

Biotech Daily

Friday July 26, 2013

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH EVEN: PATRYS UP 17%, CIRCADIAN DOWN 8%
- * CSIRO, DUKE, SINGAPORE \$20m PANDEMIC PARTNERSHIP
- * REGENEUS UP TO \$12m IPO FOR FAT STEM CELLS TECHNOLOGY
- * CALZADA, POLYNOVO TREAT LAST FREE-FLAP NOVOSORB PATIENT
- * PHOSPHAGENICS: 'TPM PATCH DELIVERS OXYCODONE OVER 72 HOURS'
- * NEUREN PLEADS SCHULTZ TO ASX 42% QUERY
- * MJGD, BSMI TRUST TAKE 6.5% OF BENITEC
- * IRWIN, BIOA TRUST TAKE 6.5% OF BENITEC

MARKET REPORT

The Australian stock market edged up 0.13 percent on Friday July 26, 2013 with the S&P ASX 200 up 6.4 points to 5,042.0 points.

Sixteen of the Biotech Daily Top 40 stocks were up, 15 fell, four traded unchanged and five were untraded.

Patrys was the best for the second day in a row, up 0.5 cents or 16.7 percent to 3.5 cents with 7.3 million shares traded, followed by Medical Developments up 13.0 percent to \$1.48 with 29,000 shares traded.

Antisense and Prana climbed more than five percent; Atcor and Phosphagenics were up more than four percent; Avita, Benitec and Pharmaxis were up more than three percent; Bionomics, GI Dynamics and Mesoblast rose more than two percent; Clinuvel, Nanosonics, Resmed and Universal Biosensors were up more than one percent; with Sirtex up 0.8 percent.

Circadian led the falls, down two cents or eight percent to 23 cents with 98,427 shares traded.

Impedimed lost 7.4 percent; Living Cell fell 5.45 percent; Alchemia and Neuren fell more than four percent; Allied Health, Cellmid, Genetic Technologies and Viralytics were down more than three percent; Acrux, Cochlear and Prima shed more than two percent; Ellex was down 1.8 percent; with CSL, Heartware, QRX and Starpharma down by less than one percent.

THE COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The Commonwealth Scientific and Industrial Research Organisation says that Australia, Singapore and the US will collaborate on a \$20 million human pandemic partnership. CSIRO Biosecurity Flagship director Dr Gary Fitt said that recent events highlighted the need to ramp up research into viruses that spread from animals to humans.

"We now know that 70 percent of new diseases in people have originated in animals," Dr Fitt said.

"We are lucky to have a strong bio-security system, backed by world-class science, but we live in an increasingly connected world with trade and people movements putting us at greater risk," Dr Fitt said.

CSIRO said that a new SARS-like virus had emerged from the Middle East and had killed 45 of 82 people infected since September 2012.

The Organisation said that the virus, known as Middle East Respiratory Syndrome (MERS), spread from the Middle East to the UK, Germany, France, Italy and Tunisia. CSIRO said that in China a new strain of highly pathogenic bird flu, known as H7N9, was spreading undetected, killing people instead of chickens.

CSIRO said its route of infection was unknown.

CSIRO said that it had signed a relationship agreement with and Duke University in North Carolina and the National University of Singapore (Duke-NUS) to create the International Collaborative Centre for One Health to take a new approach to tackling deadly viruses. CSIRO science leader and director of the Duke-NUS program in emerging infectious diseases Dr Linfa Wang said that responding to emerging threats needed a different approach and must integrate medical, veterinary, ecological and environmental research. "Bringing all of these disciplines together to develop a One Health approach rather than working independently is what our new international partnership is all about," Dr Wang said. "We are combining CSIRO's world-leading bat virology research with Duke-NUS medical expertise in the development of new and more effective methods for the discovery, treatment, prevention and control of new and emerging diseases in people." CSIRO said that research was underway with Duke-NUS to develop tests for early and rapid detection of emerging infectious diseases, such as Hendra virus and coronaviruses. CSIRO said its scientists with expertise in bat virology would test and validate the new platforms at the Australian Animal Health Laboratory in Geelong, Victoria.

REGENEUS

Regeneus says it hopes to raise up to \$12 million at 25 cents a share in an initial public offer to list on the ASX and develop its fat stem cell technology for musculo-skeletal repair. A preliminary prospectus has been released to brokers and a Regeneus executive told Biotech Daily that the company hoped to lodge a formal prospectus with the ASX in the week ending August 2, 2013.

The executive said the company hoped to raise \$10 million and up to \$12 million and list on the ASX in September 2013 under the code RGS.

Last year, Regeneus completed treatment of 40 patients in its phase II trial of its adipose stem cell treatment for knee osteoarthritis (BD: Nov 29, 2011; Apr 5, 2012).

