Biotech Daily

Monday October 10, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ANTISENSE UP 12.5%; OPTISCAN DOWN 8%**

*** HEALTHSCOPE 'BETA' TESTS PETER MAC, CIRCADIAN CANCER TEST**

*** BIOTRON: BIT225 'GOOD ANTIVIRAL ACTIVITY' AGAINST HEPATITIS C**

*** ATCOR SIGNS TWO CONTRACTS WORTH $1.9m**

*** FDA AGREES STARPHARMA PHASE III BACTERIAL VAGINOSIS TRIAL**

*** STARPHARMA AGM VOTES ON 375k CEO 'RIGHTS', EMPLOYEE PLAN**

*** MILSTEIN GONG FOR WEHI'S PROF DOUG HILTON**

*** NUSEP APPOINTS THREE DIRECTORS**

*** NORTHCAPE TAKES 6% OF PHARMAXIS**

*** FERMISCAN EGM DISSENT ON DIRECTOR OPTIONS, PAY INCREASE**

MARKET REPORT

The Australian stock market was up 0.92 percent on Monday October 10, 2011 with the S&P ASX 200 up 38.1 points to 4,201.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, eight fell, 10 traded unchanged and nine were untraded.

Antisense was the best, up 0.1 cents or 12.5 percent to 0.9 cents with 200,000 shares traded, followed by Pharmaxis up as much as 13 cents or 16.1 percent to 93.5 cents, before closing up 8.5 cents or 10.6 percent at 89 cents with 2.3 million shares traded.

Compumedics climbed 9.6 percent; Acrux and Tissue Therapies rose more than six percent; Living Cell was up 4.35 percent; Allied Health, Cathrx, Impedimed, Mesoblast and Phosphagenics were up three percent or more; both Circadian and Starpharma rose 2.06 percent; with Cochlear up 0.66 percent.

Optiscan led the falls, down 0.7 cents or 8.4 percent to 7.6 cents, with 12,500 shares traded, followed by Prana down 6.1 percent to 15.5 cents with 16,000 shares traded.

QRX lost four percent; Sirtex shed 2.6 percent; with Alchemia, Anteo, Biota, Patrys and Resmed down more than one percent.

CIRCADIAN TECHNOLOGIES

Circadian says Healthscope has completed development and validation of a commercial test candidate for cancers of unknown primary origin.
Circadian announced the potential $10 million deal with Healthscope in 2009 for the diagnostic developed in collaboration with Melbourne's Peter MacCallum Cancer Centre and National ICT Australia (BD: Feb 25, 2009).
The company said Healthscope was commencing a 'beta test' trial among Australian oncologists as the final development stage before making the test commercially available
Circadian said cancers of unknown primary CUP is a challenging form of cancer in which the site of origin of a tumor cannot be identified using standard approaches.
The test is not related to Circadian's vascular endothelial growth factor (VEGF) suite of products and was described as "a panel of genes" to test for the cancers.
Circadian said the test was expected to be available in Australia, New Zealand, Singapore and Malaysia by mid-2012.
The company said the diagnostic test was developed based on results obtained from biopsies taken from patients with multiple different tumor types.
Circadian said that Healthscope had the rights to develop, clinically validate and market the test throughout Australia, New Zealand, Malaysia and Singapore, with Circadian retaining the rights for the rest of the world.
The company said that through its wholly owned subsidiary Cancer Therapeutics it owned the exclusive worldwide rights to the test through a licensing arrangement with the Peter MacCallum Cancer Centre and National ICT Australia.
Circadian said that the diagnostic methodology identified a patient's tumor type by comparing its pattern of gene expression to a database of known tumors so that clinicians could choose the most effective treatment strategy for the cancer.
The company said that cancers of unknown primary were less publicized than other cancer types but combined they were more common than leukaemia and were the fifth most common cause of cancer death in Australia.
Circadian chief executive officer Robert Klupacs said that early diagnosis of the tumor type "could have a major effect on treatment options and improve outcomes in patients".
Circadian said Healthscope had paid an upfront fee and would pay a royalty on sales of the test and Mr Klupacs said the royalties would "provide significant support for our ongoing cancer therapeutic development programs".
"We also expect to have partnered commercialization of the test in the major territories of US and Europe by the second half of 2012," Mr Klupacs said.
Peter MacCallum's head of the cancer genomics Prof David Bowtell co-invented the diagnostic methodology with Dr Richard Tothill and said that it was "extremely gratifying that this product of our translational research efforts will be made available to clinicians throughout the region".
"The concept of personalizing treatments for patients based on highly-specialized diagnostics is now very well accepted in oncology and has been shown to have significant patient benefit," Prof Bowtell said.
"We believe that the assay will lead to earlier diagnosis, improved treatment outcomes and enhanced quality of life for patients," Prof Bowtell said.
Healthscope's advanced pathology division's scientific director Dr Keith Byron said the test was "an important addition to our existing business of providing diagnostic tools for doctors throughout our 43 hospitals and the health care industry in general".
Circadian was up one cent or 2.1 percent to 49.5 cents.

