Biotech Daily

Thursday May 5, 2011

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: VIRALYTICS UP 12.5%; LBT DOWN 14%**

*** PSIVIDA: 'GREATER ILUVIEN BENEFIT IN VETERAN DME PATIENTS'**

*** GLAXOSMITHKLINE PROFIT DOWN 97%; REVENUE FALLS 20% TO $1.5m**

*** LANG WALKER TAKES 13% OF NEUREN**

*** BENITEC EU, US GENE SILENCING PATENTS**

*** AUSTRALIAN LENDERS TAKES 5% OF ATCOR THROUGH UBS AG**

MARKET REPORT

The Australian stock market climbed 0.29 percent on Thursday May 5, 2011 with the S&P ASX 200 up 13.6 points to 4753.7 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, four traded unchanged and five were untraded.

Viralytics was best, up 0.7 cents or 12.5 percent to 6.3 cents with 7.9 million shares traded, followed by Bionomics up 9.8 percent to 61.5 cents with 631,786 shares traded.

Mesoblast climbed 6.2 percent; Sirtex was up 5.6 percent; Living Cell was up 4.2 percent; Phosphagenics was up 3.45 percent; Acrux, Pharmaxis and Prana rose more than two percent; with Biota, Cochlear, Phylogica, Psivida, Resmed and Universal Biosensors up more than one percent.

LBT led the falls, down 0.8 cents or 14.3 percent to 4.8 cents with 30,000 shares traded, followed by Genetic Technologies down 8.7 percent to 21 cents, with 821,320 shares traded.

Optiscan lost six percent; Benitec and Genera fell four percent or more; Alchemia, Cellmid, Nanosonics, Sunshine Heart and Tissue Therapies were down more than three percent; Prima shed 2.9 percent; with Cellestis, Circadian and Impedimed down more than one percent.

PSIVIDA

Psivida says that longer term diabetic macular oedema patients gain greater benefit from its Iluvien corticosteroid injection than those with recently acquired disease.

Psivida said than an analysis of the subgroup of 536 patients who had been diagnosed with diabetic macular oedema (DME) for three or more years at recruitment to the two phase III trials that made up the Iluvien (fluocinolone acetonide) study, which investigated a total of 952 patients was presented by participating ophthalmologist Dr Andrew N Antoszyk at the Association for Research in Vision and Ophthalmology, in Florida.

Psivida said that in the data reported for the subgroup at 36 months in trial A, 31.8 percent of patients treated with Iluvien experienced an improvement in best corrected visual acuity (BCVA) of 15 or more letters from baseline compared with 13.6 percent of those in the control group ($p = 0.010$), for a net benefit of Iluvien versus control of 18.2 percent.

Psivida said that in trial B, 36.4 percent of Iluvien patients in the subgroup had an improvement of 15 or more letters compared to 13.2 percent of control patients ($p = 0.004$), for a net benefit of Iluvien versus control of 23.2 percent.

The company said that on a combined basis for both trials, at three years the net benefit of Iluvien compared to control reported for patients in the subgroup was 20.6 percent, more than double that seen for the full patient population of 9.8 percent.

In the subgroup, peak efficacy was seen at month 30, with 33.6 percent of Iluvien-treated patients in trial A gaining 15 or more letters in BCVA compared to 10.2 percnet of control ($p < 0.001$) and 42.4 percent of Iluvien treated patients in trial B gaining 15 or more letters in BCVA compared to 11.3 percent of control ($p< 0.001$).

Psivida said that “consistent with the full patient population in the … study, approximately 75 percent of the patients in this subgroup treated with Iluvien were reported to have received only one Iluvien insert over the 36 month study”.

The company said there was no statistically significant difference in BCVA improvement in the subgroup of patients with less than three years’ duration of DME at entry compared to control.

In February, Psivida reported that Iluvien had shown statistically significant efficacy at 33 months but not at 36 months (BD: Feb 4, 2011).

Psivida said at the time that the best result was at 30 months and the iluvien treatement was designed to last up to 36 months, implying that it was not unexpected that efficacy would drop off at that point.

In the subgroup analysis reported yesterday, safety data showed that for patients diagnosed with diabetic macular oedema for at least three years, those receiving Iluvien experienced fewer pressure-related side effects compared to control than was reported for the full patient population in the trial, Psivida said.

By the end of the 36-month study, intraocular pressure increases to 30 millimeters of mercury (mmHg) or greater at any time point were seen in 14.8 percent of the subgroup patients (5.4% of control), as contrasted with 18.4 percent of the full patient population (4.3% of control).

By month 36, 5.3 percent of the subgroup patients had undergone an incisional surgical procedure to reduce elevated intraocular pressure (0.0% of control), compared to 4.8 percent in the full patient population (0.5% of control) and 35.9 percent of the subgroup (15.2% of control) had received pressure-lowering medication compared to 38.4 percent of the total patient population (14.1% of control).

The company said Iluvien was licensed to Alimera Sciences which planned to submit the subgroup data to the US Food and Drug Administration in support of its pending new drug application.

Psivida was up five cents or 1.3 percent to $3.95.

