Biotech Daily

Friday June 19, 2009

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP; PHOSPHAGENICS UP 26%, NOVOGEN DOWN 13%**

*** CSL EVALUATES PHOSPHAGENICS' TRANSDERMAL TECHNOLOGY**

*** US COURT TELLS VIVUS TO START ACRUX TESTOSTERONE TRIAL**

*** LIVING CELL 3 MONTHS FROM NZ DIABETES XENOTRANSPLANT TRIAL**

*** INCITIVE REQUESTS 'ACQUISITION' TRADING HALT**

*** AGENIX ASKS INVESTORS TO HELP FIND $1m CASH**

*** CORRECTION: MEDICAL THERAPIES**

MARKET REPORT

The Australian stock market climbed 0.19 percent on Friday June 19, 2009 with the S&P ASX 200 index up 7.5 points to 3,899.6 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 12 fell, 11 traded unchanged and three were untraded.

Phosphagenics was best, up 3.5 cents or 25.9 percent to 17 cents with 1.8 million shares traded, followed by Bone up 20.0 percent to 18 cents.

Chemgenex, Living Cell and Tyrian all climbed more than 11 percent; Benitec, Clinuvel and Sirtex were up more than three percent; Acrux, Biota, Optiscan, Psivida and Viralytics rose more than two percent; with Cochlear, CSL and Peplin up more than one percent.

Novogen led the falls, down 9.5 cents or 13.3 percent to 62 cents with 96,872 shares traded.

Genera and Sunshine Heart lost more than seven percent; Antisense, Circadian and Phylogica were down six percent or more; Avexa fell four percent; Heartware and Universal Biosensors shed more than two percent; Alchemia and Mesoblast were down more than one percent; with Arana and Resmed down by less than one percent.

CSL, PHOSPHAGENICS

Phosphagenics has signed a research and option agreement with CSL to evaluate its tocopheryl phosphate mixture (TPM) transdermal large protein delivery technology.
Phosphagenics said it would develop formulations containing its TPM delivery system in combination with a number of CSL's protein-based formulations.
The company said CSL would assess the formulations in a mouse model to establish efficiency of delivery after topical application.
Should the formulations prove successful the collaboration will expand to optimize the effect of the formulations, as well as testing their effect in higher order animals.
Phosphagenics said it would receive undisclosed option, milestone and royalty payments should CSL elect to pursue formulations that result from the collaboration.
Phosphagenics' chief operating officer Dr Esra Ogru said the agreement was "a significant endorsement of our drug delivery platform and is line with our commercialization strategy".
"We are very pleased to be working with CSL, one of the world leaders in the development and manufacture of vaccine and plasma protein biotherapies," Dr Ogru said.
"Our TPM technology is able to deliver large proteins, such as insulin, through the skin and into the blood stream, essentially replacing the need for invasive needle injections," Dr Ogru said.
Phosphagenics climbed 3.5 cents or 25.9 percent to 17 cents with 1.8 million shares traded.
CSL was up 42 cents or 1.35 percent to $31.55 with 3.8 million shares traded.

ACRUX

California's Judicial Arbitration and Mediation Service has ruled that Vivus must begin dosing patients in the Acrux phase III transdermal testosterone trial by April 1, 2010.
Acrux said in a media release to the ASX that the ruling relates to the dispute between its wholly-owned subsidiary Fempharm and Vivus - the US licencee of its testosterone spray for women which Vivus has branded as Luramist.
Acrux said that subsequent to a first interim ruling in April 2009, Acrux and Vivus were unable to agree on a new 'outside date' by which Vivus must begin the first phase III study of Luramist.
Commencement is defined as the date when the first patient has been dosed in accordance with the phase III protocol.
Acrux said that each party made further submissions to the Judicial Arbitration and Mediation Service panel, which set the outside date at April 1, 2010, as proposed by Acrux.
The company said the panel would keep jurisdiction over the matter until at least April 1, 2010.
Acrux chief executive officer Dr Richard Treagus told Biotech Daily there were diligence obligations and payments if Vivus failed to meet the set date.
Acrux chairman Ross Dobinson said the company was "very pleased that the arbitration panel has determined that no further delays are justified and in so doing has enforced Vivus's performance obligations under the agreement".
"The phase III trial must start within ten months and during that period we expect to see active preparation for the trial", Mr Dobinson said.
"Luramist has the potential to generate very strong commercial returns for Acrux, being the best-in-class product in a billion dollar market," he said.
Acrux was up 3.5 cents or 2.9 percent to $1.24.

LIVING CELL

Living Cell says it is three months from beginning the Western world's first xeno-transplant trial in more than a decade.

Living Cell chief executive officer Dr Paul Tan told Biotech Daily that the long-awaited New Zealand phase I/IIa clinical trial of Diabecell porcine islets of Langerhans cells for insulin dependent diabetes was expected to formally enroll patients "in the next few weeks" with the first patient dosed by September.

