

Biotech Daily

Tuesday February 15, 2011

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH EVEN: QRX UP 8%; VIRAX DOWN 15%
- * ALLIED MEDICAL, BIOMD IN MERGER TALKS; AVEXA HOLDING
- * CORRECTION: BIOMD
- * HEALTHLINX OVPLEX STAGE 1 TRIAL 'SUPERIOR TO CA125'
- * MEDICAL DEVELOPMENTS H1 PROFIT UP 143% TO \$804k
- * MEDICAL DEVELOPMENTS APPOINTS EURO-TRIAL CRO
- * BARINGS ACCEPTANCE TAKES 10% OF CYCLOPHARM

MARKET REPORT

The Australian stock market slipped 0.1 percent on Tuesday February 15, 2011 with the S&P ASX 200 down 4.8 points to 4931.0 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, nine traded unchanged and six were untraded.

QRX was best, up 10 cents or 8.3 percent to \$1.30 with 71,262 shares traded, followed by Prana up one cent or 7.1 percent to 15 cents with 622,333 shares traded.

Living Cell climbed 4.35 percent; Cellmid and Starpharma were up more than three percent; Bionomics rose 2.6 percent; with Cellestis, CSL, LBT, Pharmaxis and Phylogica up more than one percent.

Virax led the falls, easing after yesterday's 41 percent leap, down 0.6 cents or 14.6 percent to 3.5 cents with 3.75 million shares traded, followed by Antisense down 12.5 to 0.7 cents with 647,500 shares traded.

Immuron lost 9.4 percent, Viralytics fell 8.2 percent; Tissue Therapies was down five percent; Genetic Technologies fell 4.55 percent; Phosphagenics was down 3.7 percent; Impedimed, Prima and Sunshine Heart shed more than two percent; with Alchemia, Mesoblast, Patrys and Psivida down more than one percent.

BIOMD, ALLIED MEDICAL, AVEXA

Biomd says it wants to buy all of the shares in Allied Medical, a public unlisted company specializing in the sales, distribution and commercialization of medical technologies. In November 2010, Avexa said it would spend \$1.5 million in two tranches for a 24 percent stake in Allied Medical (BD: Nov 11, 2010).

Today, Biomd said it had assets in regenerative tissue engineering technologies, primarily the Adapt Cardiocel bovine cardiac patch and the acquisition of Allied Medical "would create a diversified healthcare group focused on a growing distribution business and the commercialization of new medical technologies".

Biomd said the acquisition would bring together a product pipeline developing next generation vaccines and tissue engineering technologies, as well as a profitable medical device distribution business.

Avexa said in November 2010 time that Allied Medical's major shareholder was Andrew Forrest the executive director of Fortescue Metals Group and that Allied Medical had a major interest in Coridon Pty Ltd, a vaccines-focused research and development company started by Prof Ian Frazer.

Avexa said at that time that funds raised from Avexa's investment in Allied Medical would be used to pursue the Coridon technology.

In July, Allied Medical said it would raise \$6 million to boost Coridon's development of DNA immuno-therapies, beginning with herpes simplex virus 2.

Allied Medical said in July that Coridon was a spin out from Queensland University through its commercialization arm Uniquest and directors included Uniquest general managers Andrew Davis and Dr Dean Moss, with chairman Prof Ian Frazer, the inventor of CSL's Gardasil vaccine for human papillomavirus (BD: Jul 20, 2010).

Today, Biomd said that its offer was recommended by Allied Medical's board and was subject to a greater than 90 percent minimum acceptance by its shareholders and was also subject to Biomd shareholder approval.

Biotech Daily believes Avexa is aware of the Biomd and Allied Medical agreement and does not oppose it.

Biomd said it was offering Allied shareholders 428,275,968 of its shares and on completion, Allied Medical would have 70 percent of the combined group.

Allied Medical chief executive officer Lee Rodne said the offer was "an exciting opportunity for Allied shareholders to benefit from Biomd's unique technologies".

"Biomd's lead product Cardiocel has completed phase II human trials, is about to undergo regulatory approval and adds significantly to Allied's product development pipeline," Mr Rodne said.

Biomd managing director Michael Bennett said the two companies had a corporate synergy that would allow for the building of a healthcare group that will provide technically advanced medical devices and solutions for the burgeoning healthcare market.

"It will also provide the infrastructure needed for the commercialization of new Australian medical technologies and devices," Mr Bennett said.

Biomd said Allied Medical had 1,675,000 options held by directors and executives and one term of the bid is that Biomd acquired the options in exchange for the issue of 53.6 million options exercisable at six cents each within five years of the date of issue and would issue a further 13.4 million options to its directors and advisors, subject to shareholder approval, exercisable at six cents each within five years of the date of issue. Biomd said that at December 31, 2010 it had unaudited net tangible assets of \$816,000 comprising and Allied Medical had unaudited net tangible assets of \$4,805,128. Biomd fell 2.4 cents or 27.0 percent to 6.5 cents.

