Biotech Daily

Tuesday August 31, 2010

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: VIRALYTICS UP 14%; BIONOMICS DOWN 8%**

*** SUNSHINE HEART: 'WORLD 1st MINIMALLY INVASIVE THORACOTOMY'**

*** PHARMAXIS READY FOR BRONCHITOL CF EURO-APPROVAL**

*** HALCYGEN POSTS $3m MAIDEN PROFIT; REVENUE UP 8638% TO $37m**

*** CLINUVEL SPLITS HQ TO ZUG; NEW DRUG; DR ROGER ASTON RESIGNS**

*** FLUOROTECHNICS LOSS DOWN 20%; REVENUE UP 7% TO $3.5m**

*** USCOM REVENUE DOWN 47% TO $1m; LOSS UP**

*** UBS AG SELLS 6m ACUVAX SHARES**

*** PSIVIDA REQUESTS TRADING HALT**

*** BIO-MELBOURNE BREAKFAST ON DEPRESSION RESEARCH**

MARKET REPORT

The Australian stock market fell 1.09 percent on Tuesday August 31, 2010 with the S&P ASX 200 down 48.5 points to 4404.2 points.

Nine of the Biotech Daily Top 40 stocks were up, 16 fell, four traded unchanged and 11 were untraded.

Viralytics was best, up 0.4 cents or 14.3 percent to 3.2 cents with 193,193 shares traded.

Clinuvel and Sunshine Heart climbed four percent or more; Patrys and Pharmaxis rose more than two percent; with Alchemia, CSL and Impedimed up more than one percent.

Bionomics led the falls, down 2.5 cents or 8.47 percent to 27 cents with 1,630 shares traded, followed by Phylogica down five percent to 5.7 cents with 338,829 shares traded.

Cellestis lost 4.8 percent; Biota, Genetic Technologies, Mesoblast and Virax lost more than three percent; Living Cell, Prima and Starpharma shed two percent or more; with Chemgenex, Genera, Nanosonics, QRX, Resmed and Universal Biosensors down more than one percent.

SUNSHINE HEART

Sunshine Heart says its C-Pulse aorta cuff is believed to be the first heart assist system implanted using a minimally invasive thoracotomy procedure.

In June, a C-Pulse system was implanted in a mini-sternotomy or hemi-sternotomy (BD: Jun 3, 15, 2010).

Today the company said two separate devices were inserted this week in mini-thoracotomy operations, which use small, pacemaker-like incisions between the patients' ribs, leaving the sternum intact.

The two procedures took place at Saint Luke's Mid America Heart and Vascular Institute in Kansas City, Missouri.

Saint Luke's director of mechanical circulatory support Dr Sanjeev Aggarwal said the C-Pulse heart assist system was "an important advance in the treatment of patients suffering from heart failure".

"In our initial procedure last month, the clinical effects were dramatic, with an almost immediate improvement in cardiac performance and the patient's functional status," Dr Aggarwal said.

"I am very encouraged that we were able to perform our two subsequent implants utilizing a minimally invasive pacemaker-like incision, without dividing the sternum," Dr Aggarwal said.

"This offers the opportunity to provide patients suffering from moderate heart failure with a means of mechanical circulatory support through a truly minimally invasive, low risk procedure with a short recovery period," Dr Aggarwal said

Sunshine Heart said that to date, 13 patients had been implanted under its existing worldwide C-Pulse trial protocols.

The company said the US Food and Drug Administration approved investigational device exemption feasibility study would include 20 patients to evaluate the performance of the device for patients with moderate heart failure.

Sunshine Heart said the C-Pulse system was designed to treat patients suffering from moderate heart failure caused by a failing left ventricle, using a balloon counter-pulsation technology designed to assist the left ventricle by reducing the workload required to pump blood throughout the body as well as increase blood flow to the coronary arteries.

The company said that combined, the potential benefits might help reverse the heart failure process or maintain the patient's current condition, preventing the need for later stage heart failure devices, such as left ventricular assist devices, artificial hearts or transplants.

Sunshine Heart chief executive officer Dave Rosa said the most recent procedures "accomplish our goal of successfully implanting the C-Pulse System through a mini-thoracotomy surgical method".

