Biotech Daily

Monday September 12, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ANTISENSE UP 11%; COCHLEAR DOWN 20%**

*** COCHLEAR FALLS 27% ON NUCLEUS 5 IMPLANT RECALL**

*** GI DYNAMICS NAMES SUBSTANTIAL SHAREHOLDERS**

*** PRIMA COMPLETES US PHASE IIb ENROLMENT**

*** APPHIA MAKES 82% SELLING CALZADA'S 17% AVEXA TO JONATHAN LIM**

*** WILSON HTM REDUCES TO 5.55% OF IMPEDIMED**

*** HEARTWARE SHEEP TRIAL MEETS GOOD LABORATORY PRACTICE**

*** EUROPEAN SURFACE COATING PATENT GRANTED TO ANTEO**

*** CIRCADIAN APPOINTS DR IAN LEITCH CLINICAL RESEARCH DIRECTOR**

MARKET REPORT

The Australian stock market fell 3.72 percent on Monday September 12, 2011 with the S&P ASX200 down 156.2 points to 4,038.5 points.

Three of the Biotech Daily Top 40 stocks were up, 23 fell, seven traded unchanged and seven were untraded. All three Big Caps fell.

Antisense was the best of three, up 0.1 cents or 11.1 percent to one cent with 7.1 million shares traded, followed by Living Cell up 9.6 percent to 5.7 cents with 288,878 shares traded and Prana up 3.1 percent to 16.5 cents with 259,000 shares traded.

Cochlear led the falls, down as much as 26.9 percent to $52.77, closing down $14.68 or 20.3 percent to $57.50 with 2.7 million shares traded, followed by Viralytics down 13.1 percent to 53 cents and Allied Health down 10.4 percent to 4.3 cents on modest volumes.

Alchemia lost 8.2 percent; Pharmaxis fell 7.5 percent; Phosphagenics and Phylogica fell more than six percent; Bioniche, Bionomics, Nanosonics and Tissue Therapies lost five percent or more; Genetic Technologies and Prima fell more than four percent; Mesoblast, Patrys, QRX, Resmed, Reva and Starpharma were down more than three percent; with Acrux, Biota, Compumedics, CSL and Sunshine Heart down more than two percent.

COCHLEAR

Cochlear fell as much as 27 percent on the voluntary recall of the Nucleus 5 range of implants following an increase in the number of Nucleus CI512 failures.

Cochlear chief financial officer Neville Mitchell told Biotech Daily that the Nucleus C1512 was the main product in the 2009 released Nucleus 5 range, which had grown to 70 percent of implant revenue and more than 50 percent of total revenue.

In August Cochlear said implants accounted for $648 million in revenue, with sales of 24,661 Cochlear implants, implying the Nucleus 5 was responsible for about $453.6 million in revenue (BD: Aug 9, 2011).

Mr Mitchell said that Cochlear implants comprised 75 percent of the company's total revenue with bone anchored hearing aids (Baha) and upgrades making up the rest.

Cochlear said it was with "an abundance of caution" that it recalled those hearing implants, that were not yet implanted, with less than one percent of CI512 implants failing since the launch in 2009.

The company said that if failure occurred "the implant safely shuts down without injuring the recipient".

Cochlear said it was notifying healthcare professionals and regulatory authorities.

Mr Mitchell said that the company did not know the root cause of the problem.

He said that the Nucleus 5 range incorporated more than 50 innovations in design and manufacture.

The company said that in the event of a Nucleus CI512 series implant failure, recipients could be re-implanted with the previous model, Nucleus Freedom implant range, but said that all existing recipients with a Nucleus CI500 series implant could continue to use their system as normal.

Mr Mitchell said there were "adequate supplies at this stage" of the Nucleus Freedom.

Cochlear said the Nucleus CI500 range included the generally available CI512 as well as the Nucleus CI513, Nucleus CI551 double array implant and Nucleus ABI 541 Auditory Brainstem Implant which were "only available in limited [geographical] markets".

The company said the recall did not affect any previous implant models including the Nucleus Freedom range and the Nucleus 5 external devices such as the Nucleus CP810 and any previous generation externals were not subject to this recall.

Cochlear said the latest Nucleus 5 CP810 sound processor was fully compatible with Nucleus Freedom implants so recipients could "continue to receive all the functionality the latest Nucleus 5 system offers through this combination".

"Cochlear takes reliability extremely seriously and all necessary measures are being implemented to address this unexpected occurrence," the company said.

Cochlear said the financial impact of the recall was "difficult to predict at this stage".

