Biotech Daily

Tuesday November 24, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN; VIRALYTICS UP 7%; GENERA DOWN 4.5%**

*** CYTOPIA BEGINS DOSING IN CYT387 PHASE I/II MYELOFIBROSIS TRIAL**

*** EASTLAND BEGINS RWANDA MALARIA TRIAL**

*** BIOPHARMICA - XMAS EVE RESTRUCTURE MEETING, LATE AGM**

*** CELLMID IN CAPITAL RAISING TRADING HALT**

*** HEARTWARE APPLIES TO FDA FOR DESTINATION THERAPY TRIAL**

*** ANTISENSE US PATENT FOR ATL1103; CLINICAL TRIAL IN 2010**

*** SYDNEY UNI STUDY BACKS IMPEDIMED'S DEVICE FOR LYMPHOEDEMA**

*** TYRIAN PREPARING TO LAUNCH 2nd CROP TEST**

*** IMMURON DIRECTOR ARIE NUDEL NARROWLY SURVIVES AGM**

*** 13% VOTE AGAINST VIRALYTICS M-D OPTIONS**

*** PROBIOMICS SIGNS DENMARK'S CHR HANSEN GLOBAL DISTRIBUTOR**

MARKET REPORT

The Australian stock market fell 0.7 percent on Tuesday November 24, 2009 with the S&P ASX 200 down 31.95 points to 4,685.0 points.

Six of the Biotech Daily Top 40 stocks were up, 17 fell, 12 traded unchanged and five were untraded.

Viralytics was best, climbing 0.3 cents or 7.1 percent to 4.5 cents with 3.9 million shares, traded, followed by Alchemia up 5.8 percent to 72.5 cents. Acrux climbed 4.8 percent; Psivida and Sirtex were up more than three percent; Pharmaxis rose 2.97 percent; with Resmed up more than one percent.

Genera led the falls, down four cents or 4.5 percent to 85 cents with 94,902 shares traded. Circadian, LBT and Mesoblast fell more than three percent; Avexa, Benitec, Chemgenex, Compumedics, Novogen, Phosphagenics and Universal Biosensors shed two percent or more; with Biota, Cellestis, Clinuvel and Impedimed down more than one percent.

CYTOPIA

Cytopia has begun dosing in its phase I/II clinical study of CYT387 for myelofibrosis at the Mayo Clinic in Rochester, Minnesota.

Cytopia said CYT387 was a potent, orally-active JAK1 and JAK2 inhibitor and a mutated form of the JAK2 enzyme was "implicated in a variety of haematological conditions known as the myeloproliferative neoplasms" including myelofibrosis, polycythemia vera and essential thrombocythemia.

The company said CYT387 attenuated myeloproliferative neoplasm symptoms in an in vivo preclinical model and disrupted JAK2 hyperactivity in cells from patients with myeloproliferative neoplasms and the data suggested the compound may exert a profound effect on the human diseases.

The company said the phase I/II study would investigate the safety and tolerability of CYT387 administered as a daily oral capsule dose in patients with myelofibrosis.

Cytopia said myelofibrosis was a chronic, debilitating condition in which the patient's bone marrow was replaced by scar tissue, compromising the ability to produce sufficient blood cells and a reliance on organs other than the bone marrow, including the liver and spleen.

Symptoms include an enlarged spleen, progressive anaemia and poor overall survival.

Cytopia said the study would allow preliminary assessment of the compound's activity, including its effect on spleen size, haematological symptoms and quality-of-life, as well as markers of aberrant JAK2 activity in blood.

Study chairman and Mayo Clinic's professor of haematology Prof Ayalew Tefferi said patient safety was "very important with this class of compounds and can be reliably predicted only by testing in humans".

"As such, it is premature to select the best JAK2 inhibitors in clinical development as there is a need for longer follow-up data on safety and efficacy than is currently available," Prof Tefferi said.

Cytopia chief executive officer Andrew Macdonald said the start of the CYT387 clinical study was "another significant milestone".

"Cytopia will seek to demonstrate the activity of CYT387 in other disease indications with high unmet medical need where JAK1 and JAK2 activity is important," Mr Macdonald said.

The company said commercial interest in the JAK2 target was evident with no selective JAK inhibitors having completed late stage clinical trials and few compounds in development with a desirable product profile.

Cytopia said a similar clinical-stage JAK2 inhibitor was licensed by Onyx Pharmaceuticals for $US550 million including a $US25 million up-front payment and double-digit royalties.

Over-activity of the JAK2 enzyme has also been noted in certain cancers and in inflammatory conditions, such as rheumatoid arthritis and psoriasis, the company said.

Cytopia said the dual JAK1 and JAK2 inhibition of CYT387 was likely to increase the clinical benefit in these diseases, markedly expanding the clinical and commercial opportunities for CYT387 beyond myeloproliferative neoplasms alone.

Cytopia was unchanged at nine cents.

