

Biotech Daily

Friday March 26, 2010

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH EVEN: PHOSPHAGENICS UP 13%; SUNSHINE HEART DOWN 10.5%
- * BIOMD'S ADAPT COW-PATCH SUPERIOR IN RAT HERNIA TRIAL
- * BIONOMICS BEGINS BNC105 PHASE II MESOTHELIOMA TRIAL
- * CSIRO CONNECTS AMYLOID BETA, ALZHEIMER'S, MEMORY LOSS
- * CATHRX, LBT ROADSHOWS
- * STARPHARMA EGM BACKS CEO DR JACKIE FAIRLEY SHARES
- * CIRCADIAN COMPANIES REDUCE 1.7% IN ANTISENSE
- * PRIMA EGM TO APPROVE SHARES, OPTIONS
- * COCHLEAR PLEADS SCHULTZ TO ASX 11% PRICE QUERY

MARKET REPORT

The Australian stock market was up 0.24 percent on Friday March 26, 2010 with the S&P ASX 200 up 11.5 points to 4896.9 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and five were untraded.

Phosphagenics was best, up 1.3 cents or 13.4 percent to 11 cents with 4.5 million shares traded, followed by Uscom up 9.6 percent to 57 cents with 39,000 shares traded.

Alchemia, Antisense and Psivida climbed four percent or more; Avexa, Cathrx, Nanosonics and QRX were up more than three percent; Benitec and Sirtex rose more than two percent; with CSL and Cochlear up more than one percent.

Sunshine Heart led the falls, down 0.4 cents or 10.5 percent to 3.4 cents with 260,000 shares traded, followed by Genetic Technologies down 7.5 percent to 3.7 cents.

Optiscan, Patrys and Viralytics lost more than six percent; Impedimed and Tissue Therapies fell more than four percent; Prana was down 3.3 percent; Clinuvel shed two percent; with Acrux, Biota, LBT, Novogen and Starpharma down more than one percent.

BIOMD

Biomd says a 12-month hernia trial in juvenile wistar rats has shown its Adapt-treated bovine pericardium patch outperformed an existing commercial patch and a control patch. Biomd said that on a range of measures including vascularization, flexibility and calcification the Adapt-treated patch was clearly superior to the commercial implant and the control for ventral hernia repair.

The company said there were no adverse responses observed with the Adapt patch but adverse responses were shown in both the control and commercial patch groups. Biomd said the trial was designed to compare the Adapt patch with a cross-linked, glutaraldehyde treated patch (control) and a commercially available, US Food and Drug Administration approved patch (commercial), implanted into laboratory rats to repair the hernia and left in situ for 12 months.

The company said ventral hernias usually occurred through the midline of the abdominal wall muscle with the abdominal organs protruding through the abdominal wall muscle layer under the skin to form a bulge or, in severe cases, a breakdown of the skin.

A ventral hernia can also occur when the abdominal wall muscle has been weakened by previous abdominal surgery and subsequently gets infected, Biomd said.

The company said an inguinal hernia was the protrusion of an organ, such as the intestines, through a weakened section of the abdominal wall muscle, commonly in the groin. If left untreated, the muscle defect can enlarge forming a visible bulge.

Biomd said that both forms of hernia repair require a surgical operation and about 40,000 Australians have hernias surgically repaired every year.

The company said the trial showed that in the Adapt group there was no calcification, full flexibility and there were features of durability and remodelling.

Biomd said the commercial patch group were partially calcified and encapsulated, with surface thickening suggested the formation of fibrosis and the control group had severe calcification and was encapsulated, as expected.

A detailed examination showed the Adapt explanted matrices were fully flexible and showed no signs of calcification and were free of adhesions in the major part of the matrix with only limited adhesions on the proximal and distal edges.

Histology of the Adapt explants showed a thin layer of granulation tissue on the anterior surface with neo-capillaries. The inside of the matrix was vascularized with infiltrated host fibroblasts. On both edges of the matrix, host implant integration was visible in the form of host adipose (fat) and muscle cells invading into the matrix.

Signs of host abdominal wall tissue invasion were present at both edges of the Adapt graft abdominal wall interface without any visible adhesions on the posterior side.

A positive stain for Desmin (a stain for muscle cells) was noted in the Adapt group only. The company said the anterior surface of the commercial group resulted in a semi-rigid matrix with visible calcium nodules in some implants. The posterior surface showed severe adhesions over the entire matrix. Samples showed partial encapsulation with a mixture of calcified and non-calcified areas inside the matrix.

