Biotech Daily

Tuesday July 8, 2014

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: LIVING CELL UP 18%, AVITA DOWN 18%**

*** NOVAQUEST TRIES TO AVOID PHARMAXIS $US20m, TRIAL THREAT**

*** REGENEUS LICENCES HUMAN CANCER VACCINE**

*** ELLEX WINS FIRST EUROPEAN 2RT LASER SALES FOR AMD**

*** LIVING CELL CEO DR KEN TAYLOR STARTS ON $280k**

*** DORSAVI NZ VIMOVE APPROVAL, SUNDERLAND FC UK BUYS VIPERFORM**

*** PHARMAXIS LOXL2, SSAO PROGRAMS LICENCE PROGRESS**

*** ACRUX PLEADS SCHULTZ TO ASX 13% QUERY**

*** OBJ PLEADS SCHULTZ TO ASX 14% QUERY**

MARKET REPORT

The Australian stock market slipped 0.14 percent on Tuesday July 8, 2014 with the S&P ASX 200 down 8.0 points to 5,510.9 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, 10 traded unchanged and two were untraded.

Living Cell was the best, was up one cent or 18.2 percent to 6.5 cents with 80,000 shares traded, followed by Circadian up 13.5 percent to 21 cents with 27,850 shares traded.

Ellex climbed 7.7 percent; Acrux and Analytica were up five percent or more; Medical Developments was up 4.8 percent; Atcor improved 3.6 percent; Benitec, Cochlear, Impedimed, Phosphagenics, Prima, Psivida and Starpharma rose more than two percent; Mesoblast and Sirtex were up more than one percent; with CSL up 0.4 percent.

Avita led the falls, down two cents or 18.2 percent to nine cents with 1.7 million shares traded, followed by Pharmaxis down 16.9 percent to 6.4 cents with 3.4 million shares traded.

Patrys lost 8.3 percent; Prana was down 5.9 percent; Genetic Technologies fell 4.55 percent; Admedus, Antisense, Oncosil and Osprey were down more than three percent; Anteo and Bionomics shed more than two percent; Tissue Therapies was down 1.7 percent; with Nanosonics and Resmed down by less than one percent.

PHARMAXIS

Pharmaxis says financier Novaquest's attempt to withdraw from $US20 million in agreed payments could impact its impending US phase III trial of Bronchitol for cystic fibrosis.

Pharmaxis said that Novaquest Pharma Opportunities Fund III, LP affiliate, Novaquest Capital Management, alleged on July 4, 2014 that Pharmaxis had breached the January 30, 2013 financing agreement and "an event of default will occur on August 3, 2014".

The company said that Novaquest alleged that it had not worked in a commercially reasonable manner to obtain reimbursement status for Bronchitol from key European governmental and non-governmental payers, but did not provide any detail to support the allegation of a breach of the agreement and Novaquest had failed to raise the matter through the dispute resolution required by the agreement.

Pharmaxis said it "strongly rejects the allegation it is in breach, will contest the allegation and take all appropriate steps to ensure that Novaquest complies fully with its obligations under the financing agreement.

Following ambivalent phase III trial results in 2010, regulatory refusals by European and concerns by US regulators in 2011 and 2013, and a falling share price, Pharmaxis signed a $US40 million ($A42.6 million) financing agreement with Novaquest to support the development, manufacturing and commercialization of Bronchitol for cystic fibrosis in the EU and US (BD: Jun 23, 2010; May 25, Jun 24, Oct 24, 2011; Jan 31, Mar 19, 2013).

Pharmaxis said at that time that $US20 million would be received within 30 days and an additional $US20 million could be invested from January 30, 2014, at Pharmaxis option and subject to it meeting commercial and regulatory criteria.

The company opted to receive the additional fund in October 2013 (BD: Oct 30, 2013).

Today, Pharmaxis said that it would continue to pay its sales-related payments with no obligation to refund the initial tranche of $US20 million, "but the second tranche of $US20 million under the agreement may not occur".

The company said that the first $US5 million of the second tranche was expected to be received in September 2014, 30 days after the first patient was targeted to be enrolled in the US pivotal phase III Bronchitol adult cystic fibrosis study (CF303), with three further instalments of $US5 million payable every three months.

Pharmaxis chief executive officer Gary Phillips said "the full investment of $US40 million by Novaquest is central to our business plan and the agreement entered into 18 months ago".

"This notice has consequences for the CF303 clinical trial which is a key step to FDA approval and subsequent access to the US cystic fibrosis market," Mr Phillips said.

"It also has consequences for a US partnering agreement for Bronchitol which I had expected to sign later this month," Mr Phillips said.

"This partnering deal, with a global pharmaceutical company, has significant potential value to Pharmaxis including partial funding of the trial, the payment of significant approval and sales milestones and a share of sales revenues," Mr Phillips said.

"We have also been exploring future supply chain initiatives with this prospective partner that would significantly reduce our cost base," Mr Phillips said.

"We are in discussions with Novaquest on these considerations and the structure and quantum of future investments," Mr Phillips said.

"We will also discuss the potential consequences of the Novaquest notice with our prospective US Bronchitol commercial partner and the contract research organization implementing CF303," Mr Phillips said.

Pharmaxis fell as low as 5.5 cents before closing down 1.3 cents or 16.9 percent to 6.4 cents with 3.4 million shares traded.