BIOTRON

Biotron says the headline results from its phase IIa trial of lead drug candidate BIT225 has shown “good antiviral activity” in hepatitis C virus patients.

Biotron said that the orally administered, small molecule BIT225 in combination with the current standard of care for treating hepatitis C interferon and ribavirin had greater reductions in viral levels than patients receiving interferon and ribavirin alone.

The company said that patients receiving the 400mg dose of BIT225 showed the greatest levels of virus reduction.

Biotron managing director Dr Michelle Miller told Biotech Daily that the viral load drop with the 400mg was significant and there was also a response with the 200mg dose.

Biotron said that 24 patients at the Siriraj Hospital in Bangkok, Thailand were randomly assigned to receive either 400mg or 200mg BIT225, or placebo, for the first 28 days of their standard treatment with interferon and ribavirin.

The company said that all patients were infected with genotype 1 hepatitis C, which is the most common type and the most resistant to current treatment.

Biotron said dosing was completed in August and samples were analyzed and the data subject to preliminary review by the independent data safety monitoring committee.

Dr Miller said the “highly encouraging result” was the culmination of 10 years of research and development.

“The trial has shown that BIT225 has good activity against [hepatitis C] and validates Biotron's approach to treatment of this virus,” Dr Miller said.

The company said the trial’s antiviral activity supported previously reported highly synergistic activity with interferon and ribavirin in cell culture models.

Biotron medical advisor and professor of medicine at Northwestern University in Chicago Prof Robert Murphy said the results provided “good evidence that this novel approach to treating [hepatitis C] infection has significant antiviral activity compared to the standard of care interferon plus ribavirin”.

“Tolerability was reasonable with only one person dropping out of the study because of intolerability,” Prof Murphy said.

Biotron said BIT225 was the first in a new class of direct-acting antiviral drugs for HCV, targeting the p7 protein, a viral protein essential to virus production and replication.

The company said BIT225 had the potential to be used with interferon-based therapies or with other direct-acting antiviral drugs, was also in development for HIV, with a phase Ib/IIa trial underway and had the potential to be used in the hepatitis C and HIV co-infected population, which was up to 30 percentof all HIV-positive cases.

Dr Miller said the data would be presented at the Frontiers in Drug Development for Anti-Retroviral Therapies (DART) hepatitis conference in Hawaii in December 4-8, 2011.

Biotron jumped 9.7 percent or 49.5 percent to 14.5 cents, closing up 2.8 cents or 28.9 percent at 12.5 cents with 660,979 shares traded.

ATCOR MEDICAL

Atcor says it has signed contracts worth $US1.86 million ($A1.89 million) to supply Sphygmocor systems and trial support services to two pharmaceutical companies.

Atcor said the agreements were a substantial contract with a new customer and the expansion of a contract with an existing customer for its non-invasive measure of central aortic blood pressure and arterial stiffness.

Atcor chief executive officer Duncan Ross the growth of the customer base was “a strong endorsement for Atcor” demonstrating increased penetration and market adoption.

Atcor was untraded at 6.2 cents.

