Biotech Daily

Wednesday May 22, 2013

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: NEUREN UP 11%, PHARMAXIS DOWN 15%**

*** ALCHEMIA FONDAPARINUX SALES FALL 28%, MERCK SERONO DEAL**

*** REVA 1st GENERATION STENT 'COMPARABLE TO COMPETITORS'**

*** SIEMENS UNVEILS UNIVERSAL BIOSENSORS COAGULATION TEST**

*** PHARMAXIS APPOINTS PHARMASWISS EAST EUROPE DISTRIBUTOR**

*** ANTEO, GENNOVA SALES DEAL FOR EUROPE, LATIN AMERICA**

*** BENITEC PLEADS SCHULTZ TO ASX 14% QUERY**

*** BIODIEM JAPAN BDM-I PATENT FOR MALARIA, TRICHOMONIASIS**

*** ALLAN GRAY TAKES 11% OF STARPHARMA**

*** HEARTWARE DIRECTORS' STOCK 28% DISSENT, ELECTED UNOPPOSED**

*** IDT LOSES BLACKMAN, BLACKMAN, BURNET FOR KAUFMAN, SHIGENO**

MARKET REPORT

The Australian stock market fell 0.28 percent on Wednesday May 22, 2013, with the S&P ASX 200 down 14.7 points to 5,165.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, six traded unchanged and four were untraded.

Neuren was the best, up 0.6 cents or 10.9 percent to 6.1 cents, with 10.2 million shares traded. Mesoblast climbed 9.45 percent; Phylogica was up 8.7 percent; Genetic Technologies rose 7.1 percent; Universal Biosensors was up 5.8 percent; Avita, Circadian and Tissue Therapies were up four percent or more; GI Dynamics, Phosphagenics and Reva were up more than three percent; Allied Health, Ellex and Psivida rose more than two percent; Resmed was up 1.4 percent; with Acrux and CSL up less than one percent.

Pharmaxis led the falls, down three cents or 15 percent to 17 cents with 21.1 million shares traded. Cellmid lost 6.45 percent; Medical Developments and Patrys fell four percent or more; Cochlear was down 3.3 percent; Atcor, Clinuvel, Impedimed and Living Cell shed more than two percent; with Alchemia, Anteo, Bionomics, Nanosonics, QRX and Starpharma down more than one percent.

ALCHEMIA

Alchemia says Dr Reddy's Laboratories net sales of its fondaparinux generic heparin fell 28.5 percent to $US8.8 million ($A8.99 million) for the three months to March 31, 2013.

Alchemia said the sales, resulted in a profit share of $US2.35 million, but the company would receive $US1.85 million following its contribution of $US500,000 to agreed activities to improve yields and cost of goods.

In February, Alchemia said its profit share on sales of fondaparinux for the three months to December 31, 2012 was up 90 percent to $US3.4 million ($A3.3 million) compared to the previous quarter (BD: Feb 18, 2013).

Alchemia chief executive officer Charles Walker told Biotech Daily at that time, that along with increased sales and an increase in market share of the generic anti-coagulant, the cost of goods had improved with significant reductions in manufacturing costs.

In February, Alchemia said that total net sales were $US12.3 million, of which the funds owing to Alchemia would be $US2.9 million following the contribution of $US500,000 by Alchemia to the agreed activities to improve yields and cost of goods.

The company said at that time that Dr Reddy's average market share for the three months ending December 31, 2012 was 25 percent, compared with 22 percent for the quarter ending September 30, 2012.

Today, Alchemia said that the reduced profit was "primarily a result of seasonal buying patterns which have meant that volumes in the first two months of the quarter, January and February 2013, have been significantly lower than prior months".

The company said that the sales volumes for March showed a return to high levels, at slightly weaker prices than the previous quarter.