Regeneus executive chairman John Martin told Biotech Daily the trial demonstrated safety but a high placebo response meant that efficacy was not statistically significant.

Mr Martin said that other studies were underway and more were planned

The company also has a collaboration with Cryosite for frozen stem cells and a veterinary program (BD: Jul 30, 2012; Jan 30, Apr 12, Jul 2, 2013).

Regeneus is a public unlisted company

CALZADA, POLYNOVO BIOMATERIALS

Calzada says wholly-owned subsidiary Polynovo Biomaterials has treated the tenth and final patient in its trial of Novosorb for full-thickness surgical wounds.

Calzada said the trial, conducted at the Royal Adelaide Hospital by principal investigator Prof John Greenwood, was investigating the Novosorb biodegradable temporising matrix (BTM) dermal scaffold in treating free-flap donor sites used for surgical repair.

The company said that preliminary findings from the previous nine patients, who had completed full treatment including skin graft applications, were that Novosorb performed to expectations and that the clinicians were satisfied with the outcomes.

Calzada said that final results from the 10 patient trial were expected in October 2013. The company said that the plastic surgeons involved in the trial "indicated a desire to continue using the Novosorb BTM in forearm and fibulae donor sites in their general patient population".

Calzada said that Prof Greenwood was "exploring the most efficient way to achieve this which might involve Polynovo supplying the Novosorb BTM to the [Royal Adelaide Hospital] under the Therapeutic Goods Administration special access scheme which could generate initial device sales revenue to Polynovo.

The company said that Prof Greenwood had ethics committee approval for a trial of Novosorb in third degree burn patients who had up to 50 percent body surface burns, which was expected to begin recruitment by the end of 2013.

Calzada was up 0.5 cents or 7.7 percent to seven cents.

PHOSPHAGENICS

Phosphagenics says that a 12-patient phase I trial has shown that its tocopheryl phosphate mixture (TPM) oxycodone patch delivered oxycodone over a 72 hour period. In April, the company said a phase I study of TPM-oxymorphone delivered oxymorphone into the bloodstream for 72 hours (BD: Apr 5, 2013).

Today, Phosphagenics said the delivery profile for TPM-oxycodone warranted progress to phase II trials for therapeutic pain relief.

The company said the trial was designed to characterize the delivery profile of the patch and "inform the strategic direction of the company's growing pain portfolio".

Phosphagenics chief scientific officer Dr Paul Gavin said the trial indicated that the TPM-oxycodone patch might be appropriate for multiple indications and along with previously identified pain models such as osteoarthritis, "the patch also appears suitable for harder to treat conditions such as post-herpetic neuralgia, a model of neuropathic pain".

The company said its TPM-oxymorphone program would continue as scheduled, with a phase I multiple dose trial due to commence by October 2013.

Phosphagenics said that it completed a phase I clinical trial for lidocaine several years ago and intended to develop the drug further with third parties in a similar manner to its diclofenac program, with lidocaine development recommencing by the end of 2013.

The company said it intended to begin commercial discussions with third parties in 2014, for its TPM-oxycodone and oxymorphone patches after the completion of the phase II trials and to out-licence all or part of its pain franchise.

Phosphagenics chief executive officer Harry Rosen said the progress of the pain portfolio "represents a substantially larger commercial opportunity than that contemplated when the company commenced its pain development program several years ago".

"The pain portfolio as outlined above with its capability of applying to a broad spectrum of pain indications represents an extremely valuable asset for shareholders," Mr Rosen said. Phosphagenics was up 0.5 cents or 4.55 percent to 11.5 cents.

NEUREN

Neuren 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 41.9 percent from 7.4 cents on July 19 to 10.5 cents on July 25, 2013, and noted an increase in trading volume.

Neuren fell 0.4 cents or four percent to 9.5 cents with nine million shares traded.

BENITEC BIOPHARMA

The Melbourne-based MJGD Nominees as trustee for BSMI Trust has become a substantial shareholder in Benitec with the acquisition of 4,769,091 shares or 6.47 percent of the company.

The substantial shareholder notice, signed by MJGD Nominees director George Muchnicki, said the shares were acquired for \$1,311,500 or 27.5 cents a share. Benitec is completing a placement and consolidation at that price (BD: Jul 24, 2013). Benitec was up one cent or 3.1 percent to 33 cents.

BENITEC BIOPHARMA

The Melbourne-based Irwin Biotech Nominees as trustee for BIOA Trust has become a substantial shareholder in Benitec with the acquisition of 4,769,091 shares or 6.47 percent of the company.

The substantial shareholder notice, signed by director Peter Rubinstein, said the shares were acquired for \$1,311,500 or 27.5 cents a share.

Both substantial shareholder notices were sent from MJGD Nominees as trustee for BSMI Trust, of St Kilda Road, Melbourne, but Mr Rubinstein told Biotech Daily the two holdings were completely separate.