EASTLAND MEDICAL SYSTEMS

Eastland says its Artimist sublingual anti-malaria trial has begun at Rwanda's Kigali University Hospital.

Eastland said it had completed the training program for the medical staff engaged in the clinical trial and depending on the rate of enrolment and other factors it hoped progress could be reported in about three months.

Eastland fell 0.2 cents or 2.5 percent to 7.7 cents with 1.8 million shares traded.

BIOPHARMICA

Biopharmica says the Australian Securities and Investments Commission has approved an extension for its annual general meeting to allow time for a restructure.

Biopharmica said the annual general meeting would be held on January 15, 2010 with a general meeting to be held on Christmas Eve, December 24, 2009.

The company said the extension was so that resolutions could be addressed relating to general business; the proposed spin-off of Molecular Discover Systems; the proposed investment in Advent Energy; the proposed capital raising; and the proposed issue of director options.

Biopharmica said the Australian Securities and Investments Commission determined "that it is inappropriate for companies to hold annual general meetings between December 16, 2009 and January 8, 2010" and two separate meetings would be convened to address the resolutions.

However, Biopharmica said the material issues above would be the subject of resolutions for the Christmas Eve meeting while the January annual general meeting will only vote on the remuneration report and the reelection of director Deborah Ambrosini.

The more controversial resolutions will be voted on at the Christmas Eve meeting, including the change of company name to BPH Corporate; the issue of one Molecular Discovery share for each Biopharmica share; the $14 million acquisition of Advent Energy; the placement of 95,982,330 shares at no more than 12.5 cents a share with 95,982,330 attaching options; the issue of 2,000,000 Biopharmica options to managing director David Breeze and 1,000,000 options for Ms Ambrosini; the issue of 2,000,000 Molecular Discovery options to each of Mr Breeze, Ms Ambrosini and director Greg Gilbert; and the issue to related party MEC of 24,361,248 shares and attaching options.

The general meeting will be held at North Perth Lesser Hall, 24 View Street, North Perth on December 24, 2009 at 2.30pm (WST).

In its October 2, 2009 announcement of the Molecular Discoveries spin-off, Biopharmica said it expected to hold the annual general meeting on November 12, 2009.

Mr Breeze told Biotech Daily that he was unable to explain why the delay had occurred or why the more important meeting was being held on Christmas Eve, rather than at a time when more shareholders would be able to attend.

In an update on the spin-off earlier on November 10, 2009 Biopharmica said the notice of meeting for the 2009 annual general meeting had been lodged with the relevant regulatory bodies and the company was awaiting approval of the document.

Biopharmica said at that time that an application for an extension to the required meeting date had been lodged with ASIC and Biopharmica would advise the market of the new AGM date once details have been received.

The annual general meeting will be held at 14 View Street, North Perth on January 15, 2010 at 1.30pm (WST).

Biotech Daily contacted ASIC for a comment but had no response at the time of publication.

Biopharmica fell two cents or 12.1 percent to 14.5 cents.

CELLMID (MEDICAL THERAPIES)

Cellmid (formerly Medical Therapies) has requested a trading halt pending an announcement "in relation to a proposed capital raising".

Trading will resume on November 26, 2009 or on an earlier announcement.

Cellmid last traded at 3.2 cents.

HEARTWARE

Heartware has filed its submission for investigational device exemption with the US Food and Drug Administration to use its cardiac pump for destination therapy.
Heartware said the submission related to the proposed safety and efficacy study of its ventricular assist system compared to other FDA-approved left ventricular assist devices used for destination therapy in patients with end-stage heart failure who are ineligible for heart transplantation.
The company said the proposed primary endpoint was stroke-free survival at two years after the originally implanted left ventricular assist device.
Heartware said the proposed secondary endpoints at two years included overall survival, incidence of adverse events, quality of life and neuro-cognitive status.
The company said it expected a period of communication with the FDA, during which clarification may be sought and additional information requested, a communication process that takes place in 30-day cycles.
Heartware said it hoped to begin the trial early in 2010 enrolling several hundred patients and taking three to four years to complete the study.
Heartware was untraded at 98.5 cents.

