Biotech Daily

Tuesday May 22, 2012

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PHOSPHAGENICS UP 12.5%, PSIVIDA DOWN 9%**

*** MONITORING BOARD BACKS ALCHEMIA PHASE III CANCER TRIAL**

*** GSK AUSTRALIA REPORTS $54m PROFIT FOR 2011**

*** GENETIC TECHNOLOGIES: BREVAGEN SALES INCREASING**

MARKET REPORT

The Australian stock market climbed 1.16 percent on Tuesday May 22, 2012 with the S&P ASX 200 up 47.4 points to 4,121.0 points.

Twenty-three of the Biotech Daily Top 40 stocks were up, eight fell, six traded unchanged and three were untraded. All three Big Caps were up.

Phosphagenics was the best, up two cents or 12.5 percent to 18 cents with two million shares traded, followed by Ellex up 11.8 percent to 19 cents with 3,922 shares traded.

Impedimed climbed 9.5 percent; Cellmid and Prima were up more than six percent; Alchemia, Neuren and Patrys were up four percent or more; Acrux, Anteo, Genetic Technologies, Prana and Sunshine Heart were up more than three percent; Nanosonics, Sirtex, Starpharma and Tissue Therapies rose more than two percent; CSL, Heartware, Pharmaxis, QRX, Universal Biosensors and Viralytics were up more than one percent; with Cochlear, Mesoblast and Resmed up by less than one percent.

Psivida led the falls, down 20 cents or 9.3 percent to $1.95 with 10,625 shares traded.

Allied Health lost 7.7 percent; Phylogica was down six percent; Benitec fell 5.6 percent; Optiscan was down 4.4 percent; Avita was down 3.9 percent; Clinuvel shed 2.7 percent; with Bionomics down 1.5 percent.

ALCHEMIA

Alchemia says an independent data safety monitoring board has recommended continuing its 390-patient, phase III trial of HA-irinotecan in metastatic colorectal cancer

Alchemia said the data safety monitoring board reviewed data from 39 patients receiving either Alchemia's hyaluronic acid (HA) irinotecan or irinotecan delivered as part of the folinic acid (leucovorin), 5-fluourouracil and irinotecan or FOLFIRI regimen.

The company said the board was an independent group of experts to review and evaluate data for participant safety, study conduct and progress in a trial and review of data from the initial 20 patients was specified within the study protocol submitted to the US Food & Drug Administration and European Medicines Agency.

Alchemia said that the board noted that no safety or efficacy concerns were identified.

Alchemia chief scientific officer Prof Tracey Brown said the board's recommendation to continue the phase III study was "an important milestone in the progress of this pivotal trial".

"The expectation for this study, based on our prior clinical experience, is that HA-irinotecan will provide improved clinical benefit to patients without increasing the burden of toxicity," Prof Brown said.

"While it is still early in the trial, the data presented to the [data safety monitoring board] is consistent with that expectation," Prof Brown said.

Alchemia chief executive officer Dr Pete Smith said the company was "very happy with the progress and management of this key trial".

"We are in the process of adding some additional sites in Australia and Eastern Europe to ensure that we complete recruitment and can deliver the top line results on schedule," Dr Smith said.

"This is to adjust for a higher than expected number of patients not passing the selection criteria for the trial … which is indicative of our robust design and stringent management of the trial," Dr Smith said.

Alchemia said the trial would recruit 390 irinotecan-naïve second or third line metastatic colorectal cancer patients, randomized in a double-blinded trial.

The company said the primary endpoint was progression free survival, assessed when 350 patients' disease had progressed, estimated to occur by October 2013.

Alchemia said that in a phase II study, HA-irinotecan provided a significant efficacy and clinical benefit to second line colorectal cancer patients where the progression free survival period was more than doubled (5.2 months compared to 2.4 months, $p = 0.014$) when compared with the form of irinotecan that is currently used in the clinic (BD: Apr 26, May 29, 2007).

Alchemia said that according to the American Cancer Society, colorectal cancer was the third most common form of cancer diagnosed in the US.

The company said that about 143,000 people would be diagnosed with some form of colorectal cancer in the US with 51,000 patients dying from the disease in 2012.

Alchemia said that surgery was often the first treatment for early stage colorectal cancer, but when colorectal cancer metastasized or spread to other parts of the body such as the liver, chemotherapy was commonly used.

The company said that irinotecan sold by Pfizer as Camptosar was approved for use in the management of metastatic colorectal cancer and had peak sales of $US970 million before US patent expiry in 2008.

Alchemia was up two cents or 4.4 percent to 47 cents.

GLAXOSMITHKLINE

Glaxosmithkline says it has reported to the Australian Securities and Investment Commission a total profit before tax of $54 million.

Glaxosmithkline said that it spent $58 million on research and development in 2011.

In 2010, Glaxosmithkline reported 2009 sales of $1.88 billion, a profit of $104 million and research and development expenditure of $45.2 million or 2.4 percent of sales revenue (BD: May 3, 2010).

