Biotech Daily

Monday April 4, 2011

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: CELLESTIS UP 16%; USCOM DOWN 15%**

*** QIAGEN BIDS $341m OR $3.55 A SHARE FOR CELLESTIS**

*** BIOGUIDE BRIEF: PLAYING THE BALL NOT THE MAN PAYS OFF**

*** BIOTRON PLACEMENT RAISES $1.7m; $2.48m TOTAL**

*** SUNSHINE HEART COMPLETES PILOT TRIAL 20 IMPLANTS**

*** EURO-PARTNER FOR PHOSPHAGENICS ANTI-ACNE CREAM**

*** COGSTATE $700k ANAEMIA TRIAL CONTRACT**

*** FIRST US PATENT FOR CALZADA'S POLYNOVO**

*** NUSEP'S PROF JOHN AITKEN APPOINTED ACADEMY FELLOW**

MARKET REPORT

The Australian stock market climbed 0.51 percent on Monday April 4, 2011 with the S&P ASX 200 up 25.0 points to 4886.8 points.

Fourteen of the Biotech Daily Top 40 stocks were up, fourteen fell, eight traded unchanged and four were untraded.

Cellestis was the best, up 47 cents or 15.7 percent to $3.47 with 1.1 million shares traded, followed by Viralytics up 8.7 percent to five cents with 3.0 million shares traded.

Sunshine Heart climbed 7.7 percent; Living Cell was up 6.3 percent; Mesoblast was up 5.7 percent; Patrys and Starpharma were up more than four percent; Benitec and Sirtex were up more than three percent; Alchemia and Optiscan rose more than two percent; with Prima and QRX up more than one percent.

Uscom led the falls, down 4.5 cents or 15.0 percent to 25.5 cents, with 24,800 shares traded, followed by Antisense down 14.3 percent to 1.2 cents with 16.6 million shares traded.

Impedimed lost nine percent; LBT was down 6.6 percent; Bionomics, Cellmid, Genetic Technologies and Heartware fell four percent or more; Prana and Phylogica lost more than three percent; Biota shed 2.1 percent; with Acrux and Bioniche down more than one percent.

CELLESTIS

Cellestis says the German-based Qiagen NV has made as takeover bid at $3.55 a share, valuing the company at $341.3 million.

Cellestis said its directors unanimously supported the bid which was a 24.3 percent premium to the one-month, volume-weighted, average price, to be conducted through a scheme implementation deed

Cellestis co-founder and chief executive officer Dr Tony Radford told Biotech Daily that Qiagen would be buying a going concern with most executives expected to continue with the company.

Dr Radford said Cellestis was still building its research and development work and expanding sales of its Quantiferon tuberculosis diagnostic products.

Dr Radford said the offer was good value for the early investors in the company which was floated in 2001 at 25 cents a share when the Australian dollar was worth 50 US cents.

He said that the offer of $3.55 a share should be considered in the light of the strong Australian dollar.

Dr Radford said the offer was seven times the company's current revenues.

In a media release the Cellestis board said it "unanimously recommends that the Cellestis shareholders vote in favor of the scheme and intend to vote the shares that they control, in favor of the scheme, in the absence of a superior proposal and subject to the independent expert confirming that the scheme is fair and reasonable and in the best interests of Cellestis shareholders".

Cellestis said thay under the scheme, the consideration may be structured to include a fully-franked, special dividend, payable only if the scheme becomes effective and upon receipt of a favorable Australian Tax Office ruling, and subject to Cellestis board approval.

The company said the cash payable under the scheme would be reduced by the cash amount of any special dividend paid.

Cellestis said the scheme extended to any Cellestis shares that were issued as a result of the valid exercise of options prior to the scheme record date and the company would approach option-holders to enter into private treaty arrangements to facilitate the cancellation of their options in exchange for a cash payment, subject to the scheme becoming effective and Cellestis obtaining any required regulatory approval.

Cellestis chairman Ron Pitcher said the offer price recognized "the significant value within Cellestis' Quantiferon technology, which the management team and staff at Cellestis have developed into a global leading technology in the diagnosis of latent tuberculosis".

"Cellestis' Quantiferon technology will greatly complement Qiagen's leading molecular diagnostic product portfolio and the transaction will allow Qiagen to leverage its global research and development and sales and marketing infrastructure to further enhance the development and growth of the Quantiferon technology," Mr Pitcher said.

The media release said that Qiagen had indicated its intention that the existing management team, led by Dr Radford and Dr James Rothel would remain in place to continue to drive the performance and growth of the business.

Dr Radford and Dr Rothel were described in the media release as Cellestis two major shareholders and have entered into option agreements for Qiagen to acquire up to 19.9 percent of the company, subject to Foreign Investment Review Board approval.

