# Biotech Daily

Monday August 5, 2013

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH EVEN: COMPUMEDICS UP 8%, ANTISENSE DOWN 13%**

*** NEUREN RESPONDS TO PHASE II RETT TRIAL PETITION**

*** EX-CEO DR ESRA OGRU PAYS PHOSPHAGENICS $570k 'RESTITUTION'**

*** EUROPE BEGINS TISSUE THERAPIES REVIEW IN SEPTEMBER**

*** ALLAN GRAY REDUCES TO 5% OF ACRUX**

*** ANNMAC INCREASES, DILUTED TO 10% IN AGENIX**

*** PHARMAUST EGM BACKS PELOTON PITNEY BACKDOOR LISTING**

*** VIRALYTICS TRADES ON US OTC MARKET**

*** OBJ PLEADS SCHULTZ TO ASX 54% QUERY**

## MARKET REPORT

The Australian stock market slipped 0.11 percent on Monday August 5, 2013 with the S&P ASX 200 down 5.5 points to 5,111.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and three were untraded.

Compumedics was the best, up 0.6 cents or eight percent to 8.1 cents with 35,000 shares traded.

Allied Health and Benitec climbed more than seven percent; Bionomics and Medical Developments were up more than six percent; Neuren and Phylogica were up five percent or more; Tissue Therapies rose 4.1 percent; Cellmid, Mesoblast and Osprey were up more than three percent; Nanosonics and QRX rose more than two percent; Starpharma was up one percent; with Cochlear up 0.9 percent.

Antisense led the falls, down 0.2 cents or 13.3 percent to 1.3 cents with 27.5 million shares traded.

Patrys lost 9.8 percent; Prana fell 7.3 percent; Circadian and GI Dynamics were down more than six percent; Living Cell and Prima shed five percent or more; Alchemia and Phosphagenics fell more than four percent; Atcor and Heartware were down more than three percent; Clinuvel and Optiscan shed more than two percent; Acrux was down 1.2 percent; with CSL, Resmed and Sirtex down by less than one percent.

## NEUREN PHARMACEUTICALS

Neuren says that an online petition to the US Food and Drug Administration to un-blind its phase II trial of NNZ-2566 for Rett syndrome has not compromised the trial.

Earlier today, Neuren requested a trading halt “pending an announcement to address media speculation in relation to the current phase II trial of NNZ-2566 in Rett Syndrome”.

A petition to the FDA to un-blind the trial was lodged with on-line advocacy group Change.org last week and collected more than 1,200 signatories in five days, including comments from family members of patients in the trial.

The petition – directed to the US Food and Drug Administration - was initiated by Andrea Parris who said her daughter Chelsea was 27 years old, had Rett syndrome and benefited from the trial, while not knowing whether she was on NNZ-2566 or placebo.

“I am requesting that this medication trial be opened very quickly,” Ms Parris wrote.

The petition is at: http://www.change.org/petitions/food-and-drug-administration-study-medication-nnz-2566-used-in-rett-syndrome.

Neuren executive chairman Dr Richard Treagus said that people commenting on the trial did not know whether their family members were on NNZ-2566 or placebo.

“This is a new phenomenon where social media intersects with clinical trail obligations,” Dr Treagus said.

“We need to get subjectivity and the placebo effect out of it,” Dr Treagus said

Signatories also called on the FDA to ‘fast track’ the drug.

In June, Neuren said the FDA had granted Fast Track designation for the NNZ-2566 program for Rett syndrome which began dosing in April (BD: Apr 23, Jun 5, 2013).

The company said at that time that it hoped to enroll up to 60 adult and adolescent patients to meet a target of 48 patients who complete all doses and assessments, with the trial to be completed by July 2014 and results by the end of 2014.

The company said that Rett syndrome was caused by mutations on the X chromosome of a gene called MeCP2, across all racial and ethnic groups and occurred in up to one of in 10,000 female births and affected about 20,000 girls and women in the US, alone.

Today, Neuren said that parents of subjects participating in the trial “have suggested that certain of the symptoms that their daughters experience have improved during participation in the trial”.

“The company would like to assure the market that these comments reflect subjective impressions that have not been validated by analysis of clinical data,” Neuren said.

“In particular, we would like to reiterate that, as the study is a randomized, double-blind trial, neither Neuren, the clinical investigators nor the parents can be or are aware of the treatment assignment, NNZ-2566 or placebo, for any subject,” the company said.

Neuren said that “to the best of our knowledge, the blinded nature of the trial has not been compromised” and the clinical benefit, if any, of NNZ-2566 compared to placebo would not be known until treatment assignment was un-blinded and the trial data was analyzed.

Neuren said it would announce the results of the analysis when it had been completed and reviewed by the appropriate parties, by the end of 2014.

Dr Treagus said that the trial’s data safety monitoring committee had schedule reviews and was expected to review the data every three to four months, primarily for safety, but could also look at efficacy data.

Dr Treagus said that the committee could see the un-blinded data and could recommend changes to the sponsor, including protocol changes.

