Biotech Daily

Monday July 14, 2014

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: USCOM UP 8%, GENETIC TECHNO DOWN 12%**

*** FDA SPA FOR STARPHARMA PHASE III VIVAGEL VAGINOSIS TRIAL**

*** PROBIOTEC MILK PROTEINS ECZEMA TRIAL**

*** CYNATA CONTRACTS WUXI FOR PRE-CLINICAL STEM CELL STUDIES**

*** UNIVERSAL BIOSENSORS STRIP FEES UP 56%, TOTAL REVENUE DOWN**

*** GENERATION, ASSOCIATES TAKE 6% OF COCHLEAR**

*** OPTISCAN REQUESTS FUNDRAISING TRADING HALT**

MARKET REPORT

The Australian stock market climbed 0.45 percent on Monday July 14, 2014 with the S&P ASX 200 up 24.6 points to 5,511.4 points.

Nine of the Biotech Daily Top 40 stocks were up, 13 fell, 13 traded unchanged and five were untraded.

Uscom was the best, up two cents or 8.3 percent to 26 cents with 30,000 shares traded, followed by Antisense up eight percent to 13.5 cents with 182,261 shares traded.

Ellex climbed six percent; Osprey was up 3.6 percent; Bionomics and Universal Biosensors rose more than two percent; CSL and Prana were up more than one percent; with Cochlear, GI Dynamics and Mesoblast up by less than one percent.

Genetic Technologies led the falls, down half a cent or 12.2 percent to 3.6 cents with 268,000 shares traded.

Biotron and Living Cell fell more than four percent; Admedus and Pharmaxis were down more than three percent; Acrux, Analytica and Prima shed more than two percent; Benitec, Nanosonics, Sirtex and Starpharma were down more than one percent; with Clinuvel and Resmed down by less than one percent.

STARPHARMA HOLDINGS

Starpharma says it has US special protocol assessment for the design and analyses of the phase III studies of Vivagel for the prevention of recurrence of bacterial vaginosis.
Starpharma said that the binding agreement from the US Food and Drug Administration covered the phase III study design, endpoints, statistical analyses and other aspects of the studies in support of a US regulatory submission for approval of the product.
The company said that the US FDA agreement followed earlier European Medicines Agency agreement on the design of the phase III studies.
Starpharma said it would begin two 600-patient pivotal phase III trials of Vivagel for the prevention of recurrent bacterial vaginosis at sites in North America, Europe and Asia.
The company said the two phase III, double-blind, randomized, placebo-controlled trials would be identical in design and would compare the rate of bacterial vaginosis recurrence in women using Vivagel to placebo gel during a 16 week treatment period.
Starpharma chief executive officer Dr Jackie Fairley said the special protocol assessment "effectively eliminates the US regulatory risk associated with clinical development, by specifying upfront the FDA's agreed trial design".
Dr Fairley said the special protocol assessment gave Starpharma "certainty and confidence that the studies will support a regulatory submission for the approval of Vivagel for the prevention of recurrent [bacterial vaginosis] in the US".
Starpharma said that Vivagel, or SPL7013 astodrimer sodium, was a non-antibiotic agent formulated as a vaginally-applied gel for prevention of bacterial vaginosis recurrence.
The company said Vivagel was also being developed for the management of bacterial vaginosis symptoms, which included unpleasant vaginal odor and discharge and submissions to support the symptomatic relief indication were also planned for 2014.
In 2013, Starpharma reported that a phase II trial of Vivagel for the prevention of recurrence of bacterial vaginosis failed to meet its primary endpoint with a "clinically" but not statistically significant difference between Vivagel and placebo (BD: Apr 3,4, 2013).
In 2012, Vivagel failed to meet its phase III trial primary endpoint for a clinical cure of bacterial vaginosis (BD: Nov 28, 29, 2012).
Starpharma fell one cent or 1.7 percent to 57.5 cents.

