Biotech Daily

Monday August 25, 2014

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: GENETIC TECH UP 12.5%, PATRYS DOWN 18%**

*** ORTHOCELL: 'ORTHO-ATI DURABILITY FOR TENNIS ELBOW'**

*** MING HAO ZHENG, YING FAN TAKE 9%, JIA XUN XU 6% OF ORTHOCELL**

*** ACUVAX RAISES $800k FOR ACTIVISTIC COLLECTION, BACK TO ASX**

*** TGA LISTS USCOM BP+ ON REGISTER**

*** PATRYS PLANS COMBINATION PAT-SM6 MULTIPLE MYELOMA TRIAL**

*** ANTEO MIX&GO PATENT, PROVISIONAL PATENT APPLICATIONS**

*** MAYNE APPOINTS DR ILANA STANCOVSKI CSO**

*** REGENEUS REVENUE UP 18% TO $2m, LOSS UP 45% TO $7.5m**

*** PAUL HODGKINSON REPLACES MESOBLAST CFO JENNI PILCHER**

*** ALCHEMIA APPOINTS JENNI PILCHER CFO**

*** LBT APPOINTS DR PATTI DOHERTY FOR US TRIALS**

MARKET REPORT

The Australian stock market fell 0.19 percent on Monday August 25, 2014 with the S&P ASX 200 down 10.7 points to 5,634.9 points. Fourteen Biotech Daily Top 40 stocks were up, nine fell, 14 traded unchanged and three were untraded. All three Big Caps were up.

Genetic Technologies was the best, up 0.3 cents or 12.5 percent to 2.7 cents with 110,000 shares traded. Biotron and Impedimed climbed more than seven percent; Circadian was up 5.3 percent; Avita, Medical Developments and Tissue Therapies rose more than four percent; Osprey and Psivida were up more than three percent; Analytica and Phosphagenics rose more than two percent; Cochlear and Starpharma were up more than one percent; with CSL, Mesoblast, Resmed and Sirtex up by less than one percent.

Patrys led the falls, down 0.5 cents or 17.9 percent to 2.3 cents with 13.0 million shares traded. Compumedics lost eight percent; Living Cell fell seven percent; Admedus fell 6.25 percent; Acrux, GI Dynamics, Nanosonics and Viralytics were down more than one percent; with Alchemia down 0.8 percent.

ORTHOCELL

Orthocell says that a long-term clinical study of its autologous tenocyte stem cell implantation (Ortho-ATI) treatment for tennis elbow shows the durability of the treatment.
Orthocell said that the 17-patient, open-label, pilot study showed grip strength scores of patients with chronic lateral epicondylitis, a severe form of tennis elbow, improved by an average 84 percent at one year after treatment and 207 percent at an average of 4.5 years after they underwent the Orthocell procedure.
Orthocell said the data was “the first long term efficacy data for a stem-cell based tendon regeneration treatment, that has been published globally”.
Orthocell managing director Paul Anderson said that Ortho-ATI had “proven itself to be an effective and durable long-term solution for degenerate, treatment-resistant tendons”.
The company said that tennis elbow was a painful condition caused by damage and degeneration of tendons in the elbow due to overuse.
Orthocell said that treatments such as steroid injections were limited in their effectiveness and failed to address the underlying cause of the degeneration.
The company said that Ortho-ATI took a sample of patient’s healthy tendon stem cells, culturing and expanding them in a laboratory and then re-injecting them into the damaged tissue to help it regenerate and reduce pain and inflammation.
“The results are very positive and encouraging for patients affected by painful and debilitating degenerate tendon injuries,” said Mr Anderson.
“They show long-term, sustained and statistically significant positive results in a very difficult to treat group of chronic patients,” Mr Anderson said.
Orthocell said that a single injection of a patient’s cultured tendon stem cells significantly improved clinical function at the three to five-year follow-up of patients who had previously undergone an unsuccessful course of conservative treatment such as exercise and corticosteroid injections.
The company said that the study was undertaken at the University of Western Australia in conjunction with the Perth-based Sir Charles Gairdner Hospital, led by Orthocell chief scientific officer, Prof Ming-Hao Zheng and orthopaedic surgeon Prof Alan Wang.
Orthocell said the study results were presented at the Western Australia Orthopaedic Association conference on August 23 and 24, 2014 and had been accepted for presentations at the Australian Orthopaedic Association conference in October, as well as the Australian Sports Medicine conference in Canberra also in October.
The company said that Ortho-ATI was available in Australia and New Zealand for patients who had failed conservative treatment options such as corticosteroid injections and exercise programs and had ongoing symptoms.
Separately, Prof Ming Hao Zheng and Ying Fan said they became substantial shareholders in Orthocell with 7,063,608 shares (8.56%).
The Guangzhou, China-based Jia Xun Xu said he had become a substantial shareholder in Orthocell with 5,168,276 shares (6.26%).
Orthocell was unchanged at 38 cents.

