# Biotech Daily

Friday March 9, 2012

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: LIVING CELL UP 9.5%, PHYLOGICA DOWN 6%**

*** PETER MAC, CIRCADIAN TEST FINDS 15 'UNKNOWN PRIMARY' CANCERS**

*** CSL ALBUMIN CONTAMINATION: NO REPORTED ADVERSE EVENTS**

*** RAMACIOTTI FOUNDATIONS $1.5m FOR BIOMEDICAL RESEARCH**

*** CSL'S PETER TURVEY JOINS STARPHARMA, TOO**

*** AVITA TO TRADE ON US OTCXQ, CODE CHANGE**

*** VIRAX, SOLAGRAN SUSPENDED FOR ABSENT ACCOUNTS**

## MARKET REPORT

The Australian stock market climbed 0.98 percent on Friday March 9, 2012 with the S&P ASX 200 up 41.0 points to 4212.0 points.

Eighteen of the Biotech Daily Top 40 stocks were up, six fell, 11 traded unchanged and five were untraded. All three Big Caps were up.

Living Cell was the best, up one cent or 9.5 percent to 11.5 cents with 1.6 million shares traded; followed by Allied Health up 9.1 percent to 3.6 cents with 149,142 shares traded.

Genetic Technologies climbed 8.25 percent; Viralytics was up 6.7 percent; Benitec and Ellex were up five percent or more; Compumedics Impedimed, Pharmaxis and Starpharma were up more than four percent; Biota, Mesoblast and Prana were up more than three percent; Prima and Reva rose more than two percent; Cochlear, CSL, QRX and Sirtex were up more than one percent; with Circadian and Resmed up by less than one percent.

Phylogica led the falls, down 0.3 cents or 5.7 percent to five cents, with two million shares traded, followed by Patrys down 5.4 percent to 3.5 cents with 225,000 shares traded.

Antisense lost 4.55 percent; Bionomics and Clinuvel fell than one percent; with Universal Biosensors down by 0.7 percent.

CIRCADIAN TECHNOLOGIES

Circadian says its cancer diagnostic is capable of detecting the primary source of cancers with high level of accuracy and specificity across 15 different tumor types.

Circadian said it expected to launch the test by the end of April 2012.

Circadian said Healthscope Advanced Pathology scientific director Dr Keith Byron presented data on the diagnostic technology at the 'Science and the City' meeting of the Royal College of Pathologists of Australia in Sydney.

The company said the poster presentation entitled 'Development of a Gene Expression Based Assay to Determine the Origin of Metastatic Carcinomas of Unknown Primary' showed that the test was able to detect the primary source of the tumor type with 93 percent accuracy within the first three predictions and had 98.5 percent specificity across 15 different tumor types.

Circadian said the diagnostic method was developed in collaboration with Healthscope, the Peter MacCallum Cancer Centre and scientists at the National Information and Communications Technology Australia (NICTA) research centre.

The company said that Healthscope, through subsidiary Clinical Laboratories, had rights to develop, clinically validate and market the test throughout Australia, New Zealand, Malaysia and Singapore, while Circadian retained rights to market the test in the remainder of the world.

Circadian said that Healthscope had paid an undisclosed upfront fee and would pay a royalty on sales of the test.

Circadian said that, through its wholly-owned subsidiary Cancer Therapeutics, it owned exclusive worldwide rights to the test through a licensing arrangement with the Peter MacCallum Cancer Centre and NICTA.

The company said the diagnostic methodology identified a patient's tumor type by comparing its pattern of gene expression to a database of known tumors.

Circadian said that by correctly identifying a patient's tumor type, it was hoped clinicians could choose the most effective treatment strategy for the cancer.

The company said that cancers of unknown primary origin were less well known than other cancers, but more common than leukaemia and combined was the fifth most common cause of death due to cancer in Australia.

Circadian said that there were about 2,900 cases of cancers of unknown primary a year in Australia with US incidence about 32,000 cases a year, with 14,000 a year in the UK.

Dr Byron said it was "very pleasing to be able to share, for the first time, the data we have generated over the past three years of development".

"Healthscope is excited that after the extensive development program we have undertaken with our partners that we are now on the cusp of commercializing this ground breaking diagnostic technology," Dr Byron said.

Peter MacCallum Cancer Centre's head of the cancer genomics program, Prof David Bowtell, a co-inventor of the diagnostic methodology, said the data "we have published today is extremely exciting".

"It is very gratifying that this product of our translational research efforts will be made available to clinicians throughout the region," Prof Bowtell said.

"The concept of personalizing treatments for patients based on highly specialized diagnostics is now very well accepted in oncology and has been shown to have significant patient benefit," Prof Bowtell said.

"We believe that the assay will lead to earlier diagnosis, improved treatment outcomes and enhanced quality of life for patients," Prof Bowtell said.

Circadian was up half a cent or 0.9 percent to 54 cents.

CSL

The Australian Therapeutic Goods Administration has quarantined CSL Biotherapies human albumin solutions (4% and 20%) while a safety assessment is undertaken.

The TGA said that CSL notified it on March 7, 2012 that some batches of human albumin solutions manufactured prior to January 25, 2012 had been contaminated with the temperature control agent, ethylene glycol, as a consequence of an equipment failure.

The TGA said CSL was conducting further testing to quantify the levels of contamination and the extent of the batches affected but, as a precaution, the regulator had "put arrangements in place to quarantine stocks held by hospitals, the Australian Red Cross Blood Service and CSL from further use or issue until safety implications have been fully assessed".

