Biotech Daily

Thursday September 4, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ADMEDUS UP 10%, ANTISENSE DOWN 13%**

*** GENERA HPV, RESPIRATORY TESTS TO TGA; STI TESTS, MORE TO COME**

*** REPRODUCTIVE HEALTH: 'SALES THIS YEAR, PROFIT IN 2017'**

*** ASCEND PLANS BASAL CELL, BREAST CANCER TRIALS FOR 2015**

*** TISSUE THERAPIES PLEADS SCHULTZ TO ASX 21% QUERY**

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

*** USCOM: 'FOUR STUDIES SUPPORT BROAD MONITOR APPLICATIONS'**

*** RESONANCE JOINS US LIVER DISEASE FORUM**

*** CONSTABLES BELOW 5% OF ANTISENSE**

*** BIOPROSPECT REQUESTS 'RESTRUCTURE' TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.44 percent on Thursday September 4, 2014 with the S&P ASX 200 down 24.8 points to 5,631.3 points. Ten of the Biotech Daily Top 40 stocks were up, 17 fell, six traded unchanged and seven were untraded.

Admedus was the best, up 1.5 cents or 10 percent to 16.5 cents with 5.5 million shares traded.

Analytica climbed 8.8 percent; Neuren was up 7.1 percent; Ellex rose 5.8 percent; Prana was up 4.3 percent; Tissue Therapies was up 3.5 percent; Avita and Nanosonics rose two percent or more; Clinuvel climbed 1.8 percent or more; with Alchemia up 0.8 percent.

Antisense led the falls, down two cents or 13.3 percent to 13 cents with 2.6 million shares traded, followed by Biotron down 11.5 percent to 11.5 cents with 1.4 million shares traded.

Patrys lost 8.7 percent; Acrux, Benitec, Impedimed and Medical Developments fell more than four percent; Bionomics, Cellmid, GI Dynamics and Mesoblast were down more than three percent; Cochlear, Starpharma and Universal Biosensors shed more than two percent; Atcor, Living Cell and Viralytics were down more than one percent; with CSL and Sirtex down by less than one percent.

GENERA BIOSYSTEMS

Genera says it has submitted a conformity assessment application to the Australian Therapeutic Goods Administration for its Paptype human papillomavirus detection assay.
Genera said that the Paptype was its lead molecular diagnostic assay developed on its Ampasand multiplexing platform, with the follow-on assay, RTI-Plex, a 17-plex respiratory viral panel assay to be added to the submission by September 26, 2014.
The company said that following TGA approval, the products would be included on the Australian Register of Therapeutic Goods and then gain Conformité Européenne (CE) mark for commercial supply in the 26 member states of the EU, as well as within Australia.
Genera executive chairman Lou Panaccio said the company expected TGA approval in 2015, which would “put us in a position where we can aggressively market both Paptype and RTI-Plex to any pathology laboratory in Australia and Europe”.
The company said it had assistance from Healthscope Pathology and Sonic Healthcare in the studies required for the validation of the two products.
Genera said that the current generation of Paptype, based on solid phase polymerase chain reaction (PCR) confered material workflow benefits to customers compared to the first generation of Paptype approved by the TGA in 2010, with manual operator handling steps cut from 11 to three, and assay run time, excluding PCR, declining from 3 hours 45 minutes to under 1 hour 10 minutes.
Genera said that since 2010, the utility of incorporating simultaneous genotyping of certain high risk human papillomavirus types into a human papillomavirus testing assay had been validated with the FDA and other regulatory agencies.
The company said the global market for human papillomavirus testing was expected to exceed $US2 billion a year annum as human papillomavirus testing moved to replace the pap smear as the front line screening tool in the fight against cervical cancer in women.
Genera said that proposed amendments to Australia’s National Cervical Screening Program meant the Government was likely to undertake an education campaign about the benefits of human papillomavirus testing and the Australian market was projected to grow to 1.3 million tests a year by 2016 with universal availability through its proposed inclusion on the Medicare Benefits Schedule for all women aged 25 to 69 years.
Genera said that under the proposed Australian cervical screening guidelines requirement for partial genotyping, only those human papillomavirus tests with the ability to simultaneously genotype certain high risk human papillomavirus types would “most likely be commercially viable in terms of pathology laboratories economic considerations when conducting human papillomavirus tests”.
The company said that the commercial opportunity for RTI-Plex was also substantial, where a relevant existing American Medical Association current procedural terminology (CPT) code existed (CPT 87633) providing reimbursement for pathology laboratories at the rate of about $US568 per test.
Genera said that market entry for RTI-Plex into the US market would initially occur under an internally validated analyte specific reagents (ASR) regime prior to a 510(k) regulatory approval being sought with the US Food and Drug Administration.
The company said that RTI-Plex aided the early identification of causative agents of respiratory disease, allowing for cost reduction and reduced patient hospitalization time.
Genera said it was completing the STI-Plex assay for the simultaneous detection of five sexually transmitted infections in women and hopes to be seek TGA approval in 2015, followed by the US market under the ASR regime prior to a 510(k) approval.
Genera said it would roll-out a dozen or more tests based on its Ampasand technology platform.
Genera was untraded at 27 cents.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says it expects the first sales of its Embryocellect pre-implantation genetic screening test by the end of the year and to be profitable in 2017.