According to ASX data Dr Radford and Dr Rothel hold 11,449,690 shares and 11,449,689 shares respectively of the 96,151,778 shares on offer.

The media release said Cellestis would not solicit any competing transaction and under specified circumstances Cellestis had agreed to pay Qiagen a $3.5 million break fee.

The scheme implementation is expected to be completed in July 2011.

Cellestis was up 47 cents or 15.7 percent to $3.47 with 1.1 million shares traded.

MARC SINATRA'S BIOGUIDE BRIEF: CELESTIS

Well, there seems to be little doubt that foreign companies think Australian biotech is all right – and cheap, even given the strength of the Australian dollar.

First, Cephalon took a slice of Mesoblast and a slice of Chemgenex. They then came back for the rest of the Chemgenex pie. Now, Germany company Qiagen has decided to just skip the slice and go for the whole Cellestis pie.

Cellestis has been one of Australian biotechnology's quiet achievers, having toiled through two iterations of its Quantiferon test for tuberculosis before nailing it with the third "in-tube" version.

The $3.55 offer per share seems okay, but is not great.

There are those who speculate Cellestis will eventually reach a tipping point in sales in the US and once this point is reached, it is thought sales will rapidly escalate as the majority of places testing for TB switch en-masse to Quantiferon.

If you are a believer in this scenario, than $3.55 isn't a good offer at all. If you aren't a believer, than the offer price is pretty good. Will we see a rival bidder enter the fray? It seems possible.

The Quantiferon tests would be quite a good fit with the world's largest diagnostics company, Quest Diagnostics. With its reach, Quest could probably get Quantiferon sales to that "tipping point" much more quickly than Qiagen.

Quantiferon would also fit with several other large diagnostic companies.

At this stage, though, a higher offer is mere speculation. What is certain is that Australian biotechnology companies are in demand on the world stage and this bodes well for the future of the industry.

Marc Sinatra
Analyst

BIOTRON

Biotron says it has raised $1,710,000 through the placement of 18,000,000 shares at 9.5 cents each.
Biotron said the placement followed its share plan which raised $770,000 last week (BD: March 28, 2011).
The company said the funds would be used for a proof-of-concept phase Ib/IIa study of BIT225 in HIV infected patients and to ensure it could "assess the alternatives for the maximizing of returns to shareholders which may focus on completing a commercial deal with a pharmaceutical company to continue the development of BIT225 to a marketable drug or further clinical studies which the company can undertake to add value to a subsequent commercial deal with a pharmaceutical company" (BD: Feb 24 2011).
The company said in February it hoped to raise up to $3,472,863 in the share plan.
Biotron was unchanged at 11.5 cents.

SUNSHINE HEART

Sunshine Heart says it has implanted all 20 patients in its pilot trial of the C-Pulse aorta cuff pump as of March 31, 2011.

Sunshine heart said the C-Pulse studies were designed to assess safety and provide indications of performance of the device in class III and ambulatory class IV, or moderate to severe, heart failure patients suffering from symptoms such as shortness of breath and reduced mobility.

Sunshine Heart chief executive officer Dave Rosa said that completing enrollment of the 20 patients was “Sunshine Heart’s most historic milestone to date”.

Mr Rosa said the company was “on target to achieve a number of additional critical milestones in the calendar year”.

Sunshine Heart said the C-Pulse aorta cuff used an intra-aortic balloon counter-pulsation technology, assisting the left ventricle by reducing the workload required to pump blood throughout the body and increasing blood flow to the coronary arteries.

Ohio State University chief of cardiovascular medicine Dr William Abraham said the C-Pulse system “addresses some of the fundamental aspects of heart failure, notably low cardiac output, poor peripheral perfusion and inadequate blood flow to the coronary arteries”.

“The C-Pulse Heart Assist System offers the potential to treat patients with moderate to severe heart failure who, despite the best available treatments, remain substantially disabled,” said Dr Abraham.

Sunshine Heart said the C-Pulse system was an earlier intervention than other mechanical therapies, such as left ventricular assist devices, did not directly contact the patient’s blood and could be turned on or off at any time allowing the patient intervals of freedom to perform certain activities.

The company said the C-Pulse could also be implanted in a minimally invasive procedure, which could reduce procedural time, hospital stays, overall cost and patient risk as compared to a traditional sternotomy.

The 20 patient US Food and Drug Administration-approved feasibility study was available to men and women between the ages of 18 to 75 who suffered from class III or ambulatory class IV heart failure and for whom standard drug therapy had failed.

After six-months of follow-up with all patients, Sunshine Heart said it would submit the feasibility data to the FDA and seek approval for the pivotal trial protocol.

Sunshine Heart previously said it expected the pivotal trial would require about $US40 million (BD: June 3, 2010).

Mr Rosa said in June 2010 that the company was hoping to gain Conformité Européenne (CE) mark approval by October 2011, based on completing this pilot trial in October 2010.

