Biotech Daily

Thursday August 13, 2009

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: VIRALYTICS UP 15%, SUNSHINE DOWN 25%**

*** PHOSPHAGENICS OPTION ON METABOLIC DRUG TO RUB AWAY FAT**

*** IMMURON JUMPS 210% ON BIG PHARMA INFLUENZA TALKS**

*** US ARMY PAYS AVITA $480k; POSITIVE PILOT STUDY RESULTS**

*** BIOTA TO RETURN $20m -- 11¢ PER SHARE**

*** VIRALYTICS: 12 PATIENTS TO GO IN THREE PHASE I TRIALS**

*** PHOSPHAGENICS SHARE PLAN TO RAISE UP TO $9m**

*** LAST NAIL IN DIA-B, PALLANE MERGER COFFIN**

MARKET REPORT

The Australian stock market was up 2.14 percent on Thursday August 13, 2009 with the S&P ASX 200 up 92.8 points to 4435.9 points.

Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, 11 traded unchanged and one was untraded. All three Big Caps were up.

Viralytics was best, up 0.4 cents or 15.4 percent to three cents with 762,767 shares traded, followed by Alchemia up five cents or 11.0 percent to 50.5 cents with 593,100 shares traded.

Phosphagenics and Universal Biosensors climbed more than eight percent; Chemgenex was up 7.3 percent; Cytopia climbed 6.7 percent; Heartware rose 2.5 percent; Biota, Cochlear, Impedimed and Novogen were up more than one percent; with Cellestis, CSL and Resmed up by less than one percent. Outside the Top 40, a Virax shareholder update pushed its shares up 74 percent to 7.5 cents with 3.2 million shares traded.

Sunshine Heart led the falls for the second day in a row, down 2.5 cents or 25 percent to 7.5 cents with 734,964 shares traded, followed by Genetic Technologies down 16.1 percent to 5.2 cents and Compumedics down 14.6 percent to 20.5 cents.

Labtech and Prana lost more than six percent; Bionomics, Optiscan and Psivida fell more than four percent; Clinuvel, Peplin and Tissue Therapies were down more than three percent; Circadian, Genera and Mesoblast shed two percent or more; Pharmaxis and Progen were down more than one percent; with Sirtex down 0.23 percent.

PHOSPHAGENICS, METABOLIC

Phosphagenics has signed a collaborative research and option agreement with Metabolic for its fat-reduction drug AOD9604, this time as a transdermal cosmetic compound.

Neither company would discuss upfront fees or milestone payments.

Metabolic's phase II trial of AOD9604 taken orally showed little or no efficacy in subjects compliant with US Food and Drug Administration rules on diet and exercise (BD Feb 21, 2007).

But the trial showed some efficacy in the non-compliant subjects, those who did not complete exercise and dietary targets.

Phosphagenics vice-president of research and development Dr Paul Gavin told Biotech Daily that there was preclinical data in mice showing the compound had fat reduction properties and winning approval as a transdermal cosmetic would be far easier and not require FDA approval.

Dr Gavin said that three of Phosphagenics staff had previously worked on AOD9604 with its inventor Monash University's Prof Frank Ng in the 1990s: chief operating officer Dr Esra Ogru; and research scientists Dr Roksan Libinaki and Dr Robert Gianello.

Dr Gavin said the pre-clinical proof-of-concept work would cost less than $100,000 and the company hoped to have a human cosmetic trial beginning in February 2010 with results by mid-2010.

In a joint media release, the companies said that if all went well with the trials a product could be released by the end of 2010.

Dr Gavin said Phosphagenics had experience in introducing new compounds to its tocopheryl phosphate mixture, or TPM, transdermal delivery technology based on phosphorylated vitamin E.

The collaboration agreement allows Phosphagenics to elect to licence Metabolic's AOD9604 for use as a cosmetic pharmaceutical product aimed at reducing cellulite and the size of fat cells localized under the skin.

If Phosphagenics exercises its option to licence the compound, it will pay Metabolic an undisclosed royalty on future sales of product.