In the same announcement, Alchemia said it would collaborate with the Swiss-based Merck Serono SA to support a phase II trial of hyaluronic acid-irinotecan (HA-Irinotecan) with Merck Serono's antibody, Erbitux (cetuximab), for patients with metastatic colorectal cancer, to be conducted by Royal Melbourne Hospital oncologist and principal investigator Prof Peter Gibbs.

In February, Alchemia closed recruitment in its 415-patient, phase III trial of metastatic colorectal cancer patients randomized to received at least one treatment of HA-Irinotecan or irinotecan, each delivered as part of the 5-fluourouracil, leucovorin and irinotecan (FOLFIRI) regimen (BD: Feb 28, 2013).

Today, Alchemia said the Merck Serono collaboration would begin with the first of 45 patients who were candidates for second-line treatment to be enrolled by October 2013 at up to 10 sites in Australia, with the trial scheduled to run for about 24 months.

Alchemia said that if its phase III trial was successful and the drug was approved for use in irinotecan-containing chemotherapy regimens, there was the possibility that HA-Irinotecan would progressively replace the current form of irinotecan.

The company said that under treatment guidelines about 60 percent of metastatic colorectal cancer patients should be considered for treatment with chemotherapeutic drugs, such as irinotecan, in combination with Erbitux and the phase II study was intended to generate data supporting the clinical use of HA-Irinotecan with Erbitux.

"By conducting this trial we expect to generate data demonstrating that HA-Irinotecan when administered as part of the FOLFIRI regimen, is safe to use in combination with Erbitux," Prof Gibbs said. "This will enable oncologists to feel confident in prescribing Alchemia's drug as a safe and potentially more effective alternative to irinotecan in combination chemotherapy regimens."

"It is gratifying to report that another major pharmaceutical company has recognized the value of our technology," Mr Walker said.

Alchemia fell half a cent or 1.3 percent to 37.5 cents.

REVA MEDICAL

Reva says that data from its first generation Rezolve sirolimus-eluting bioresorbable stent shows the scaffold is comparable to competitor stents.

Reva said it presented the 12-month data on eight of the 22 patients in the first generation 'Restore' clinical trial at the Paris Course on Revascularization this week in Paris, France.

The company said that an analysis of patients who completed 12-month angiographic follow-up to-date, demonstrated a mean in-stent late lumen loss of 0.20mm.

Reva said that a finding of 0.20mm meant that there was very little change in the lumen area between the time of treatment when blood flow was restored and the time of follow-up and that permanent drug-eluting stents historically exhibited late lumen loss values in the range of 0.20mm to 0.40mm, which corresponded to positive long-term outcomes.

The director of invasive cardiology at the Instituto Dante Pazzanese de Cardiologia in Sao Paulo, Brazil and principal investigator Dr Alexandre Abizaid said that the 12- month late lumen loss was "well within the range of safety and performance of drug-eluting metal stents and bioresorbable scaffolds that are used today".

"This preliminary analysis is very encouraging as it indicates that the Rezolve scaffold has the potential to successfully treat coronary artery disease, with the added benefit of resorbing from the body over time, allowing the artery to return to its natural function," Dr Abizaid said.

Reva said that since its most recent report of clinical data, which included an analysis of all patients through a six-month follow-up, two additional patients were retreated for focal in-stent restenosis, or renarrowing of the artery at the implant site and an additional patient died from unknown causes.

Reva chairman Bob Stockman said the company learned a great deal from the trial.

"The low late lumen loss is a very positive indication of the effectiveness of the Rezolve product platform and we remain very encouraged by this result," Mr Stockman said.

"The adverse clinical events relating to restenosis occurred in patients that were enrolled in the early stages of the study; the learning from these early cases led to improved lesion preparation techniques for optimal bioresorbable scaffold placement, as well as design enhancements in Reva's commercial product, Rezolve2, which began clinical enrollment earlier this year," Mr Stockman said.

Reva said that the Rezolve2 stent was a lower profile, sheathless version of the first-generation scaffold with improved deliverability and a 30 percent increase in strength.