Mr Rosa subsequently told Biotech Daily that there were delays beyond the company’s control at several trial centres.

Sunshine Heart receives reimbursement for C-Pulse systems implanted in patients in its trials.

Sunshine Heart was up 0.3 cents or 7.7 percent to 4.2 cents.

PHOSPHAGENICS

Phosphagenics says it has begun the second stage of a development agreement with an unnamed dermatology company to develop a transdermal prescription drug for acne.
Phosphagenics said it would undertake formulation development studies for the product that combines its tocopheryl phosphate mixture or TPM transdermal delivery technology with a specified but unnamed anti-acne drug.
Phosphagenics chief executive officer Dr Esra Ogru told Biotech Daily that the unnamed European-based major dermatology company would pay all development costs which included establishing its stability profile and final formulation before entering clinical trials.
Dr Ogru said the European dermatology company would probably take over all development work itself in three or four months time.
In a media release Phosphagenics said commercial arrangements for the final product, which would be available as a prescription medication, would be discussed when the trial was completed, which was expected by the end of 2011.
Phosphagenics said that earlier studies on the product candidate demonstrated “very effective delivery into the skin and tolerance of the drug”.
Dr Ogru said the agreement was the second of its kind by the company in dermatology this year, with a collaboration with a US company on a psoriasis product to begin phase I trials later this year, announced in February (BD: Feb 7, 2011).
“The TPM platform technology offers profound benefits for the field of dermatology,” Dr Ogru said.
“It is able to enhance the delivery of therapeutic actives into the skin for increased efficacy, while reducing adverse side effects such as irritation,” Dr Ogru said.
Phosphagenics said that acne was a chronic skin disease involving inflammation of the sebaceous glands affecting an estimated 80 percent of teenagers and many adults, especially women aged 30-40 years and the topical acne product market was estimated at more than $2 billion a year.
Phosphagenics was unchanged at 11.5 cents with 4.1 million shares traded.

COGSTATE

Cogstate says it has signed a $700,000 contract with an unnamed pharmaceutical company to use its tests in a phase III trial for the treatment of iron deficiency in anaemia.
Cogstate said it provide its cognitive testing technology and associated services to both the randomized, double-blind, placebo-controlled study as well as the open-label extension study.
Cogstate chief science officer Dr Paul Maruff said that iron deficiency was “the most common cause of anaemia worldwide”.
“Research in patients with iron deficiency anemia has shown a correlation between low levels of haemoglobin and reduced cognitive function,” Dr Maruff said.
“The underlying hypothesis for this study is that an increase in haemoglobin levels through [intra-venous] iron replenishment will result in a corresponding improvement in cognitive function,” Dr Maruff said.
Cogstate said the primary outcome of the study was an increase in haemoglobin and cognition would be tested in consenting patients within the US arm of the study.
The company said it was the first time its technology would be used in a pharmaceutical company sponsored study of iron deficiency in anaemia.
Cogstate said it had previously studied the effects of anaemia on cognition.
Cogstate fell one cent or 5.3 percent to 18 cents.

CALZADA, POLYNOVO BIOMATERIALS

The US Patent and Trademark Office has allowed the Calzada-owned Polynovo a patent entitled 'Chain Extenders', Polynovo's first US patent.
Calzada said Polynovo had patents granted in other jurisdictions.
The company said the allowed patent covered biocompatible biodegradable thermoplastic polyurethanes and polyurethane-ureas comprising novel chain extenders, which were designed for melt processes such as extrusion or injection moulding, used to manufacture fibres, non-woven fabrics, tubes and three dimensional forms.
Polynovo chief executive officer Laurent Fossaert said the patent was "good news for the business".
"The chain extenders patent is a key piece of intellectual property for our thermoplastic technology and will be extremely useful for devices, such as coronary stents, requiring stiff but non-brittle biodegradable polymers," Mr Fossaert said.
Calzada chief executive officer Dr Stewart Washer told Biotech Daily that the US patent would provide protection until 2025.
Calzada was up half a cent or 9.1 percent to six cents with 2.1 million shares traded.

NUSEP

Nusep says the inventor of its Spermsep technology Prof John Aitken has been elected as a fellow of the Australian Academy of Science.
Nusep said Prof Aitken was the chairman of the company's scientific advisory committee.
The company said the Academy was "the most prestigious Australian scientific organization and election to the Australian Academy of Science recognizes a career that has significantly advanced, and continues to advance, the world's scientific knowledge".
Nusep said Prof Aitken was distinguished for his work on mammalian sperm function, fertilization and early embryonic development with applications in fertility treatments and contraception.
The company said Prof Aitken was the laureate professor of biological sciences in the University of Newcastle's School of Environmental and Life Sciences.
Nusep was up two cents or 10 percent to 22 cents.