ACUVAX

Acuvax says it has raised $800,000 through placements at 0.05 cents a share to acquire Activistic Pty Ltd and its funds collection system (BD: Jun 23, 24, Jul 1, 2014).
Acuvax said the placement would fund existing activities, due diligence and costs of the proposed acquisition of Activistic and be used for working capital and re-compliance cost.
The ASX said that Acuvax would be reinstated tomorrow.
Acuvax was in a suspension and last traded at 0.1 cents.

USCOM

Uscom says its Uscom BP+ central blood pressure measurement device has been added to the Australian Register of Therapeutic Goods.
Uscom said that the Australian Therapeutic Goods Administration listing on the Register was essential prior to sale in Australia.
The company said that the Uscom BP+ used supra-systolic oscillometry to measure the blood pressure at the heart, which was a better predictor of cardiovascular risk and provided better treatment guidance.
Uscom said that the TGA listing meant the Uscom BP+ could be sold in Australia by distributors and directly by the company.
The company said that the global blood pressure device market was estimated at about $US2 billion and growing at 11.5 percent a year.
Uscom executive chairman Dr Rob Phillips said the company had US Food and Drug Administration and Conformité Européenne (CE) mark approval “and now TGA approval” and was preparing for a Chinese Food and Drug Administration submission.
Uscom was untraded at 27 cents.

PATRYS

Patrys says its phase Ib/IIa clinical trial of PAT-SM6 with carfilzomib and dexamethasone would evaluate the safety and tolerability for patients with multiple myeloma.
Patrys said the study would enroll nine patients who were refractory and/or intolerant to bortezomib, a currently-marketed proteasome inhibitor.
The company said that secondary endpoints of the trial would include the overall response rate, duration of response, time to progression and a series of well-established laboratory assays will measure immunological and disease parameters.
Patrys said that the study would be a single-arm study with a two stage design, and that after testing the drug combination on nine patients, the trial would be terminated if two or fewer patients responded, that is, a partial response or better.
The company said that if the trial went to the second stage, a total of 24 patients would be treated and the design would allow for statistical analyses to be made and a determination whether the combination of PAT-SM6, carfilzomib and dexamethasone was superior to carfilzomib and dexamethasone alone.
The company said that each patient would be treated with up to four cycles of PAT-SM6 at 6mg/kg/dose in combination with carfilzomib at 20-27mg/m2 and dexamethasone 40mg.
Patrys said that each cycle would consist of three doses of PAT-SM6, six doses of carfilzomib and four doses of dexamethasone administered over a one month period, with patients followed up for six months.
The company said that the phase Ib/IIa trial was expected to begin at the end of 2014 with all patients recruited within 18 months.
Patrys said the study would be conducted by Germany’s University Hospital of Würzburg’s Prof Hermann Einsele and Dr Leo Rasche with the Technical University of Dresden also recruiting patients into the study.
The company said that manufacturing of PAT-SM6 for the trial was “progressing well” and discussions with Amgen subsidiary Onyx in relation to the trial were ongoing.
Patrys said that the trial protocol had been approved by the Onyx Clinical Trial Review Committee and Onyx was committed to providing carfilzomib for the study.
The company said that it had submitted the required documents to Germany’s Paul Ehrlich Institut for the first stage of the regulatory review process.
Patrys fell 0.5 cents or 17.9 percent to 2.3 cents with 13.0 million shares traded.

