Biotech Daily

Wednesday September 14, 2011

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: UNIVERSAL BIO UP 6%; COCHLEAR DOWN 15%**

*** COCHLEAR TESTING IMPLANTS; FALLS ON RENEWED COMPETITION**

*** UNIVERSAL BIOSENSORS BENEFIT FROM FDA LIFESCAN APPROVAL**

*** ANTISENSE BEGINS FINAL DOSING IN PHASE I ATL1103 TRIAL**

*** PRIMA TO ENROL 1st PHASE III OVARIAN CANCER PATIENT BY YEAR-END**

*** IM MEDICAL HOPES TO RAISE UP TO $3.3m**

*** CM CAPITAL INCREASES, DILUTED TO 25% OF SUNSHINE HEART**

*** PHOSPHAGENICS, COY COSMETIC COMPANY PARTNER FOR STUDY**

*** EASTLAND SAYS TRIAL ON-TRACK, FUNDING TO BE RESOLVED**

MARKET REPORT

The Australian stock market opened up but closed down 1.64 percent on Wednesday September 14, 2011 with the S&P ASX200 down 66.9 points to 4,005.8 points.

Eight of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and seven were untraded.

Universal Biosensors was the best, up six cents or 6.4 percent to $1.00 with 215,269 shares traded.

Cellmid and Sunshine Heart climbed five percent or more; Compumedics rose 4.65 percent; Viralytics was up 3.7 percent; with Bionomics up 1.1 percent.

Cochlear led the falls, down $8.80 or 14.6 percent to $51.30 with 2.3 million shares traded.

Alchemia, Circadian and Genera lost more than seven percent; Phylogica was down 6.7 percent; Anteo, Living Cell and Nanosonics fell five percent or more; Benitec lost 4.2 percent; Phosphagenics was down 3.3 percent; Acrux, CSL, Mesoblast, Prima and QRX shed more than two percent; with Patrys, Pharmaxis, Reva and Tissue Therapies down by more than one percent.

COCHLEAR

Cochlear is believed to be examining between 100 and 200 failed Nucleus Five 512 series implants to find the cause of the fault that prompted Monday's recall (BD: Sep 12, 2011).
Cochlear chief financial officer Neville Mitchell said that about 25,000 Cochlear Implant 512 units had been surgically implanted and there was a failure rate below one percent.
Mr Mitchell would not say how many hearing implants had been explanted but said that the company would carry out a thorough examination to determine the fault or faults.
Mr Mitchell said that implant went from working, to working intermittently and then failing.
He said there were no reports of any shocks or any other harm to users.
"Cochlear is currently examining the explanted units," Mr Mitchell said.
"We want to do this in a really controlled environment, do it carefully and thoroughly and get to the root cause," Mr Mitchell said.
"We don't want to rush it and we are committed to get it right," Mr Mitchell said.
The CI 512 is the primary implant of the 2009-released Nucleus Five range and has contributed more than 50 percent of Cochlear's revenue.
Separately, analysts have said Cochlear's share price was affected today by the Swiss-based Sonova announcing US Food and Drug Administration market re-entry of the Advanced Bionics Hires 90K cochlear implant, which was recalled in November 2010.
On its website Sonova said the Advanced Bionics Hires 90K would be available in the US and had approval from other regulatory bodies, including Health Canada and European regulators to resume distribution of the implant.
The company said Advanced Bionics "instituted a voluntary recall in November 2010 after becoming aware of a rare issue with the Hires 90K cochlear implant".
"Of the more than 28,000 implanted Hires 90K devices, only two (0.007%) explanted devices were confirmed to have the issue," Sonova said.
Sonova said it acquired Advanced Bionics in December 2009.
On Monday Cochlear fell as much as 26.9 percent to $52.77 on news of the recall, closing down $14.68 or 20.3 percent to $57.50, recovering 4.5 percent yesterday to $60.10 and today lost a further $8.80 or 14.6 percent to $51.30 with 2.3 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says Johnson & Johnson's Lifescan has received US Food and Drug Administration clearance to market its Onetouch Verio blood glucose system.
Universal Biosensors chief executive officer Paul Wright said the Onetouch Verio received initial clearance in February 2011 and the new clearance related to a new meter to be used in conjunction with the previously approved strips manufactured in Melbourne.
Mr Wrights said the approval was a major milestone for his company and Lifescan.
Mr Wright told Biotech Daily that the new meter was developed by Lifescan and the approval "does not trigger a milestone payment".
"Once Lifescan launches the new meter in the US this will increase UBI's strip volume sales," Mr Wright said.
"Lifescan will ultimately determine when to launch the approved product in the US as part of its global rollout of Onetouch Verio," Mr Wright said in a media release.
Universal Biosensors said the North American self-monitoring blood glucose market was dominated by Lifescan with about 33 percent of market share in 2009.
The company said there were estimates that the US market would grow from $US2.77 billion in 2008 to $US5.5 billion in 2015 or 40 percent of the world market with a compound annual growth rate of 11 percent.
Universal Biosensors was up six cents or 6.4 percent to $1.00.