GLAXOSMITHKLINE

Glaxosmithkline Australia says its net profit after tax was down 97.1 percent to $3 million for the 12 months to December 31, 2010 on revenue down 20.2 percent to $1.5 billion.
Glaxosmithkline said research and development expenditure was up 24 percent to $56 million or 3.7 percent of total revenue.
For the year to December 31, 2009, Glaxosmithkline's revenue was $1.88 billion, net profit after tax was $104 million and research and development expenditure was $45.2 million or 2.4 percent of total revenue.
said consumer healthcare sales were strong, increasing by seven percent to $321 million but pharmaceuticals were down 26 percent to $1.1 billion and chemicals or the manufacture of plant-based medicinal alkaloids for the pain relief market (opioids) was down by 18 percent to $70 million.
Glaxosmithkline pharmaceuticals general manager Deborah Waterhouse said total profits were lower in 2010 compared to 2009 "mostly due to reduced Relenza sales, the impact of exchange rate movement and some one-off costs".
"Our investment in research and development has increased by 24 percent and we remain one of Australia's top 15 investors," Ms Waterhouse said.
"Our focus for 2011 is on improvements in business efficiency, investing in new initiatives and product approvals as well as continuing our commitment to advancing medicine through research and development," Ms Waterhouse said.
Glaxosmithkline said revenue from domestic pharmaceutical sales increased in 2010 and would provide the opportunity to increase the investment in the manufacturing facility in Boronia.
"While a decrease in tablet manufacturing at GSK's Boronia site impacted sales and revenue in 2010, solid dose packaging and innovative blow-fill-seal production grew steadily," Ms Waterhouse said.
"Solid dose packaging will continue to increase at the Boronia site with further investment over the next three years and there is a strong pipeline of new blow-fill-seal products in development which will further expand the site's capability," Ms Waterhouse said.
"Our chemicals business is export driven and although high worldwide demand for product remains, like many others the business experienced a decline in earnings predominantly due to the current strong Australian dollar," Ms Waterhouse said.
"As a result of these two factors our export sales reduced from $942.9million in 2009 to $584.6million in 2010," Ms Waterhouse said.
"Research and development is the foundation of GSK's business," Ms Waterhouse said.
"Our pipeline of new products is strong and our scientists work with Australian researchers and doctors to discover new ways of treating and preventing disease," she said.
Ms Waterhouse said Glaxosmithkline had more than 30 discovery projects underway and the medicines research unit was the only phase I facility supported by a pharmaceutical company in Australia.
She said Glaxosmithkline employed 1620 people across Australia.
Glaxosmithkline Australia is a private subsidiary of the UK-based Glaxosmithkline.

NEUREN PHARMACEUTICALS

Sydney property developer Langley Alexander Walker has become a substantial shareholder in Neuren with the acquisition of 66,479,000 shares or 13.04 percent.
Yesterday Neuren announced the placement to Mr Walker at 1.3 cents a share as part of a larger capital raising.
Neuren fell 0.1 cents or 6.25 percent to 1.5 cents with 2.1 million shares traded.

BENITEC

Benitec says two patents it owns or licenced have been granted or allowed in Europe and the US respectively.
Benitec said the Commonwealth Scientific and Industrial Research Organisation-owned patent EP1068311-B1 'Methods and Means for Obtaining Modified Phenotypes' had been granted in Europe and it was the exclusive licencee for human therapeutics,
The company said the patent included claims to silencing of genes by using either a hairpin RNA having a double-stranded RNA portion, or a DNA molecule which formed the hairpin RNA, and which targets the coding region of a gene incorporated in a cell.
Benitec said the double-stranded RNA portion was composed of a sense and an antisense nucleotide sequence, each of which was at least 10 consecutive nucleotides long and which were 75 to 100 percent identical to a region of the target gene sequence.
The European patent provides broad protection for Benitec's gene silencing technology using DNA directed RNA interference (ddRNAi).
Benitec said chief executive officer Dr Peter French would present the company's investment case at the Bioequity conference in Paris on May 23, 2011.
The company said the US Patent and Trademark Organization had issued a notice of allowance on April 14, 2011 for Benitec's patent entitled 'RNAi expression constructs with liver-specific enhancer/promoter'.
Benitec said the claims covered a ddRNAi therapeutic capable of producing three or more gene silencing molecules specifically targeting the hepatitis C virus and the methods of using the construct were also included.
The company said the construct comprised one or more liver specific DNA machinery elements.
Benitec said it had licenced the use of ddRNAi for targeting hepatitis C to Tacere Therapeutics, which had sub-licenced the technology to Pfizer for clinical development of a ddRNAi therapeutic for hepatitis C, a disease that affects up to 200 million people worldwide.
Benitec said the patents provided it with a "dominant position in the field of gene silencing".
Benitec fell 0.1 cents or 4.2 percent to 2.3 cents.

ATCOR MEDICAL

Australian Lenders Fund through a UBS AG prime broker agreement has become a substantial shareholder in Atcor with the acquisition of 7,001,812 shares or 5.22 percent.
The initial substantial shareholder notice said the shares were acquired for $721,718 or an average price of 10.3 cents a share and the registered holder was UBS Nominees.
The Hong Kong office of UBS AG also filed an initial substantial holder for the same shares with a prime brokerage agreement attached.
Atcor was up one cent or 9.1 percent to 12 cents.