Biotech Daily

Wednesday December 2, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PHARMAXIS UP 11%; COMPUMEDICS DOWN 8%**

*** PHARMAXIS: PHASE III BRONCHITOL BENEFIT FOR CYSTIC FIBROSIS**

*** PHOSPHAGENICS BEGINS PHASE Ib OXYCODONE PATCH TRIAL**

*** PHYLOGICA REQUESTS CAPITAL RAISING TRADING HALT**

*** HEALTHLINX TO SELL OVARIAN CANCER TEST IN UK IN 2010**

*** ADVANCED SURGICAL EUROPEAN, TGA KNEE APPROVALS**

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*** GSK, OPTISCAN APPOINTMENTS TO IP COUNCIL**

*** KARMELSONIX REQUESTS CAPITAL RAISING TRADING HALT**

MARKET REPORT

The Australian stock market was up 0.9 percent on Wednesday December 2, 2009 with the S&P ASX 200 up 43.4 points to 4762.4 points.

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

Pharmaxis was best, up 27 cents or 10.9 percent to $2.76 with 1.2 million shares traded, followed by Benitec up 9.8 percent to 4.5 cents, QRX up 9.6 percent to 85.5 cents and Phylogica up 9.1 percent to 12 cents.

Avexa and Viralytics climbed five percent or more; Novogen was up more than four percent; Universal Biosensors was up 3.6 percent; Alchemia, Sirtex and Sunshine Heart rose more than two percent; with Chemgenex, Circadian and Phosphagenics up more than one percent.

Compumedics led the falls, down 1.5 cents or 7.9 percent to 17.5 cents with 8,000 shares traded followed by Acrux down 5.8 percent to $2.27 and Nanosonics down 5.5 percent to 60.5 cents.

Prima and Tissue Therapies lost more than three percent; Mesoblast shed 2.1 percent; with Heartware, Impedimed and Living Cell down more than one percent.

PHARMAXIS

Pharmaxis says headline results from its second six-month dosing of its phase III Bronchitol trial for cystic fibrosis are “significant”.

Pharmaxis said the lung function of patients treated with Bronchitol for a full 12-months improved from 6.5 percent at six months to 8.0 percent ($p<0.001$) at 12 months.

The company said that the lung function of patients who were on placebo for the first six months of the study improved by 10.3 percent ($p<0.001$) when switched to Bronchitol.

Pharmaxis said the Bronchitol trial was conducted in two phases. The first six-month, placebo-controlled blinded phase met its primary endpoint by improving lung function as measured by a change in forced expiratory volume in one second (FEV1) by a statistically significant 6.5 percent ($p=0.003$) compared to placebo (BD: May 4, 2009).

The second six-month unblinded, non-placebo controlled phase was to determine the safety of Bronchitol in patients with cystic fibrosis following 12 months of treatment and to assess the long term effects on lung function.

Pharmaxis said the patients treated with placebo during the initial six month blinded phase of the trial were switched to Bronchitol during the subsequent six month open phase.

Pharmaxis chief executive officer Dr Alan Robertson said the results were very impressive and were “of significant clinical relevance”.

“For cystic fibrosis patients, consistent loss of lung function, averaging one to two percent per year is the leading cause of death,” Dr Robertson said.

“The improvements now shown with Bronchitol treatment over a 12 month period hold out the promise that, with longer usage, Bronchitol can change the course of cystic fibrosis,” Dr Robertson said. “Bronchitol is the first dry powder formulation to report results of this nature in [cystic fibrosis] and it offers convenience for patients who otherwise have to deal with complex daily treatment regimens.”

“Many people have been involved in the development of Bronchitol and this result is a tribute to their dedication and effort,” Dr Robertson said.

Pharmaxis said a total of 170 subjects (Bronchitol=97, placebo=73) consented to participate in the open label phase and of these, 81 (83.5%) and 49 (67.1%) completed the six month open label phase.

For the 170 subjects that entered the open label phase, the average age was 23 years and the mean lung function on entry was 63 percent of the predicted normal FEV1.

Pharmaxis said the ages ranged from six years to 56 years and the lung function ranges were from 26 percent to 92 percent of the predicted FEV1.

Pharmaxis said that reported treatment-related adverse events were experienced by 40 subjects.

Four of these events related to the condition being aggravated with cough, haemoptysis, or wheezing were experienced by three subjects each.

Pharmaxis said the majority of adverse events were mild to moderate in severity and many of the frequently reported adverse events were a consequence of the underlying disease.

The company said the trial was conducted in 40 centres in the UK, Ireland, Australia and New Zealand and additional data from the trial including other lung function parameters and effects on exacerbation will be presented at a forthcoming scientific meeting.

Bronchitol is designed to hydrate the airway surface of the lungs, and promote normal lung mucus clearance.

It has received orphan drug designation and fast track status from the U.S. Food and Drug Administration and orphan drug designation from the European Medicines Agency. A marketing application has been submitted and accepted for review by the EMEA.

