Biotech Daily

Wednesday June 27, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PSIVIDA UP 15%, QRX DOWN 59%**

*** QRX FALLS 71% AS FDA REJECTS QRX MOXDUO - MORE DATA WANTED**

*** BURNET LICENCES CD4, SYPHILIS TESTS TO SCOTLAND'S OMEGA**

*** HEALTHSCOPE, CIRCADIAN CANCERS OF UNKNOWN PRIMARY TEST**

*** KOREAN STUDY BACKS HEALTHLINX OVPLEX OVER CA125 ALONE**

*** RAFF GROUP TAKES 5% OF GENERA**

MARKET REPORT

The Australian stock market climbed 0.75 percent on Wednesday June 27, 2012 with the S&P ASX 200 up 29.9 points to 4,043.2 points.

Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and two were untraded. All three Big Caps were up.

Psivida was the best, up 27 cents or 15.2 percent to $2.05 with 6,750 shares traded, followed by Sunshine Heart up 10 percent to 2.2 cents with 1.3 million shares traded.

Anteo and Starpharma climbed more than four percent; Mesoblast was up 3.1 percent; Circadian and Pharmaxis rose more than two percent; Acrux, Cochlear, Heartware and Prima were up more than one percent; with CSL, Sirtex and Resmed up by less than one percent.

QRX led the falls, down as much as $1.20 or 70.6 percent before closing down $1.00 or 58.8 percent at 70 cents with 6.4 million shares traded. Genera fell 18.4 percent to 15.5 cents with 18,750 shares traded, followed by Ellex down 13.3 percent to 13 cents with 9,500 shares traded and Impedimed down 12 percent to 22 cents with 320,476 shares traded.

Neuren lost 8.3 percent; Genetic Technologies was down 7.7 percent; Allied Health was down 5.6 percent; Compumedics fell 4.35 percent; Alchemia and Prana were down more than three percent; Nanosonics and Phylogica shed more than two percent; Bionomics, Biota, Living Cell and Viralytics were down more than one percent; with Clinuvel down 0.6 percent.

QRX PHARMA

QRX fell as much as 70.6 percent on the FDA complete response letter rejecting its application for dual opioid pain relief drug Moxduo IR and requiring further data.

QRX chief executive officer Dr John Holaday told an investor and media teleconference this morning that the company was “completely surprised” by the rejection of Moxduo immediate relief (IR) but would be proceeding with the approval process and had fixed a meeting in August 2012 with the FDA to discuss the way forward.

Dr Holaday said the FDA letter referred to the areas to be addressed for approval as “the combination rule [that the drug be] safer or more effective”.

He said the FDA did not refer to other issues such as manufacturing, tampering or packaging.

“The decision was unexpected and disappointing to all concerned,” Dr Holaday said.

Dr Holaday said that complete response letters, which were the FDA alternative to approval, “are not uncommon”.

In November 2011, Psivida licencee Alimera received a complete response letter rejecting Iluvien for diabetic macular oedema, but the injected steroid treatment was subsequently approved in Europe for the subset of chronic diabetic macular oedema patients.

Psivida’s head of investor relations Brian Leedman told Biotech Daily that Alimera was continuing with its FDA application, but Psivida would focus on a similar drug and device for a different indication, uveitis.

QRX is preparing its European application for Moxduo.

Dr Holaday said the data filed to the FDA for the application related to earlier trials comparing Moxduo’s 12mg morphine and 8mg oxycodone combination to just 12mg morphine alone or 8mg oxycodone alone.

Last year, QRX said its 375-patient Study 022 phase III post-bunionectomy comparison trial showed that Moxduo had a mixed superior safety profile to equi-analgesic doses of either 24mg morphine alone or 16mg oxycodone alone (BD: Jun 14, 2011).

QRX said the Study 022 primary endpoint of respiratory depression, measured by oxygen desaturation, was less severe and of shorter duration in patients receiving Moxduo IR, but the difference was only significant against 16mg oxycodone and not 24mg morphine.

QRX said moderate to severe vomiting was less frequent in the Moxduo patients when compared to oxycodone, but was not significant compared to morphine and while there was a trend in favor of Moxduo on nausea, there was no significant difference compared to either morphine or oxycodone.

Today, Dr Holaday said the data from the 022 study was not part of the package filed to the FDA, which only saw data form the earlier trial.