Reproductive Health chief executive officer Dr Michelle Fraser told an investor conference in Melbourne that the company's Embryocellect diagnostic was designed to test whether embryos had the correct chromosomes prior to implanting in prospective mothers.

Dr Fraser said that by testing the embryos and rejecting unsuitable ones, women would be saved the time and effort of implanting embryos only to find later that they did not develop normally.

Dr Fraser said that in younger women, up to 50 percent of embryos had the wrong number of chromosomes and in women over the age of 40 years up to 90 percent of embryos had the wrong number of chromosomes.

Dr Fraser said that 96 percent of those embryos did not implant properly, about four percent miscarried and the survivors had Down syndrome or other genetic problems.

Dr Fraser said it was better to pay for a screening service, than an in-vitro fertilization (IVF) implant that didn't work.

"It saves money for IVF, particularly for women over 40, and is helpful to convince them either not to have children or to accept donor eggs," Dr Fraser said.

Dr Fraser said that the Embryocellect system was based on intellectual property licenced from the University of Adelaide and was made in partnership with the Wilmington, Massachusetts-based Kapa Biosystems, which had a manufacturing facility in Cape Town, South Africa.

She said that the Embryocellect system was intended to be cheaper, easier to use and simpler to read than competitor products, the parameters the clinics are assessing.

Dr Fraser said that the micro-array, DNA amplification and fluorescent labelling kits provided 20 embryo tests at $180 per embryo with the lead competitor Illumina's 24Sure costing between $220 and $360 per embryo, which provided more detailed data information from its micro-array.

She said that in Australia 15 to 30 percent to in-vitro fertilization cycles were using pre-implantation genetic screening, with the US conservative on the issue and the global rate at three percent.

Dr Fraser said that in-vitro fertilization was growing at 10 percent a year and China was a leader in the use of the technique as Chinese women travelled to obtain qualifications and work and came home in their thirties to have children.

She said that the IVF market was expected to grow to $21.6 billion by 2020 with about 20 percent undertaking testing and she hoped to take about 10 percent of the testing market.

Dr Fraser said that the company had "a soft launch" of the product in July and had spoken with five clinics in Australia and five in Asia, Europe and the Middle East to trial the test.

She said that as a research tool, the test did not require regulatory approval and was labeled as "research use only", similar to the blood test for Down syndrome.

Dr Fraser said that Reproductive Health could apply for Conformité Européenne (CE) mark or Australian Therapeutic Goods Administration approval, but that would be primarily for marketing purposes.

She said that the company required individual centre ethics approval and the training of staff in how to conduct and read the test.

Dr Fraser said that when the company listed on the ASX in April it raised $3 million at 20 cents a share which "will see us through to profitability".

