Biotech Daily

Tuesday June 28, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: LBT UP 29%, VIRALYTICS DOWN 8%**

*** NOVOGEN'S GLYC-101 SAFE, EFFICACIOUS FOR WOUND CLOSURE**

*** NOVOGEN: TRIPHENDIOL ACTIVITY IN PANCREATIC CANCER IN MICE**

*** NAVIGENICS SETTLES GENETIC TECHNOLOGIES PATENT CASE**

*** PRIMA SHARE PLAN RAISES $20.25m; TOTAL $41.25m**

*** VICTORIA LAUNCHES BIOTECHNOLOGY ADVISORY COUNCIL**

*** FRANCE PROVIDES FULL REIMBURSEMENT FOR HEATWARE PUMP**

*** NUSEP SIGNS THERMO FISHER DISTRIBUTION DEAL**

*** WILSON HTM TAKES 9% OF AVITA**

*** PHOSPHAGENICS EXPECTS $1m FROM COSMETIC SALES**

MARKET REPORT

The Australian stock market climbed 0.28 percent on Tuesday June 28, 2011 with the S&P ASX 200 up 12.5 points to 4,474.3 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, nine traded unchanged and two were untraded.

LBT was the best, up one cent or 28.6 percent to 4.5 cents with 122,037 shares traded, followed by Optiscan up 12.1 percent to 6.5 cents with 220,770 shares traded.

Living Cell climbed 9.8 percent; Phosphagenics was up 8.3 percent; Heartware was up 6.3 percent; Cathrx and Cellmid rose more than four percent; Benitec and Prana were up more than three percent; Cochlear, CSL and QRX rose more than two percent; with Clinuvel, Sirtex and Universal Biosensors up more than one percent.

Viralytics led the falls, down 0.6 cents or 7.8 percent to 7.1 cents with 20.5 million shares traded, followed by Pharmaxis down five percent to 85.5 cents with 642,763 shares traded.

Alchemia, Acrux, Cellestis, Genetic Technologies and Phylogica shed more than two percent; with Anteo, Mesoblast, Nanosonics and Sunshine Heart down more than one percent.

NOVOGEN

Novogen's 81 percent subsidiary Glycotex says two phase II trials of GLYC-101 topical gel have shown tolerability and efficacy in post laser ablation wounds treatment.

Novogen said the topical gel being developed to stimulate and modulate the natural cascade of wound healing activities of several cell populations was applied directly on the wound surface.

The company said the phase II clinical trials evaluated the effect of GLYC-101 on wound closure in patients undergoing carbon dioxide laser skin resurfacing.

Novogen said the first trial was a pilot, randomized, double-blind, placebo-controlled clinical study in Beverly Hills, California enrolling 12 healthy subjects undergoing laser skin ablation.

The company said that in addition to assessing safety endpoints, the study investigated efficacy endpoints, including the promotion of wound healing and cosmetic outcomes, over a one month period following laser skin ablation.

Novogen said the study was not statistically powered to determine efficacy, but all wound sites, regardless of treatment, displayed complete wound closure without signs of delayed healing, with a median time to complete wound closure of 15 days for all ablated sites, regardless of treatment.

Novogen said the 1.0 percent dose of GLYC-101 gel, was well tolerated with no serious adverse events.

The company said the second 26 subject, randomized, double-blind, placebo-controlled trial evaluated the effect of investigational GLYC-101 gel on complete wound closure following carbon dioxide laser skin resurfacing on the lower eyelid area.

Novogen said the subjects were randomized to receive either GLYC-101 0.1 percent, GLYC-101 1.0 percent, or placebo gel on one lower eyelid and a different test article on the other lower eyelid applied topically to the laser-ablated area immediately following the laser procedure and for four consecutive days thereafter for a total of five applications.

The primary efficacy endpoint of the study was time to complete wound healing and the secondary efficacy point was cosmetic outcomes, including scarring, observed over the course of one month following the initial application of GLYC-101 gel or placebo.