Reva said it began implanting Rezolve2 in patients in March 2013 and it expected to enroll 125 patients by September this year to provide the data for European Conformité Européenne (CE) mark approval.

Reva was up two cents or 3.45 percent to 60 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says Siemens AG has showcased its product range, leading with the co-developed Xprecia Stride coagulation analyzer prothrombin time system.

Universal Biosensors said that the German-based Siemens unveiled the Xprecia Stride handheld system at the European Congress of Clinical Chemistry and Laboratory Medicine in Milan, Italy and the Xprecia Stride was the first of a family of analyzers being developed with Siemens expected to be launched on the market this year.

Universal Biosensors chief executive officer Paul Wright said the unveiling of Xprecia Stride was "the culmination of a significant amount of collaborative effort between Universal Biosensors and Siemens and reaffirms their strong commitment to the product".

Universal Biosensors climbed four cents or 5.8 percent to 73 cents.

PHARMAXIS

Pharmaxis says it has appointed Valeant Pharmaceuticals' Pharmaswiss SA as a distributor for Bronchitol in Poland and 10 other Eastern European countries.
Pharmaxis said that the Switzerland-based Pharmaswiss operated in 17 Central and Eastern European countries with expertise in regulatory affairs, compliance, sales, marketing and distribution.
Pharmaxis chief executive officer Gary Phillips said that Poland had more than 6,000 cystic fibrosis patients and was "a solid market where our European Union approval applies".
Pharmaxis said that Pharmaswiss would take responsibility for pricing approval with the Polish reimbursement authority, a process expected to take about 18 months and would distribute Bronchitol in Slovenia, Croatia, Serbia, Bosnia and Herzegovina, Montenegro, Macedonia, Latvia, Lithuania, Estonia and Kosovo.
Pharmaxis fell three cents or 15 percent to 17 cents with 21.1 million shares traded.

ANTEO DIAGNOSTICS

Anteo says it has a sales partnership with the Seville Spain-based Gennova Scientific to distribute its Mix&Go surface chemistry to researchers in Europe and Latin America.
Anteo said that Gennova developed and sold antibodies and other products for immunochemistry, histology and flow cytometry applications, as well as developing and supplying clinical diagnostic products to customers, predominantly in Spain, Portugal, and Latin America.
Anteo said it would sell Mix&Go surface chemistry to Gennvoa, which would distribute co-branded product to their customers in industrial and clinical research.
The company said that Mix&Go sold by Gennova could be used to functionalize a variety of beads, biosensor surfaces, glass slides and microtitre plates, with additional products to be added based on customer requests.
Anteo said that the sales revenue would be shared by the two companies.
The company said the partnership would better expose Mix&Go to scientists in Europe and Latin America.
Anteo said that Mix&Go had a novel approach to attaching large fragile bio-molecules such as proteins to various surfaces used in research and development and diagnostics and could be envisaged as a 'molecular Velcro, binding bio-molecules gently but firmly, so they did not suffer any loss in activity.
Gennova chief executive officer Carmen Pérez said the agreement "beneficially extends our product range and provides major advantages for our customers".
"In addition to this agreement the two companies are investigating a number of products in development that may be improved through the inclusion of Mix&Go," Ms Pérez said.
Anteo fell 0.1 cents or 1.5 percent to 6.4 cents with one million shares traded.

BENITEC BIOPHARMA

Benitec has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company's share price rose 14.3 percent from 1.4 cents on May 20 to 1.6 cents on May 21, 2013, and noted an increase in trading volume.
Benitec was unchanged at 1.5 cents with three million shares traded.