Pharmaxis climbed 27 cents or 10.9 percent to $2.76 with 1.2 million shares traded.

PHOSPHAGENICS

Phosphagenics has begun a phase Ib clinical trial of two versions of its oxycodone tocopheryl phosphate mixture or TPM transdermal patch.

Phosphagenics said the trial was a pharmacokinetic study in 20 healthy volunteers at the Royal Adelaide Hospital under principal investigator and professor of anaesthesia Prof Guy Ludbrook.

The company said the primary objective of the trial was to compare two transdermal patch candidates, a matrix and reservoir system, to deliver oxycodone.

Phosphagenics said each of the 20 subjects would be administered with an oxycodone patch on a once daily basis for up to 10 days.

The company said oxycodone levels would be monitored to assess which of the two patch systems could deliver oxycodone into the blood stream at therapeutic levels in a reproducible and sustained manner and to determine which would be best suited for commercial development.

Phosphagenics said the trial was scheduled to be completed “by early 2010” and the better candidate would advance to phase II/III trials, scheduled for 2010.

Phosphagenics’ chief operating officer Dr Esra Ogru said the tocopheryl phosphate mixture oxycodone patch system appeared “potentially suitable for chronic pain management”.

“The results of our first trial earlier this year were a world first and were suggestive of the potential for the TPM system to change the way in which chronic pain could be treated in the future,” Dr Ogru said.

“Currently, patients treated with oral oxycodone obtain pain relief for only a short period of time,” Dr Ogru said.

Several websites including www.drugs.com and the US National Institutes cite three to five hours as active duration of oxycodone hydrochloride, but the NIH website says that the extended release version should be taken every 12 hours.

Dr Ogru said an earlier Phosphagenics trial indicated that its oxycodone patch “may provide sustained drug delivery for a matter of days”.

“This trial will help determine just how long we can provide patients with sustained pain relief,” Dr Ogru said.

Phosphagenics said it aimed “to become the first company to offer chronic pain sufferers an oxycodone patch that will provide sustained pain relief”.

The company said that a trial earlier this year on 50 subjects, demonstrated that its formulation did not cause sensitization or irritation, one of the major barriers preventing the use of most opioids in topical delivery systems (BD: Sep 15, 2009).

At that time, Phosphagenics said the drug continued to be released from the skin to the bloodstream for four days after the patch was removed

Phosphagenics said today that it was “highly likely that the TPM patch may have application to the majority of opioids, giving clinicians many alternatives in the treatment of chronic pain”.

Phosphagenics said US sales of oxycodone was more than $US1.5 billion a year.

The company said that although oxycodone was an opioid derivative it was more potent than morphine, but produced less adverse side effects.

Phosphagenics said oxycodone was “the drug of choice for chronic pain management of patients suffering from debilitating diseases such as cancer”.

The company said oxycodone could be administered orally or intravenously.

Phosphagenics was up 0.1 cents or 1.3 percent to 7.6 cents.

PHYLOGICA

Phylogica has requested a trading halt pending an announcement regarding a “a capital raising of up to 15 percent of the expanded capital”.

Phylogica said in August that it was in advanced negotiations with a number of large pharmaceutical and biotechnology groups regarding new discovery partnerships using its library of phylomers or protein fragments (BD: Aug 26, 2009).

The company said negotiations had “moved to such an advanced stage that Phylogica hopes to complete formal documentation shortly and also needs to demonstrate a sound financial capacity to deliver these services”.

Trading will resume on December 4, 2009 or on an earlier announcement.

Phylogica was up one cent or 9.1 percent to 12 cents.

HEALTHLINX

Healthlinx says it will market its ovarian cancer diagnostic Ovplex in the United Kingdom from February 2010.

Healthlinx said UK distributor Intus Healthcare completed a commercial arrangement with hospital and healthcare services group Spire Healthcare to process and market Ovplex.

The company said the UK market potential was more than 750,000 units potentially worth more than $5 million.

Healthlinx said Ovplex was “the most accurate commercially-available ovarian cancer diagnostic”.

The company said the UK deal would be the first time the Ovplex diagnostic would be available outside Australia.

Healthlinx managing director Nick Gatsios said Ovplex was “a best in market ovarian cancer diagnostic, as are our distribution partners”.

Healthlinx said Spire was the second largest private hospital group in the UK, with a network of 36 hospitals nationwide and offered services including pathology, diagnostic tests and investigations as well as surgical procedures.

The company said more than 240,000 new cases of ovarian cancer were diagnosed each year worldwide and more than 130,000 women die from the disease. The UK accounts for more than 7,000 of these diagnoses and 4,000 lives lost every year.

“The reason why it is the most lethal of the reproductive tract cancers is that 75 percent of women with ovarian cancer are not diagnosed until the late stage of the disease,” Mr Gatsios said.