Novogen said that the time to complete wound closure was shorter for all GLYC-101 applications combined at each concentration compared to placebo ($p = 0.0062$ and $p = 0.0331$ for GLYC-101, 0.1 percent and GLYC-101, 1.0 percent, respectively).

The company said that by day 12, about 94 percent and 82 percent of subjects receiving GLYC-101, 0.1 percent and GLYC-101, 1.0 percent, respectively, exhibited complete wound closure compared to approximately 64 percent of subjects receiving placebo.

All subjects had complete wound closure by Day 35.

The company said that no serious adverse events considered to be related to GLYC-101 were reported.

Novogen said that the preliminary clinical activity of GLYC-101 was consistent with the results of the mechanism of action studies.

Novogen said that GLYC-101 was shown to regulate wound macrophage function by inducing production of tumor necrosis factor alpha in murine (mouse) and human cells.

The company said that activation of wound macrophages by GLYC-101 was one of the potential mechanisms by which the beta-glucan could benefit chronic wounds where inefficient inflammatory response was one of the underlying causes of impaired healing.

Novogen was up one cent or 6.7 percent to 16 cents.

NOVOGEN

Novogen says pre-clinical mouse data shows that triphendiol has anti-proliferative activity in pancreatic cancer as both a monotherapy and a chemosensitiser.
Novogen said its 71.3 percent US subsidiary Marshall Edwards had undertaken the studies of the prodrug of its lead candidate NV-143, in collaboration with lead author University of Alabama at Birmingham Medical Center's Dr Ewan Tytler
The article entitled 'Triphendiol (NV-196), Development of a Novel Therapy for Pancreatic Cancer' was published in the journal Anti-Cancer Drugs and an abstract is at http://www.ncbi.nlm.nih.gov/pubmed/21666438.
Novogen said the studies detail the in-vitro activity of triphendiol in pancreatic cancer cells as well as its in-vivo activity in animal models of pancreatic cancer.
The company said that both studies showed that pre-treatment with triphendiol enhanced the cytotoxic effect of gemcitabine, the standard-of-care for advanced pancreatic cancer.
Novogen said that in previous laboratory studies, triphendiol demonstrated anti-cancer activity against a broad range of tumor cell lines, including breast, colorectal and ovarian.
Novogen said that triphendiol was converted in-vivo into an active metabolite called NV-143 and in addition to being more active than triphendiol as a single agent, NV-143 appeared to be superior in its ability to synergize with chemotherapy in pre-clinical studies.
Novogen said that Marshall Edwards had completed the NV-143 pre-clinical studies required for an investigational new drug application, which it planned to submit to the US Food and Drug Administration in July 2010.
Marshall Edwards chief medical officer Dr Robert Mass said the data supported the clinical development strategy for NV-143, in combination with standard-of-care chemotherapy, while expanding the potential drug combinations to be considered in the randomized phase II clinical trials.

GENETIC TECHNOLOGIES

Genetic Technologies says it has executed a settlement and licence agreement for an undisclosed amount with Navigenics Inc over patent infringement.
Genetic Technologies said Navigenics of Foster City, California, was the first counterparty to settle the patent infringement suit, which was filed last month in the District Court of Colorado (BD: May 26, 2011).
Genetic Technologies chief executive officer Dr Paul MacLeman said the company was "very pleased by the early progress of this most recently filed assertion suit".
"To have a counterparty settle within the first month of filing the suit is very encouraging and speaks volumes, not only to the strength of the patents, but also the caliber of the assertion process," Dr MacLeman said.
The company said the commercial terms of the agreement were confidential.
Genetic Technologies fell half a cent or 2.8 percent to 17.5 cents.

PRIMA BIOMED

Prima says its share plan was oversubscribed raising $250,000 more than the hoped for $20 million at 28 cents a share.
Prima said it hoped the placement would raise $18 million but accepted oversubscriptions to $21 million (BD: Mat 25, 26, 2011).
The company said the funds were for the development of its CVac ovarian cancer vaccine including phase III trials.
Prima was unchanged at 29 cents with 4.3 million shares traded.

