancer," Dr Hutson said.

Bionomics said renal cancer accounted for two to three percent of human malignancies and more than 85 percent of kidney cancers.

The company said about 200,000 cases were diagnosed worldwide each year, with 55,000 people diagnosed in the US. Bionomics said the five year survival rate for patients with metastatic disease was less than two percent.

Bionomics chief executive officer Dr Deborah Rathjen said the company was "pleased to be working with such an experienced clinical consortium as the Hoosier Oncology Group. "Metastatic renal cancer has a poor prognosis and there exists a real need for new therapies despite relatively recent advances in treatment," Dr Rathjen said.

"It is encouraging that a renal cancer patient enrolled in the phase I study of BNC105 conducted in Australia under an [investigation new drug] application to the US FDA showed clinical benefit," Dr Rathjen said.

"In addition to the potential clinical benefits of BNC105, we believe that renal cell cancer offers a strong market opportunity for BNC105 if successfully developed," she said.

Dr Rathjen said global sales of Sutent were \$US847 million in 2008 and reported sales of Nexavar in 2008 were \$US677.8 million with sales projections for Afinitor, which was approved in the US and Europe in 2009 for renal cancer, exceeded \$US500 million.

Bionomics was up half a cent or 1.5 percent to 33.5 cents.

LIVING CELL TECHNOLOGIES

Living Cell says there have been "several cases of the fraudulent sale of shares in the company and the issue of fake LCT share certificates".

The company said it was "only aware of four fraudulent sales in the United Kingdom".

Living Cell said that its Australian share registry, in common with all listed companies, did not issue share certificates, but some certificates were issued through its American Depository Receipt program in the United States "in exceptional circumstances".

Living Cell said potential investors were urged to be wary and contact the company secretary if they have any concerns or wish to be directed to a reputable broker.

The company said it had advised the ASX and several of those affected had alerted the City of London Police.

Living Cell fell one cent or 4.65 percent to 20.5 cents.

ACRUX

AcruX has applied to the US Food and Drug Administration for market approval for its Axiron treatment of testosterone deficiency or hypogonadism in men.

AcruX said the new drug application (NDA) had been submitted and if approved by the FDA, would be available to US patients by July 2011.

AcruX chief executive officer Dr Richard Treagus said that filing the application was “a major milestone for Axiron and for AcruX” and the process of selecting a marketing partner for Axiron was “proceeding as planned”.

In September 2009 AcruX announced the results of its phase III Axiron trial and said it would have a partner by the end of 2010 (BD: Sep 29, 2009).

Today, the company said that global sales of testosterone therapies had grown to more than \$US1 billion a year, with \$US700 million sales of testosterone gels in the US.

AcruX said the new drug submission followed a pre-NDA meeting with the FDA and the results from the phase III Axiron trial, which showed that after four months of treatment, 84 percent of subjects achieved average blood levels of testosterone within the normal range, exceeding the requirement of 75 percent agreed with the FDA.

Analysis of mood, sexual desire, sexual activity and sexual performance before and after the four months of treatment showed statistically significant improvement from baseline.

AcruX was down three cents or 1.5 percent to \$2.02.

HEARTWARE

Heartware hopes to raise about \$US50 million through the sale of 1,500,000 shares of common stock, equivalent to 52,500,000 Australian CHESS depository interests (CDIs). Heartware did not specify a sale price for the shares but said the January 25, 2010 closing price of common stock on the Nasdaq market was \$US35.17 a share and the closing price of CDIs was \$A1.15 a share.

At \$US35.17 a share Biotech Daily calculated a total capital raising of \$US52,755,000 but expects there will be a discount below the current price.

Heartware said it had given the underwriter and book-builder JP Morgan 30 days to confirm its interest in 225,000 shares of common stock.

Heartware said it intended to use the net proceeds from this offering for general corporate and working capital purposes.

The company did not specify an opening or closing date for the offer which is effectively an initial public offering on the Nasdaq.

Biotech Daily believes the offer opened with the publication of the prospectus and closes on or about February 25, 2010.

Heartware fell 5.5 cents or 4.8 percent to \$1.09.

COGSTATE

Cogstate expects to record its “third consecutive profitable half year result” of about \$500,000 for the six months to December 31, 2009.

Cogstate said the expected net profit after taxation was subject to audit adjustments was in line with guidance at the October annual general meeting and full details would be released in the half-year financial statements on February 23, 2010.

The company said the profit was driven by sales revenue of \$5.1 million for the half year, up 30.77 percent from \$3.9 million for the previous corresponding period.

Cogstate fell one cent or 3.2 percent to 30.5 cents.

ANTEO DIAGNOSTICS

Anteo says its net operating cash burn for the three months to December 31, 2009 was \$543,000 with cash at the end of the quarter of \$1,065,000.

Anteo chief executive officer Dr Geoff Cumming told Biotech Daily that the company's 1.2 cent options were being traded and raising funds for the company.

Dr Cumming said there were 180 million options worth about \$2.116 million if exercised.

Anteo announced its first licencing agreement with Bangs Laboratories on January 13 2010 and Dr Cumming said revenue from that deal was not included in the Appendix 4C announcement (BD: Jan 17, 2010).

Dr Cumming said since the Bangs announcement there had been considerable interest in the company.

Anteo fell half a cent or 8.8 percent to 5.2 cents with 13.1 million shares traded.

NOTITIA GROUP

The Notitia Group is planning an Australia Asia Pacific biotechnology conference to be held at the Brisbane Convention Centre from August 17 to 19, 2010.

Notitia's Asia-Pacific general manager Nigel Pretty told Biotech Daily that his group had been "watching the bio space for 18 months or so" and believed there was a need for a conference focused on the region rather than Australia.

Mr Pretty said he was aware that his conference was two months ahead of the Ausbiotech Melbourne conference planned for October 19-22, 2010.

Ausbiotech chief executive officer Dr Anna Lavelle told Biotech Daily that neither her organization nor New Zealand Bio nor US Bio were associated with Mr Pretty's event.

Mr Pretty said he had signed up Virgin Blue as a sponsor and had "half a dozen" other confirmed sponsors including France's Biotech Finances, pharmaceutical services company Aptuit and Novartis.

Mr Pretty said that although the conference website said six exhibits had been confirmed as sold of the more than 200 available, there were about 15 exhibitors confirmed at a cost of \$5,000 for three days.

He said delegates would pay \$1200 for the three days and "about 500 to 600 had signed up", with a target of 2,500 for the August conference.

Mr Pretty said Queensland Treasurer Andrew Fraser who is also the State's Innovation Minister has been invited to open the conference.

Mr Pretty said his organization was also in discussions with University of Pennsylvania president Dr Amy Gutman who was appointed by President Barack Obama in November 2009 as chair of the Presidential Commission for the Study of Bioethical Issues.

He said the Notitia Group was also in discussions with the Michael J Fox Foundation regarding keynote speakers.