Today the company said that profit margins "fluctuated in recent years with last year being impacted by restructuring and other one off costs".

The company said that Glaxosmithkline Australia consisted of three different businesses: pharmaceuticals, consumer healthcare and opiates and employed about 1600 staff.

Glaxosmithkline said that domestic sales in 2011 were up 6 percent to $968 million, but export sales were down to $477 million compared to $585 million in 2010.

The company said that pharmaceutical sales were down seven percent to $1,029 million, consumer healthcare was up 10 percent to $353 million and opiates down by 11 percent to $63 million.

Glaxosmithkline's pharmaceuticals general manager Geoff McDonald said the investment in research and development increased by three percent compared to the previous year.

"That was followed, in February this year, by our announcement of a further $60 million investment to expand our Boronia manufacturing site, creating 58 new highly-skilled jobs by 2017," Mr McDonald said.

The Victoria Government said that it "supported" the company's $60 million Boronia upgrade but did not say how much taxpayers money was contributed (BD: Feb 6, 2012).

"We have a long and proud history in Australia dating back to 1886 and we're one of the nation's top 15 investors in local research and development," Mr McDonald said.

"The domestic pharmaceuticals business, the prescription medicines division, produced an improvement in total sales turnover of three percent and underlying growth of seven percent … due to strong and sustained sales growth in respiratory and vaccines, off-setting the impact of Valtrex, an antiviral for the treatment of genital herpes infection, coming off patent," Mr McDonald said.

Glaxosmithkline said that consumer healthcare had a 10 percent increase in sales revenue with the key driver an increase in demand for Panadol products, in particular Panadol Osteo.

The company said that the opiates business was "largely export driven and, like many others, was heavily impacted by the strong Australian dollar".

Glaxosmithkline said that storm damage to crops in 2011 reduced supply already negatively impacted by severe drought from previous years but overall volume growth and customer demand remained strong.

Glaxosmithkline's global chief executive officer Andrew Witty said that "three and a half years ago, we set out to fundamentally change GSK to create a more balanced business capable of addressing the market challenges we face, delivering sustainable financial performance and providing new value to patients and consumers.

"Our record in 2011 demonstrates that we are succeeding," Mr Witty said.

Glaxosmithkline Australia is a wholly-owned subsidiary of the UK-based Glaxosmithkline PLC, which is listed on the London and New York Stock Exchanges.

Last night GSK closed up 30 US cents or 0.7 percent to $US44.48 with 1.85 million shares traded on the New York Stock Exchange; and up four pence or 0.3 percent to GBP14.045 with 531,372 shares traded on the London Stock Exchange.

GENETIC TECHNOLOGIES

Genetic Technologies says it has executed credentialing contracts for its Brevagen test with four preferred provider organizations covering about 13 million lives in the US.

The company said that progress with preferred provider organizations was a key driver of improved revenue collection for the Brevagen breast cancer diagnostic.

Genetic Technologies said that total revenue received from Brevagen sales from January to April 2012 was more than 63 percent of all revenue received since the test was launched in June 2011.

The company said that in addition to the improvement in reimbursement, the month of April saw appreciable sales uptake, with unit sales increasing to 48 percent higher than the year-to-date monthly average.

Genetic Technologies chief executive officer Dr Paul MacLeman told Biotech Daily that the January to April monthly sales rate was increasing over the previous six months monthly sales rate.

Dr MacLeman said that company previously disclosed that it had tested 125 billable samples in the six months to December 31, 2011.

Dr MacLeman said the list price of the test was $US945 and Genetic Technologies received an undisclosed percentage of that fee.

In a media release, Dr MacLeman said the increase in unit sales and revenue generation was “illustrative that we are on the right track with regard to both sales messaging and credentialing contract execution for Brevagen”.

“With the increased sales presence we now have in place in new US territories, we are looking forward to continued commercial growth, particularly as we execute on credentialing contracts with further US [preferred provider organizations],” Dr MacLeman said.

Genetic Technologies said that credentialing contracts with four of the top ten preferred provider organizations allowed for expedited claim adjudication, providing improved cash flow while obtaining an acceptable level of reimbursement, and reduceing the costs incurred through appealing denials.

The company said that once Brevagen volumes reached a significant level and it had gathered the clinical utility data, the company would approach insurers directly to contract.

In 2011, the US Centers for Medicare and Medicaid certified Genetic Technologies Australian laboratory under the US Clinical Laboratories Improvements Amendments, allowing Brevagen to be sold in 42 states (BD: April 28, 2011).

Genetic Technologies said that following receipt of a certificate of compliance issued by the Centers for Medicare and Medicaid Services the company had submitted applications allowing Brevagen to be sold in Pennsylvania, Rhode Island, Nevada, Tennessee and Maryland.

The company said it had submitted relevant applications in California and Florida and expected approval shortly, with submission of data to New York also in progress.

Genetic Technologies was up 0.3 cents or 3.6 percent to 8.6 cents.