ANTEO DIAGNOSTICS

Anteo says it has filed a new international Patent Cooperation Treaty application covering its Mix&Go biological adhesive entitled ‘Conjugating Molecules to Particles’.
Anteo said the filing followed a provisional application filed in August 2013 and “the sophisticated process described in it has been broadly exemplified successfully demonstrating a range of additional approaches that become possible through the use of our core Mix&Go technology”.
The company said that the patent filing safeguarded the intellectual property and was expected to lead to granted patents in a range of jurisdictions.
Anteo said that the applications for Mix&Go covered by the filing broadened the field of use to new and beneficial areas, including the development of new separation products and a more sophisticated approach to increase the sensitivity and performance of immunoassays.
The company said that previously Mix&Go had been used in immunoassays to bind capture antibodies or proteins but it could be used to improve the detection side of the assay which offered considerable benefits.
Anteo said it decided not to continue to Patent Cooperation Treaty application with the ‘Coating of Particles’ application, also filed last year, but had filed another provisional application, entitled ‘Heterofunctional Binding Systems’ which allowed the company to coat a much broader range of materials including both hydrophilic and now hydrophobic surfaces, which in principle allowed the technology to be used as a preparatory coat on almost any material.
The company said that potential applications for the invention described in the filing extended “well beyond just particles”.
Anteo said there was “potential for further patentable applications to emerge as we work to further exemplify the existing filings, as well as protect other novel opportunities arising from Anteo research activities”.
Anteo chief executive officer Dr Geoff Cumming said that protecting the Mix&Go technology and its potential uses was “an ongoing priority”.
Anteo was unchanged at 14.5 cents with 2.2 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says it has appointed Dr Ilana Stancovski as its chief scientific officer effective from September 1, 2014.
Mayne said that Dr Stancovski would be responsible for leading Mayne Pharma’s research and development operations world-wide.
The company said that Dr Stancovski had more than 20 years experience in positions in the pharmaceutical industry and academia.
Mayne said that Dr Stancovski was previously Actavis Group’s hospital division vice-president of research and development and made “a significant contribution to expanding the company’s portfolio of complex generic and long-acting injectables, including a number of potential first-to-file projects”.
Mayne said that prior to Actavis, Dr Stancovski was Intas Pharmaceuticals’ vice-president of scientific affairs held management roles at other pharmaceutical and biotechnology companies.
The company said that Dr Stancovski held a Doctorate of Philosophy from the Israel’s Weizmann Institute and had worked as a post-doctoral scholar at the California Institute of Technology (Caltech) and Massachusetts Institute of Technology (MIT).
Mayne was up 1.5 cents or 1.9 percent to 82 cents.

REGENEUS

Regeneus says that revenue for the year to June 30, 2014, was up 18 percent to $2,094,643 with net loss after tax up 45 percent to $7,523,000.
Regeneus said that apart from licencing revenue its human health division had revenue of $765,215 and animal health was $232,821.
The company said that net tangible asset backing per share was up from negative 2.8 cents at June 30, 2013 to 4.45 cents at June 30, 2014, with diluted loss per share constant at 5.0 cents.
Regeneus said that it had cash and cash equivalents of $2,507,497 at June 30, 2014 compared to $410,658 at June 30, 2013.
Regeneus was unchanged at 26 cents.

MESOBLAST

Mesoblast says it has appointed Paul Hodgkinson as chief financial officer replacing Jenni Pilcher, effective from September 1, 2014.
Mesoblast said that Mr Hodgkinson had pharmaceutical experience in all aspects of finance, strategic planning, business development and licencing, manufacturing and supply chain, and procurement.
The company said that from 2011 to 2014, Mr Hodgkinson was chief financial officer the Novartis Australia and New Zealand responsible for divisions comprising pharmaceuticals, Alcon, Sandoz, vaccines, diagnostics, consumer and animal health.
Mesoblast said that prior to Novartis, Mr Hodgkinson was an executive with Astrazeneca UK, before being appointed chief financial officer from 2006 to 2011.
Mesoblast was up one cent or 0.2 percent to $4.27.

ALCHEMIA

Alchemia says that Jenni Pilcher has been appointed as chief financial officer effective from September 1, 2014.
Alchemia said that Ms Pilcher had extensive financial leadership experience and was currently the chief financial officer and company secretary of Mesoblast, where she has been an executive for the past seven years.
The company said that at Mesoblast, Ms Pilcher built the finance group and partnered with executive director Prof Silviu Itescu to execute four capital raises totaling more than $230 million with Australian, US and UK investors and was involved in transactions including out-licencing, a company acquisition, a product acquisition, and a contract manufacturing partnership.
Alchemia said that prior to Mesoblast, Ms Pilcher spent six years with Spotless Group, in a variety of financial roles, and previously worked in finance at the UK Cadbury Schweppes Plc and Medeva Plc, both based in the United Kingdom.
The company said that Ms Pilcher held a Bachelor of Business Studies from New Zealand’s Massey University.
Alchemia fell half a cent or 0.8 percent to 59 cents with 1.1 million shares traded.

LBT INNOVATIONS

LBT says it has appointed Dr Patti Doherty as the co-ordinator and supervisor for the US automated plate assessment system trial due to begin later this year.

LBT said that Dr Doherty's services were provided through Popper & Company - a company associated with LBT non-executive director Dr Caroline Popper.

The company said that given Dr Doherty's skills and experience and having considered its options, the LBT board considered it in the company's best interests for Dr Doherty to co-ordinate and supervise the US trial.

LBT said that Dr Doherty would assist in the identification of trial sites, provide support such as negotiation, institutional review board liaison, training and monitoring and assess the US-based clinical research associate.

The company said that Dr Doherty specialized in clinical support and strategic guidance through product development and was a principal of Popper & Co with previous work including almost four years as director of clinical studies at Exagen Diagnostics in California and three years as clinical research coordinator at New Mexico Heart Institute.

LBT said that its automated plate assessment system trials would be at three sites, with two in Australia and one in the US.

LBT was unchanged 12 cents.