Biotech Daily

Friday September 4, 2009

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH UP: CYTOPIA UP 53%; ANTISENSE DOWN 9%**

*** FDA GREENLIGHTS COCHLEAR NUCLEUS 5 LAUNCH**

*** FDA APPROVES CYTOPIA US PHASE I/II CYT387 MYELOFIBROSIS TRIAL**

*** LARGE SCALE LAB TRIAL SUPPORTS GENERA'S PAPTYPE HPV TEST**

*** US PACEMAKER PATENT FOR USCOM**

*** AGENIX VARIES CONVERTIBLE NOTE**

*** CATHRX APPOINTS AMANDA WONG CFO**

MARKET REPORT

The Australian stock market edged up 0.13 percent on Friday September 4, 2009 with the S&P ASX 200 up 5.9 points to 4435.5 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 11 fell, nine traded unchanged and three were untraded.

Cytopia was best, climbing as much as 6.5 cents or 68.4 percent to 16 cents before closing up five cents or 52.6 percent at 14.5 cents with 536,605 shares traded, followed by Cathrx up eight cents or 32.65 percent to 32.5 cents with 35,445 shares traded.

Genetic Technologies, Impedimed and Universal Biosensors climbed more than nine percent; Acrux and Genera were up more than seven percent; Living Cell and Psivida rose more than six percent; Starpharma was up 5.4 percent; Phosphagenics was up 4.55 percent; Chemgenex and Uscom were up more than three percent; Compumedics rose 2.5 percent; with Biota, Clinuvel and CSL up more than one percent.

Antisense led the falls, down 0.4 cents or 9.1 percent to four cents with 110,000 shares traded, followed by Benitec down 7.9 percent to 3.5 cents and Tyrian down 0.1 cents or 5.3 percent to 1.8 cents with 6.4 million shares traded.

Optiscan and Prana shed more than two percent; with Alchemia, Peplin, Progen and Resmed down more than one percent.

COCHLEAR

The US Food and Drug Administration has approved the two pre-market approval supplements for Cochlear's Nucleus 5 system.
Cochlear said the full system of implant and sound processor would be released in the US on September 8, 2009 and the new system had "the world's thinnest cochlear implant … the world's most advanced sound processor for a cochlear implant" and a bi-directional remote assistant.
Cochlear has said the Nucleus 5 implant and external processor were compatible with the Nucleus Freedom system and could be released independently (BD: Jul 14, 2009)
The company said the Nucleus 5 was approved for sale in Europe with a roll-out expected in the next six months and was already available in the UK.
Cochlear climbed 28 cents or 0.46 percent to $61.37.

CYTOPIA

Cytopia says the US Food and Drug Administration has approved its investigational new drug application for phase I/II trials of CYT387 for myelofibrosis.
Cytopia said the small-molecule oral JAK1 and JAK2 kinase inhibitor CYT387 was designed for the treatment of haematological disorders.
Cytopia said myelofibrosis was a life-threatening scarring of the bone marrow.
The company said the study would be conducted at the Mayo Clinic in Rochester Minnesota under the chairmanship of Dr Ayalew Tefferi, a key opinion leader in the treatment of myeloproliferative disorders and expected to open enrolment by the end of 2009, with further details following site ethics committee approval.
The company said CYT387 was the second compound to enter clinical trials with the anti-cancer vascular-disrupting agent CYT997 in Australian phase II studies.
Cytopia said that hyperactivity of the JAK2 enzyme was known to cause haematological conditions known as myeloproliferative disorders or MPDs, a group of diseases including myelofibrosis, polycythemia vera and essential thrombocythemia.
Cytopia said it had also identified potential activity of CYT387 in a range of cancers "which may substantially enlarge the value of this compound".
The company said that dual JAK1 and JAK2 inhibition was likely to increase the clinical benefit in these disease indications and broaden therapeutic opportunities for CYT387.
Cytopia said JAK kinase inhibitors with similar profiles were being trialed in inflammatory diseases such as rheumatoid arthritis.
The company said CYT387 had optimized JAK1 and JAK2 inhibition while minimizing unwanted activity seen with other JAK2 inhibitors in clinical development.
Cytopia's chief executive officer Andrew Macdonald said approval of the second trial was a milestone in the development of the company's suite of small molecule drugs.
"With a strong package of preclinical data, the prospects for CYT387 are excellent," Mr Macdonald said.
Cytopia said there was "considerable commercial interest in the JAK2 target" with no selective JAK inhibitors having completed late stage clinical trials and few compounds in development that met a desirable product profile.
Cytopia said it would seek to develop CYT387 through a commercial partnership and had been in discussions with potential partners for some time. The company said that a similar JAK2 inhibitor in clinical development was recently licenced by Onyx Pharmaceuticals for $US550 million including a $US25 million up-front payment and double-digit royalties.
Cytopia climbed as much as 6.5 cents or 68.4 percent to 16 cents before closing up five cents or 52.6 percent at 14.5 cents with 536,605 shares traded.

GENERA BIOSYSTEMS

Genera says a study of 894 cervical smear tests has shown its Paptype false negative rate to be significantly lower than the market leading Hybrid Capture 2 test.

