Biotech Daily

Wednesday December 15, 2010

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: PHYLOGICA UP 16%; LIVING CELL DOWN 9%**

*** EARLY LOOK SHOWS HEALTHLINX OVPLEX BEATS CA-125 ALONE**

*** PATRYS APPROVED FOR HIGHER DOSE IN PAT-SM6 MELANOMA TRIAL**

*** FDA GUIDES PHARMAXIS ON BRONCHITOL FOR CYSTIC FIBROSIS NDA**

*** TYRIAN UNDERWRITTEN RIGHTS ISSUE RAISES $3.98m**

*** LBT EXPECTS INCREASED LOSS FOR H1 2010**

*** CIRCADIAN COMPANIES INCREASE, DILUTED TO 17% IN ANTISENSE**

MARKET REPORT

The Australian stock market edged up 0.02 percent on Wednesday December 15, 2010 with the S&P ASX 200 up 0.9 points to 4767.8 points.

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

Phylogica was best, up 0.8 cents or 16 percent to 5.8 cents with 1.7 million shares traded.

Advanced Surgical and Prana climbed four percent or more; Acrux, Impedimed, Patrys and Resmed were up more than three percent; with Alchemia, Cochlear and Optiscan up one percent or more.

Living Cell led the falls, down 1.5 cents or 9.4 percent to 14.5 cents with 165,152 shares traded, followed by Cellmid down 5.6 percent to 3.4 cents with 5.3 million shares traded.

Phosphagenics lost 4.2 percent; Mesoblast, Psivida and QRX shed more than two percent; with Cathrx, Chemgenex, Circadian, Clinuvel, Tissue Therapies and Universal Biosensors down more than one percent.

HEALTHLINX

Healthlinx says an analysis of the first 500 samples of its 1150 sample ovarian cancer biomarker study shows Ovplex is a superior diagnostic compared to CA125 alone.

Healthlinx said the initial analysis of the first part of its ovarian cancer biomarker study confirmed a statistically significant increase in diagnostic performance - defined as "the diagnostic efficiency of Ovplex and CA125 … compared on the basis of the area under the curve of receiver operator curves".

The company said the enhanced performance of Ovplex was also established specifically for early stage ovarian cancer.

In a table Healthlinx said the area under the curve for all stages gave a 4.0 percent ($p<0.05$) advantage to the Ovplex five-measure panel which includes the CA-125 biomarker.

For early stage cancers, Healthlinx said Ovplex was 0.923 efficient compared with CA-125 which rated 0.802 efficiency ($p<0.01$).

Healthlinx said the data represented preliminary statistical comparisons of area under the curve of receiver operator curves generated from the first part of the second larger multi-national, multi-centre biomarker study.

The company said that biomarker measurements in more than 500 samples had been completed, a subset of the full Ovplex study that would include a total of 1150 samples to be collected in Australia, Singapore and the UK.

Healthlinx said that measurement of all Ovplex biomarkers was performed in more than 500 samples as the first part of the biomarker study.

The company said that epithelial ovarian cancer patients and normal subjects had undergone independent preliminary analysis by Emphron Informatics draw comparisons with the previous smaller Ovplex trial.

Healthlinx said the primary end point for the study was to undertake a receiver operator curves analysis of control subjects versus all epithelial ovarian cancer patients.

The company said that the first part of the study "demonstrated that Ovplex significantly outperformed the diagnostic capability of CA125 alone".

The company said that similar analysis of control subjects versus early stage (stages I-II) epithelial ovarian cancer patients demonstrated an even more marked advantage of Ovplex over CA125 alone.

Healthlinx said the AGR2 and HTX010 biomarkers added further diagnostic potential to the panel.

The company said that the findings "so far demonstrate in a totally independent and broader sample set that Ovplex has similar or better performance to our previous biomarker trial and provides strong confirmation of the advantage Ovplex provides over the use of CA125 alone".

Healthlinx said the best way to exploit the diagnostic value of AGR2 and HTX010 would be determined in a series of modeling studies to be performed with Emphron Informatics.

Healthlinx managing director Nick Gatsios told Biotech Daily that figures for sensitivity and specificity would be released by March 2011 following a scheduled scientific advicsory committee meeting.

"Based on these preliminary data the company will progress the AGR2 assay through regulatory approval for use in the panel once this Ovplex study is completed," Mr Gatsios said in a media release.

Healthlinx said discussions had begun with commercial partners with "the internal resources and expertise to take the research based AGR2 assay through the regulatory pathway and scale up production for commercial distribution".

Healthlinx was up 0.4 cents or 4.8 percent to 8.8 cents.