PROBIOTEC

Probiotec says it has begun a 60-patient trial investigating the effectiveness of glycomax lactoferrin and bovine whey-derived immunoglobulin rich fraction for atopic dermatitis.
Probiotec said that the trial was part of its ongoing research and development program with Griffith University and other research organizations.
The company said the study would be undertaken with the Sydney-based St George Dermatology and Skin Cancer Clinic's Prof Stephen Shumack and Dr Phillip Tong.
Probiotec said that it was also undertaking a 90-patient gene expression study using lactoferrin and immunoglobulin with Griffith University.
The company said the trial would examine the effect of speciality milk proteins, lactoferrin and immunoglobulin, on atopic dermatitis, or eczema, an inflammatory skin condition that affected up to 10 percent of adults in Australia and was more prevalent in children.
Probiotec chief executive officer Wayne Stringer told Biotech Daily that the double-blind, randomized, controlled trial would study the safety and efficacy of the oral encapsulated milk-derived products for eczema and about 90 patients would be involved in the dose-escalation, gene expression study, which would also look at blood markers for eczema.
Probiotec said the trial was expected to be completed by July 2015.
Probiotec was untraded at 48 cents.

CYNATA THERAPEUTICS

Cynata says that the Shanghai, China-based contract research organization Wuxi Apptec will conduct preclinical safety studies with its Cymerus stem cell technology.
Cynata said the studies would be conducted at Wuxi Apptec's US Food and Drug Administration-registered facility in St Paul, Minnesota.
The company said that the pre-clinical program was designed following a review of the regulatory expectations in major jurisdictions, which included interaction with regulatory authorities.
Cynata said that the data generated from the studies would support its clinical trial program, expected to begin in 2015.
Cynata's product development vice-president Dr Kilian Kelly said the scientists that would run this project had "extensive experience conducting similar studies with other cellular therapy products, which gives us confidence that our program will be conducted to the highest standards".
"We expect these safety studies, as part of the broader preclinical program, to facilitate regulatory clearance of our planned clinical trial in graft versus host disease," Dr Kelly said.
Cynata said that the Cymerus technology facilitated large-scale production of mesenchymal stem cells from a single donor, a key element for pharmaceutical companies as they move into stem cell medicine.
Cynata was up 2.5 cents or 6.25 percent to 42.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says its Johnson & Johnson quarterly service fees continue to rise, up 55.55 percent for the 12 months to June 30, 2014, despite a fall in total revenue.
In its Appendix 4C Quarterly report, Universal Biosensors said the fees generated by sales of the Lifescan Onetouch Verio blood glucose test strips was up 80.3 percent for the three months to June 30, 2014 compared to the three months to June 30, 2013.
For the 12 months to June 30, 2014 service fees were up 55.55 percent to $4,388,000 compared to the previous 12 months.
The Appendix 4C report said that total receipts from customers for the six months to June 30, 2014 was $5,260,883 down 41.5 percent from $8,990,752 for the six months to June 30, 2013.
Universal Biosensors chief financial officer Salesh Balak told Biotech Daily that the fall in total income was due to the end of lower-margin test strip manufacturing at the company's Rowville plant.
Universal Biosensors said its cash burn for the three months to June 30, 2014 was $2,261,838 with cash at the end of the quarter of $15,869,583.
The company said it expected to receive a Federal Government Research and Development Tax Incentive of more than $6 million.
Universal Biosensors was up half a cent or 2.7 percent to 19 cents.

OPTISCAN

Optiscan has requested a trading halt pending "an announcement to the market concerning fundraising, upon finalization of the arrangements".
Trading will resume on July 16, 2014 or on an earlier announcement.
Optiscan last traded at 3.6 cents.

COCHLEAR

The London-based Generation Investment Management has increased its substantial shareholding in Cochlear from 2,908,223 shares (5.10%) to 3,501,751 (6.14%).
Generation partner Peter Harris said the company held the shares “in its capacity as investment manager for a range of client portfolios” and said the registered holders included, Citigroup, HSBC Bank Australia, JP Morgan Chase Bank, State Street Bank, Skandinaviska Enskilda Banken, Credit Agricole and Bank of New York (BD: Sep 26, 2013).
Generation said that between September 21, 2013 and July 9, 2014 it acquired 652,586 shares for $38,428,790 or an average price of $58.89 a share and sold 59,058 shares for $3,399,246 or an average price of $57.37 a share.
Cochlear climbed 39 cents or 0.6 percent to $62.81 with 139,436 shares traded.