ANTISENSE THERAPEUTICS

Antisense says dosing of subjects has begun in the final stage of the phase I trial of growth hormone receptor-targeting drug ATL1103.

Antisense said the trial of ATL1103 was for a range of potential indications related to high IGF-I levels and excessive growth hormone activity, including the growth disorder acromegaly, diabetic retinopathy, nephropathy and some cancers.

The company said the primary objective was to assess the safety, tolerability and pharmacokinetics of subcutaneous ATL1103, with a secondary objective to obtain data on the effect of ATL1103 on IGF-I levels in the blood of the subjects

Antisense said that reducing elevated levels of serum IGF-I to normal was the therapeutic endpoint in the treatment of the growth disorder acromegaly, and reducing the effects of IGF-I had a potential role in the treatment of diabetic retinopathy, nephropathy and certain forms of cancer.

Antisense said the multiple dosing stage followed the completion of the initial single ascending dose stage of the trial in which 24 subjects were administered four dose levels of ATL1103 as a single injection starting at 25mg and escalating to 75mg, 250mg and 400mg or placebo.

The company said that no serious adverse events were reported in the first stage of the trial with general safety observations appearing to be in line with those reported in the clinical testing of other second generation antisense drugs at similar doses.

Antisense said that based on a review by the data monitoring committee of the safety data from the single ascending dose stage, the 250mg dose level has been selected for the multiple dose component of the study.

The company said that multiple dosing would be undertaken in 12 subjects, with six subcutaneous doses of either ATL1103 or placebo administered on Days 1, 3, 5, 7, 14 and 21, with subjects monitored to Day 35.

Antisense said the ATL1103 phase I trial was a randomized, placebo-controlled, double-blind study of single ascending doses and multiple doses of ATL1103 in healthy adult male subjects aged between 18 and 45 years.

The company said the phase I trial was not primarily designed to assess the efficacy of ATL1103, which would occur in larger and longer term clinical trials in patients, but the monitoring of serum IGF-I in subjects in the multiple dose stage should provide a useful guide or indication of the potential effectiveness of ATL1103 as a treatment.

Antisense said the ATL1103 phase I trial was blinded, so definitive details on the outcomes would not been known until the study was un-blinded and all the clinical trial data was entered into the trial data base and the database locked for statistical analysis.

The company said it expected this to be finalized in time for the results to be reported by the end of this year, ahead of previous expectations.

Antisense said it was also undertaking an ATL1103 cancer experimental program in parallel with the phase I trial.

The company said the cancer program had been established with University of California Los Angeles' Dr Pinchas Cohen whose laboratory team will look at ATL1103's effect on exploratory markers of cellular activity relevant to cancer in the serum of the subjects from the multiple dose stage of the Phase I trial of ATL1103.

Antisense said the data would assist in determining the potential of ATL1103 to prevent certain forms of cancer in high risk individuals.

Antisense was unchanged at 0.9 cents with 20.1 million shares traded.

PRIMA BIOMED

Prima hopes to enroll its first phase III trial ovarian cancer patients in Australia and Europe by the end of 2011 with the first US patients expected to be enrolled in February 2012.
Prima said it expected to complete enrolment of 800 patients by April 2013.
The company said the cancer vaccine study to be known as Canvas would be event-driven and timelines would be dependent on patient outcomes, such as how long they stayed in remission and stayed alive, so timelines were indicative only.
Prima said the multinational, randomized, double-blinded, placebo-controlled trial of CVac as a maintenance treatment for epithelial ovarian, primary peritoneal, or fallopian tube cancer in complete remission intended to definitively establish that CVac was able to extend the time in remission, extend overall life expectancy and improve quality of life.
Prima said it had applied for manufacturing authorization for its CVac immunotherapy manufacturing facilities in Melbourne and Leipzig Germany and the facilities had been inspected by the respective regulators.
The company said the application was with Germany authorities and a decision from the Australian Therapeutic Goods Administration was “due in the near future”.
Prima fell half a cent or 2.6 percent to 19 cents with 8.1 million shares traded.

