Biotech Daily

Thursday April 21, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PHYLOGICA UP 12%; ANTISENSE DOWN 18%**

*** PBS COMMITTEE KNOCKS BACK PHARMAXIS BRONCHITOL**

*** HEARTWARE 250-PATIENT DATA: 7% DEVICE EXCHANGE**

*** JAPANESE COMPOSITION PATENT FOR PRIMA'S CVAC**

*** NARHEX DEVELOPMENTS TAKES 9% OF NARHEX**

*** DR BRUCE GRAY SELLS 1.15m SIRTEX SHARES**

*** PERPETUAL TAKES 5% OF SIRTEX**

*** ONYX TAKES 8%, DIRECTOR PETER DYKES TAKES 14% OF FERMISCAN**

*** GIACONDA DEED OF COMPANY ARRANGEMENT EXECUTED**

*** PROBIOMICS HAS LESS THAN TWO QUARTERS CASH**

MARKET REPORT

The Australian stock market climbed 1.14 percent on Thursday April 21, 2011 with the S&P ASX 200 up 54.8 points to 4913.8 points. Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, eight traded unchanged and four were untraded. All three Big Caps were up.

Phylogica was best, up 0.8 cents or 12.12 percent to 7.4 cents with three million shares traded, followed by Compumedics up 9.5 percent to 11.5 cents with 35,000 shares traded.

Bionomics climbed 6.9 percent; Prima was up 4.2 percent; Circadian, Genetic Technologies and Universal Biosensors were up more than three percent; Alchemia, Clinuvel, Prana and Sirtex rose more than two percent; Acrux, Mesoblast, Starpharma and Tissue Therapies were up more than one percent; with Cellestis, Cochlear, CSL and Resmed up less than one percent.

Antisense led the falls, down 0.3 cents or 17.65 percent to 1.4 cents with 26 million shares traded, followed by Living Cell down 7.7 percent to 12 cents with 576,892 shares traded.

Cathrx lost 5.1 percent; Benitec, Genera, Phosphagenics and Sunshine Heart were down more than three percent; Heartware and Impedimed shed more than two percent; with Biota and Viralytics down more than one percent.

PHARMAXIS

Pharmaxis says there has been a delay to the listing of Bronchitol on the Australian Pharmaceutical Benefits Scheme.

Pharmaxis said its first submission to list Bronchitol for the treatment of cystic fibrosis was reviewed at the March meeting of the Pharmaceutical Benefits Advisory Committee and was not recommended for inclusion, due to what the Committee described as "uncertainties in where Bronchitol will fit in clinical practice and consequent difficulties in identifying the right comparator in one clinical setting that leads to uncertain cost-effectiveness".

The company said a resubmission had been prepared to address the issues raised by the Committee and would be made at the earliest opportunity.

Pharmaxis chief executive officer Dr Alan Robertson said cystic fibrosis was a disease "where there have been no new treatments approved for more than 18 years and Bronchitol will have an effect on the way other products are used".

"We are working with the [cystic fibrosis] community to more accurately predict these likely changes and remove any ambiguities," Dr Robertson said.

"It is a difficult climate for new drug submissions but we are committed to the process and to securing satisfactory reimbursement for patients with cystic fibrosis," Dr Robertson said.

"The majority of new drugs take at least two submissions before being recommended for PBS listing and, while I am disappointed by this outcome, I am confident we will soon be able to finalize the process," Dr Robertson said.

The company said that in April 2009 Bronchitol was awarded orphan drug designation in Australia for the treatment of patients with cystic fibrosis to improve lung function and reduce exacerbations and was approved for marketing by the Therapeutic Goods Administration in February this year.

Pharmaxis said Australia had about 2,800 people living with cystic fibrosis.

Pharmaxis was unchanged at $3.05.

HEARTWARE INTERNATIONAL

In its media release on April 16 (April 15 US EST) Heartware discussed its 94 percent survival at 180-days for 250 patients, but said little about adverse events.

In a presentation to the International Society of Heart and Lung Transplantation meeting in San Diego posted at the same time, Heartware disclosed that 17 of 250 patients (6.8%) required device exchanges of which 11 (4.4 %) were due to thrombus events.

In the media release the co-principal investigator and chief of the Division of Thoracic and Cardiovascular Surgery at the University of Louisville Prof Mark Slaughter said "the adverse event profile from the [continued access protocol] data was consistent with the very positive rates demonstrated in the Advance trial, with particularly low observed rates of bleeding and infection".

However the slide on device exchange in the presentation showed that 14 patients (10%) in the bridge-to-trial cohort required device exchanges while three patients (3%) of the continued access protocol required device exchanges.