"As we approach the end of our feasibility study, we are encouraged by the interest of our centers and we remain dedicated to developing this minimally invasive, cost-effective treatment that is intended to relieve the symptoms of moderate heart failure," Mr Rosa said.

The company said that the C-Pulse system was an earlier intervention than other mechanical therapies, such as left ventricular assist devices and did not make direct contact with patient's blood and could be turned on or off at any time allowing patients intervals of freedom to perform certain activities.

The C-Pulse system can also be implanted as a minimally invasive procedure, thereby potentially reducing procedural time, hospital stays, overall cost and patient risk as compared to a traditional sternotomy, the company said.

Sunshine Heart was up 0.1 cents or four percent to 2.6 cents with 746,668 shares traded.

PHARMAXIS

Pharmaxis has a strategic marketing and sales service agreement with Quintiles for the commercialization of Bronchitol for cystic fibrosis in Europe.

The company said that ahead of regulatory approval for Bronchitol expected by the end of 2010, it has signed a six year agreement with Quintiles to support the launch and commercialization of the product in Western Europe.

Pharmaxis acting chief executive officer Gary Phillips said the company would "move into the key European markets with a clear commercialization plan".

"We will be bringing on board the European expertise and capabilities of a well-recognized team of leaders in the field," Mr Phillips said.

"Bronchitol is a new advance in the treatment of cystic fibrosis and it's vital that we engage fully with the [cystic fibrosis] communities, healthcare professionals, funding bodies and governments across Europe as efficiently as possible," Mr Phillips said.

"We have selected Quintiles to help manage market launch and accelerate product uptake because the local experience of the Quintiles organization will allow rapid access to each of the individual country markets," Mr Phillips said.

Pharmaxis said Quintiles was "a global biopharmaceutical services company offering clinical, commercial, consulting and capital solutions" with 20,000 staff in 60 countries.

The company said that two phase III trials showed that Bronchitol provided early and sustained improvement in lung function in people with cystic fibrosis.

Pharmaxis said that once Bronchitol was approved it would be launched across Western Europe, beginning in Germany and the UK in the first quarter of 2011.

Pharmaxis said its contract sales representatives would be supported and managed by Quintiles throughout Western Europe while marketing and market support will be managed by the Pharmaxis office in the UK.

The company said Quintiles would provide "a broad range of commercial support for Bronchitol including development of the overall market access strategy, pricing and reimbursement, local market access and recruitment and management of field-based sales teams and product managers".

Pharmaxis was up 4.5 cents or 2.3 percent to $2.03.

HALCYGEN

Following its acquisition of Mayne Pharma, Halcygen has reported its first full-year net profit after tax for the 12 months to June 30, 2010 of $3,253,119.

The company said revenue increased 8,638 percent to $36,712,915.

Halcygen acquired Mayne Pharma last year for $US15 million ($A16.5 million), with an earn-out deal from expected revenues (BD: Sep 29, 2009).

A detailed account of the transaction and the Mayne Pharma Faulding operation was published earlier this month (BD: Aug 3, 2010).

Halcygen said research and development expenses amounted to $5,293,859 or 14.4 percent of total revenue.

The company said net asset backing per share was 17.2 cents at June 30, 2010 compared to 10.1 cents at June 30, 2009.

Halcygen said diluted earnings per share was 2.55 cents compared to the previous year's loss of 4.94 cents a share.

Halcygen said it would pay a fully-franked dividend of two cents a share on November 18, 2010, with a record date of October 29, 2010.

The company said it had $19,708,613 in cash at June 30, 2010.