VICTORIAN BIOTECHNOLOGY ADVISORY COUNCIL

Victoria's Minister for Technology Gordon Rich-Phillips has called for applications for a new advisory council for Victoria's biotechnology sector.

A Victorian Government media release said that the council was a Coalition election commitment with $1.2 million being provided over four years to operate the council.

Mr Rich-Phillips said the Victorian Biotechnology Advisory Council would "provide advice to the Victorian Government on current and emerging opportunities and threats to the sector, as well as supporting the implementation of the Government's biotechnology policy".

The media release said that the council would assist the Government provide "a coordinated approach to fostering innovation and promoting growth in Victoria's life sciences industry".

"Appointments to the council will be selected for their skills, experience and understanding of a range of issues relevant to biotechnology and life sciences," Mr Rich-Phillips said.

The council will report to Mr Rich-Phillips and more information including the council's terms of reference is available at www.biotechnology.vic.gov.au.

Applications close July 25, 2011.

HEARTWARE INTERNATIONAL

Heartware says France will fully reimburse its ventricular assist system, effective from July 4, 2011.

Heartware said that publication of the decision in the Ministry of Labor, Employment and Health's official journal on June 22, 2011 was the final step to receiving reimbursement of a medical device in France.

Heartware was up 13 cents or 6.3 percent to $2.19.

NUSEP

Nusep says it has signed a new three year distribution agreement with Thermo Fisher Scientific for its separation gels.

Nusep said the agreement had a minimum guaranteed purchase commitment of $US850,000 ($A813,700) over the first 15 months.

The company said the distribution agreement would provide access to its Nuview gels in the Bio-Rad and Invitrogen format cassettes which accounted for about 90 percent of all gels sold in the US.

Nusep said the minimum purchase was a doubling of Nusep's gel sales over the last financial year.

Nusep managing director Dr Hari Nair that the "significant distribution agreement … strengthens our relationship with one of the world's premier life science companies and gives us worldwide reach for our gel products".

Nusep was unchanged at eight cents.

AVITA MEDICAL

Wilson HTM Investment Group has become a substantial shareholder in Avita with the acquisition of 19,293,000 shares or 9.18 percent of the company.

The initial substantial shareholder notice said Wilson HTM most recently bought 7,412,000 shares for $818,931 or an average price of 11.05 cents a share.

Avita was unchanged at 11.5 cents with 1.15 million shares traded.

PHOSPHAGENICS

Phosphagenics says it expects to earn $1 million in revenue by July 31, 2011 for its Elixia range of personal care products launched last year (BD: April 21, 2010).

Phosphagenics managing director Harry Rosen told Biotech Daily last year that the expected sales of the cosmetics range would help fund the company's transdermal research.

Both the biotechnology research and the cosmetic range use the company's tocopheryl phosphate mixture or TPM technology to penetrate the skin.

The Elixia range includes moisturizers, cream skin cleanser, body lotion and several products described as "anti-ageing" and will be available through Pulse pharmacies including Vitamin Me and Roy Young

Today Phosphagenics said the Terry White Group and Symbion Pharmacy Services would stock its products.

Phosphagenics chief executive officer Dr Esra Ogru said more than 20,000 units of Elixia had been sold since the company launched three new cosmetic lines in April this year.

Dr Ogru said while the entire range had experienced outstanding sales, the Bodyshaper Cellulite Contour Crème containing AOP9604 (formerly Metabolic's AOD9604) "in particular had far exceeded initial sales forecasts".

Dr Ogru said manufacturers had been forced to double initial production capacity and almost 10,000 units of the fat-buster cream had been sold.

Dr Ogru indicated the company was also in late stage discussions with a large Asian based distributor and had just finalized negotiations with a specialist distributor into spa, salons and beauty outlets in Hong Kong and Macau.

"Asia is also a major focus for brand growth and we are continuing negotiations with key distributors in this region," Dr Ogru said.

"Moreover, our strategic push into the United States in the second half of this year will mean our Elixia products are stocked on shelves in US department stores," Dr Ogru said.

Phosphagenics was up one cent or 8.3 percent to 13 cents.