"We don't need to undertake research and development and don't need to have clinical trials," Dr Fraser said.

Reproductive Health was unchanged at 20 cents.

ASCEND BIOPHARMACEUTICALS

Ascend says it will begin clinical trials of its ASN-002 immunotherapy for basal cell carcinoma and ASN-004 therapeutic cancer vaccine for breast cancer in 2015.
Ascend said that the Australian phase II trial of ASN-002 intra-tumoral and intra-lesion immunotherapy for basal cell carcinoma was expected to begin by July 2015, with interim results expected in mid to late 2015.
The company said that the phase Ib study of the ASN-004 therapeutic cancer vaccine for breast cancer was expected to start by the end of 2015, with both trials dependent on the completion of fundraising.
Ascend said that basal cell carcinoma was a type of non-melanoma skin cancer, diagnosed in an estimated two million people every year and the most prevalent form of cancer in Australia, the US and Europe.
The company said that although surgery was the primary treatment, it was an undesirable option for many patients for clinical or cosmetic reasons.
Ascend said that ASN-002 was based on an adenovirus, a type of cold-virus, that had been engineered to produce an anti-cancer protein called interferon-gamma and the company had a licence to develop ASN-002 (formerly TG1042) from French biopharmaceutical company Transgene.
The company said that two clinical studies had been completed in 51 patients with lymphomas in the skin, demonstrating that ASN-002 was safe, well tolerated and conferred favorable clinical responses.
Ascend chief executive officer Dr Clement Leong said that ASN-002 had been “de-risked by the previous clinical studies and there is a strong biological rationale for its use in [basal cell carcinoma] patients”.
“In addition, we believe that the previous clinical results provide support for the use of ASN-002 in treating a number of other cancers with important medical needs, including lymphomas of the skin, melanomas and bladder cancers,” Dr Leong said.
Ascend said that its ASN-004 therapeutic cancer vaccine for breast cancer was an injectable treatment based on the OM-MUC-1 product and platform developed at Melbourne’s Burnet Institute that created an immune response to attack breast cancers.
The company said that OM-MUC-1 had been studied in more than 10 clinical trials and in 100 patients, with a recent study of OM-MUC-1 in 31 women showing it reduced the rate of breast cancer returning from 53 to six percent at the 10-year mark.
Ascend said that breast cancer was the most common cancer in Australian women, with about 14,000 new cases diagnosed every year and metastatic breast cancer killed more than 425,000 people worldwide every year.
“There are still a number of important clinical needs in breast cancer,” Dr Leong said.
“A significant percentage of early stage breast cancer patients will have their cancer return after primary treatments and metastatic breast cancer is currently incurable,” Dr Leong said. “ASN-004 has good potential to treat patients in these two breast cancer settings and we are looking forward to commencing further trials shortly.”
Ascend is a public unlisted company.

TISSUE THERAPIES

Tissue Therapies has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.
The ASX said the company’s share price rose 21.3 percent from 37.5 cents on September 1 to 45.5 cents on September 4, 2014 and noted an increase in trading volume.
Tissue Therapies was up 1.5 cents or 3.5 percent to 44.5 cents.

PSIVIDA

Psivida says that the Swedish Medical Products Agency has approved Iluvien for vision impairment associated with chronic diabetic macular oedema

Psivida said that Iluvien had been approved in 10 European Union countries including Austria, Denmark, France, Germany, Italy, Norway, Portugal, Spain, Sweden and the UK for vision impairment associated with chronic diabetic macular oedema, considered insufficiently responsive to available therapies, and was commercially available in the UK Kingdom and Germany.

The company said that Iluvien was in the national phase, pending approval, in Belgium, the Czech Republic, Finland, Ireland, Luxembourg, the Netherlands and Poland following completion of the mutual recognition procedure for subsequent authorizations.

Psivida said that Iluvien was under review by the US Food and Drug Administration with a Prescription Drug User Fee Act (PDUFA) date of September 26, 2014.

