# Biotech Daily

Friday July 10, 2009

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: PEPLIN UP 11%, NOVOGEN DOWN 13%**

*** PRANA POST-HOC ANALYSIS BACKS PHASE II ALZHEIMER'S TRIAL DATA**

*** DREAM PHARMA DISTRIBUTES ACRUX'S ELLAVIE IN SOUTH KOREA**

*** FDA REVIEWS NANOSONICS DISINFECTOR; APPROVED IN ISRAEL**

*** CATHRX PLACEMENT, RIGHTS ISSUE RAISE $6.9m**

*** TISSUE THERAPIES, QUT WIN $713k 'SMART STATE' GRANT**

*** IMPEDIMED ADDS TWO MORE UK NHS HOSPITAL CUSTOMERS**

*** NEUREN SHARE PLAN TO RAISE UP TO $2.3m**

*** EVADO LAUNCHES CLINCIAL TRIAL SOFTWARE IN ASIA**

*** CORRECTION: TYRIAN DIAGNOSTICS**

## MARKET REPORT

The Australian stock market recovered 0.82 percent on Friday July 10, 2009 with the S&P ASX 200 up 30.8 points to 3,794.1 points.

Twelve of the Biotech Daily Top 40 stocks were up, six fell, seven traded unchanged and 15 were untraded.

Peplin was best, up six cents or 11.1 percent to 60 cents with 667,640 shares traded, followed by Nanosonics up 10.7 percent to 46.5 cents.

Biota climbed 5.8 percent to $1.375; Avexa and Phosphagenics were up more than four percent; Viralytics was up 3.0 percent; Optiscan and Sirtex rose more than two percent; Chemgenex, Pharmaxis and Resmed were up more than one percent; with Circadian, CSL and Heartware up by less than one percent.

Novogen led the falls, retreating 11 cents or 13.3 percent from yesterday's 33 percent rise to 71.5 cents with 93,485 shares traded, followed by Cathrx down 11.1 percent to 40 cents. Polartechnics lost 5.6 percent; Alchemia, Cellestis and Cochlear shed more than one percent; with Acrux down 0.87 percent.

PRANA BIOTECHNOLOGY

Prana says a post-hoc analysis of its phase IIa clinical trial data of PBT2 for Alzheimer's disease supports evidence published last year in The Lancet (BD Jul 30, 2008).

The senior author of The Lancet Neurology paper and Prana's chief European clinical advisor, Imperial College London's Dr Craig Ritchie, will present an update on the efficacy of PBT2 at the Vienna International Conference on Alzheimer's disease on July 12, 2009.

Dr Ritchie's paper entitled 'PBT2 for Alzheimer's Disease: An Update on Clinical Development' will present the earlier findings as well as the post-hoc analysis.

Prana said the Lancet paper documented that patients on PBT2 showed significant improvement in two measures of executive function after 12 weeks of treatment.

Prana's chief executive officer Geoffrey Kempler said that a follow-up to the Lancet paper showed a statistically significant improvement in the overall executive function z-score component of the neuropsychological test battery in patients receiving 250mg PBT2 compared with placebo.

Prana said the post-hoc analysis of the responses of individual patients in the trial, showed that 41 percent of the 27 patients receiving PBT2 demonstrated substantial cognitive improvement compared to only four percent of the 28 patients on placebo.

Dr Ritchie said patients on PBT2 "very clearly benefited from the drug and their overall cognitive function, especially executive function, improved".

"The results would be reflected in an improvement in day to day functioning in the lives of people with Alzheimer's disease and confirms the importance for PBT2 to be further developed as a therapy for patients afflicted with the disease," Dr Ritchie said.

The Lancet Neurology article is entitled 'Safety, efficacy, and biomarker findings of PBT2 in targeting A-beta as a modifying therapy for Alzheimer's disease' and is available at: http://www.thelancet.com/journals/laneur/article/PIIS1474-4422(08)70167-4/abstract.

The article said 74 early stage Alzheimer's disease patients participated in the trial, with 19 patients taking PBT2 50mg once daily for 12 weeks, 27 patients on PBT2 250mg and 28 assigned to placebo.

Prana said last year that the safety and tolerability profile of PBT2 was similar to placebo and there were no study withdrawals related to adverse events, nor any serious adverse events in PBT2-treated patients.

