Biotech Daily

Wednesday June 6, 2012

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH FLAT: ANTISENSE UP 19%, GENETIC TECH DOWN 13%**

*** US 606 PATIENT DATA SHOWS SIRTEX SIR-SPHERES SAFE, EFFICACIOUS**

*** BIODIEM LICENCES ANU DEGUE FEVER TECHNOLOGY**

*** PORTUGAL APPROVES PSIVIDA'S ILUVIEN FOR DME**

*** OPTISCAN SCOPE 'MORE ACCURATE, 100% SENSITIVE'; 1st ROYALTY**

*** SALOMAO & ZOPPI EVALUATE GENERA'S SIROCCO, TESTS**

*** CBA REDUCES TO 5.3% OF RESMED**

*** LANDON CLAY, EAST HILL TAKE 12% OF BIOTA**

*** HEARTWARE LOSES DIRECTOR CHRISTINE BENNETT**

*** RUSSIA, JAPAN GRANT BONE AXCESS PATENTS**

*** OMI DROPS SYRINGES, COAL, TIN - GOES GRAPHITE MINING**

MARKET REPORT

The Australian stock market climbed 0.29 percent on Wednesday June 6, 2012 with the S&P ASX 200 up 11.6 points to 4,043.7 points. Eight of the Biotech Daily Top 40 stocks were up, 11 fell, 14 traded unchanged and seven were untraded. All Big Caps were up.

Antisense was the best, up 0.3 cents or 18.75 percent to 1.9 cents with 45.4 million shares traded.

Living Cell and Prana climbed six percent or more; Optiscan and Starpharma were up more than three percent; Cochlear rose two percent; Bioniche and CSL were up one percent or more; with Acrux and Pharmaxis up by less than one percent.

Genetic Technologies led the falls, down two cents or 13.3 percent to 13 cents with 465,490 shares traded, followed by Uscom down 11.1 percent to eight cents with 7,500 shares traded.

Phosphagenics and Prima lost three percent; Alchemia, Avita, Phylogica and QRX shed more than two percent; Mesoblast and Universal Biosensors were down more than one percent; with Sirtex down 0.7 percent.

SIRTEX MEDICAL

Sirtex says a 600-patient retrospective study has found its SIR-Spheres are well-tolerated and effective internal radiotherapy for unresectable, colorectal cancer liver metastases.

Sirtex said the new study of more than 600 heavily pre-treated patients was presented at the American Society of Clinical Oncology meeting in Chicago, by lead investigator North Carolina State University's Dr Andrew Kennedy.

Sirtex said its SIR-Spheres were the only fully US Food and Drug Administration-approved microsphere radiation therapy for the treatment of colorectal liver metastases.

"This is the largest, most comprehensive study to date evaluating the use of selective internal radiation therapy in liver metastases from colorectal cancer," Dr Kennedy said.

"The data presented at ASCO confirm the safety and efficacy of this treatment option for patients and provide truly useful, validated information for clinicians," Dr Kennedy said.

"It is our hope that these results will help encourage appropriate patient selection discussion during tumor boards and with individual patients and their families," Dr Kennedy said.

Sirtex said that the investigator-initiated retrospective study presented at ASCO analyzed the outcomes of using SIR-Spheres microspheres in US patients treated since 2002, with endpoints including safety and tolerability, tumor response and survival.

The company said the study focused on 606 patients (233 women, 373 men) at 10 institutions, who received a total of 966 selective internal radiation therapy (SIRT) treatments.

Sirtex said the mean age was 61.5 years with a range from 20.8 years to 91.9 years and active extra-hepatic disease was present prior to the first SIRT procedure in 35.1 percent of patients.

The company said that more than 92.6 percent of patients had received prior chemotherapy, with more than 30 percent having had prior liver surgery or ablation.

Sirtex said that the median overall survival for these heavily pre-treated patients was 9.6 months from their first SIRT treatment, with a median follow-up of 8.6 months.