STARPHARMA

Starpharma says the US Food and Drug Administration has agreed to its phase III clinical trial program of Vivagel for bacterial vaginosis.

Starpharma said it intended to conduct two phase III trials in parallel, each with about 220 participants, with the primary endpoint of clinical cure, as assessed by resolution of symptoms and other standard clinical criteria measured against a placebo gel.

The company said that it had “very positive phase II results” for Vivagel for bacterial vaginosis and had presented the proposed design of phase III studies and associated aspects of the development program to support a New Drug Application to the FDA.

In May, Starpharma said its 132-patient dose-ranging phase II trial of Vivagel for bacterial vaginosis demonstrated efficacy of the 1% dose, resulting in 74 percent of patients achieving clinical cure two to five days after completion of therapy compared to 22 percent in the placebo group ($p = 0.0002$) (BD: May 23, 2011).

The company said at that time that two to three weeks after completion of therapy, 46 percent of patients achieved clinical cure of bacterial vaginosis compared to 12 percent for the placebo ($p = 0.006$).

In August Starpharma says it is ready to begin its 200-patient, US phase II study of Vivagel for a second indication, the prevention of bacterial vaginosis in women with a prior history of disease recurrence (BD: Aug 15, 2011).

Today, Starpharma said it was in agreement with the FDA on the phase III clinical trial design, including definition of primary and secondary endpoints, patient numbers and other design parameters.

The company said it would submit its phase III protocols as soon as possible and it was expected the trials would begin early in 2012 and be completed by the end of the year.

Starpharma chief executive officer Dr Jackie Fairley said the company was “very pleased that the FDA agreed with our proposed clinical program in this important, final phase of the development of Vivagel as a treatment for bacterial vaginosis and particularly that the design is so similar to our successful phase II trial”.

“We look forward to advancing the program as rapidly as possible and to executing a commercial licence following its completion,” Dr Fairley said.

“[Bacterial vaginosis] is the most common vaginal infection in the world, and affects an estimated one-third of the adult female population in the US,” Dr Failey said.

“The global market for topical [bacterial vaginosis] treatments alone is estimated at approximately $US350 million and we and others believe Vivagel has the potential to be a very important product in the management of this serious and unpleasant condition,” Dr Fairley said.

Starpharma was up two cents or 2.1 percent to 99 cents.

STARPHARMA

Starpharma shareholders will vote to 375,000 conditional free ‘performance rights’ to chief executive officer Dr Jackie Fairley and an employee performance rights plan.

The Starpharma annual general meeting notice said Dr Fairley’s rights were conditional on performance, with 125,000 rights if the company’s share price reaches $1.50 by September 30, 2012, a further 125,000 rights if the share price is above $2.00 at that date and a further 125,000 rights pending several business indicators.

The company will ask shareholders to approve a performance rights program for employees, re-elect director Peter Bartels and elect director Zita Peach.

The meeting will be held at Norton Rose, Level 15, RACV, 485 Bourke Street, Melbourne on November 10, 2011 at 4pm (AEDT).

WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

Walter and Eliza Hall Institute director Prof Doug Hilton is the first Australian to win the Seymour & Vivian Milstein award for excellence in interferon and cytokine research.
A WEHI media release said Prof Hilton would be presented with the award at the joint meeting of the International Cytokine Society and the International Society for Interferon and Cytokine Research in Florence, Italy.
WEHI said cytokines were chemicals that transmitted messages between cells, particularly in the immune system and interferons were a subset of cytokines that enhanced immune responses to viruses and other pathogens, and can be used to treat cancers.
The Institute said that the Milstein Award was established in 1988 by American philanthropists Seymour and Vivian Milstein to recognize exceptional contributions to cytokine and interferon research.
WEHI said the late Mr Milstein was a New York real estate magnate who was a strong supporter of medical research and patient care organizations and the Milsteins were inspired to establish the award in 1988 by the emerging medical applications of interferons.
The Institute said Prof Hilton's award recognized his research into how cytokines signal between cells, including the discovery of many molecules involved in this process.
WEHI said Prof Hilton had worked on cytokine biology since the 1980s.
"In the past two decades we have seen many new treatments for cancer, infectious diseases and autoimmune conditions evolve from laboratory discoveries about basic cytokine biology," Prof Hilton said.
The media release said that after completing undergraduate studies at Monash University, Prof Hilton undertook research training at the Walter and Eliza Hall Institute, where he discovered the cytokine leukaemia inhibitory factor, currently under investigation for its role in conditions including infertility and cancer.
The Institute said Prof Hilton investigated the cytokine erythropoietin at the Whitehead Institute in Cambridge, Massachusetts, returning to WEHI in 1993, where he led the discovery of cellular receptors for two cytokines, interleukin-11 and interleukin-13, as well as the suppressors of cytokine signaling family of proteins, which could be important in viral infections and the development of cancer.
Prof Hilton heads the institute's molecular medicine division and became director in July 2009.

