Biotech Daily

Friday October 2, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NOVOGEN UP 4%; CATHRX DOWN 16%**

*** AVEXA CLOSES PHASE III HIV TRIAL FOR EARLY REGISTRATION**

*** PHOSPHAGENICS PLAN RAISES $7m**

*** HELICON BRANCHES INTO GOLD, COPPER MINING**

*** FERMISCAN $4.5m LOSS; MARK FORDREE NEW CEO; LEON CARR GOES**

MARKET REPORT

The Australian stock market fell 2.1 percent on Friday October 2, 2009 with the S&P ASX 200 down 99.4 points to 4601.7 points.

Eight of the Biotech Daily Top 40 stocks were up, 19 fell, nine traded unchanged and four were untraded.

Novogen was best, up three cents or 4.35 percent to 72 cents with 28,261 shares traded.

Compumedics, Mesoblast and Sunshine Heart climbed more than two percent; Bionomics and Heartware were up more than one percent; with Cellestis, Impedimed and Resmed up by less than one percent.

Cathrx led the falls, down 6.5 cents or 16.25 percent to 33.5 cents with 55,000 shares traded followed by Psivida down 15 percent to $3.74.

Genetic Technologies lost 7.1 percent; Prana fell 6.5 percent; Benitec was down 5.9 percent; Antisense, Avexa, Chemgenex, Clinuvel and Living Cell fell four percent or more; Circadian and Genera were down more than three percent; Alchemia, Biota, Nanosonics, Sirtex and Universal Biosensors shed more than two percent; Acrux and Cochlear were down more than one percent; with CSL and Peplin down by less than one percent.

AVEXA

Avexa has closed its phase III trial of apricitabine for HIV and will discuss the 24-week results with the US Food and Drug Administration, hoping for early registration of the drug.
Avexa's chief executive officer Dr Julian Chick told Biotech Daily that more than 200 patients had passed the 24-week mark in the trial originally planned to run for 48 weeks, closing in early 2011.
Dr Chick said that following discussions with the FDA, "the fastest route to registration is to stop the study and look at the data".
Dr Chick was unable to tell Biotech Daily what was expected in the data, but confirmed the phase II 96-week data (BD: Mar 16, 2009) and phase III 16-week data (BD: Jun 4, 2009) demonstrated that apricitabine - or ATC - significantly reduced HIV viral load in patients.
"I think this is a very big plus for us," Dr Chick said. "If the results are successful they could give limited or conditional approval."
He said the independent data safety monitoring board had approved the continuation of the trial in May 2009 (BD: June 4, 2009) and there were no new safety issues.
Dr Chick said the FDA could request "one small study" which could either be a confirming phase III trial or "a post-market phase IV trial".
In its media release to the ASX, Avexa said the apricitabine phase III study would be closed and the data unblinded and analyzed, with the results due by April 2010.
Dr Chick said Avexa could have registration by 2011 and on the market almost immediately. He said Merck's Isentress was approved on October 12, 2007 and was on the market the immediately afterwards.
Avexa said the 24-week data would provide important information on ATC when used with other anti-HIV drugs, especially those recently approved.
"Depending on the result, these data may clarify ATC's role in modern treatment regimens and determine the potential for ATC's use in combination therapy," Avexa said.
"The unblinding of our phase III trial is a critical period in the development of ATC," Dr Chick said in the media release.
"The rationale for closing the trial, which was expected to run through 2011, was based on two key factors. First, the results may offer key insight into ATC's role in the overall HIV treatment landscape and discussions with regulatory authorities may clarify the ATC approval path," Dr Chick said.
"Secondly, this will allow for a mature enough data point to enable potential partners the ability to make a definitive decision on the licensing of ATC," he said.
Avexa said its phase III trial had been conducted with more than 130 sites worldwide and compares ATC to 3TC in drug-resistant HIV patients.
The company said that all patients who enrolled in the 16-week dose determination arm had completed 24 weeks of treatment and patients from the earlier phase IIb study, which used the 800mg ATC dose, had been successfully treated with ATC for up to three years.
Avexa said that was evidence of the safety, efficacy and durability of 800mg ATC for HIV.
Avexa fell half a cent or 4.35 percent to 11 cents with 2.3 million shares traded.

PHOSPHAGENICS

Phosphagenics says shareholders subscribed for almost all the shares available in its plan to raise $7 million through the issue of shares at 9.2 cents each.
Phosphagenics said 928 investors applied for 74,831,085 shares raising $6,884,502.58 and leaving a rounded down shortfall of 1,255,871 shares worth $115,497.42 for the underwriter BBY.
Phosphagenics was unchanged at 10 cents.

HELICON GROUP

Helicon says it will retain its China biotechnology interests while funding a Peruvian gold and copper mine.

Helicon told the ASX that it had "an exclusive conditional option to acquire 100 percent of Arequipa Resources" which had the right to earn a 50 percent interest in El Serrano Resources SA, a Peruvian company that will own 100 percent of Peru's El Serrano copper and gold project.

Helicon said an option agreement has been entered into between Helicon, Arequipa and two major shareholders of Arequipa, Dr Saliba Sassine and Graeme Boden who are also directors of Helicon.

As part of the transaction, Helicon will invest $US4 million ($A4.6 million), of which $US300,000 will be paid to the present tenement owners and $US3,700,000 will be spent over 24 months on exploration and development programs.

The $300,000 loan will be part of the $US4 million commitment.

Helicon will also issue 30 million new shares and 60 million new options exercisable at 20 cents by May 31, 2013 to Arequipa shareholders.

If the transaction is approved, Dr Sassine will receive 9,500,000 shares and 36 million options and Mr Boden will receive 6,750,000 shares and 14,000,000 options as consideration for the transfer of their Arequipa shares.

"Helicon will continue to pursue its healthcare strategy in China," the company said.

Helicon said it had been looking at new opportunities because of the slow pace of the product approval process by the China State Food and Drug Administration.

Helicon was suspended by the ASX until October 6, 2009.

Helicon last traded up 5.5 cents or 68.75 percent at 13.5 cents.

FERMISCAN

Fermiscan says that recently appointed director, form EG Capital principal Mark Fordree has been appointed acting chief executive officer.

The company said that major shareholder and former director Leon Carr "no longer has an executive position within Fermiscan".

Fermiscan said its new board was "reviewing strategy delivery and evaluating the most effective ways to create shareholder value with the presently limited cash resources".

The company said "material uncertainties existed over future profitability and cash flows".

Fermiscan said a program of cost reductions had been adopted and the Sydney Breast Clinic had been sold for $1.0 million in a management buyout.

Fermiscan bought the Clinic last year for $5.5 million (BD: May 28, Jun 16, 2008).

The company is involved in protracted legal proceedings against the inventor of its x-ray diffraction test of hair for breast cancer, Prof Veronica James, with an estimate of costs by Prof James' solicitor Jane Owen at $1.5 million.

Fermiscan said it had discussions with institutional and professional investors to secure additional equity funding.

The company said it was "likely that these discussions may not be completed for some time and directors have not yet secured commitments".

Fermiscan was up half a cent or 7.9 percent to 6.9 cents.