Dr Tan said Living Cell had accepted a preliminary decision from the New Zealand Minister of Health Tony Ryall to issue a new conditional authorization for the trial.

Living Cell said in a media release to the ASX that the Minister's letter stated that "the proposed condition that would require [Living Cell] to amend the inclusion criteria of [its] study to limit participation in the study to patients with brittle diabetes who suffer from significant metabolic instability is essential to ensure that the study complies with international guidelines, which require that participants obtain maximum benefit possible from their participation in the study".

"The other proposed changes to the existing conditions are matters that LCT has agreed are appropriate during the peer review process, or are changes of a procedural, rather than a substantive nature …." Living Cell quoted the Minister saying.

The company said that the clinical protocol for the New Zealand diabetes trial had been amended according to the proposed new conditions from the Minister.

Dr Tan told Biotech Daily that the ethics committee overseeing the trial would have to sign-off on accepting the Minister's changes and then the company would have to report back to the Minister. Dr Tan said he expected the changes to be a formality.

Dr Tan said 200 patients were waiting for the trial to begin and the company had completed screening on 20 patients, all of whom were likely candidates for the trial.

Xeno-transplant trials have been out of favor in Western countries since the late 1990s, although they have not been formally banned in either Europe of the US.

Living Cell has conducted trials of its encapsulated pig cells in Russia with two type 1 diabetes patients becoming insulin independent and others showing decreased dependence on insulin.

Living Cell climbed two cents or 11.8 percent to 19 cents.

INCITIVE

Incitive has requested a trading halt pending an announcement "in relation to a proposed acquisition".

Incitive has been developing drugs for inflammation and auto-immune diseases, based on bromelain extracted from pineapple stems.

Last year the company completed the acquisition of Perforx from the Peter MacCallum Cancer Institute and closed the program to develop ICV0019 for cancer.

The then Incitive managing director Donald Home told Biotech Daily his company had committed up to $1.35 million to the project but it didn't reach its milestones and "the program was stopped early".

He said the research on perforin as an apoptosis-related protein only reached the in vitro stage (BD: Mar 27, 2008).

Mr Home resigned on January 30, 2009 and the company's animal health assets were licenced to Peptech Animal Health on April 3, 2009.

A rights issue raised $783,907 in April (BD: Apr 17, 2009).

Trading will resume on June 22, 2009 or on an earlier announcement.

Incitive last traded at 0.7 cents.

AGENIX

Agenix has called for shareholders to help it find institutional and sophisticated investors to raise funds for the company.

In an 'update on company operations' Agenix said "the survival of the company and its path back to trading depends on immediately raising capital in the form of a private placement of convertible notes" from two sources, institutional investors and sophisticated private investors.

Agenix said the call for the convertible note placement was due to its voluntary trading suspension "arising from control issues flowing from the China debacle, now resolved" with uncertainty over the major source of planned capital from Shanghai Rui Guang Bio-Pharma Development Co (SHRG).

Agenix received its $91, 253 May payment, but SHRG was unable to raise an expected $2.8 million. Agenix Biopharmaceutical (Shanghai) has all rights to market the hepatitis B anti-viral Youheding (adefovir dipivoxil) outside China and the Chinese parties retain all rights in China (BD: Apr 17, 2009).

The companies have agreed to a joint venture for the pipeline of generic tenofovir for hepatitis B, new generation generic adefovir, generic capecitobine (two acyclic nucleotide anti-cancer indications for colorectal cancer and liver cancer) and a natural Chinese integrase inhibitor technology for HIV.

Agenix said the proposed capital raising would fund current operations "to enable a re-listing of our securities on the ASX and undertake a rights offer".

Agenix said about $1 million would be sought, which would help put the company "in a position to enforce the obligations of the final settlement deed and to drive the strategic objectives of the company".

"Should the company fail to raise sufficient funds in the immediate term, the ability of the company to maintain operations is unsustainable," Agenix said.

Agenix said it had discussions "with a number of institutions … but these potential investors are dissuaded by the fact that the shares are not presently trading".

"Therefore, the company is looking to provide sophisticated private investors with a direct opportunity to invest through a private placement of convertible notes and the board invites you to contact us right away if you are in a position to assist," Agenix said.

Agenix said one major shareholder said "he intends to get behind it and help Agenix through this difficult period but he is not prepared to do it alone".

The company said it had prepared documentation for a rights issue once trading resumes.

Agenix is in a voluntary suspension and last traded at 1.7 cents.

CORRECTION: MEDICAL THERAPIES

Last night's edition reported that Gregory Glen Worth's holding in Medical Therapies became substantial with a total of 13,637,809 shares or 7.27 percent.

Mr Worth acquired 10,330,000 shares between April 22 and May 18, 2009 for $109,476.91, an average price of 1.06 cents and not as published.

The sub-editor's slide rule and logarithm tables have been confiscated and he will undertake the one-week professional development course: How To Use A Calculator 101.

Medical Therapies was untraded at 2.5 cents.