A following slide said that 325mg of aspirin showed benefit for thrombus without increased gastro-intestinal bleeding or haemorrhagic stroke, compared to lower doses of aspirin.

Of the 24 patients who died, 10 were due to multi-system organ failure, four from intra-cerebral bleeding, four died from right heart failure, two were undetermined with one each dying from respiratory failure, sepsis, bone marrow suppression and controller failure.

Heartware climbed on Monday April 18 to $2.20 but has since fallen, closing today down five cents or 2.6 percent to $1.86.

PRIMA BIOMED

Prima says the Japanese Patent Office has granted its subsidiary Cancer Vac Pty Ltd a composition of matter patent.
Prima said the claims in the patent entitled 'Composition including mannose receptor bearing cell and antigen and immuno-regulatory mannose receptor-bearing cell population" provided for the manufacture of mannan fusion protein conjugated vaccine to a patient's own dendritic cells.
Prima said its lead product CVac was a therapy treatment for ovarian cancer administered post-surgery and post-chemotherapy to delay relapse and control metastases.
The company said its development of Cvac was focused on targeting the tumor-specific antigen mucin-1, an antigen highly expressed on the surface of ovarian cancer cells.
Prima said the granted patent claims would allow the conjugation of mucin-1 as well as other cancer antigens to mannan fusion protein.
The company said that Japan provided orphan drug designation exclusivity of 10 years from marketing approval date and it intended to file for Japanese designation.
Prima said CVac received orphan drug designation from the US Food and Drug Administration and the European Medicines Evaluation Agency in 2010.
Prima was up 1.5 cents or 4.2 percent to 37.5 cents with 7.8 million shares traded.

NARHEX LIFE SCIENCES

Narhex Life Sciences Developments has become a substantial shareholder in Narhex with the acquisition of 40,000,000 shares or 9.3 percent of the company.
The notice authorized by director Stephen Kent of Dallas, Victoria said Narhex Life Sciences Developments acquired the shares for $120,000 or 0.3 cents each.
A director of the ASX-listed company David Mandel told Biotech Daily that Narhex Life Sciences Developments was a private group funding the science of its DG-17 and DG-35 compounds for HIV and the structure was created as the listed company emerged from administration.
Mr Mandel said Narhex Developments would fund the first $500,000 of $1 million in developmental costs and then the public company would fund the balance.
Mr Mandel said Narhex Developments had relationships in China and as part of the recapitalization, it had taken a position in the public company.
Narhex fell 0.4 cents or 16 percent to 2.1 cents.

SIRTEX MEDICAL

Sirtex founder Dr Bruce Gray has reduced his substantial holding in Sirtex from 12,328,764 shares (22.11%) to 11,179,369 shares (20.05%).
Dr Gray said he had sold 1,149,395 shares for $5,940,135 or an average price of $5.17.
Sirtex was up 15 cents or 2.9 percent to $5.25.

SIRTEX MEDICAL

Perpetual and its subsidiaries have become substantial shareholders in Sirtex with the acquisition of 2,850,000 shares or 5.11 percent of the company.
The initial substantial shareholder notice said the shares were acquired by a range of nominee companies including JP Morgan Chase, Citicorp, National, Cogent, UBS and RBC Dexia and were acquired on March 31, 2011 and April 19, 2011 at $5.15 and $5.40.

FERMISCAN

Onyx Capital has increased its substantial shareholding in Fermiscan from 40,000,000 shares (6.91%) to 48,400,000 shares (8.31%).
In a change of substantial shareholder notice signed by director Wes Culley of Level 27, 101 Collins Street Melbourne, Onyx said it bought the shares in an off-market transfer for $50,000 or 0.595 cents per share.
Director Peter Dykes filed an Appendix 3Y director's interest notice saying that as a director of Onyx his directed and indirect holding increased from 75,100,000 shares by 8,400,000 shares to 83,500,000 shares, of which 30,000,000 were held by General Investment Services and 5,050,000 shares were held by Jampari Pty Ltd, with 50,000 shares held directly.
Fermiscan fell 0.1 cents or 20 percent to 0.4 cents.

GIACONDA

Giaconda administrator Nicholas Crouch says the second creditors meeting has approved a deed of company arrangement announced last month (BD: Mar 24, 2011).
Mr Crouch of Crouch Amirbeaggi Insolvency Accountants said the meeting approved the deed on March 31 and has been executed by all parties.
Mr crouch said there would be an extraordinary general meeting for shareholders to vote on the deed of company arrangement.
Giaconda last traded at 3.4 cents.

PROBIOMICS

Probiomics says its net operating cash burn for the three months to March 31, 2010 was $84,000 with cash at the end of the quarter of $141,000.
Probiomics did not disclose whether it had any other funding sources available.
Probiomics was unchanged at 1.2 cents.