In the 250mg dose PBT2 produced a significant reduction in amyloid beta 42 of 13 percent in the spinal fluid, compared to placebo (p=0.006) and the effect of PBT2 was dose related (p=0.023).

In the cognitive tests, patients on the 250mg dose performed significantly better than placebo in two tests of executive function.

In the 'Trail Making Part B' test, patients completed the task in an average of 42 seconds faster than at the beginning of the trial, while the placebo group was an average six seconds slower.

The difference between PBT2 250mg and placebo was statistically significant (p=0.009) and the effect of PBT2 was dose-related (p=0.031).

In the 'Category Fluency test', patients improved their word generation response in 60 seconds by an average of 2.4 more words than at the beginning of the trial compared with a decrease of 0.3 words in the placebo group.

Mr Kempler said planning was underway for a phase IIb clinical trial of PBT2.

"Comprehensive analysis of our existing data suggests that in this trial, the longer treatment period using a much larger number of patients will confirm PBT2's ability to provide even greater cognitive benefit," Mr Kempler said.

Prana was unchanged at 16 cents.

ACRUX

Acrux says Dream Pharma Corp will market and distribute its transdermal estradiol spray Ellavie for menopause symptoms in South Korea.

Acrux said Dream Pharma was a wholly-owned subsidiary of the South Korean diversified conglomerate Hanwha Group.

Acrux said it would receive fees on signing, on confirmation of marketing authorization and on market launch and an ongoing distribution fee based on net sales of Ellavie.

Acrux said Dream Pharma was responsible for marketing authorization in South Korea, using the product dossier previously approved by the US Food and Drug Administration.

Ellavie is marketed in the US as Evamist and is under evaluation by regulatory authorities in Australia and Sweden.

Acrux chief executive officer Dr Richard Treagus said Dream Pharma was "a successful and rapidly growing pharmaceutical company … with the strong backing of its parent company".

"We are very pleased to be partnering Ellavie in our first Asian market, building on the recently announced deals in Southern Africa and Switzerland," Dr Treagus said.

Acrux fell one cent or 0.87 percent to $1.14.

NANOSONICS

Nanosonics says the US Food and Drug Administration has completed its initial review of the company's section 510(k) device equivalence submission for the Trophon EPR.

Nanosonics Trophon EPR is the company's lead product and is designed for the disinfection of ultrasound transducers

Nanosonics said it would respond to the FDA's initial review within the statutory 30-day period and was "on-track for the appointment of US distributors prior to the end of 2009".

Nanosonics said these partners continued to confirm significant market demand for a fully automated infection control system such as the Trophon EPR.

The company said it received Israeli regulatory approval on July 7, 2009.

Nanosonics said the distributor in Israel was Luxembourg Pharmaceuticals "a leading importer and distributor of high quality life sciences products" and would introduce the Trophon EPR in the near term.

Nanosonics was up 4.5 cents or 10.7 percent to 46.5 cents.

CATHRX

Cathrx says its renounceable one-for-two entitlement offer raised $5.3 million with a placement raising a further $1.6 million.

Cathrx said both the placement and the entitlement offer were fully underwritten by Wilson HTM Corporate Finance.

The company said the entitlement offer received applications for 19,343,227 shares at 25 cents each raising $4,853,014.75.

Cathrx said the shortfall of 1,958,507 new shares worth $489,626.75 was placed with Wilson HTM.

The company said a total of 27,565,753 shares had been issued through the entitlement offer and placement, increasing the total number of shares on issue to 70,169,220.

Cathrx chief executive officer Neil Anderson said the proceeds would advance the company's sales and marketing efforts, fund ongoing development and commercialization activities including clinical studies and for general corporate purposes.

Cathrx fell five cents or 11.1 percent to 40 cents.

## TISSUE THERAPIES

Tissue Therapies and the Queensland University of Technology have won a Queensland grant to develop wound healing products using the single protein formulation of Vitrogro.
The $712,903 Smart State Grant over three years augments a $249,945 investment from QUT and $462,961 from Tissue Therapies for the commercialization program.
Tissue Therapies chief executive officer Dr Steven Mercer said his company was “very grateful for this superb example of practical support from the Queensland Government”.
“This grant effectively reduces the costs and accelerates the development of a suite of new Vitrogro single protein molecules for commercial wound care products,” Dr Mercer said.
“This is the culmination of the scientific development of single protein formulations of Vitrogro that mimic the wound healing biology of the original multi-protein complex,” Dr Mercer said.
“The single protein formulation substantially reduces the cost of manufacture and speed and ease of regulatory approval,” he said.
Tissue Therapies was unchanged at 16.5 cents.