The company said the study found that reported adverse events were typically transient in duration and mild or moderate in severity.

Sirtex said that 45 percent of patients had fatigue, 28 percent experienced nausea and one percent had liver failure.

The company said that 2.1 percent of all treatments required an overnight stay following the procedure.

Sirtex said that the US experience of SIRT using SIR-Spheres microspheres for unresectable, heavily pre-treated colorectal liver metastases confirmed recently published data from international studies by Hendlisz, Seidensticker and Bester, who independently reported median overall survivals of 10.0 months, 8.3 months and 11.9 months, respectively, in similar cohorts of patients with chemotherapy refractory disease.

Sirtex Medical Inc president Mike Mangano said that the study results, "collected from experienced treatment sites across the US, are further evidence of the safety and efficacy of SIR-Spheres microspheres in heavily pre-treated patients".

"This also highlights that SIR-Spheres microspheres provide clear survival benefits with limited toxicity in a patient population with few treatment options," Mr Mangano said.

Sirtex fell four cents or 0.7 percent to $5.95.

BIODIEM

Biodiem says it has signed a term sheet to licence vaccine technology from the John Curtin School of Medical Research at the Australian National University.
Biodiem said the technology's first disease indication of the technology was dengue fever and it could also facilitate the design of vaccines against other infectious diseases including Murray Valley encephalitis and Japanese encephalitis.
The company said that dengue fever was caused by a mosquito-borne virus affecting between 50 million and 100 million people a year and according to the World Health Organization the incidence was increasing significantly.
Biodiem said that although only a small percentage of cases were fatal, non-fatal cases can be extremely debilitating.
The company said that dengue fever had no existing vaccine and control methods included variably effective attempts to address mosquito populations.
Biodiem said that the acquisition would complement its product portfolio of vaccine and antimicrobial technologies and the strategy to provide treatments for infectious diseases with attractive market potential.
The company said that the agreement would provide an exclusive licence to the technology in exchange for royalties to the Australian National University on any sales, or received as a result of outlicencing the technology for specific disease targets.
Biodiem said the agreement allowed it to outlicence the technology for other disease targets to accelerate development with minimal financial outlay by Biodiem.
Biodiem chief executive officer Julie Phillips said her company would acquire "a valuable asset which supports existing research work in the area of infectious disease vaccines and can also be licensed for other infectious diseases".
"The work done to date by the ANU researchers provides a base for strong intellectual property and exciting new vaccine development opportunities for licencees," Ms Phillips said.
Biodiem was unchanged at 7.7 cents.

PSIVIDA

Psivida says Portugal has granted marketing authorization for Iluvien for vision impairment associated with diabetic macular oedema, insufficiently responsive to available therapies.
Psivida said the Autoridade Nacional do Medicamento e Produtos de Saúde, Infarmed (National Authority of Medicines and Health Products) authorization followed the completion of the decentralized regulatory procedure in the European Union.
The company said that the Portuguese authorization was the third national approval in the EU, preceded by Austria and the UK.
Psivida chief executive officer Dr Paul Ashton said the company was pleased to receive marketing authorization in Portugal.
"We now have marketing authorization in three of the seven targeted EU countries," Dr Ashton said."We look forward to Iluvien receiving approval in the four remaining … countries, France, Germany, Italy and Spain, in the coming months."
The company said that more than one million people were living with diabetes in Portugal and according to partner Alimera's estimates, more than 55,000 people suffered from vision loss associated with diabetic macular oedema.
Psivida said that Iluvien was an injectable, sustained-release intravitreal insert that released sub-microgram levels of fluocinolone acetonide for up to 36 months for the treatment of chronic diabetic macular oedema.
Psivida was unchanged at $1.90.

OPTISCAN

Optiscan says a 178-patient trial has shown that its confocal microscope technology was 5.2 times more accurate for neoplasia than the standard and 100 percent sensitive.

