Biotech Daily

Tuesday October 23, 2012

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: VIRALYTICS UP 21%, USCOM DOWN 12%**

*** SHAREHOLDERS APPROVE BIOTA, NABI MERGER FOR US LISTING, $26m**

*** SIRTEX SIR-SPHERES 'EXTEND SURVIVAL 5 MONTHS'**

*** RESONANCE FERRISCAN LIVER IRON TEST FOR 2 CLINICAL TRIALS**

*** AVEXA, VALEVIA SHOW AVX13616 IN-VITRO ANTI-BACTERIAL ACTIVITY**

*** GI DYNAMICS STUDY BACKS ENDOBARRIER RE-IMPLANTATION**

*** USCOM 'MORE ACCURATE THAN BLOOD PRESSURE IN PREGNANCY'**

*** SIRTEX AVOIDS SPILL BY 0.015% OR 8,000 VOTES**

*** CBIO EX-EXECUTIVES COUNTERSUE INVION**

MARKET REPORT

The Australian stock market edged up 0.05 percent on Tuesday October 23, 2012 with the S&P ASX 200 up 2.1 points to 4,543.1 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 10 fell, 10 traded unchanged and five were untraded.

Viralytics was the best, up seven cents or 21.2 percent to 40 cents with 418,041 shares traded, followed by Neuren up 18.2 percent to 40 cents with 20.9 million shares traded, on no news, Optiscan up 12.9 percent to 10.5 cents with 346,000 shares traded and Avita up 12.0 percent to 14 cents with one million shares traded.

Benitec and Cellmid climbed more than six percent; Phosphagenics, Psivida and Sunshine Heart were up more than three percent; Reva rose 2.5 percent; with Anteo, Clinuvel, Nanosonics, Resmed, Sirtex and Starpharma up more than one percent.

Uscom led the falls, down two cents or 11.8 percent to 15 cents with 20,000 shares traded, followed by Genera down 11.1 percent to 12 cents with 35,000 shares traded.

Allied Health lost eight percent; Antisense fell 6.7 percent; Alchemia, Biota, Mesoblast and Prima were down three percent or more; Acrux shed 2.3 percent; Pharmaxis was down 1.2 percent; with Cochlear and CSL down by less than one percent.

BIOTA HOLDINGS

Biota and Nabi shareholders have passed all merger meeting resolutions at their two meetings overnight in Bethesda, Maryland and in Melbourne this afternoon.

Biota said its shareholders “voted overwhelmingly in favor of the merger” with 94 percent of shares voted supporting the resolutions and 82 percent of voters in favor.

Biota said that Nabi resolutions were “approved by the requisite majority votes” and included an increase to 200,000,000 Nabi shares, the issue of shares to Biota, approval of a share consolidation between four-to-one and eight-to-one and the change of Nabi’s name to Biota Pharmaceuticals Inc (BD: Apr 23, 2012).

Biota said it would seek the final approval of the Supreme Court of Victoria on October 26 and if court approval was granted, the last day of trading of Biota shares on the ASX would be October 30, 2012.

Biota chairman Dr James Dr Fox said that if the merger was approved and implemented, Biota Pharmaceuticals shares would begin trading on the Nasdaq on November 9, 2012.

Dr Fox said the merger implementation date was November 9, when Nabi must deliver a certificate to Biota confirming it had net cash of at least $US27 million ($A26.2 million) issue the new shares in Biota Pharmaceuticals, which would constitute the scheme consideration and on Nabi providing confirmation that the new shares in Biota Pharmaceuticals had been issued, all Biota shares on issue would be transferred to Nabi.

Dr Fox said that if Nabi did not deliver the $US27 million net cash certificate, Biota could terminate the scheme and the merger would not proceed, Biota shareholders would retain their Biota shares, the company would retain its listing on the ASX and Nabi would not issue new shares in Biota Pharmaceuticals.

Biota fell two cents or 3.1 percent to 63 cents, with 946,722 shares traded.

SIRTEX MEDICAL

Sirtex says a 58-patient study has shown median overall survival of SIR-Spheres treated patients was 8.3 months compared to 3.5 months for best supportive care ($p < 0.001$).

Sirtex said the study by investigators from the University of Magdeburg, Germany, showed that patients with metastatic colorectal cancer experienced a statistically-significant survival benefit from treatment with SIR-Spheres microspheres, compared to patients who received the best available supportive care for their disease.

The study, led by Dr Ricarda Seidensticker, was entitled ‘Matched-pair comparison of radioembolization plus best supportive care versus best supportive care alone for chemotherapy refractory liver-dominant colorectal metastases’ and was published in Cardiovascular and Interventional Radiology.

An abstract is at: http://link.springer.com/article/10.1007/s00270-011-0234-7.