Neither company would quantify the commercial value of the deal nor whether there would be any up-front payment to Metabolic.

In the joint media release, the companies said Metabolic developed AOD9604, a fragment of growth hormone, for the treatment of obesity.

Metabolic's approach "was based upon the normalization of well-known hormonal and metabolic defects associated with both ageing and obesity," the companies said.

Using Phosphagenics' TPM delivery technology AOD9604 would be delivered locally, allowing users to choose where to remove fat and where to keep it.

The company said the topical delivery route sent the compound to the subcutaneous fat area directly, without having to travel through the systemic circulation to reach the targeted tissue.

Phosphagenics said its TPM technology was effective in delivering a range of both small and large molecules into, and through the skin to target the local tissue around the site of application.

The size of the AOD9604 molecule is well within the range of molecules already delivered by the TPM technology, Phosphagenics said.

Phosphagenics and Metabolic said "the biological properties of AOD9604 combined with the transdermal properties of TPM have the potential to make for an ideal cosmetic product for the reduction of unwanted fat stores beneath the skin".

Phosphagenics was up one cent or 8.3 percent to 13 cents with 1.9 million shares traded.

Metabolic was up 0.4 cents or 13.8 percent to 3.3 cents with 2.1 million shares traded.

IMMURON

Immuron says it is in discussions “with a top-25 global pharmaceutical company” on a joint development of its cow colostrum influenza treatment and prevention product.
Immuron said the talks followed the release of “very positive results” in its pre-clinical trials (BD: Aug 4, 2009).
The company said no further details could be released regarding the discussions.
Immuron jumped 8.8 cents or 209.5 percent from 4.2 cents to a high of 13 cents before closing up 6.3 cents or 150 percent at 10.5 cents with 18.9 million shares traded.

AVITA MEDICAL

Avita says it has received an initial $US400,000 ($A480,000) payment as part of the $US1.45 million ($A1.74 million) grant awarded by the US Department of Defense.
In May the company announced the newly established US Armed Forces Institute of Regenerative Medicine grant.
Avita said 10 US clinical investigational sites would participate in the study of the Recell wound treatment technology invented by the Royal Perth Hospital’s Prof Fiona Woods.
Avita said it had completed the screening and selection of participating sites including armed forces, private and university hospitals and burns centres.
The company said investigators include “many high profile burns specialists” including the president of the American Burns Association, the editor-in-chief of the journal Burns, the dean of the Loyola University School of Medicine, the director of the US Army Institute of Surgical Research Center and the University of Texas Health Science Center surgery department vice-chairman.
Avita said an investigators and key staff meeting was held in July at Wake Forest University Baptist Medical Center in North Carolina where initial training began.
The company said that more than 2,500 patients had been treated with Recell outside the US to date, but data from a pilot trial conducted at two of the participating US sites, Wishard Hospital Burn Center in Indiana and Wake Forest University Baptist Medical Center had been collected and analyzed to support substantial claims regarding the performance of the Recell regenerative technology.
Avita chief executive officer Dr William Dolphin said the US pilot data was “extremely encouraging – not unexpected and in keeping with previously published results on the use of Recell in the treatment of burns, but confirmatory data is always welcome”.
The company said the pilot study compared healing rates in burn victims treated with the standard-of-care, split thickness skin grafts and Recell.
Avita said Recell “performed extremely well”, with 10 of 14 patients displaying full healing within two weeks and 13 of 14 patients reaching this point within three weeks compared to the average healing time for split thickness skin grafts of four to five weeks.
Results from the study will be presented at the European Burns Association Meeting in Lausanne, Switzerland on September 3-5, 2009 with other European studies.
Wake Forest burn center director Dr James Holmes said Recell was “a game-changing technology” that would offer “tremendous benefits to the military and civilian populations, reducing morbidity, mortality and length of hospital stay”.
Avita said that as well as developing clinical treatments, the US Armed Forces Institute of Regenerative Medicine would serve as a training facility for Recell.
Avita climbed 1.5 cents or 14.3 percent to 12 cents.