PATRYS

Patrys says it has approval to dose the second group of patients in its 10-patient PAT-SM6 melanoma trial.
Patrys said that based on safety data from its first group of three patients, an independent data safety monitoring board approved the move to a second group of patients at a higher dose level.
The company said that PAT-SM6 was a natural human antibody that had shown "great promise as a potential treatment for multiple types of cancer including melanoma".
Patrys said it was the first reported clinical product to target the GRP78 protein on the surface of cancer cells, which played a number of key roles in cancer cell survival, growth and metastases.
The company said the trial was being held at the Royal Adelaide Hospital Cancer Centre and associated Pain and Anaesthesia Research Clinic, with a primary goal to evaluate the safety and tolerability of three increasing doses of PAT-SM6 in melanoma patients and multiple secondary endpoints aimed at measuring the anti-tumor activity of PAT-SM6.
Patrys said melanoma was a serious global medical problem, with an expected doubling of incidence every 15 years.
The company said Australia had the highest rate of skin cancer in the world, with about 10,000 cases diagnosed each year.
Patrys said that current treatments for metastatic melanoma were largely ineffective, resulting in a five year survival rate of 16 percent.
The company said results were expected to be finalized and reported by June, 2011.
Patrys was up 0.3 cents or 3.1 percent to 10 cents with 1.2 million shares traded.

PHARMAXIS

Pharmaxis says the US Food and Drug Administration has provided guidance on its Bronchitol for cystic fibrosis new drug application
Pharmaxis said the pre-new drug application meeting was held on December 10, 2010.
Pharmaxis chief executive officer Dr Alan Robertson said the meeting "provides us with the guidance we need to submit the Bronchitol [application]".
"We appreciate the advice of the FDA and look forward to working with the FDA," Dr Robertson said.
Pharmaxis did not disclose the nature of the FDA guidance.
Pharmaxis said that two, long-term, phase III trials of Bronchitol in patients with cystic fibrosis demonstrated a clinically important improvement in lung function, in addition to an improvement in a variety of other measures.
The company said that loss of lung function was the principal reason for reduced life expectancy for people with cystic fibrosis.
Pharmaxis said it expected to submit the application by July 2011.
Pharmaxis fell one cent or 0.35 percent to $2.82.

TYRIAN DIAGNOSTICS

Tyrian says its fully-underwritten rights issue has raised $1,383,563 from the issue of 172,945,425 shares at 0.8 cents a share.
Tyrian expected to raise up to $3,988,131 through the issue of up to 498,516,341 shares and today said the 325,570,916 shortfall shares were expected to be placed by Patersons Securities on or about December 21, 2010.
Tyrian was unchanged at 0.8 cents.

LBT INNOVATIONS

LBT says it expects to lose $800,000 for the six months to December 31, 2010, compared to $522,000 in the previous corresponding period.
LBT said the preliminary unaudited result followed the profit for the 12 months to June 30, 2010 of $1.49 million, which included receipt of a $3.4 million licencing milestone payment from Biomérieux for the company's Previ Isola.
The company said no milestone payments were due from Biomérieux in the current financial year, but minimum royalty provisions were in place.
LBT said that royalty payments were "unlikely to exceed the contracted minimum levels in the next calendar year based on the current growth rate of applicator sales".
The company said the minimum royalty payment for 2010 was $US360,000 and the minimum royalty for 2011 was $US600,000.
LBT said one factor in the expected increase in the half-year loss was the investment in research and development of its automated plate assessment system technology, announced at its annual general meeting on November 15, 2010 (BD: Dec 6, 2010).
The company said that development of the automated plate assessment system (APAS) would continue during 2011.
LBT was untraded at 7.6 cents.

ANTISENSE, CIRCADIAN

Two Circadian-related companies have been diluted in and one has increased its substantial holding in Antisense.
The total change is from 132,165,909 shares (22.42%) to 150,915,909 shares (16.99%).
The companies were Circadian's wholly-owned subsidiary Polychip Pharmaceuticals and Polychip's 42.38 percent subsidiary Syngene.
Polychip's 101,906,497 shares were diluted from 17.29 percent to 11.47 percent, while Syngene increased from 30,259,412 shares (5.13%) to 49,009,412 shares (5.52%).
Circadian has previously told Biotech Daily (BD: Feb 5, 2010) that the Packer family-owned Consolidated Press Holdings held 19.9 percent of Syngene and the Howard Florey Institute also owned about 20 percent, with the remainder owned by about 40 other holders.
The substantial shareholder notice said that Syngene acquired the 18,750,000 shares for $150,000 or 0.8 cents a share in the recent rights issue.
Antisense was unchanged at 0.7 cents with 2.8 million shares traded.
Circadian fell one cent or 1.6 percent to 60 cents.