Optiscan executive chairman Gus Holt told Biotech Daily that the trial used the company's first generation technology in the Pentax ISC-1000 and compared it with high resolution endoscopy.

Optiscan said a paper presented at Digestive Diseases Week in San Diego in May, 2012 compared the diagnostic yield, performance characteristics and clinical impact of high resolution endoscopy (HRE) with endoscope-based confocal laser endomicroscopy (ECLE) followed by targeted biopsy with HRE alone with targeted biopsy and random biopsy for detection of Barrett's oesophagus neoplasia.

Optiscan said the paper concluded that compared to high resolution endoscopy with random biopsy, high resolution endoscopy with endoscope-based confocal laser endomicroscopy and targeted biopsy improved detection of Barrett's oesophagus neoplasia with significantly fewer biopsies.

Optiscan said the study further sconcluded that endoscope-based confocal laser endomicroscopy led to greater sensitivity for diagnosis of neoplasia compared to high resolution endoscopy alone and impacted decision making.

The company said that 178 of 200 enrolled patients were evaluated at the time of analysis and on a per biopsy analysis, the overall diagnostic yield for neoplasia was 5.2 fold greater using ECLE (45.6% v 8.8%), despite fewer biopsies being obtained; despite fewer biopsies, 100 percent sensitivity was achieved with no missed disease; on a per patient analysis, of high resolution endoscopy with ECLE led to a four-fold increase in diagnostic yield for Barrett's oesophagus neoplasia.

Optiscan said that in 26 group B (HRE with ECLE) lesions, ECLE changed the HRE diagnosis to a correct diagnosis in 15 patients (53.6%) and correctly changed the treatment plan in nine patients (34.6%).

The company said that the data underpinned a "diagnose and treat" process that delivered significant patient, clinician and health care system benefits.

Optiscan said the trial was performed at Johns Hopkins Medical Institutions in Baltimore, Maryland; New York's Mount Sinai School of Medicine; Boston's Massachusetts General Hospital; Philadelphia's University of Pennsylvania and Germany's University of Mainz.

Mr Holt told Biotech Daily that the company received its first royalty payment for the Pentax ISC-1000.

Mr Holt said that although the payment was small it showed that the first generation six-year old technology had "showed some traction in the market".

Mr Holt said the company had developed the second generation confocal microscope, which was being prepared for market.

Optiscan said that three American Medical association category 1 current procedural terminology (CPT) codes on the use of optical endomicroscopy in the GI tract had recently been approved and were scheduled for implementation in January 2013.

The company said the CPT codes were the most widely accepted nomenclature used to report medical procedures and services under US private and public health insurance programs and were a prerequisite for obtaining coverage from health insurers.

Optiscan said the codes were "a significant milestone in the path to widespread adoption of a new technology".

Optiscan said that Barrett's oesophagus affected about 3.3 million adults in the US alone and could lead to oesophogeal adenocarcinoma, a dangerous cancer with a five year survival rate of about 17 percent and the fastest growing form of cancer in the US.

Optiscan was up 0.3 cents or 3.3 percent to 9.5 cents.

GENERA BIOSYSTEMS

Genera says it has signed a Sirocco diagnostic evaluation agreement with the Sao Paulo, Brazil-based Salomao & Zoppi Diagnosticos SA.
Genera said it would a Sirocco instrument and related equipment, training and reagents to enable the evaluation of Genera's Paptype human papillomavirus test and RTIplex respiratory pathogen test, intended to be incorporated into Salomao & Zoppi's test panel.
Genera said the agreement provided for the two companies to work collaboratively to develop new tests using Genera's Ampasand silica bead-based platform and Sirocco automated instrument (BD: Apr 24, 2012).
The company said that Salomao & Zoppi had identified a number of multiplexed assays for introduction in Sao Paulo, the richest state in Brazil, which comprises more than 40 million people.
Genera said that any resultant commercial agreements for the use of its technology in Brazil would be negotiated during the evaluation period, including any development payments for developing new tests.
The company said that subject to clinical trial protocols and equipment supply, the initial evaluation trial was expected to be completed within the next three months.
Genera's chief scientific officer Dr Karl Poetter said the company had "a well-developed strategy to expand the menu of proprietary tests running on Sirocco and our Ampasand silica bead based multiplexing platform".
"A progressive laboratory like [Salomao & Zoppi] is an ideal test development partner for Genera," Dr Poetter said.
Genera's executive chairman Lou Panaccio said the agreement and any subsequent commercial supply arrangements had "the potential to generate meaningful revenues for Genera and will greatly assist in the placement of additional Sirocco instruments and Ampasand tests in other jurisdictions".
Genera was untraded at 21 cents.