Last year, the FDA introduced a new pathway called ‘Breakthrough Designation’ that, if satisfied with early clinical data, could expedite approval for the drug (BD: May 31, 2013).

Neuren was up half a cent or 5.3 percent to 10 cents with 5.2 million shares traded.

## PHOSPHAGENICS

Phosphagenics says former chief executive officer Dr Esra Ogru has sold her shares and the company will receive about $570,000 as the first restitution of misappropriated funds.
Last month, Dr Orgu was first suspended in her role as chief executive officer pending an investigation into “irregular transactions in relation to its invoicing and accounting records”, she later resigned as a director and when Deloitte Forensic quantified the amount at $5.7 million was sacked as chief executive officer (BD: Jul 1, 22, 24, 2013).
In her Appendix 3Z Final Director’s Interest Notice, Dr Ogru said she held 5,711,610 shares, 2,000,000 conditional rights and her husband Vedat Isikgel held 215,000 shares.
Today, Phosphagenics said that the shares had been sold on the market under an irrevocable direction from Dr Ogru.
The company said that the sale of about $570,000 would be received on settlement “as the first restitution of identified misappropriated funds”.
Phosphagenics said it had “taken steps to secure other assets of persons referred to in its announcement of July 24, 2013 and remains confident of recovering a substantial proportion of the misappropriated funds”.
Phosphagenics fell half a cent or 4.55 percent to 10.5 cents.

## TISSUE THERAPIES

Tissue Therapies says the European Medicines Agency has confirmed that the review of its Vitrogro wound treatment manufacturing quality data will start on September 6, 2013.
Last week, Tissue Therapies said it expected European approval and sales for Vitrogro within six months and had the funds to reach beyond first sales (BD: Jul 29, 2013).
Tissue Therapies has faced a number of delays with European bodies changing Vitrogro’s classification and referring it to separate regulatory bodies (BD: Mar 18, 2013).
Today the company said the review was “the last step” in the process of granting Conformité Européenne (CE) mark, allowing the start of sales of throughout the European Union for difficult to heal wounds.
Tissue Therapies said that no onsite inspections were involved and the maximum time allowed for the EMA to complete the review was 210 days and reviews were usually completed in less than the maximum time.
The company said that if the full 210 days were used for the review Vitrogro sales should begin by July 2014 and it would continue to work with opinion leaders, as well as optimizing health economic and reimbursement data to maximize the sales launch.
Tissue Therapies rose one cent or 4.1 percent to 25.5 cents with 1.7 million shares traded.

## ACRUX

Allan Gray Australia (formerly Orbis Investment Management) has reduced its substantial holding in Acrux from 10,260,256 (6.16%) to 8,596,312 shares (5.15%).
Allan Gray said that between April 19 and July 31, 2013 the company bought and sold four parcels of sales totaling 1,913,523 shares for $6,939,939 or an average price of $3.627 a share.
In April, Allan Gray increased its holding in Acrux from 8,566,799 shares (5.14%) to 10,260,256 (6.16%) at an average price of $3.755 a share (BD: Apr 23, 2013).
In March, Allan Gray returned to its substantial holding in Acrux following a February reduction below five percent selling shares at prices around $3.86, having acquired shares in December 2012 at about $2.70 each (BD: Dec 19, 2012; Feb 14, Mar 20, 2013).
Acrux fell four cents or 1.2 percent to $3.37 with 300,750 shares traded.

## AGENIX

Annmac Investments as trustee for the Anne McNamara Investment Trust increased its share-holding in Agenix but has been diluted through a share issue at 2.3 cents a share.
In the change of substantial shareholder notice, Annmac said it increased and was diluted from 9,540,785 shares (10.86%) to 11,279,775 shares (9.82%).
Annmac said that it acquired 1,739,130 shares for $40,000 or 2.3 cents following approval by shareholders (BD: May 17, 2013).
Agenix was unchanged at 2.5 cents.

## PHARMAUST

All resolutions relating to Pharmaust's acquisition of Pitney Pharmaceuticals for its cancer platform technologies have been passed with no dissent (BD: Apr 30, Jul 5, Aug 1, 2013).
Pharmaust was up 0.1 cents or 9.1 percent to 1.2 cents.

## VIRALYTICS

Viralytics says that its American depository receipts (ADRs) have begun trading on the US Over The Counter Quality Exchange (OTCQX) under the code VRACY.
Viralytics said that each ADR was equivalent to three Australian shares.
Viralytics chief executive officer Dr Malcolm McColl said that trading on the OTCQX was "part of a broader strategy to promote the company and our technology in the United States".
"Whilst joining OTCQX is a logical next step in the growth of Viralytics, we remain committed to our ASX listing and Australian investors who continue to support the company," Dr McColl said.
Viralytics was unchanged at 30 cents.

## OBJ

OBJ 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 53.8 percent from 1.3 cents on July 30 to 2.0 cents on August 2, 2013, and noted an increase in trading volume.
OBJ fell 0.1 cents or 5.9 percent to 1.6 cents with 17.8 million shares traded.