Halcygen was unchanged at 58 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says non-executive director Dr Roger Aston has resigned effective from September 1, 2010 and the headquarters will be in Melbourne and Switzerland.
Dr Aston was appointed to the board in March 2005 and was executive chair from September 2005 until December 2007.
Clinuvel said it has expanded its development program with a new proprietary molecule, CUV9900 to be used as a skin protectant in a number of skin diseases, in various formulations to complement its lead drug Scenesse or afamelanotide.
The company said its clinical and regulatory efforts would be "sharply focused in both Europe and North America to maximise the company's chances of successfully registering Scenesse in both jurisdictions".
Clinuvel said that from August 15, 2010, the principal business, clinical and regulatory activities would be moved to offices in canton Zug, Switzerland, with a satellite office in New Jersey to coordinate US activities.
Clinuvel said it would continue to maintain a physical presence and support staff in Melbourne.
Clinuvel said CUV9900 would complement Scenesse for a number of potential therapeutic applications.
The company said CUV9900 was a proprietary synthetic analogue of alpha-melanocyte stimulating hormone, which was part of the same family of molecules, known as melanocortins, as the active ingredient of Scenesse, afamelanotide.
Clinuvel said research had shown that CUV9900 was a potent skin protectant and formulation work had begun with the first formulations expected to be available for clinical testing by April 2011.
The company said the development program for CUV9900 had been fully costed.
Clinuvel said that Scenesse was being administered on a compassionate basis to the majority of erythropoietic protoporphyria patients who had completed the company's first phase III trial and under the Italian special provision listing, which allows the drug to be prescribed to erythropoietic protoporphyria patients prior to formal approval, with the cost of the drug reimbursed to Clinuvel by the Italian national health system.
Clinuvel was up one cent or 4.8 percent to 22 cents.

FLUOROTECHNICS

Fluorotechnics says it net loss after tax for the 12 months to June 30, 2010 was down 20 percent to $4,470,266 with revenue up seven percent to $3,486,211.
Net tangible assets per share decreased 40.8 percent from 4.9 cents last year to 2.9 cents at June 30, 2010.
Fluorotechnics said the financial year was "one of mixed outcomes for the company".
"Receiving endorsements from some of the world's leading scientists for our High Performance Flat-Top tower was significant and provides a credible source of reference for our sales people when talking to prospective customers," the company said.
"However the current economic environment in our major markets of Europe and North America has meant that our product sales have been far slower than initially expected," Fluorotechnics said.
Fluorotechnics was unchanged at 12.5 cents.

USCOM

Uscom says its loss after tax increased 59.8 percent to $1,757,677 for the 12 months to June 30, 2010 on revenue down 46.97 percent to $1,019,005.
Uscom said that its net tangible assets per share was 0.05 cents at June 30, 2010, compared to 0.06 cents at June 30, 2009, down 16.7 percent.
Earlier this month Uscom said it would hold a strategic review of its sales and distribution for several reasons including the expiry of the Spacelabs distribution agreement on December 13, 2010 (BD: Aug 20, 2010).
Uscom said at the time and in today's announcement that it had been affected by the global economic slowdown.
Uscom was untraded at 34 cents.

ACUVAX

UBS AG has reduced its substantial holding in Acuvax from 57,470,000 shares (8.23%) to 51,470,000 shares (6.82%).
The substantial shareholder notice said that UBS sold the 6,000,000 shares as part of a master prime brokerage agreement.
Acuvax was up 0.05 cents or 20 percent to 0.3 cents.

PSIVIDA

Psivida has requested a trading halt pending an announcement.
Trading will resume on September 2, 2010 or on an earlier announcement.
Psivida last traded at $3.51.

BIO-MELBOURNE NETWORK

Monash Alfred Psychiatric Research Centre director Prof Jayashri Kulkarni will discuss diagnostics and treatments for depression at the Bio-Melbourne September Bio-Breakfast.
Bio-Melbourne Network chief executive officer Michelle Gallaher said that Prof Kulkarni had made "some exciting developments in alternative treatments for depression including using transcranial magnetic stimulation and oestrogen treatment".
"These developments are very important given that many of the drugs currently on the market were developed in the 1990s and there have been very few anti-depression drugs developed in recent years," Ms Gallaher said.
The Bio-Melbourne Network said Prof Kulkarni would focus on the prevalence of depression in the Australian population and what new drugs were in development for its treatment.
Neural Diagnostics chief executive officer Dr Roger Edwards will present on the developments in devices and the use of biomarkers to diagnose depression, whether this is a growing market and who the players are.
The Bio-Breakfast will be held on September 7, 2010 in the Supper Room, Melbourne Town Hall, Swanston St, Melbourne with registration from 7:15am.
For more information go to: www.biomelbourne.org/events/view/144.