# Biotech Daily

Tuesday June 22, 2010

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: ANTISENSE UP 7%, COMPUMEDICS DOWN 21%**

*** PHARMAXIS PHASE III CYSTIC FIBROSIS TRIAL MISSES ENDPOINT - DESPITE IMPROVED LUNG FUNCTION**

*** HEALTHLINX CM1 BIOMARKER MAY DETECT PROSTATE CANCER**

*** TAYLOR COLLISON UNDERWRITES $2m LIVING CELL OPTIONS**

*** XCEED SELLS CALZADA WEDGE FOR $865k**

*** IMMURON SHARE PLAN RAISES $691k**

*** SIGNIFICANT DISSENT AT CBIO MEETING**

*** GENETIC TECHNOLOGIES APPOINTS LEWIS STUART US G-M**

## MARKET REPORT

The Australian stock market fell 1.2 percent on Tuesday June 22, 2010 with the S&P ASX 200 down 54.3 points to 4558.3 points.

Ten of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and seven were untraded.

Antisense was best, up 0.1 cents or 6.67 percent to 1.6 cents with 622,500 shares traded.

Impedimed and Tissue Therapies climbed more than five percent; Chemgenex was up 4.7 percent; Phylogica rose 2.6 percent; with Bionomics, Nanosonics and Optiscan up more than one percent.

Compumedics led the falls, down 3.5 cents or 21.2 percent to 13 cents with 10,000 shares traded, followed by Living Cell down 2.5 cents or 9.8 percent to 23 cents with 166,173 shares traded.

Cellmid and Prana lost more than eight percent; Phosphagenics fell 7.7 percent; Biota fell 4.2 percent; Cellestis, Prima and Universal Biosensors were down more than three percent; Alchemia, Benitec, Clinuvel, Mesoblast and Viralytics shed two percent or more; with Cathrx, Cochlear and Genera down more than one percent.

PHARMAXIS

Pharmaxis says its second phase III trial of Bronchitol for cystic fibrosis narrowly missed its primary endpoint despite showing an average 8.2 percent lung function improvement over 26 weeks.

In a conference call after the market closed tonight, Biotech Daily was unable to confirm the impact of Pharmaxis failing to meet the primary endpoint despite other positive results.

Pharmaxis chief operating officer Gary Phillips said the control was a 50mg dose of mannitol.

Pharmaxis said the 318 patient trial in the US and six other countries confirmed earlier headline results from Pharmaxis six-month dosing of its phase III trial for cystic fibrosis (CF) showing that the lung function of patients treated with Bronchitol (mannitol inhalation powder) for a full 12-months improved from 6.5 percent at six months to 8.0 percent ($p<0.001$) at 12 months (BD: Dec 2, 2009).

Pharmaxis said at that time that the leading cause of death for cystic fibrosis patients was the loss of an averaging one to two percent of lung function a year.

Pharmaxis said today the latest results supported the early and sustained improvement in lung function in cystic fibrosis patients seen in the first phase III study and Pharmaxis would meet the US Food and Drug Administration later this year to discuss a new drug application for Bronchitol.

The company said that patients treated with Bronchitol had an 8.2 percent (107mL) improvement in lung function as measured by forced expiratory volume over one second (FEV1) compared to baseline over the 26 weeks of the study which was significant ($p<0.001$) and similar to the 6.3% improvement seen in the earlier study.

Pharmaxis said significant improvements from baseline were seen on Bronchitol at six, 14 and 26 weeks of treatment ($p\leq0.001$).

Pharmaxis said the primary endpoint comparing the FEV1 improvement of Bronchitol to control over the 26 weeks, narrowly missed statistical significance ($p=0.059$) despite the overall treatment effect across 26 weeks expressed as a percentage being similar to that reported in the earlier trial, known as CF301.

The company said that the FEV1 percentage improvement of Bronchitol compared to control in the second trial, known as CF302, over the 26 weeks was significant ($p=0.029$).

Secondary endpoints targeting other measures of lung function also showed significant improvement in patients on Bronchitol compared with control, including forced vital capacity ($p=0.022$), and percentage FEV1 predicted ($p=0.024$).

“Patients who are already receiving current best standard of care have shown improvement in their lung function in both multi-centre trials and this effect has recently been shown to be sustained over 18 months,” Mr Phillips said.

“CF patients are frequently burdened with multiple treatments including nebulisers and we hope that Bronchitol’s formulation as a dry powder delivered by a small portable inhaler has the potential to bring an effective therapy to CF patients in a way that assists them in managing their disease,” Mr Phillips said.

Pharmaxis said Bronchitol was well-tolerated overall and demonstrated a similar rate of adverse events across treatment groups. Similar to the earlier study, seven percent of recruited subjects were unable to tolerate Bronchitol and were not entered into the study, while the withdrawal rate during the study was 15 percent.

The most common treatment related adverse event was cough, which was similar between the treatment arms.