Avexa was up 0.2 cents or five percent to 4.2 cents with 1.7 million shares traded.

BIOMD

Last night's edition reported that Biomd had requested a voluntary suspension following a trading halt for a "proposed capital raising".

The trading halt and suspension were called for the "potential transaction" (see above). The mistake was in the first Biomd notice to the ASX, later corrected, and the new subeditor has survived the correction.

HEALTHLINX

Healthlinx says its Ovplex ovarian cancer test has been shown to be superior to CA125 alone in the first 485 samples of an 1150 sample trial.

The Ovplex test has five biomarkers including the current industry standard CA125 and the company is also evaluating two other biomarkers AGR2 and HTX010.

At a media lunch organized by Monsoon Communications, Healthlinx chief scientific officer Dr Dominic Autelitano said the company was considering a test with six biomarkers as well as the previously proposed five biomarker test.

Dr Autelitano said that CA125 had poor specificity and sensitivity and could be misleading. Cancer antigen 125 is a glycoprotein in the blood serum of patients with ovarian or other glandular cell carcinomas. Mosby's Dictionary says the CA125 test has "a high degree of sensitivity and specificity for ovarian cancer" as well as determining response to therapy. Dr Autelitano said that in all categories, the first stage of the 1150-sample trial had demonstrated the Ovplex test had fewer errors than CA125 alone.

He said that benign or borderline tumors including cysts, endometrioses and low malignant potential tumors were "a grey area and hard to pick".

In a media release, Healthlinx said that of 358 samples, including 180 normal samples and 178 malignant ovarian cancer samples, CA125 misclassified 50 women (13.97%), while the standard Ovplex test misclassified 32 women (8.9%).

Healthlinx said that with the AGR2 biomarker, the test misclassified 22 women (6.16%). Dr Autelitano said that at this stage Healthlinx was not providing sensitivity and specificity data but counting all false positives and all false negatives as misclassifications. Adding the more difficult to diagnose 127 benign patient cohort CA125 had 73 wrong diagnoses (15.05%) of the total 485 samples while the standard Ovplex test had 51 mistaken diagnoses (10.52%).

Dr Autelitano said the 485 samples were separate from a previous trial of 358 samples first reported in November 2007 (BD: Feb 21, 2008; Aug 4, 2009).

Healthlinx said the analysis of the first part of the study confirmed superior performance of Ovplex over CA125 in all stages of ovarian cancer including early stage disease.

Healthlinx said that the inclusion of the benign group was designed to further test the diagnostic capacity of the Ovplex panel in a clinically relevant patient cohort as well as to determine the performance of AGR2 in this setting.

Healthlinx said that comparisons of the area under the curve of receiver operator curves demonstrated a statistically significant increase in diagnostic performance of the original Ovplex panel over CA125 alone, with the inclusion of AGR2 adding additional benefit. Healthlinx said that based on the data and the scientific advisory committee review and ratification, the company would complete the analysis of the addition 600-700 samples in the multi-national study currently being collected; progress with the commercial development of ARG2 as a cancer biomarker; and progress the integration of AGR2 into the Ovplex panel.

Dr Autelitano said he expected the trial to be completed in 12 to 18 months. Healthlinx was up 2.6 cents or 46.4 percent with 67.8 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says its revenue is up 22.8 percent to \$5,111,000 and net profit after tax is up 142.9 percent to \$804,000 for the six months to December 31, 2010. Medical Developments said basic earnings per share was 1.6 cents, a 166.7 percent increase over the six months ended December 31, 2009.

The company said no dividend would be paid.

Medical Developments said it had "undergone an aggressive program to review, restructure, implement changes and develop its existing business as well as to expand the company's business development outreach".

"This program which focused on systematic restructuring of our distribution arrangements into the dental, cosmetic and podiatry markets, together with the restructured New Zealand operation, has resulted in significant improvements and performance, which will continue in the future," the company said.

Medical Developments was untraded at 45.5 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says it has hired a European-based contract research organization for its pivotal clinical trial in Europe.

Medical Developments said the randomized, double-blind, multi-centre, placebo-controlled study would evaluate the safety and efficacy of Penthrox (methoxyflurane) for the treatment of acute pain in patients presenting to emergency departments with minor trauma.

The company said it expected the successful completion of the trial to facilitate a marketing authorization to sell Penthrox in the European Union.

Medical Developments said the first patient was expected to be enrolled by December 2011 and the trial was expected to be funded from its own cash reserves.

CYCLOPHARM

Barings Acceptance has become a substantial shareholder in Cyclopharm with the acquisition of 17,052,895 shares or 9.97 percent of the company.

The initial substantial shareholder notice said Barings was based at Russell Bedford House 250 City Road, London, the same address as Barleigh Wells which last week said it had disposed of the same number of shares for \$1,364,232 or eight cents a share in an off-market transfer (BD: Feb 7, 2011).

Cyclopharm was untraded at 7.1 cents.