ANTISENSE THERAPEUTICS

The US Patent Office has allowed Antisense a patent entitled 'Modulation of Growth Hormone Receptor Expression and Insulin like Growth Factor Expression' for ATL1103.
Antisense said the granting of the patent was considered a formality and would take place in the coming months.
The company said the patent forms part of its portfolio of intellectual property protecting ATL1103 and its uses, including patent applications under examination in Europe, Japan, Canada, New Zealand and Australia and a further US patent application directed to methods of treatment.
Antisense said the allowed US patent ran to 2024 and might be extended to 2029 once the drug is registered.
The patent applications in Europe, Japan and Australia when granted will provide a similar extended period of patent protection.
Antisense said additional patent protection was also provided internationally for ATL1103 by Isis Pharmaceuticals' antisense technology and manufacturing patents and patent applications to which Antisense had a world-wide licence.
Antisense said ATL1103 was a second-generation antisense drug targeting the growth hormone receptor and was on-track to be its next drug in clinical development.
The company said major animal toxicology studies on ATL1103 had been completed, and supported plans for the development of ATL1103 as a potential treatment for acromegaly and diabetic retinopathy.
Antisense said two acute toxicology studies were required to complete the preclinical safety testing for ATL1103. Dosing in the safety pharmacology study had been completed and the study data was being analyzed. Work on the final acute study, genetic toxicology testing, was expected to begin before the end of 2009.
Antisense said it was "on track to be in a position to submit an application for a human clinical trial by the end of the first half of 2010".
The company said its technology partner and major shareholder Isis Pharmaceuticals expected to complete the manufacture of ATL1103 compound by July 2010 for the proposed human trial expected to begin later in 2010.
Antisense was unchanged at 6.1 cents.

IMPEDIMED

A University of Sydney study says Impedimed's device "is the only measurement specific to extracellular fluid and is ideally suited for early detection and monitoring of lymphedema".

The study, entitled 'Assessment of Breast Cancer-Related Arm Lymphedema-Comparison of Physical Measurement Methods and Self-Report' published this month in the journal Cancer Investigation compared physical measurement methods and self-report in the assessment of breast cancer-related arm lymphoedema.

The study observed that the results from physical measurement methods other than Impedimed's bioimpedance spectroscopy "may be confounded by changes not related to lymphoedema such as muscle and fat".

"Therefore, early lymphoedema build-up may go undetected when using these measurement methods," Impedimed reported the study saying.

Impedimed chief executive officer Greg Brown said the study added weight to "the debate about the need for standardized, objective metrics driving evidence-based medicine".

Mr Brown said that if lymphoedema could be detected early, progress to the irreversible stages of the condition might be prevented".

Impedimed fell 1.5 cents or 1.8 percent to 81 cents.

TYRIAN DIAGNOSTICS

Tyrian Diagnostics says it has completed the manufacture of several thousand prototype tests for a multisite evaluation of its second crop diagnostic.

Tyrian said its second agricultural diagnostic test as part of its collaboration with Bayer Cropscience was designed to assess crops for contaminants that affect grain pricing.

The company said Bayer had an exclusive worldwide licence for the Tyrian tests.

Tyrian said Bayer approved the next stage of product development following the completion of a proof-of-concept study evaluating several hundred prototype tests.

Laboratory-based testing will be performed using the prototype tests in a multi-site evaluation across North America and Europe.

Tyrian was unchanged at 1.6 cents.

IMMURON

Immuron director Arie Nudel has narrowly survived the annual general meeting with 23,645,567 proxy votes (51.35%) in favor and 22,403,836 votes (48.65%) opposed.

The reelection of Prof Roy Robins-Browne was supported by 38.3 million proxy votes while 7.8 million votes opposed him.

The remuneration report and a prior issue of shares were passed overwhelmingly.

Immuron was up 0.5 cents or 6.7 percent to eight cents.

VIRALYTICS

A significant minority of Viralytics shareholders opposed the issue of 2,000,000 options to managing director Bryan Dulhunty.

A total of 46,204,937 proxy votes (86.6%) supported the issue, but 7,152,942 votes (13.4%) opposed the issue.

About 10 percent of proxy votes opposed the remuneration report, but directors Peter Molloy and Paul Hopper were reelected overwhelmingly.

Viralytics was up 0.3 cents or 7.1 percent to 4.5 cents with 3.9 million shares traded.

PROBIOMICS

Denmark's CHR Hansen AS will manufacture and market Probiomics' probiotic strain, Lactobacillus fermentum PCC globally.

Probiomics said the compound could be used in dietary supplements, over the counter drugs, sports nutrition, slimming products, clinical nutrition, beverages, and dairy products.

Probiomics said CHR Hansen was a global leader in the development of natural ingredient solutions for food, pharmaceutical, nutritional and agricultural industries.

Probiomics chairman Patrick Ford said the agreement was "a ground-breaking deal for our company".

"It means that our probiotic strain Lactobacillus fermentum PCC will now be available in markets worldwide including Australia," Mr Ford said.

Probiomics said the agreement was the culmination of clinical trials undertaken jointly by Probiomics and Chr Hansen over six months in conjunction with Griffith University and the Australian Institute of Sport on the immune system in a group of 99 athletes.

The company said that the double-blinded, placebo-controlled study showed that Lactobacillus fermentum PCC was effective in reducing the severity and illness load of chest infection and medication use associated with respiratory tract infection.

The company said that consuming PCC moderated the negative effects of exercise stress on the immune system.

The study is expected to be published at the beginning of 2010.

Probiomics said it was the second Australian Institute of Sport study "clearly supportive of PCC".

Probiomics was up 1.2 cents or 75 percent to 2.8 cents with 28.2 million shares traded.