



Biotech Daily

Thursday January 27, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: VIRALYTICS UP 9%; SUNSHINE HEART DOWN 14%**
- * **PHARMAXIS ON THE VERGE OF BRONCHITOL REVENUE**
- * **BIONICHE HOLDS IPO PRICE OF \$1.50**
- * **VIRALYTICS SAYS THREE MORE COXSACKIEVIRUSES SHOW EFFICACY**
- * **MÉTIER TRIBECA EXPANDS PHOSPHAGENICS' US COSMETIC RANGE**
- * **KARMELSONIX HAS ONE QUARTER CASH**
- * **BIOTRON HAS LESS THAN TWO QUARTERS CASH**
- * **TISSUE THERAPIES SCHULTZ TO 23% PRICE FALL QUERY; H1 LOSS UP**
- * **CBIO APPOINTS EMEA'S DR THOMAS LÖNNGREN DIRECTOR**

MARKET REPORT

The Australian stock market slipped 0.04 percent on Thursday January 27, 2011 with the S&P ASX 200 down 1.7 points to 4806.1 points.

Ten of the Biotech Daily Top 40 stocks were up, 18 fell, eight traded unchanged and four were untraded.

Viralytics was the best, was up 0.3 cents or 9.4 percent to 3.5 cents with 2.9 million shares traded, followed by Heartware up 6.1 percent to \$2.78 with 123,820 shares traded.

Starpharma climbed 3.5 percent; Biota and CSL rose more than two percent; with Chemgenex, Patrys, Phylogica and Psivida up more than one percent.

Sunshine Heart led the falls, down half a cent or 14.3 percent to three cents with 1.3 million shares traded, followed by Tissue Therapies down 8.1 percent to 56.5 cents with 1.4 million shares traded.

Living Cell lost 7.1 percent; Compumedics was down 6.25 percent; Benitec was down 5.1 percent; QRX fell 4.2 percent; LBT and Prana were down more than three percent; Cellestis, Genera and Pharmaxis shed more than two percent; with Alchemia and Nanosonics down more than one percent.

PHARMAXIS

Pharmaxis chief executive officer Dr Alan Robertson says that when it is finally approved Bronchitol will target a \$1.1 billion cystic fibrosis market.

Dr Robertson told a December 2010 quarterly report investor teleconference today that while delays had set back the approval of Bronchitol in Europe by up to six months, the process was nearing its end and approval would be "very soon" in Australia.

Dr Robertson said the company's approved Aridol dry powder test for asthma would be launched in the US this month.

Dr Robertson said that phase III trials showed that Bronchitol produced an average eight percent improvement in lung function for cystic fibrosis patients, whose main problem was a decline in lung function of one to two percent a year.

He said the only competitor product on the market was Roche's Pulmozyne and there were no other new products for cystic fibrosis.

Dr Robertson said there were about 40,000 cystic fibrosis patients in Europe implying a market of \$520 million a year and a further 30,000 patients in the US paying about \$22,000 a year each for Pulmozyne, implying a market of \$600 million.

Dr Robertson said that once formal Australian Therapeutic Goods Administration was granted Pharmaxis would begin distribution and would be listed under the Pharmaceutical Benefits Scheme for reimbursement.

He said that when Bronchitol was approved by the US Food and Drug Administration, Pharmaxis would receive US reimbursement under an existing code.

Dr Robertson said Pharmaxis would meet with the FDA this month to discuss the chemistry and manufacturing part of its new drug application for Bronchitol.

Dr Robertson said that confidentiality arrangements with the European Medicines Agency meant that he could not detail the "outstanding issues" in the application for Bronchitol for cystic fibrosis, announced this week (BD: Jan 25, 2011) but was confident that they would be addressed in time to have the drug approved by July 2011.

Dr Robertson said he expected to see sales of Bronchitol from one month after European Medicines Agency approval.

He said the company was actively recruiting patients for its phase II trial of ASM8 for difficult to treat asthma and work on PXS25 was demonstrating increased elasticity in lung fibrosis patients.

Dr Robertson said the company spent \$8.4 million on operating expenses in the three months to December 31, 2010 and had \$67 million in cash on that date.

Pharmaxis fell eight cents or 2.8 percent to \$2.78.

BIONICHE

Bioniche opened on the ASX at its initial public offer price of \$1.50 and traded between \$1.48 and \$1.52 on its first day.

Bioniche raised \$30 million in Australia and Canada at \$1.50 a share for its Australian ASX listing to develop its phase III bladder cancer drug Urocidin (BD: Jan 20, 2011).

Bioniche fell to \$1.48 but at the end of the trading day several trades took the closing price up to \$1.52.

A total of 82,034 shares were traded.