BIOTA

Biota says it intends to return $20 million to shareholders estimated at 11 cents per share.
The company said the return followed an “extensive review of the cash requirements for the growth of the business and the improved trading conditions forecast in the near term”.
Biota said the record date for the payment would be November 19, 2009, subject to shareholder approval at the annual general meeting on November 12, 2009.
Shareholders would receive payment in early December 2009.
Biota said it had sought a class ruling from the Australian Taxation Office on whether any part of the payment was not a capital return and considered an unfranked dividend.
Biota said it would announce full year results on August 19, 2009.
Biota was up four cents or 1.96 percent to $2.08 with 1.6 million shares traded.

VIRALYTICS

Viralytics says its phase I trial of Cavatak for melanoma has completed patient enrollment and a phase I head and neck cancer trial has been approved for multiple sites.
Viralytics said it needed to enroll seven more patients in its direct injection of Cavatak into late stage head and neck tumor patients to complete enrolment and new sites were due to begin recruitment soon.
Viralytics said the third phase I trial was the intravenous infusion of Cavatak into patients with late stage melanoma, breast cancer and prostate cancer requiring five more patients to complete enrolment.
The company said the intravenous phase I trial was designed primarily to confirm that patients tolerate infectious virus circulating in their blood streams.
Viralytics said that following interest from head and neck clinicians it had ethics approval from the Hunter New England human research ethics committee to include two Sydney hospitals as additional trial sites and patient recruitment would begin shortly.
Viralytics said it had lodged a second ethics application to open a second site for patient recruitment for its melanoma, breast and prostate cancer phase I trial.
The company said clinical protocols to assess the activity of Cavatak had been either approved or lodged in six major Australian hospitals.
Viralytics managing director Bryan Dulhunty said the support from the medical community highlighted “the increasing clinical acceptance of Viralytics oncolytic virus technology”.
“Patient recruitment and completion of the two remaining trials can now be expected to progress rapidly,” Mr Dulhunty said.
“With 20 patients now treated with Cavatak and no serious product-related adverse events, we are increasingly confident about our prospects of moving into phase II trials,” Mr Dulhunty said.
Viralytics phase I trial of direct injection of Cavatak into the tumors of late stage melanoma patients has treated its last patient and has a 24 days to 84 day observation period.
While not a primary aim of this trial, interim data previously reported that one third of the patients in the trial displayed some reductions in volume of injected lesions coinciding with detection of elevated levels of specific serum cytokines indicating possible host generated anti-tumor responses.
The company said the phase I trial data was “expected to provide strong supporting evidence in gaining an investigational new drug application approval for a phase II trial”.
Viralytics said the data indicated that Cavatak exerts its anti-cancer activity through two distinct mechanisms: directly killing the cancer and the destroyed cancer cell activating the person’s own immune system into attacking further cancerous cells.
Viralytics was up 0.4 cents or 15.4 percent to three cents.

PHOSPHAGENICS

Phosphagenics is offering eligible shareholders up to $15,000 each in shares to raise a minimum of $5 million and up to $9 million.

Phosphagenics said the shares would be priced at a 20 percent discount to the average market price for the five days to the close of the offer on September 25, 2009.

Phosphagenics said the funds would support the launch of personal care products in the US and Australia; oxycodone clinical trials; development of an insulin patch; a diclofenac clinical trial; and collaborative research with Metabolic.

The company said the record date was August 20, 2009, the offer would open on August 26, 2009 and close on September 25, 2009.

Phosphagenics said BBY Ltd would underwrite up to $5 million of the share plan.

DIA-B, PALLANE

Dia-B Tech says that it has received a notice of termination from Pallane Medical that the reverse takeover will not go ahead.

Dia-b said the notice was in relation to the share sale agreement for the acquisition of Pallane, which has failed due to the underwriter, Winteray, failing to underwrite the $12 million of shares it promised to underwrite (BD: Aug 3, 11; Jul 29, 2009).

The company said its proposed acquisition of Pallane would no longer be completed on the terms of the original agreement and it was “in discussions to determine how best to move forward”.

Dia-B is in a voluntary suspension and last traded at 1.4 cents.