Psivida chief executive officer Dr Paul Ashton said the company was “pleased to see another marketing authorization for Iluvien, expanding the potential for its future sales in the EU”.

“We look forward to the FDA’s action on Iluvien,” Dr Ashton said.

“We are entitled to a $US25 million milestone payment from our licencee Alimera Sciences upon FDA approval of Iluvien,” Dr Ashton said.

“We are also entitled to share in the net profits from Alimera’s sales of Iluvien on a country-by-country basis including in the EU and the US,” Dr Ashton said.

Psivida was untraded at $5.15.

USCOM

Uscom says that four studies demonstrate the widespread clinical applicability of its ultra-sonic cardiac output monitor, the Uscom 1A.

Uscom said that the studies were from authors affiliated with the Imperial College, London, the Liverpool Women’s College, Liverpool, the Department of Anesthesiology, Gang Gung Hospital, Taiwan, the Department of Medicine at the University of Queensland, the Great Ormond Street Hospital for Children and University College, London.

The company said that studies reported on the ‘Accuracy and precision of Uscom in pregnancy using 3D comparisons’; ‘Uscom fluid guidance in liver transplantation’; ‘Uscom fluid guided management in critically ill children’; and ‘Review of adult, child and neonatal applications of Uscom for fluid management’.

Uscom said that the four studies brought the total number of publications and presentations supporting the Uscom 1A effectiveness to more than 350.

Uscom executive chairman Dr Rob Phillips said the publications “further define the improvements that Uscom is now making to clinical practice and remind us that our technology is changing clinical care and can save real lives, daily”.

“Fluid management is the most common critical care intervention, yet approximately 50 percent of all such interventions are unnecessary and ineffective and may cause heart failure and death,” Dr Phillips said.

“Uscom has changed the clinical approach to fluid management with a reported 91 percent success rate in even the most difficult critical care patients, thereby almost eliminating these life threatening complications,” Dr Phillips said.

Dr Phillips said that improved guidance of fluid was being applied to the management of sepsis, hypertension, heart failure and liver transplantation.

Uscom was untraded at 25 cents.

RESONANCE HEALTH

Resonance says it has been invited to join the Washington DC-based Forum on Facilitating Drug Development for the Treatment of Liver Disease.
Resonance said that the Forum provided the opportunity for key opinion leaders and stakeholders to work together in the development of safe and effective therapies and diagnostic tools to treat liver fibrosis and cirrhosis.
The company said that non-alcoholic fatty liver disease, chronic hepatitis B and chronic hepatitis C infection were the leading causes of chronic liver disease and hepatocellular carcinoma in the US and as a result of the growing healthcare issues associated with liver disease.
Resonance said the Forum was established to advanced the treatment of liver disease and stakeholders included the National Institutes of Health, the US Food and Drug Administration, specialist physicians, academics, patient communities and major pharmaceutical companies.
The company said it was participating in this Forum as a medical device company focused on developing non-invasive diagnostic tools specifically aimed at liver disease including the assessment of iron overload, fatty liver disease and liver fibrosis.
Resonance was up 0.2 cents or four percent to 5.2 cents.

ANTISENSE THERAPEUTICS

Jason and Catherine Constable have again decreased their substantial shareholding in Antisense from 7,447,056 shares (5.167%) to 5,949,056 (4.12%).
The Ballarat, Victoria-based Mr and Ms Constable held 87,920,107 shares prior to the Antisense 10-for-one consolidation and in July reduced from 8,792,011 shares (6.1%) to 7,447,056 shares (5.167%) (BD: Sep 27, 2013; Jul 2, 2014).
The shareholder notice said that Mr and Ms Constable sold 1,498,000 shares for $233,656 or 15.6 cents a share.
Antisense fell two cents or 13.3 percent to 13 cents with 2.6 million shares traded.

BIOPROSPECT

Bioprospect has requested a trading halt “pending an announcement regarding a corporate restructure”.
Trading will resume on September 8, 2014 or on an earlier announcement.
Bioprospect last traded at 0.5 cents.