Dr Holaday said that at all points along the way the FDA had indicated that the package presented was sufficient for approval and the company would continue with the approval process despite the delays.

QRX chief operating officer Dr Edward Rudnic said the approval process could be six to 18 months away, but the company was hoping for less than 12 months.

Dr Rudnic said he did not know whether the FDA wanted more data or a further trial.

QRX had $27.3 million in cash at March 31, 2012.

Today’s announcement was supported by QRX Moxduo partner Actavis chief executive officer Doug Boothe who said that his company was “disappointed by the complete response letter, [but] we are supportive of QRX’s continued efforts to work with the FDA to fully address their questions in a timely manner” (BD: Jan 22, 2012).

QRX fell as much as $1.20 or 70.6 percent before closing down $1.00 or 58.8 percent at 70 cents with 6.4 million shares traded.

BURNET INSTITUTE

Omega Diagnostics says it has licenced point-of-care tests for CD4 and syphilis developed by Melbourne's Burnet Institute.

Omega did not announce the commercial terms of the licence.

In an announcement to the London Stock Exchange, the Alva, Scotland-based Omega said it had produced the first batch of prototype CD4 tests that had passed preliminary evaluation at the Burnet Institute was

Omega said that testing for the number of CD4 T-cells was "a vital component for the management and care of people suffering from HIV" and was required to determine when HIV patients should commence antiretroviral treatment.

The company said that the World Health Organisation recommended patients be tested at least every six months to monitor their health during antiretroviral treatment.

Omega said the market for monitoring CD4 T-cells was dominated by flow cytometry, a technique which required expensive laboratory-based equipment, trained laboratory technicians and cold chain storage for reagents, all requiring the test to be carried out in centralized locations.

The company said that CD4 testing was a bottleneck to commencing antiretroviral treatment where HIV patients living in rural areas had difficulty accessing a clinic and where the time between testing and reporting results could lead to a significant patient loss to treatment.

Omega said there was a clear unmet need for a lower cost point-of-care test for doctors' surgeries and resource-poor clinics.

The company said the Burnet Institute developed a point-of-care CD4 test that met the need and it had manufactured a first small-scale batch of prototype devices.

Omega said it intended to complete the technology transfer before the launch of the CD4 test at the International AIDS Conference in Washington DC from July 22 to 27, 2012.

The company said manufacturing scale-up and field trial evaluations were required before commercial sales and it did not expect revenue in its financial year to March 31, 2013.

Omega said it had also licenced a point-of-care test for syphilis from the Burnet Institute.

The company said that in many developing countries, congenital syphilis was a leading cause of still births and deaths among neonates and the Burnet Institute had developed a point of care test which could specifically detect immunoglobulin M (IgM) class antibodies.

Omega said the Burnet test had the advantage of differentiating between active infections and those that have been treated in the past.

The company said that the technology transfer for the test was yet to commence, but it was expected to be a simpler manufacturing process than for CD4.

Omega founder and chief executive Andrew Shepherd said the licences were "an important development for our infectious diseases business and we are delighted the Burnet Institute has chosen Omega to develop these important tests".

"The CD4 test overcomes many of the limitations commonly associated with the traditional technique of flow cytometry, offering a cost-effective means of obtaining immediate results," Mr Shepherd said.

"Establishing when a patient should commence therapy will improve health and help to reduce transmission of the virus," Mr Shepherd said.

Burnet deputy director Prof David Anderson, the leader of the team that developed the test, said, there were 15 million people who should be getting access to antiretroviral therapy but were not "just because they can't get access to an affordable CD4 test in their communities".

"This test will provide access for even the most remote and disadvantaged patients," Prof Anderson test.

CIRCADIAN TECHNOLOGIES

Circadian says development partner, Healthscope Advanced Pathology, will launch its test for cancers of unknown primary origin on July 16, 2012.

Circadian said the test would be available in Australia, New Zealand, Singapore and Malaysia under the brand Cupguide and the company would receive double-digit royalties from Healthscope.

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

Circadian said that in March 2012 Healthscope reported the test was able to detect the primary source of tumor type with 93 percent accuracy within the first three predictions and had 98.5 percent specificity across 15 different tumor types (BD: Mar 19, 2012).

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

Circadian said that Healthscope had paid an undisclosed upfront fee for the test.