Cochlear fell $19.41 or 26.9 percent from $72.18 to a low of $52.77 on the news and closed the day down $14.68 or 20.3 percent to $57.50 with 2.7 million shares traded.

GI DYNAMICS

GI Dynamics says ATV Associates, Domain, Polaris, Medtronic Johnson & Johnson Development, Cutlass Capital and Seedling LLC are its substantial shareholders.

GI Dynamics listed last week (BD: Sep 6, 2011).

The company said ATV Associates held the equivalent of 36,746,408 Chess Depositary Instruments or 13.27 percent of the company followed by Domain (13.27%), Polaris (13.18%), Medtronic (12.76%), Johnson & Johnson Development (12.28%), Cutlass Capital (5.55%) and Seedling LLC (5.33%).

GI Dynamics fell 8.5 cents or 9.2 percent to 83.5 cents.

PRIMA BIOMED

Prima says it has completed patient enrolment in its US phase IIb trial of its CVac immunotherapy ovarian cancer vaccine.

Prima said it began enrolment for the 60-patient, randomized, open-label trial in July 2010 (BD: Jul 23, 2010).

The company said at that time that the trial would evaluate the safety and efficacy of CVac as a single agent for epithelial ovarian cancer patients who are in clinical complete remission following first or second-line chemotherapy at sites including the Fred Hutchinson Cancer Center in Seattle Washington and the Peter MacCallum Cancer Center in Melbourne and hoped recruitment would be completed by April 2011.

Prima said today that the first patient cohort, of seven patients, completed the first treatment in February, with no therapy-related adverse effects (BD: Feb 1, 2011).

The company said the trial was being conducted at five sites in Australia and 15 across the US, including the Stanford Medical Centre.

Prima said the trial's primary objectives were to confirm the manufacturing comparability of multiple sites, potency assay, safety of CVac and compare disease-free progression between CVac and the control group.

The company said that to assess disease-free progression clinical assessments would be performed every four weeks, with imaging by computed tomography or magnetic resonance imaging performed every 12 weeks, until progression or withdrawal of the patient from trial.

Prima chief executive officer Martin Rogers told Biotech Daily that preliminary results would be presented in June 2012, with detailed results in 2013.

Mr Rogers said

"The completion of enrolment into the CVac phase IIb trial represents an important milestone for the company in our pathway towards commercialization for Cvac," Mr Rogers said in a media release.

In February the European Medicines Agency approved an 800-patient, a double-blind, placebo-controlled phase III clinical registration trial of CVac, pending country and hospital approvals, with enrolment expected to begin in "mid-2011" and be completed by the end of 2012, with interim data expected in late 2012 or early 2013 (BD: Feb 21, 2011).

Mr Rogers told Biotech Daily that Prima was in the process of applying for US Food and Drug Administration and Australian Therapeutic Goods Administration approval for the phase III trial.

Prima fell one cent or 4.9 percent to 19.5 cents with 9.1 million shares traded.

AVEXA, CALZADA

Apphia Investments has ceased its substantial holding in Avexa selling 144,500,564 shares (17.05%) to Jonathan Keng Hock Lim.

The Singapore-based Apphia said in a notice filed by Wilson HTM, that it sold the shares in an off-market transfer for $7,369,529 or 5.1 cents a share.

Apphia acquired the shares in October 2010 for $4,046,016 or 2.8 cents a share, when Calzada sold the stake for a loss of $270,000 (BD: Oct 19, 2010).

Mr Lim's notice, also filed by Wilson HTM, said he had become a substantial shareholder with 144,500,564 shares or 17.05 percent of the company and gave his address as care of Paul Dickson of Woff Street, Beaumaris, Victoria.

Avexa fell 0.3 cents or six percent to 4.7 cents.

Calzada fell 0.5 cents or 7.8 percent to 5.9 cents.

IMPEDIMED

Wilson HTM has reduced its substantial holding in Impedimed from 10,488,240 shares (6.7%) to 8,682,814 shares (5.55%).
Impedimed raised $10 million through the placement of 14.3 million shares at 70 cents a share at the end of last year (BD: Dec 3, 2010)
Wilson HTM said it had bought and sold shares through a range of accounts between June 6 and September 6, 2011.
The largest parcel of shares sold was 1,536,047 shares sold for $819,564 or 53.4 cents a share.
Impedimed fell half a cent or 0.9 percent to 55 cents.