Both surfaces were attached to the omentum by adipose cells. The matrix showed surface thickening caused by connective tissue deposits. Limited host-implant integration occurred on the edges of the matrix via adipose cells. Host cell infiltration consisted mainly of host fibroblasts and a few lymphocytes. A number of foreign body giant cells were present in the granulation tissue present on the anterior surface of the explants. The commercial group explants showed some calcification with a significant amount of adhesions over the entire width of the graft.

In the control group the anterior surface had a completely calcified matrix and the posterior surface was rigid and calcified, with adhesions attached to the majority of the

implant. Light microscopy of a mid cross-section indicated encapsulation of the implants with severe intrinsic calcification.

The mid transverse view in the control group indicated a solid calcified graft section with some adhesions on the lateral edges.

Biomd managing director Michael Bennett said the results were "extremely encouraging, particularly given the significant evidence of true remodeling and regeneration taking place".

"This is something not exhibited by currently available commercial hernia repair products," Mr Bennett said.

"We will now focus on moving towards a human clinical trial of the Adapt-treated patch for hernia repair," Mr Bennett said.

Biomd was untraded at 5.1 cents.

BIONOMICS

Bionomics says it will begin a 60-patient phase II clinical trial of vascular disrupting agent BNC105, in patients with advanced mesothelioma, the asbestos-related cancer. Bionomics said the trial was the second phase II clinical study of BNC105 with a US phase II trial of BNC105 for renal cancer underway (BD: Jan 27, 2010).

The company said the trials followed a BNC105 phase I study in patients with advanced cancers at Melbourne's Peter MacCallum Cancer Centre, Western Hospital, Austin Health and the Royal Melbourne Hospital.

Bionomics said the trial was a collaboration with the Australasian Lung Cancer Trials Group and the NHMRC Clinical Trials Centre to conduct the clinical trial in mesothelioma. The company said the University of Western Australia's Faculty of Medicine Prof Anna Nowak was the trial's principal investigator.

Bionomics said mesothelioma was a cancer usually caused by exposure to asbestos and malignant cells typically developed in the protective lining that covers most of the body's internal organs, with the most common site the outer lining of the lungs and internal chest wall.

Dr Nowak said mesothelioma was "a substantial problem".

"An early clinical trial of BNC105 suggested some promise in mesothelioma," Dr Nowak said. "This phase II trial will provide hope and an opportunity to participate in a research study for people with mesothelioma who do not have other options for treatment".

Bionomics chief executive officer Dr Deborah Rathjen said there was "virtually no effective treatment after first line chemotherapy and patients typically have a life expectancy of less than one year".

"The long latency, or time for the disease to develop, means that we are yet to see the peak incidence of mesothelioma over the next decade," Dr Rathjen said.

Bionomics said that in 2005, there were 597 new cases of mesothelioma diagnosed in Australia and in 2006 there were 486 deaths attributed to mesothelioma. It usually is a fatal cancer, typically manifesting in patients 20 to 40 years after exposure to asbestos.

The trial is a single arm, unblinded study for patients with mesothelioma who have progressed on platinum or pemetrexed chemotherapy.

BNC105 will be administered on days one and eight of 21 day cycles and treatment will continue until disease progression.

The primary objective is to determine the tumor response rate, with secondary endpoints including progression-free survival, quality of life, overall survival and treatment duration. Bionomics was unchanged at 33.5 cents.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says that an increased accumulation of amyloid in the temporal inferior cortex disrupts connections with the hippocampus, causing the neurons to die

The Commonwealth Scientific and Industrial Research Organisation media release said a study conducted with the University of Melbourne, the Mental Health Research Institute of Victoria, Edith Cowan University and Neurosciences Australia "provided new insights into the loss of structure in regions of the brain and its potential association with Alzheimer's disease".

The CSIRO said the findings were recently reported in Neurology and suggested a buildup of deposits of the protein amyloid-beta in the brain's temporal inferior cortex, which was connected to the hippocampus, which in turn was involved in memory.

The media release said Alzheimer's disease was characterized by a build-up of amyloidbeta plaques in the brain and a loss of neurons.

CSIRO's director of neurodegenerative diseases research, Dr Cassandra Szoeke, said the puzzle for researchers was that the parts of the brain that had shrunk or atrophied due to neuron loss were not the same as those showing increased deposits of amyloid-beta. Using magnetic resonance imaging (MRI) scans to study Alzheimer's disease-affected brain tissue, the researchers found that atrophy of the hippocampus was associated with plaque deposits in the temporal inferior cortex.