## IMPEDIMED

Impedimed says two more British National Health Service institutions have adopted its LDex U400 lymphoedema monitoring system.
Impedimed said University College London Hospital and Blackburn with Darwen Primary Care Trust had adopted the system for detect lymphoedema in breast cancer patients.
A consultant nurse at University College’s cancer and supportive care team Kay Eaton said the L-Dex device was used to monitor lymphoedema and the effects of treatment.
Ms Eaton said it “would be useful in a few cases to rule out any lymphoedema present in breast cancer survivors whose status is unclear”.
Impedimed said a 2008 publication by Dr Sandi Hayes et al from Queensland University of Technology concluded that lymphoedema occurred in about one third of breast cancer patients post-treatment, of which 40 percent to 60 percent was missed in its early stages by manual assessment methods.
Impedimed chief executive officer Greg Brown said that having prestigious institutions as UCLH and BWD PCT adopt L-Dex for monitoring treatment efficacy in lymphoedema patients was “very important for the acceptance of L-Dex”.
Impedimed was untraded at 65 cents.

## NEUREN

Neuren is offering eligible shareholders up to $10,000 worth of shares at three cents a share to raise up to $2,317,177.17.
Neuren said that up to 77,239,293 shares would be issued under the plan and each director intended to take up their full entitlement.
Neuren said the share plan offer was being made “to give shareholders the opportunity to subscribe for shares at a discounted share price of three cents per share without having to incur brokerage fees and to raise additional funds for the company to meet working capital requirements”.
The company said shareholders at the record date of July 16, 2009 would be eligible to participate in the plan.
The offer closes on July 14, 2009.
Neuren fell 0.4 cents or 11.1 percent to 3.2 cents with 3.2 million shares traded.

## EVADO

Evado has launched its clinical trial software at the annual National Conference for Clinical Research in Penang Malaysia,

The private Melbourne-based company said the conference was “the biggest annual clinical research meeting of its kind in the Asian region”.

Evado said medical researchers would benefit from the web-based computing software which it said helped speed the collection of data for clinical trials.

The company said the software eliminated paper for data collection and was developed with assistance from Intel and Microsoft.

Evado chief executive officer Jennie Anderson said Asian-based clinical research organizations and hospitals were faster to adopt new electronic based clinical report forms than their Australian and New Zealand counterparts.

“They understand technology can save significant amounts of time and money in accurate data collection and this helps them to get their products approved and in the market faster,” Ms Anderson said.

“The new functionality was developed to meet the needs of our Asian customers,” Ms Anderson said.

Evado said its software was enabled for Intel multi-core processors, meaning it would “run faster than ever” and Version 2 was designed to support the international clinical data interchange standards consortium.

Evado said it would give a small donation to Dr Christina Ng’s Empowered Foundation which provided advocacy services for poor Malaysian cancer patients, for every delegate who left their business card at the Evado stand.

“We thought supporting a local NGO made more sense than spending money on plastic give-aways,” Ms Anderson said.

Evado is a form based technology that can be run as a web application on either a PC or a tablet computer and can store the data from 1 to 20,000 trials.

Evado said its software gave clinicians in multiple locations the ability to simultaneously view real-time clinical records any place and anytime during the study or trial and clinical researchers, reviewers and investigators can collaborate online.

## CORRECTION: TYRIAN DIAGNOSTICS

In last night’s Market Report, Tyrian was reported leading the falls down half a cent or 16.7 percent to 2.3 cents with 300,000 shares traded.

In fact the company was down half a cent or 16.7 percent to 2.5 cents with 330,000 shares traded.

Curiously, Commsec Iress reported 330,000 shares traded while the ASX website said 300,000 shares were traded.

The mistake was made by the former sub-editor and the human resources manager hiring all these lackluster sub-editors will be replaced forthwith.

Tyrian was untraded at 2.5 cents.