“Their chances of surviving five years are probably only 20 percent,” Mr Gatsios said.

“But if the disease is diagnosed in the early stages of the disease the five year survival rate is increased to 80 percent,” he said. “That is why it is so important to provide better diagnostic tests for ovarian cancer, particularly early stage disease where it can make a significant difference.”

Healthlinx said it was continuing research and development on its next generation ovarian cancer diagnostic to further improve accuracy and earlier detection.

Healthlinx was up 1.1 cents or 12.9 percent to 9.6 cents.

KARMELSONIX

Karmelsonix has requested a trading halt pending an announcement regarding a “a capital raising”.

Trading will resume on December 4, 2009 or on an earlier announcement.

Karmelsonix last traded at five cents.

ADVANCED SURGICAL DESIGN & MANUFACTURE

Advanced Surgical Design & Manufacture says its Active Knee has class III Conformitée Européenne (CE) Mark approval

The company said the class III approval was the highest classification for this type of device and is above the Class IIb rating previously held.

Advanced Surgical said Active Knee was "fully compliant with the revised EU Medical Device Directive, requiring that joint replacements meet the class III rating".

The company said it was "in a position to intensify its sales and distribution" in Europe.

Advanced Surgical said "a number of competing knees have failed to satisfy this new regulatory standard and are now having to be withdrawn from European sale".

In October Advanced Surgical sold the intellectual property associated with the Active Knee to Stryker for $3 million (BD: Oct 30, 2009).

At the time of publication it was not clear what revenue would return to the company from sales of the knee and no one from the company was available for comment.

Advanced Surgical said the Australian Therapeutic Goods Administration had reissued its conformity assessment certificate for Australian regulatory approval.

The company said its UK distributor had appointed Medical Developments of Athens as exclusive distributors in Greece. Advanced Surgical said the Active Knee was being supplied to six hospitals and the first knees have been successfully implanted.

Advanced Surgical fell one cent or 1.7 percent to 59 cents.

AGENIX

Agenix says it is closer to resolve the long-running attempt to acquire Chinese pharmaceutical assets with the signing of a deed of variation (BD: Apr 17, 2009)

Agenix said it hoped the new agreement would vary the commercial terms of the final and binding all in settlement to resolve the dispute.

Under the earlier agreement, Shanghai Rui Guang Bio-Pharma Development Co (SHRG) was to pay the total amount of RMB44,000,000 ($A7 million) by November 30, 2009.

Agenix said it did not receive the balance of proceeds due by November 30, 2009.

Security for the payment of this sum includes personal guarantees from Jonathan Zheng and Richard Zhang, directors of the vendors under the 2007 transaction documents.

The deed of variation is intended to implement a revised timetable for payments.

The company said the Chinese parties paid an installment of RMB1,500,000 on November 30, 2009 and a RMB355,450 liability had been passed to the Chinese parties.

Agenix said the overall effect was that there had been a total reduction of RMB1,855,450 from the outstanding settlement sum owed to Agenix to RMB37,644,550.

In the event the deed of variation was not fully executed by all parties, Agenix and the Agenix WFOE reserved rights to enforce the original transaction documents, and will take all necessary steps to protect its position.

Agenix chairman Nick Weston said the company had not received any payment since August, could revert to the original purchase documentation and litigate and, at the same time, because it was not clear that the framework was no longer workable, maintained negotiations with the Chinese parties that should formalize a revised payment schedule.

Agenix said it would detail the terms of the deed, once it was executed by all parties.

Separately Agenix said convertible notes raised $600,000 matured on December 1, 2009. and had been fully converted to shares with Annmac Investments receiving 16,144,110 shares and Sino Sky Holdings receiving 31,418,630 shares.

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

ADVISORY COUNCIL ON INTELLECTUAL PROPERTY

Optiscan chief executive officer Vicki Tutungi is one of four new appointments to the Advisory Council on Intellectual Property.

The Federal Government's Parliamentary Secretary for Innovation and Industry Richard Marles announced four appointments to the Council, described as "a key advisory panel on Australia's intellectual property system".

Mr Marles said the Council contributed to the strategic direction of Australia's IP system, provided an important advisory service to the Government and performed independent reviews of key intellectual property issues.

"The Rudd Government is committed to maintaining an effective and robust intellectual property system and these appointments to ACIP will bring further experience and depth of knowledge to the council," Mr Marles said.

The Government's media release said the new council members were Ms Tutungi who had previously held a number of roles at the Commonwealth Scientific and Industrial Research Organisation, including chief of the division of manufacturing and materials technology; SAAB Systems senior systems engineer Dr Derek Rogers; Glaxosmithkline Australia general counsel Julia Banks, and Queensland University of Technology professor of intellectual property and innovation Prof Brian Fitzgerald.

Mr Leon Allen was reappointed as chair of the Advisory Council on Intellectual Property Appointments to the council are for three years beginning on January 1, 2010.