BIODIEM

Biodiem says it has been allowed a further patent covering the use of its antimicrobial compound BDM-I for malaria and trichomoniasis, infections caused by protozoa.
Biodiem said the claims had been granted in Europe and the US and the Japanese allowance strengthened its broad BDM-I patent portfolio particularly for the treatment of common infections affecting women.
The company said that an earlier patent covering BDM-I for of vulvo-vaginitis, an infection of the vulva and vagina, had been granted in Europe, the US and Japan covering infections caused by yeast, such as Candida or thrush, as well as gonorrhea or chlamydia.
Biodiem said that vulvo-vaginitis was one of the most widespread female health complaints across all demographics.
Biodiem chief executive officer Julie Phillips said that BDM-I was “active against a range of pathogenic micro-organisms including bacteria, fungi and protozoa”.
“This latest protozoal patent coupled with our previous vulvo-vaginitis patent in key markets means we now have a comprehensive intellectual property set for the treatment of common female genital health complaints caused by both sexually transmitted diseases such as chlamydia, trichomoniasis and gonorrhea, and also general infections such as thrush,” Ms Phillips said.
“We will seek opportunities to collaborate and to explore development of BDM-I for use in these diseases,” Ms Phillips said.
Biodiem said that its BDM-I development program was being conducted through collaborations to establish BDM-I’s antimicrobial activity in models of infectious disease.
Biodiem was untraded at 2.7 cents.

STARPHARMA

Allan Gray Australia (formerly Orbis Investment Management) has increased its holding in Starpharma from 23,151,172 shares (9.45%) to 32,269,032 shares (11.38%).
Allan Gray said that between March 28, 2011 and May 17, 2013 the company bought and sold shares with the single largest transaction the acquisition of 3,997,366 shares for $4,609,047 or an average price of $1.153 a share.
Starpharma fell one cent or 1.1 percent to 88 cents.

HEARTWARE

Heartware shareholders expressed strong dissent against resolutions to the annual general meeting but all votes were carried.
The greatest shareholder opposition was to the granting of 25,000 restricted stock units equivalent to 875,000 Australian shares and worth $2,528,750 at today’s price of $2.89, with 3,857,450 US voter shares (28.1%) opposing the grant and 9,856,904 votes (71.9%) in support of the resolution.
The 3,857,450 opposing shares make up 23.6 percent of the equivalent of 16,353,959 US shares on offer.
Seven other resolutions relating to the issue of stock units or options were opposed by more than 2.5 million or more than 15 percent of all available shares on issue.
An advisory vote on executive remuneration was opposed by more than 1.6 million votes or about 10 percent of all available shares on issue.
Despite the significant dissent, directors Douglas Godshall, Seth Harrison and Robert Stockman were elected unopposed with 14 million votes in support.
Heartware was untraded at $2.89.

IDT AUSTRALIA

IDT says that directors Alan Blackman and Robert Burnet will step aside effective from June 30, 2013.

IDT said that Mr Blackman and Mr Burnet had served as directors for 27 years and have been an important part of the deployment of the globally-certified facilities and capabilities the company had developed.

The company said that following the investment by Japan's I'rom Holdings Reo Shigeno would be appointed as a non-executive director from June 1, 2013.

Earlier this month, IDT said that I'rom would take a 19 percent stake in the company (BD: May 6, 2013).

Today, IDT said Mr Shigeno was the chief financial officer of I'rom's Australian subsidiary Healthy Clinical Research Pty Ltd and would bring his experience with that organization in driving the growth of the I'rom site management organization strategy.

The company said that prior to I'rom Mr Shigeno held roles in the financial services industry.

IDT said that former CSL chief financial officer Graeme Kaufman would also be appointed as a non-executive director from June 1, 2013.

The company said that Mr Kaufman held senior roles and board positions in a number of companies and was instrumental in the ASX listing of CSL.

IDT said that Mr Kaufman had held senior roles at Circadian, Amrad and Mesoblast and was the current chairman of bionomics and a director of Cellmid.

IDT said that founder and chairman Dr Graeme Blackman would stand aside as chairman by October 2013.

IDT was up two cents or 8.7 percent to 25 cents.