Genera said the major clinical study on its Paptype human papillomavirus detection assay, was conducted with Melbourne's Royal Women's Hospital, a World Health Organisation reference centre for the study of human papillomavirus (HPV).

The study collected specimens from 894 women who were referred to the hospital for further examination, after receiving abnormal Pap smear results.

The specimens were tested with Paptype and Qiangen's Hybrid Capture 2, which Genera said was "the clear market leader in the $US350 million HPV testing market".

Genera said the study's objective was to compare the two tests in the detection of histologically-proven high grade cervical pre-cancerous lesions - that is, high-grade precancerous changes, identified and confirmed by a pathologist examination of tissue specimens.

Genera said that of 531 specimens shown by histology to be positive for cervical pre-cancer the HC2 test returned 111 false negatives (20.9%), compared to 47 from Paptype (8.9%).

The company said a false negative meant the fails to correctly identify a patient with disease and this would mean that significantly more women would have undetected cervical pre-cancerous lesions if tested with HC2, than with Paptype.

Genera's chief executive Dr Allen Bollands said the result was "excellent … and confirms the superiority over HC2 that was hinted at by our pilot study, the results of which were released late last year" (Oct 15, 2008).

"In Paptype, we have a test which is not only competitive in terms of its operational features, but also in the value of results that it generates," Dr Bollands said.

"HPV testing is forecast to become a billion dollar-plus market and with appropriate commercial backing, there's no reason why Paptype couldn't account for a significant portion of that," Dr Bollands said.

Genera said the study also showed that as the cervical pre-cancer advances towards cancer, Paptype's likelihood of detecting it increased.

Genera said 327 women in the study were shown histologically to have either the most serious form of cervical pre-cancer CIN3, or actual cancer.

Paptype had a false negative rate amongst these women of just 5.5%, compared to 16.2% for HC2.

The company said three of the HC2 false negatives were called "indeterminate" by Paptype, with the test unable to detect any human DNA in the specimen, indicating the possibility of specimen mishandling.

In a clinical situation, with Paptype, this would lead to a retest, but Genera said the HC2 test did not have that control, meaning there was no way of distinguishing a genuine HPV negative result, from one caused by an absence of specimen.

The company said Paptype's human control meant a reduced risk of false negatives.

Genera said that unlike HC2, Paptype not only detected the cancer-causing types of HPV, but could simultaneously and specifically identify the different genotypes.

The study also reported a high level of correlation between the genotypes detected by Paptype and those detected by a reference HPV genotyping test, manufactured by Roche.

Genera said the clinical trial scientists at the Royal Women's Hospital reported that the automation of genotyping results generation for Paptype was more reliable than the manual process involved in the Roche assay.

Genera was up 4.5 cents or 7.0 percent to 68.5 cents.

USCOM

Uscom says the US Patent office has allowed a patent describing a novel method for optimizing pacemakers.
Uscom said the electrophysiology market was rapidly growing and the patent described a simpler and more accurate method for optimizing pacemakers after implantation.
The company said pacemakers were often inserted as part of the treatment for heart failure to assist the heart function effectively.
Uscom said it was focused on developing the electrophysiology applications of its ultra-sonic cardiac output monitors and was committed to an application-specific partnership with a specialist electrophysiology company.
Companies with a substantial electrophysiology and pacemaker business include St Jude, Guidant, Boston Scientific and Medtronic, Uscom said.
The company said its monitor could "simplify and improve current methods of pacemaker management".
Uscom was up three cents or 3.7 percent to 85 cents with 1,000 shares traded.

AGENIX

Agenix says has a deed of variation with convertible note-holders to vary shareholder approval of the October 2008 note placement from October 1, 2009 to December 1, 2009.
The company said in October 2008 that payment in full would be required by October 1, 2009 in the event that shareholder approval was not obtained (BD: Oct 7, 2009).
Agenix said at that time the proceeds were to fund the US phase II Thromboview trial and legal action in China (see Biotech Daily; August 29, 2008).
The company said the variation also changed the conversion price for the final payment of $100,000 payable by Sino Sky Holdings from two cents to half a cent per share in line with the conversion number granted in the August 2009 convertible note placement.
Agenix said that under the deed of variation, payment of the settlement sum by Shanghai Rui Guang Bio-Pharma Development Company (SHRG) by which SHRG was to pay Agenix the total amount of RMB44,000,000 ($A8 million) by November 30, 2009 would constitute an early redemption event and Sino Sky could request repayment of its investment under the 2008 deed, subject to the liquidity requirements of the company.
The company said it was finalizing its 2007-'08 financial report with the auditors and expected to lodge it and send notices for the annual general meeting "shortly".
Agenix is in a voluntary suspension and last traded at 1.7 cents.

CATHRX

Cathrx says Amanda Wong has been appointed chief financial officer replacing Simon Chiu, effective from September 28, 2009.
Cathrx said Mr Chiu would remain with in the company's finance division.
Cathrx said Ms Wong had Bachelor degrees in Arts, Economics and Law.
Cathrx was up eight cents or 32.65 percent to 32.5 cents.