Sirtex chief executive officer Gilman Wong said that the patients “were treated in the salvage setting, when they had exhausted all other treatment options”.

“This was the first comparative study of SIR-Spheres microspheres, in this group of patients in which survival was the primary endpoint,” Mr Wong said.

“We are particularly pleased that the authors chose to point out in this article that the benefit they observed with SIR-Spheres compared favorably with that seen in clinical trials with biologic agents such as cetuximab and panitumumab,” Mr Wong said.

“These positive findings add to the rapidly growing evidence demonstrating the effectiveness of SIR-Spheres microspheres in the treatment of patients with liver metastases from primary colorectal cancer,” Mr Wong said.

Sirtex was up 13 cents or 1.3 percent to $10.20.

RESONANCE HEALTH

Resonance says it has two multi-year contracts with an unnamed pharmaceutical company to provide Ferriscan services, for an undisclosed sum.
Resonance said that one contract would involve working with up to 15 magnetic resonance imaging facilities that would image patients participating in the clinical trial.
The company said it would provide Ferriscan image analysis services to measure liver iron concentration and a cardiac iron assessment for thee patients.
Resonance said that it recently gained regulatory approval for the measurement of the parameter 'cardiac T2' which provided an indirect assessment of cardiac iron overload.
The company said the second contract would see it working with up to 20 magnetic resonance imaging facilities across a number of countries and would provide a range of services to support the use of Ferriscan in the clinical trial.
Resonance said it was "pleased with the growing uptake of [its] cardiac iron image analysis services and the medical community's recognition of Ferriscan's superior performance for assessing liver iron concentration".
Resonance was up 0.4 cents or 33.3 percent to 1.6 cents.

AVEXA

Avexa said that in-vitro testing of its anti-bacterial compound AVX13616 has shown positive activity against a broad range of bacteria.
Avexa says that its Basl, Switzerland-based research partner Valevia Pharmaceuticals GmbH reported that in ore-clinical in-vitro studies AVX13616 showed positive activity against Clostridium difficile, multi-drug resistant Staphylococcus aureus, penicillin-resistant Streptococci and Vancomycin-resistant enterococci.
Avexa interim chief executive officer Dr Jonathan Coates said the strains tested were "clinical isolates from recent hospital cases, so the resistance profile of these bacterial strains is highly relevant".
"AVX13616 showed no cross-resistance with other currently marketed classes of antibiotics," Dr Coates said.
Avexa said that the activity of AVX13616 against Clostridium difficile had led to an initial focus on infections caused by the bacterium.
The company said that AVX13616 had demonstrated topical use activity, suggesting potential uses of AVX13616 in nasal decontamination in the hospital setting.
Dr Coates told Biotech Daily that human nasal passages were "the major repository for Staphylococcus aureus and in particular in hospitals".
"The eradication of this source in patients by the direct application of an agent would therefore decontaminate the hospital," Dr Coates said.
Dr Coates said there were older generation drugs currently in use for this indication during outbreaks and the non-transdermal profile of AVX13616 made it "an excellent candidate for the topical treatment of other gram-positive infections of the skin, such as diabetic foot ulcers".
"Hospital-acquired infections are a serious health problem which are estimated to affect nearly two million patients annually in the US alone," said Dr Coates in a media release.
"The cost of treating these infections is estimated at over $US10 billion per annum," Dr Coates said. "The growing problem of drug-resistant bacteria continues to drive growth in new and expanding market opportunities."
Avexa said that Valevia was in partnering discussions with third parties for the development of AVX13616 and clinical trials were planned for late 2013 to early 2014.
Avexa was up half a cent or 19.2 percent to 3.1 cents with 4.7 million shares traded.

GI DYNAMICS

GI Dynamics says that re-implantation of its Endobarrier could result in further weight loss, long-term weight loss maintenance and improvement in other co-morbid conditions.

GI Dynamics said the study presented at the United European Gastroenterology Week was the first evaluating the long-term benefits and safety of re-implanting Endobarrier to extend weight loss benefits for three years and the data suggested that Endobarrier could be re-implanted about one year after completion of the initial treatment period.

In a separate presentation, GI Dynamics said that with collaborators it had shown in animal models and clinical studies that like gastric bypass surgery, the Endobarrier affected critical metabolic hormones, including the gut peptides glucagonlike peptide-1, gastric inhibitory peptide and peptide YY, as well as insulin, glucagon, ghrelin and leptin.

The company said that the re-implantation study showed improvement in cholesterol, blood pressure and fasting blood glucose, a key measure of blood sugar levels used to diagnose diabetes.

GI Dynamics said the findings supported earlier evidence that Endobarrier “provided sustained weight loss and glycaemic control benefits long after its removal and suggest that these benefits can be extended and improved by repeating Endobarrier therapy for an additional year”.