NUSEP

Nusep says it has appointed John O'Connor, David Roffe and Ward Wescott as directors.
In a media release Nusep executive chairman John Manusu said that he had told the 2010 annual general meeting that a review would be conducted to bring new directors with additional skills to help the company enter the therapeutic plasma fractionation market.
Nusep said that Mr O'Connor had more than 30 years experience in the financial markets, had worked for and run a number of stock-broking organizations in Australia and the US and had worked with biotechnology companies including the Novogen group.
The company said Mr Roffe had more than 25 years experience in the bio-medical field including running the information systems of a major Australian hospital group, was a director of Gradipore until 1997 and had knowledge in the rollout of medical software.
The company said Mr Ward had more than 30 years experience in the finance market including over 10 years working for US banks in Asia, including Citibank.
Nusep fell two cents or 18.2 percent to nine cents.

PHARMAXIS

Northcape Capital has increased its substantial shareholding in Pharmaxis from 11,546,897 shares (5.06%) to 14,272,395 shares (6.23%).
The substantial shareholder notice said that between March 3 and September 6, the Sydney-based Northcape acquired 3,057,939 shares for $3,584,833 or $1.17 a share and sold 332,241 shares for $591,614 or $1.78 a share.
Pharmaxis climbed as much as 13 cents or 16.1 percent to 93.5 cents, before closing up 8.5 cents or 10.6 percent at 89 cents with 2.3 million shares traded.

FERMISCAN

Up to 18.7 percent of votes cast at Fermiscan's stock issue and remuneration meeting opposed six of 10 resolutions.
Four resolutions relating to a prior issue of 75,000,000 shares at 0.35 cents each and the future issue of 282,142,855 shares along with 107,142,858 shares each to directors Richard Wright and Carmelo Bontempo were passed overwhelmingly.
The greatest dissent was on the doubling of the remuneration pool available to directors from $250,000 to $500,000 with 9.08 million proxy (18.7%) against and 39.52 million shares (81.3%) in favor.
Shareholders expressed dissent against the granting of 25,000,000 options each to Mr Wright and Mr Bontempo and 5,000,000 each to directors Peter Dykes and Robert Whitton, along with a further 100,000,000 options through the placement manager "to persons to whom an equity issue can be made without disclosure" with 8.93 million proxy votes (18.4%) against and 39.68 million proxy votes (81.6%) in favor.
The company said in the notice of meeting that about 10 percent of the funds would go to the company's Italian and French trial of a non-invasive diagnostic test for the detection of breast cancer, with 30 percent to identify any potential new businesses and 60 percent for working capital (BD: Sep 5, 2011).
Fermiscan has previously published a prospectus for its one-for-two share rights issue at one cent a share to raise up to $767,000 (BD: Nov 23, 2010; Feb 4, 2011).
Fermiscan said at that time the funds were to complete Italian and French trials of the x-ray diffraction of hair test for breast cancer developed by Prof Veronica James, acquired by Fermiscan and subsequently sold to the SBC Research which disputes Fermiscan's ownership of the intellectual property (BD: Jan 16, 2011).
Fermiscan was up 0.3 cents or 25 percent to 1.5 cents with 6.5 million shares traded.