IM MEDICAL

IM Medical says it hopes to raise up to $3,316,486 in a non-renounceable one-for-six rights issue at 0.5 cents a share.
IM said each new share would come with an attaching option exercisable at one cent by September 30, 2016.
The company said the offer was not underwritten and was subject to a minimum subscription of $2.5 million,
IM said Patersons Securities was the lead manager for the issue.
The company said the funds would recapitalize the company and pay outstanding creditors and converting loans.
IM said a shareholder group associated with the previous management blocked the conversion of loans at last month’s extraordinary general meeting (BD: Aug 17, 2011).
The company said the ASX provided conditional waivers for the rights issue including the disclosure of the financial trading performance of the radiology business, the use of the funds and if the radiology business was sold and the company acquires a business or assets or otherwise changes its activities that it complies with the Listing Rules.
IM said it intended to sell the radiology business to Capitol Health for 45.5 million Capitol shares and up to $600,000 in performance related payments.
The company said that major shareholder and director Dr Mark Scott intended to sell his entire holding in the company to clients of Patersons Securities.
IM is in a suspension and last traded at five cents.

SUNSHINE HEART

CM Capital VT4B as trustee for Venture Trusts 4A and 4B increased its share-holding in Sunshine Heart but has been diluted through placements from 275,142,260 shares (27.2%) to 300,142,260 shares (25.24%).
CN said the 25,000,000 shares were acquired for $1,000,000 in a private placement at four cents a share.
Sunshine Heart was up 0.2 cents or five percent to 4.2 cents with 1.8 million shares traded.

PHOSPHAGENICS

Phosphagenics says an unnamed cosmetic and dermatology company will conduct a human study on an unnamed cosmetic using its transdermal delivery system.
Phosphagenics chief executive officer Dr Esra Ogru said the partnership with another cosmetic company was further endorsement of the efficacy of the company's tocopheryl phosphate mixture or TPM technology.
"There is growing recognition from leading global cosmetics and dermatology companies that TPM can be a major point of difference for them in the marketplace," Dr Ogru said.
"We have consistently demonstrated that TPM enables superior delivery of active ingredients topically and transdermally and have proven the versatility of this technology by applying it both to cosmetic and pharmaceutical compounds," Dr Ogru said.
Phosphagenics fell half a cent or 3.3 percent to 14.5 cents with 2.9 million shares traded.

EASTLAND MEDICAL SYSTEMS

Eastland says its African trials are funded and enrolling patients for the sublingual Artimist paediatric malaria trial.
Last week Eastland said it received a confusing email alleging that due to cash-flow problems, which the company rejected, Artimist trial sites would not be initiated (BD: Sep 2, 2011).
Eastland said it received an email from London Pharma employee Clive Booles saying that he had been asked by the directors of Protopharma "to inform you that due to cash-flow issues the Ghana and Tanzania sites for the study will not be initiated".
Eastland said at that time that Mr Booles was not an officer of Protopharma which it had contracted for the trials of the sublingual treatment of paediatric malaria and in turn Protopharm had contracted London Pharma to undertake aspects of the Artimist program.
Today, Eastland said there had been a delay in contacting the Protopharma directors as a one irector had been involved in an accident and was not available.
The company said Protopharma directors confirmed that the trial was progressing and the Burkina Faso site was still enrolling and treating patients and they expected that the trials would begin in Ghana and Tanzania as soon as the financial situation was resolved.
Eastland said there would be more than the required 150 patients so no part of the trial should be compromised.
Eastland said Protopharma's actions would have an impact on the completion date for the trial, the company was awaiting confirmation of a date from Protopharma.
Eastland said it was up-to-date with its payments to Protopharma on invoices received for confirmed expenditure and was fully funded to meet its contractual obligations to Protopharma.
Eastland said it was working with Protopharma to assist in resolving its cash-flow issues and have offered a number of solutions.
Eastland fell 0.2 cents or 10.5 percent to 1.7 cents with 1.1 million shares traded.