VIRALYTICS

Viralytics says three group A Coxsackieviruses A13 (CVA13), A15 (CVA15) and A18 (CVA18) show similar oncolytic activity to Cavatak (CVA21) against malignant melanoma. Viralytics said an article in the 'Virology Journal' co-authored by Viralytics chief scientific officer Prof Darren Shafren showed that each of the viruses grew quickly in human melanoma cells expressing ICAM-1 and the intra-tumoral injection of preformed subcutaneous melanoma tumors in mice with CVA13, CVA15 and CVA18 resulted in significant tumor volume reduction.

The company said that the in vitro and in vivo studies showed that the administration of CVA13, CVA15 or CVA18 together with Cavatak, could be employed as a potential multivalent oncolytic viral therapy against malignant melanoma.

An abstract of the article entitled 'Oncolysis of malignant human melanoma tumors by Coxsackieviruses A13, A15 and A18' is available at: www.virologyj.com/content/8/1/22.

Viralytics said that the use of CVA13, CVA15 or CVA18 in the oncolysis of ICAM-1 expressing cancers was covered by US and European patents granted to Viralytics.

The company said the studies were undertaken over a number of years by researchers in the School of Biomedical Sciences and Pharmacy at the University of Newcastle.

Viralytics said it was in discussion with the US Food and Drug Administration to conduct a phase II Cavatak for melanoma trial and was concluding phase I clinical evaluation in patients with late stage melanoma, breast, prostate and head and neck cancer.

Viralytics was up 0.3 cents or 9.4 percent to 3.5 cents with 2.9 million shares traded.

PHOSPHAGENICS

Phosphagenics says its New York partner, Métier Tribeca, will launch eight new cosmetic products in the US.

Phosphagenics said the agreement enabled Métier Tribeca to expand its existing color cosmetics treatment range from two to 10 products and would be marketed through department stores and available from dermatologists.

Phosphagenics chief executive officer Dr Esra Ogru told Biotech Daily that along with the existing moisturizers Métier Tribeca would market tinted and non-tinted moisturizers with the anti-aging peptide argireline, a day skin protector cream, a night anti-aging cream with argireline, a face-wash and a body wash.

In a media release Phosphagenics said the products would use its tocopheryl phosphate mixture transdermal technology and would be manufactured and sold by Métier Tribeca.

Phosphagenics said Métier Tribeca had been marketing the cosmetics range under its brand Le Métier de Beauté for the past 12 months.

In a media release to the ASX Dr Ogru said the partnership was "proof of efficacy and the commercial case for topical TPM products".

Phosphagenics said its tocopheryl phosphate mixture reduced irritation by encapsulating the active ingredients and delivered them more effectively than most other formulations.

Phosphagenics was unchanged at 13 cents.

KARMELSONIX

Karmelsonix says its net operating cash burn for the three months to December 31, 2010 was \$1,418,000 with cash at the end of the quarter of \$1,680,000.

Karmelsonix did not disclose whether it had any other funding sources and no one was available from the company at the time of publication.

Karmelsonix fell 0.1 cents or five percent to 1.9 cents with 1.2 million shares traded.

BIOTRON

Biotron says its net operating cash burn for the three months to December 31, 2010 was \$553,000 with cash at the end of the quarter of \$889,000.

Biotron did not disclose whether it had any other funding sources and no one was available from the company at the time of publication.

Biotron fell half a cent or four percent to 12 cents.

TISSUE THERAPIES

Tissue Therapies has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price rose from 69 cents on January 21, 2011 to 53 cents, a 23.2 percent fall today, January 27, 2011 and noted an increase in trading volume.

Tissue Therapies said it was in the process of preparing its preliminary half year results and subject to auditor review and board approval of the accounting recognition, at this stage, the loss for the half year ended December 31, 2010 was expected to be \$3,321,000, compared to a loss of \$1,562,000 for the half year ended December 31, 2009.

The company said the variation was caused by the expense of manufactured inventory used in clinical trials.

Tissue Therapies fell five cents or 8.1 percent to 56.5 cents with 1.4 million shares traded.

CBIO

CBio has appointed former European Medicines Agency executive director Dr Thomas Lönngren as a non-executive director.

CBio said Dr Lönngren was the executive in charge of this EMEA and has also joined the scientific advisory board of pharmaceutical company H Lundbeck AS and will advise Novo Nordisk.

CBio director Dr Goran Ando is Novo Nordisk's vice-chairman.

CBio said Dr Lönngren was a senior advisor to the US-based healthcare fund Essex Woodlands and European Union regulatory consultancy group NDA.

CBio chairman Stephen Jones said the appointment of Dr Lönngren was "a coup for CBio as Dr Lönngren's knowledge of drug development and regulatory affairs is both contemporary and unmatched elsewhere".

CBio said Dr Lönngren qualified as a pharmacist from Sweden's University of Uppsala in 1976 and held a Masters of Science in social and regulatory pharmacy and from 1976 to 1978 he lectured at the University of Uppsala and in 1990 was appointed operations director of the Swedish Medical Products Agency, later becoming deputy director-general. CBio was up eight cents or 27.6 percent to 37 cents.