The TGA spokeswoman told Biotech Daily that all relevant batches of albumin would have been discarded and any toxicity symptoms would appear within 24 to 72 hours and once that period passed the TGA did not expect any further complications.

Last year the US Food and Drug Administration issued CSL a 'Warning Letter' relating to its production of biological vaccine Afluria and monovalent influenza bulks and the company was previously the subject of an FDA 'Untitled Letter' (BD: Jun 22, 2011).

The letters related to an inspection between April, 2010 in which investigators "documented deviations from current good manufacturing practice (CGMP) requirements in the manufacture of licensed biological vaccine products and monovalent influenza bulks" including Afluria and Influenza A (H1N1) Monovalent vaccine and cited US regulations from which it alleged CSL had deviated (BD: June 30, 2010).

The FDA said it had issued a Form FDA 483, "which described a number of significant objectionable conditions relating to your facility's compliance with CGMP".

A CSL spokeswoman told Biotech Daily at that time that the FDA warning related to "the way we document and manage processes and investigations" and not the physical establishment in Parkville.

Today, the TGA spokeswoman said that "TGA audits confirm the FDA that there were no safety issues, but there were a whole range [of items] not reaching targets".

CSL said in a statement posted on its website, but not published on the ASX, that it had notified the TGA of the contamination issue on March 7, 2012 and that further testing was underway to determine the number of batches affected and the levels of ethylene glycol that they may contain.

"The current available evidence indicates that patient safety has not been compromised by this issue," CSL said.

"Based on available toxicity data and projections of the highest possible amounts of albumin that could be administered to a patient, adverse events arising from the use of this product are unlikely to occur," CSL said.

"In addition, CSL Biotherapies has reviewed all adverse event reports associated with albumin in its safety database from January 1, 2008 to present and has found no changes in the safety profile of the product over this period," the company said.

CSL said that albumin was an intravenous fluid derived from human blood, primarily used as a treatment in surgical, burns and trauma patients.

CSL Biotherapies said that a hairline fracture in a tank used in the manufacture of albumin resulted in leakage of ethylene glycol into the tank during processing.

The company said that use of the tank was immediately ceased and the fracture repaired.

Production recommenced and testing confirmed that albumin products manufactured following the repairs contained no detectable levels of ethylene glycol.

CSL said it had increased manufacturing to ensure ongoing supply of albumin.

CSL climbed 60 cents or 1.85 percent to $33.00 with 3.1 million shares traded.

## RAMACIOTTI FOUNDATIONS

Charitable foundation manager, Perpetual, says that applications for the more than $1.5 million Ramaciotti Awards for biomedical research have opened.

Perpetual manages the Ramaciotti Foundations and said the awards would be made to Australian biomedical researchers in October 2012, through the Ramaciotti establishment and equipment grants and medal of excellence.

Perpetual said the establishment and equipment grants of up to $75,000 were open to groups or individuals in universities, public hospitals or institutes undertaking biomedical research.

Perpetual said that establishment grants provided financial support for emerging researchers, while equipment grants go towards the purchase of a major piece of equipment.

Perpetual's philanthropy general manager Andrew Thomas said the Ramaciotti Foundations had granted more than $51 million to biomedical research since Vera Ramaciotti established the Foundations with a $6.7 million investment in 1970.

Perpetual said the $50,000 Ramaciotti medal for excellence recognized "an outstanding contribution to clinical or biomedical research, or the way in which healthcare is delivered".

Applications close on May 31, 2012.

More information is at: http://www.perpetual.com.au/ramaciotti.

Last year, the Ramaciotti Foundations will distribute $2.6 million to biomedical research projects in Australia including $1 million for a cryo-electron microscopy research centre, (BD: Oct 19, 2011).

Perpetual said at that time that the $1 million Ramaciotti Biomedical Research Award was granted every two years and announced the distribution of 22 establishment and equipment grants of up to $75,000.

## STARPHARMA

Starpharma has appointed Peter Turvey as a director effective from March 19, 2012.

Earlier this week, Mr Turvey was appointed as one of two new principals of the Foursight Associates advisory service in science, technology and innovation, which is also the co-chief scientists for the Government of Victoria (BD: Mar 7, 2012).

Starpharma said that Mr Turvey recently retired from CSL, where he held the positions of general counsel, company secretary and executive vice-president, licensing for the research and development division over two decades.

Starpharma said that Mr Turvey was involved in CSL's transformation from a government-owned enterprise to a global plasma and biopharmaceutical company.

Starpharma was up six cents or 4.15 percent to $1.505.

## AVITA MEDICAL

Avita says it expects to begin trading its American depositary receipts (ADRs) on the Over-The-Counter Quality Exchange (OTRCQX) on or about March 12, 2012.

Avita currently trades under the code AVMXF and the ADRs will be traded under the symbol AVMXY, with each ADR equal to 20 Australia shares.

Avita said it had appointed Roth Capital Partners as its principal American liaison and the Bank of New York Mellon as the depositary bank for its ADR program.

Avita was unchanged at 20 cents.

## VIRAX HOLDINGS, SOLAGRAN

Virax and Solagran were suspended from trading on the ASX on March 1, 2012, following their failure to lodge half-year statutory accounts to December 31, 2012.

The ASX named 10 companies of which Solagran and Virax were the only biotechnology companies listed as failing to provide the accounts.

Virax last traded at 0.9 cents.

Solagran last traded at 3.9 cents.