HEARTWARE

Heartware says its miniature ventricular assist device (MVAD) has met the objectives for good laboratory practice in animal studies, a step towards human clinical studies.
Heartware said the pre-clinical trial data objectives for system performance, haemo-compatability and bio-compatibility was presented at the International Society for Rotary Blood Pumps meeting and pre-clinical studies showed the miniature device had comparable blood flow characteristics to the company's left ventricular assist device.
The presentation showed that of nine sheep, two developed "iatrogenic" or medical procedure-caused outcomes, with one sheep having pericardial effusion or the escape of blood or fluid into the outer layer of the heart and a second sheep had cardiac tamponade or a stoppage of blood flow. The other seven sheep "survived to term".
Heartware said there were no device-related thrombo-embolic events despite sub-therapeutic international normalized ratio for anti-coagulaiton.
The company said the MVAD pump was a development-stage device, about one-third the size of the Heartware left ventricular assist device (HVAD), requiring less invasive surgery.
Heartware said the miniature pump was expected to be implanted without the need for a median sternotomy of the rib cage, as was demonstrated in the preclinical study presented at the Congress.
The company said that by reducing the invasiveness of the surgery, it hoped to be able to treat a greater proportion of heart failure patients.
Heartware said the MVAD was based on the same impeller suspension technology used in the HVAD, with its single moving part held in place through a combination of passive-magnetic and hydrodynamic forces.
The company said the MVAD, like the HVAD, was designed to support the heart's full cardiac output, with the capability for partial support.
The surgical director at Chicago's Northwestern Memorial Hospital Prof Edwin McGee Jr said the MVAD "was successfully implanted via a left thoracotomy, without cardio-pulmonary bypass and exhibited excellent blood handling characteristics during the course of the study".
"At the 90-day explant date, there was no evidence of device wear or thrombus and end-organ gross and histological results were positive," Prof McGee said.
Heartware chief executive officer Doug Godshall said that based on the outcomes, "we remain on-track to commence human clinical studies of the MVAD system, with a newly designed controller, early next year".
"We look forward to exploring the potential of the MVAD pump for both left and right ventricular support, as well as the potential to benefit smaller-sized patients or those with smaller hearts, including pediatric patients," Mr Godshall said.
Heartware was untraded at $1.62.

ANTEO DIAGNOSTICS

Anteo says the European Patent Office has granted the 'Generation of Surface Coating Diversity' patent announced as intended to grant in March 2011 (BD: Mar 9, 2011).
Anteo said the patent covered the intellectual property that led to the discovery of the Mix&Go technology, ensuring that the process used to bind antibodies to more than 8,000 different types of surfaces could not be copied in the European market.
The company said the patent covered additional screening exercises that could be initiated to identify new 'glues' for a broad range of other industries and sectors.
Anteo said that the Australian Patent Office had accepted its application for a patent entitled 'Use of Metal Complexes' and it expected the patent to be granted within six months.
The company said there were many commercially important reasons to bind biological molecules onto synthetic materials such as plastics, for example, creating pathology tests for various diseases, in which molecules were often fragile and do not react well when exposed to non-biological conditions.
Anteo said the 'Use of Metal Complexes' patent covered the use of Mix&Go to facilitate the binding process.
The company said the patent's acceptance was important as it protected the Mix&Go technology, as well as the methods for generating alternative versions of Mix&Go.
Anteo said additional patents had been filed to extend the protection for Mix&Go.
Anteo chief executive officer Dr Geoff Cumming said the grant of the European patent and the acceptance of the Australian patent application were "further steps in building greater value into this game-changing technology".
Anteo was unchanged at seven cents with 4.3 million shares traded.

CIRCADIAN TECHNOLOGIES

Circadian has appointed Dr Ian Leitch as its director of clinical research effective today.
Circadian said that initially, Dr Leitch would be based in the US for the newly-created position and would relocate to Australia in 2012.
The company said Dr Leitch had more than 15 years of research and management experience from drug discovery through clinical development in early stage and large biotechnology and pharmaceutical companies.
Circadian said that previously Dr Leitch worked in Amgen's medical sciences group in California developing novel therapeutics in Amgen's oncology pipeline where he had responsibility for the oversight, design, management and execution of phase I and phase II clinical studies in oncology.
Prior to Amgen, Dr Leitch was at the US-based Miravant Medical Technologies, specializing in photodynamic medicine using light-activated drugs and light delivery devices and was previously a senior research officer at the University of Newcastle, based at the John Hunter Hospital.
Circadian said Dr Leitch held a Ph D from Monash University's Department of Pharmacology completing part of the degree at the University of California, Santa Barbara as part of an Education Abroad program scholarship.
Circadian was untraded at 57 cents.