REGENEUS

Regeneus says it has licenced the rights to develop and commercialize a human version of its canine cancer vaccine from the Northern Sydney Local Health District.
Regeneus said that the technology was developed at the Kolling Institute of Medical Research's Bill Walsh Translational Cancer Research Laboratory which is part of Sydney's Royal North Shore Hospital in Sydney.
Regeneus chief executive officer Prof Graham Vesey said that the company had "secured the rights for human applications of the cancer vaccine technology following pre-clinical efficacy data and promising safety data generated from the treatment of a variety of dogs with a wide range of cancer types".
Regeneus said that it held the rights of the vaccine technology for veterinary applications.
The company said that the production of the cancer vaccine for an individual patient required a patient tumor sample taken by complete surgical removal or by small biopsy.
Regeneus said it would fund a first-in-man safety trial scheduled to begin by April 2015 and further research at the Bill Walsh Cancer Research Laboratory to support the trial.
The company said the University of Sydney Northern Clinical School oncologists Prof Stephen Clarke and Prof Nick Pavlakis would be the investigators on the trial.
"Following the positive results we have seen in canines, this has been an encouraging prelude to undertaking a human clinical trial," Prof Clarke said.
Regeneus said that the trial design and target tumor type would be finalized prior to seeking ethics approval.
"The therapeutic vaccine has the potential to target a wide range of hard-to-treat cancers with a single product," Prof Vesey said. "As the vaccine uses the patient's own tumor cells and can be prepared under the supervision of the treating clinician, the local regulatory environment for biological therapies in Australia may allow for an accelerated clinical pathway for the autologous cancer vaccine removing the need for expensive and time consuming phase III trials."
Regeneus said it would be responsible for the clinical and commercial development of the cancer vaccine for human applications and would pay royalties to Northern Sydney Local Health District on the commercial use of the product.
Regeneus fell one cent or 2.6 percent to 37 cents.

ELLEX MEDICAL LASERS

Ellex says it has secured its first commercial sales in Europe for its 2RT retinal therapy, following its Conformité Européenne (CE) mark approval (BD: Feb 24, 2014).
Ellex said that the retinal rejuvenation therapy (2RT) laser devices had been installed and commissioned and the first early-stage age-related macula degeneration patients had been treated.
The company said the sales were made in Germany and Austria and followed the establishment of a regional headquarters in Berlin.
Ellex chief executive officer Tom Spurling said that "since securing the CE mark earlier this year we have commenced a limited commercial roll out of 2RT to early adopters and key opinion leaders in Europe".
"We are particularly pleased that leading doctors in the largest ophthalmic market in Europe, have been quick to adopt the technology," Mr Spurling said.
Ellex said that the Düsseldor, Germany-based Breyer & Kaymak Augenchirurgie surgeon Dr Hakan Kaymak planned to present his clinical experiences with 2RT at the German National Ophthalmology Conference in Leipzig in September 2014.
Ellex was up 2.5 cents or 7.7 percent to 35 cents.

LIVING CELL TECHNOLOGIES

Living Cell says that acting chief executive officer Dr Ken Taylor has been appointed chief executive officer on a base salary of $NZ300,000 ($A280,147) a year.
Living Cell said Dr Taylor would be eligible for up to 700,000 share options under the directors and employees share option plan which were exercisable at various margins above the volume weighted average price of the shares.
Living Cell was up one cent or 18.2 percent to 6.5 cents.

DORSAVI

Dorsavi says the New Zealand Medicines and Medical Devices Safety Authority has approved the use and sale of its Vimove body movement measurement system.
Dorsavi said that Vimove's wearable sensors measured movement and muscle activity for healthcare professional use and was available at medical, physiotherapy and osteopathy clinics in Australia, Canada and Europe.
The company said that patients could be assessed through a series of movements or exercises performed in or outside the clinic, at home or at work, where Vimove can monitor activities and provide feedback to the patient and the healthcare practitioner.
Dorsavi said the device allowed healthcare professionals to manage back pain or musculoskeletal conditions and offer personalized treatment.
The company said that the north-east England-based Sunderland Association Football Club would use its wearable sensor technology Viperform to screen and manage players.
Dorsavi said that Viperform could be used to manage injuries and evaluate readiness for return to play through hamstring, knee, lower back and running assessments.
The company said that Viperform's sensors provided immediate analysis by recording and sending information on player movement and muscle activity to a computer, tablet or recording device for on-field feedback.
Dorsavi chief executive officer Andrew Ronchi said that the signing of Sunderland followed the establishment of a sales team in the UK and Europe.
Dorsavi fell three cents or 6.5 percent to 43 cents.

PHARMAXIS

Pharmaxis says it hopes to sign a licencing agreement for its lysyl oxidase (LOX) inhibitors program with a pharmaceutical company by October 2014.
Pharmaxis said that the agreement would see a fully-funded and comprehensive pre-clinical development program of LOX inhibitors at its drug discovery unit which would provide payments for successful development milestones on the way to market as well as from product sales by the partner.
The company said the LOXL2 enzyme was implicated in several fibrotic diseases including pulmonary fibrosis, liver fibrosis and some cancers.
Pharmaxis said it had presented its work at international conferences in the last 12 months, confirming pharmaceutical company interest in drugs for this target.
The company said that a candidate compound had been identified in its semicarbazide-sensitive amine oxidase inhibitors (SSAO) program that had "excellent drug-like properties and is in the final stages of pre-clinical development" and it was in discussions with companies interested in taking the compound into the clinic in early 2015.
The company said that the SSAO enzyme was implicated in several inflammatory diseases with high unmet clinical need including chronic obstructive pulmonary disease and non-alcoholic steato-hepatitis.

ACRUX

Acrux 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 13.04 percent from $1.1505 to $1.3005 today, July 8, 2014, but did not note an increase in the trading volume".

Acrux closed up 6.5 cents or 5.65 percent to $1.215 with 4.4 million shares traded.

OBJ

OBJ 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 13.75 percent from 8.0 cents on July 7 to 9.1 cents, today, July 8, 2014, and noted an increase in trading volume.

OBJ closed up 0.6 cents or 7.5 percent to 8.6 cents with 29.8 million shares traded.