The CSIRO said that the results indicated that the increased accumulation of amyloid in the temporal inferior cortex disrupted connections with the hippocampus, causing the neurons to die.

"By helping to better understand the mechanisms involved in the progression of the disease, the study may guide the development of new strategies for early diagnosis," Dr Szoeke said.

The study involved advanced techniques for analyzing and comparing different types of brain scans.

CATHRX

Directors and executives of Cathrx and LBT were in Melbourne today as part of extended roadshows to promote and explain their respective companies' business plans. Cathrx hopes to raise \$11 million to advance of developing reprocessable cardiac catheters.

Cathrx chief executive officer Jeffrey Goodman and chief financial officer Amanda Wong told Biotech Daily that there was no modular system like Cathrx's available in single use and nothing that could be reprocessed and reused in the US.

The Cathrx range is available in Europe and has Conformitée Européenne (CE) mark but the company has not yet begun a registration process in the US.

Mf Goodman said that the company was "on very early stage talks with a US distributor and reprocessor familiar with US Food and Drug Administration procedures".

Mr Goodman said an FDA 510k diagnostic application would take about a year and could be completed by mid-2011.

Cathrx has previously announced a partnership with Germany's Pioneer and Mr Goodman said he hoped to have a US partnership within 12 months.

"Reprocessing is a big opportunity minimizing cost and reducing waste," Mr Goodman said.

He said reprocessed catheters made up 60 percent of the German market.

Cathrx was up half a cent or three percent to 17 cents.

LBT INNOVATIONS

In a separate meeting LBT chief executive officer Lusia Guthrie and director Stephen Mathwin told Biotech Daily they were not a on a capital raising mission but were explaining the company's progress to investors.

Ms Guthrie said her company's Microstreak agar plate technology licenced to France's Biomérieux in 2007 and marketed as Previ Isola was earning milestones and "double digit" royalties.

In a presentation slide entitled 'Estimated size of potential target labs' LBT said there were 26,485 laboratories processing millions of slides a day.

Ms Guthrie said her company was hoping to unveil its new technology in the coming weeks.

Ms Guthrie said LBT was looking for a partner for the technology which was unrelated to plate streaking, but was in the field of clinical microbiology.

Ms Guthrie said a patent had been filed for the in-vitro diagnostic and a demonstrator model was being prepared.

LBT fell 0.1 cents or 1.1 percent to nine cents.

STARPHARMA

Starpharma shareholders voted in favor of the grant of 1,428,571 shares and 750,000 "rights" to chief executive officer Dr Jackie Fairley.

The single resolution was passed by 77,258,022 proxy votes (89.2%) in favor with 9,326,112 proxy votes (10.8%) against.

Starpharma fell one cent or 1.4 percent to 69 cents.

ANTISENSE, CIRCADIAN

Two Circadian related companies have reduced their substantial holding in Antisense from 142,165,909 shares (24.12%) to 132,165,909 shares (22.42%).

The companies selling Antisense shares were Circadian's wholly-owned subsidiary Polychip Pharmaceuticals and Polychip's 42.38 percent subsidiary Syngene. Circadian chief executive officer Robert Klupacs and company secretary Natalie Korchev 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.

Antisense was up 0.1 cents or four percent to 2.6 cents with 3.8 million shares traded. Circadian was up half a cent or 0.7 percent to 73.5 cents.

PRIMA BIOMED

Prima shareholders will vote on resolutions issuing shares and options to Springtree Special Opportunities Fund, Dr Zilficor Yassine and the National Security Corp.

The meeting will also vote on an employee option scheme.

Prima said it had provided 71,430 shares to Dr Yassine on December 3, 2009 "in consideration of medical consultancy services provided ...to the value of \$10,000".

The meeting will be held at the Sofitel Wentworth Hotel, 61-101 Phillip Street, Sydney on April 30, 2010 at 6pm.

Prima was unchanged at 14.5 cents with 1.1 million shares traded.

COCHLEAR

Cochlear Cell has told the ASX that it was not aware of any information it had not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from \$66.34 cents on March 17, 2010 to \$73.90, an 11.4 percent increase, on March 26, 2010 and noted an increase in trading volume.

Cochlear was up \$1.38 or 1.9 percent to \$73.38.