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

The company said that the Cupguide diagnostic methodology identified a patient's tumor type by comparing its pattern of gene expression to a database of known tumors and it was hoped that by correctly identifying a patient's tumor type, clinicians could choose the most effective treatment strategy for the cancer.

Circadian said that cancers of unknown primary origin were less well-known than other cancer types, but were more common than leukaemia and the fifth most common cause of death due to cancer in Australia, with about 32,000 cases diagnosed each year in the US, 14,000 a year in the UK and 2,900 a year in Australia.

Circadian chief executive officer Robert Klupacs said the company was "absolutely delighted that after all of the efforts of the collaborative partners that Cupguide will now be available to oncologists and pathologists".

"We are extremely hopeful that Cupguide will have a major impact in significantly improving the clinical diagnosis of [cancers of unknown primary origin]," Mr Klupacs said.

Healthscope's advanced pathology division scientific director Dr Keith Byron said his company was "proud and excited that after the extensive development program we have undertaken with our partners that we will now be able to provide this ground breaking diagnostic technology on a commercial basis".

"The test is an important addition to our existing business of providing diagnostic tools for doctors throughout our 43 hospitals and the health care industry," Dr Byron said.

Peter MacCallum's head of the cancer genomics and co-inventor of the diagnostic methodology Prof David Bowtell said the approach was initially developed in his laboratory several years ago, but the assay needed to be made more generally available.

"Circadian and Healthscope have been critical to taking the work forward and it is very gratifying that this product of our translational research efforts will be made available to clinicians throughout the region," 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 said that NICTA's Dr Adam Kowalczyk was also a co-inventor of the methodology.

Circadian was up one cent or 2.9 percent to 36 cents.

HEALTHLINX

Healthlinx says a preliminary analysis of 220 samples from its pivotal South Korean Ovplex trial has shown a significant advantage over the use of CA125 alone.
Healthlinx said the blinded samples were analyzed for the five Ovplex biomarkers by Seoul Clinical Laboratories and the anonymous raw data was then used to generate an Ovplex probability score.
The company said that Mosaic Medical acted as trial coordinators and maintained the anonymity of the sample collection until after analysis was complete.
Healthlinx said that a new diagnostic algorithm generated from interim data collected from 742 patient samples from the ongoing Ovplex multinational trial was used to predict the status of the South Korean sample cohort and the interim analysis demonstrated that Ovplex provided a statistically significant advantage over the use of CA125 alone, particularly with respect to correctly classifying patients with benign gynaecological conditions.
The company said that Ovplex reduced the number of false positive diagnoses compared to CA125 alone.
Healthlinx said that the final analysis of the Korean trial data would take place after completion of the current multinational Ovplex trial and implementation of the new diagnostic algorithm.
Healthlinx managing director Nick Gatsios said the interim results were “very exciting”.
“This is a further independent sample set that have been through the Ovplex algorithm and again the fact that the Ovplex test delivered a statistically significant improvement over CA125 alone has been demonstrated,” Mr Gatsios said.
“Clearly the final results will be driven by the completion of the larger multi centre, multi national study but this is still very exciting and encouraging to see that Ovplex reduces the false positive rates significantly over CA125 alone,” Mr Gatsios said.
The company said that the trial would be reviewed in detail by principal investigator, Prof Byoung-Gie Kim of Samsung Medical Center, with a formal submission to the Korean US Food and Drug Administration to follow.
Healthlinx said Seoul Clinical Laboratories was co-funding the study and would obtain an licence to distribute Ovplex in South Korea, which had about 250,000 tests a year.
The company said that in 2004 ovarian cancer was not rated as one of the top 10 cancers, but by 2009 it ranked as the seventh most prevalent and was predicted to be the fourth most prevalent cancer by 2015.
Healthlinx was up 0.1 cents or 33.3 percent to 0.4 cents with 26 million shares traded.

GENERA BIOSYSTEMS

The Raff Group has become a substantial shareholder in Genera with the acquisition of 3,786,789 shares or 5.03 percent.
The initial substantial shareholder notice from directors Dr John and Olga Raff said that over five years 3,698,789 shares were acquired for $925,000 or 25 cents a share, with 88,000 shares acquired on June 25, 2102 for $14,960 or 17 cents a share.
Dr Raff is the former chief executive officer of Starpharma and the former chairman of the Bio-Melbourne Network.
Genera fell 3.5 cents or 18.4 percent to 15.5 cents.