The Pontificia Universidad Católica de Chile’s Dr Alex Escalona said that a prior study showed that Endobarrier “could safely be re-implanted in patients previously treated for one year”.

“We are very pleased to see the data from this study which builds on our feasibility study and indicates that patients who have successfully completed an initial course of Endobarrier therapy can not only maintain a majority of their weight loss during the interim treatment period, but can also achieve additional weight loss and metabolic benefits with a second round of Endobarrier therapy,” Dr Escalona said.

GI Dynamics said that the data was presented in a poster entitled ‘One year follow-up after re-implantation of the endoscopic duodenal-jejunal bypass liner’.

The company said that 24 obese patients, who were previously implanted with Endobarrier for one year and who had completed at least 31 weeks of follow-up post Endobarrier removal, were invited to participate and 19 patients were re-implanted, with Endobarrier and 14 completed a second year of treatment.

GI Dynamics said that there was a total body weight loss of 22.6 kg ($p < 0.0001$); a decrease in body mass index from 43.8 +/- 5.9 to 33.5 +/- 5.2 ($p < 0.0001$); total reduction in triglyceride levels of 55.7 ($p < 0.118$); and a decrease in fasting blood glucose from a mean of 106.6 +/- 5.2, a diagnosis of prediabetes according to the American Diabetes Association, to a mean of 93.4 +/- 21.3, a reading the Association considered to be within the normal range ($p < 0.034$); with no procedure-related complications

GI Dynamics chief executive officer Stuart Randle said that Endobarrier treatment had “already been proven to be effective in treating type 2 diabetes and obesity for one year, with sustained benefits observed for up to 12 months following explant”.

“This re-implantation data expands our current understanding by demonstrating that the overall health benefits of initial Endobarrier therapy can be safely extended and improved following a second treatment period,” Mr Randle said.

The company said that the Endobarrier was available in The Netherlands, Austria, Germany and the United Kingdom, as well as Australia and Chile.

GI Dynamics said it had received conditional approval from the US Food and Drug Administration to begin a pivotal clinical trial of Endobarrier for the treatment of patients who have uncontrolled type 2 diabetes and are obese.

GI Dynamics fell four cents or 6.6 percent to 57 cents.

USCOM

Uscom says that research published in the British Journal of Anaesthesia shows that its monitor is more accurate than blood pressure in measuring circulation in pregnancy.
Uscom said the research by the Chinese University of Hong Kong looked at the effect of the pregnant uterus on the great vessels and circulation as patients lay on their back and then on their side and found that its ultra-sonic cardiac output monitor (Uscom) detected changes in circulation that previously had been demonstrated solely by using intra-arterial catheters, a method not considered for routine use due to its invasiveness.
The company said that blood pressure had become the method for monitoring circulation in pregnancy, but in this study the non-invasive Uscom method was demonstrated to be as accurate as the invasive method and more accurate than blood pressure monitoring.
Uscom executive chairman Rob Phillips said that "accurate monitoring of circulation in pregnancy is critical for the health of the mother and the foetus and this study demonstrates that Uscom is more accurate than blood pressure for monitoring circulation during pregnancy".
An abstract of the article, entitled 'Haemodynamic effects from aortocaval compression at different angles of lateral tilt in non-labouring term pregnant women' is available at: http://bja.oxfordjournals.org/content/early/2012/10/10/bja.aes349.abstract.
Uscom fell two cents or 11.8 percent to 15 cents.

SIRTEX

The Sirtex remuneration report was opposed by 10,222,703 votes or 24.985 percent, narrowly avoiding the second trigger for a board spill at its annual general meeting.
Sirtex said that 30,691,928 votes (75.015%) supported the remuneration report.
The Sirtex 2012 annual report said that founder Dr Bruce Gray's, ACN 132 442 114 Pty Ltd owned 10,090,604 shares or 18.094 percent of the company.
Biotech Daily has calculated that a further 8,000 shares would have been required to reach the 25 percent threshold for the board spill resolution.
The company said that Grant Boyce was re-elected as a director with 27,064,043 votes (66.16%) in favor and 13,845,026 votes (33.84%) against.
Sirtex said the issue of performance rights to chief executive officer Gilman Wong was supported by 30,534,138 votes (74.87%) and opposed by 10,250,815 votes (25.13%).

INVION (FORMERLY CBIO)

Invion says that former CBio executives, including former chairman Stephen Jones, are being sued for $1,200,000 and have lodged a counterclaim for $1,246,666.96
Invion said that it began proceedings against Mr Jones, the chief executive officer, chief financial officer and company secretary in February 2012 relating to their resignations on or about October 12, 2011 and gross payments made to the officers (BD: Jun 25, 2012)
The company said "the counterclaims lack merit and will vigorously dispute them".
Invion was untraded at 5.3 cents.