RESMED

The Commonwealth Bank of Australian and related entities have reduced their substantial holding in Resmed from 97,060,032 shares (6.32%) to 82,628,335 shares (5.31%).
The Commonwealth Bank said the sharse were held by nominee firms including Citicorp SBN and JP Morgan as well as companies including Bank of New York Melon, Citibank, JP Morgan Chase, RBC Dexia, HSBC Bank Plc and Westpac Bank.
Resmed was up three cents or one percent to $3.17 with 6.1 million shares traded.

BIOTA HOLDINGS

Landon Clay, East Hill Holding Co and associates have increased their substantial shareholding in Biota from 20,577,735 shares (11.33%) to 22,520,767 shares (12.35%).
Biota was unchanged at 74 cents.

HEARTWARE INTERNATIONAL

Heartware director Dr Christine Bennett has filed a final director's interest notice.
In materials to the Heartware annual general meeting chairman Ray Larkin Junior said Dr Bennett had been a director since 2004.
Heartware was untraded at $2.29.

BONE MEDICAL

Bone says that both Russia and Japan have granted patents for its Axcess oral peptide formulation technology.

Bone said that Japan had granted a patent for its Axcess II oral peptide formulation technology, while Russia had granted a patent for its Axcess IV oral peptide formulation technology.

Bone has been developing oral treatments of osteoporosis and arthritis.

Bone chairman, chief scientific officer and the inventor of the Axcess technology, Dr Roger New said Axcess II patent provided coverage for oral peptide products Capsitonin, oral calcitonin for osteoporosis and arthritis pain, and Capthymone, oral parathyroid hormone for osteoporosis.

Dr New said that both products offered significant potential advantages over the current leading therapies for these diseases.

Dr New said the Axcess IV patent provided protection for the oral peptide product Capthymone.

“It is estimated that some 34 million Russians are at high risk of bone fracture due to osteoporosis or osteopenia, making this a population with perhaps one of the most significant disease burdens from these illnesses anywhere in the world,” Dr New said.

“Russia is actively seeking to build a strong and competitive biopharmaceutical industry that can also leverage improved medical care for its citizens, so the grant of the Axcess IV patent is particularly welcome in that market,” Dr New Said.

Bone said that the Russian patent was the third issued patent for Axcess IV, following New Zealand.

Bone fell 0.1 cents or 20 percent to 0.4 cents with 2.45 million shares traded.

OMI HOLDINGS (FORMERLY OCCUPATIONAL AND MEDICAL INNOVATIONS)

OMI say it has the right to acquire Opirus Minerals Pty Ltd, the holder of the rights to a flake graphite exploration project in South Korea.

OMI said the acquisition would involve a significant change in the nature and scale of its activities and it would seek shareholder approval to proceed with the acquisition and if approval was obtained, the company would re-comply with Chapters 1 and 2 of the ASX Listing Rules, as well as change its name and raise further capital.

OMI was formerly a developer of safer syringes but was suspended from the ASX and had administrators appointed in 2009 (BD: Sep 1, Dec 14, 2009; Jan 25, 2010).

The company returned to trading and hoped to go coal and tin mining (BD: May 19, 2011).

OMI was up 0.2 cents or 66.7 percent to 0.5 cents with 57 million shares traded.