Mr Phillips said the trial was important and allowed the company to complete the regulatory dossier that will be discussed with the FDA later this year.

Pharmaxis last traded at $3.12.

## HEALTHLINX

Healthlinx says it has data that may be the basis for its development of a more accurate prostate cancer diagnostic to the current standard.

Healthlinx said the prostate specific antigen (PSA) test was the most commonly used biomarker for diagnosis of prostate cancer and was the most widespread form of prostate cancer screening tool with a specificity of 63.1 per cent and sensitivity of 34.9 per cent.

The company said the “poor performance highlights the need for a statistically improved more effective method to detect prostate cancer”.

Healthlinx said prostate cancer was the ninth most common cancer and was often associated with over-diagnosis and unnecessary surgery, with a diagnostic market opportunity of more than $US350 million a year.

The company said that early data suggested that one of its proprietary biomarkers CM1 showed “significant potential for fulfilling this un-met market need and justifies priority development”.

Healthlinx said it examined plasma concentrations of CM1 in prostate cancer patients using a well defined set of 30 prostate cancer plasma samples obtained from a Melbourne-based clinical centre and 14 male controls.

The company said the samples represented a range of prostate cancer stages as well as a broad range of Gleason scores.

Plasma concentrations of CM1 were largely below the limit of detection in the control male population tested, with only three samples registering measurable CM1.

“In sharp contrast, 27 of 30 prostate cancer plasma samples showed clearly measurable and elevated concentration of CM1,” Healthlinx said.

Healthlinx said the elevated concentrations of CM1 in prostate cancer patients showed no obvious correlation with pre-operative concentration of PSA, suggesting that this measurement may complement current PSA-aided diagnosis.

Healthlinx managing director Nick Gatsios said his company was “in discussions with a group of clinicians who are reviewing the data with the view that a study will be designed to validate the diagnostic utility of our technology in a clinical environment”.

Healthlinx fell half a cent or four percent to 12 cents.

## LIVING CELL TECHNOLOGIES

Living Cell says Taylor Collison has underwritten the exercise of 9,523,810 options at 21 cents each, expiring on June 30, 2010, raising $2,000,000.10 for the company.

Living Cell said that a total of 10,568,655 options were held by long-time supporters, including staff and directors.

The company said Taylor Collison could place any of the remaining unexercised options on the same terms.

Living Cell said the funds would be used to advance the company’s platform technologies, principally the phase II human clinical trial program for Diabecell encapsulated porcine islets of Langerhans for insulin dependent type 1 diabetes.

Living Cell finance director John Cowan told Biotech Daily that the options were all granted at no cost on August 30, 2004.

According to ASX data, the company listed on the ASX on September 1, 2004, following a capital raising at 20 cents a share.

Living Cell fell 2.5 cents or 9.8 percent to 23 cents.

## CALZADA, XCEED CAPITAL

Xceed Capital Ltd (Xceed) is pleased to advise that it has sold its 8.3% holding (28,804,832 shares) in Calzada Limited at $0.03 per share ($865,224).
This transaction is consistent with the strategy foreshadowed earlier this year of positioning Xceed to seek a new investment.
Calzada fell 0.3 cents or 10 percent to 2.7 cents.
Xceed was unchanged at 1.1 cents.

## IMMURON

Immuron says that its share purchase plan raised $691,387.20 through the issue of 10,636,702 shares.
Immuron said in April the share plan offer at 6.5 cents allowed for a maximum of 24,000,000 shares or a maximum raising of $1,560,000 (BD: APR 19, 2010).
Immuron was up 0.2 cents or 2.99 percent to 6.9 cents.

## CBIO

CBio's meeting to approve three prior share issues were easily passed but with up to 10.5 percent of votes against the resolutions.
CBio said more than 18.86 million proxy votes supported the three resolutions with up to 2,316,330 proxy votes against.
CBio was unchanged at 32 cents.

## GENETIC TECHNOLOGIES

Genetic Technologies has appointed Lewis Stuart as general manager of its North American molecular diagnostics business.
Genetic Technologies said the new division was the result of its recent acquisition of US assets including the Brevagen risk assessment test for non-hereditary breast cancer.
The company said Mr Stuart had more than 28 years experience in US and European health sector sales and marketing across multiple therapeutic categories including women's health, infectious disease and endocrinology.
Genetic Technologies chief executive officer Dr Paul MacLeman said the appointment was "an important milestone" as the company prepared for the US launch of Brevagen and the expansion of its molecular diagnostics business.
The company said that Mr Stuart was most recently senior vice-president of commercial operations at cardiovascular drug developer CV Therapeutics, where he led the launch of Ranexa and played a significant role in increasing the company's market cap from $300 million to its $1.5 billion acquisition by Gilead.
Mr Stuart held US and European sales and marketing positions, including six years at Pfizer's Agouron Pharmaceuticals as well as positions at Bristol Myers Squibb, Solvay Pharmaceuticals, Centocor and Upjohn.
Genetic Technologies was unchanged at 3.6 cents.