Biotech Daily

Wednesday December 3, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ANTEO UP 17%, UNIVERSAL BIOSENSORS DOWN 9%**

*** CSL: 'R&D SPEND EXPECTED TO INCREASE TO BUILD PIPELINE'**

*** WEHI: APOPTOSIS, NECROPTOSIS LINK TO SKIN DISEASE**

*** BIOTRON RECRUITS 60-PATIENT THAI HEP C TRIAL**

*** UNILIFE, UNNAMED COMPANY 10-YEAR EYE INJECTION AGREEMENT**

*** GENETIC TECHNOLOGIES SHARE PLAN FOR UP TO $3m**

*** OBJ COSMETICS DERMAPORTATION LICENCE TO NY'S COTY**

*** COGSTATE OFFLOADS AXON SPORTS**

*** CIRCADIAN APPOINTS OPT-302 OPHTHALMIC DISEASE ADVISORS**

MARKET REPORT

The Australian stock market climbed 0.77 percent on Wednesday December 3, 2014 with the S&P ASX 200 up 40.5 points to 5,321.8 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, 12 traded unchanged and one was untraded.

Anteo was the best on no news, up two cents or 17.4 percent to 13.5 cents with 3.9 million shares traded, followed by Uscom up 10 percent to 22 cents with 142,382 shares traded.

Starpharma climbed 8.3 percent; Mesoblast was up 7.9 percent; Circadian and Nanosonics rose more than six percent; GI Dynamics and Sirtex were up more than five percent; Admedus and Avita were up more than four percent; Acrux, Benitec, CSL, Medical Developments and Prima rose more than two percent; Cochlear, Impedimed, Living Cell and Resmed were up more than one percent; with Psivida up 0.2 percent.

Universal Biosensors led the falls, down 1.5 cents or 9.4 percent to 14.5 cents with 99,933 shares traded.

IDT and Tissue Therapies lost more than five percent; Bionomics fell 4.3 percent; Alchemia and Oncosil were down more than three percent; Clinuvel, Optiscan and Pharmaxis shed two percent or more; with Viralytics down 1.6 percent.

CSL

CSL chief scientific officer and head of research and development Dr Andrew Cuthbertson says the company will keep building its pipeline and expenditure was likely to increase.

Following the annual investors' research and development briefing, Dr Cuthbertson told Biotech Daily that CSL had "a number of projects in late stage and phase III development" and that he expected research and development expenditure "will grow in line with CSL's growth".

Dr Cuthbertson said that the company spent "around eight or nine percent of revenue" on research and development which amounted to $466 million ($A544.3 million) in 2013-'14, which would "almost certainly go up".

"We need to keep building the pipeline at the front end," Dr Cuthbertson said.

Dr Cuthbertson said that along with new product development CSL was expanding the markets for existing products, both geographically and by indication.

He said that typically the company might take a product marketed in Central Europe and broaden it geographically to the rest of Europe, the US, Australia and the rest of the world.

Dr Cuthbertson said that at the same time CSL would seek to expand the drug for other uses, thereby increasing the revenue from $50 million to $200 million.

Dr Cuthbertson gave as an example the use of Beriplex for haemorrhage in Europe, which had been renamed KCentra for the US and expanded its indications to warfarin reversal and surgical haemorrhage.

Dr Cuthbertson said that at CSL "we stick to things we understand".

He said that the research and development pipeline was ambitious but "generally we do most of it".

A table provided in the presentation materials listed five categories of research projects, eight drugs in pre-clinical testing, with three in phase I, four in phase II, six in phase III, two at registration and a raft of products at commercial or phase IV level.

Dr Cuthbertson said that the projects listed were the major projects with others in early phase development not specified.

He said that the company was expecting to file a dossier for regulatory approval of recombinant factor-IX for haemophilia B in the next few days

Dr Cuthbertson said that the drug would see the reduction from two or three infusions a week to once a week and possibly once every two weeks.

The presentation included a slide for an article published in the journal 'Blood' showing that the recombinant fusion protein linking coagulation factor IX with albumin provided a 5.3-fold longer half-life to 92 hours, compared to an existing marketed recombinant factor IX drug.

Dr Cuthbertson said that a 1,200-patient phase II trial had begun for CSL112 for secondary heart attacks.

He said that CSL112 was "an interesting breakthrough" because the rapid infusion of high density lipoproteins, known as "good cholesterol" was believed to prevent atherosclerosis plaques breaking off and blocking arteries.

Dr Cuthbertson said that CSL had prioritized its portfolio from high to mediaum and lower across immunoglobulins, haemophilia, speciality products and breakthrough medicines.

The two high priority breakthrough drugs given as examples were CSL312 an anti-Factor-XIIa drug for hereditary angio-oedema and the CSL and Janssen phase I collaboration on CSL362 for acute myeloid leukaemia.

CSL was up $1.72 or 2.0 percent to $86.35 with 1.96 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that inflammatory skin diseases such as psoriasis may result from abnormal activation of cell death pathways

The Institute said that cell death pathways were previously believed to suppress inflammation, a surprise finding that could help to develop new disease treatments.

The Institute said that Prof John Silke, James Rickard and colleagues made the discovery while investigating how cell death pathways were linked to inflammatory disease development.

The study, entitled 'TNFR1-dependent cell death drives inflammation in Sharpin-deficient mice' was published in the journal Elife and the full article is available at: http://elifesciences.org/content/3/e03464.

WEHI said that infected or cancerous cells, or those that were unnecessary to the body were instructed to die in a programmed process called apoptosis, without affecting or harming surrounding cells and without mounting an immune response.

The Institute said that another form of cell death, necroptosis, also instructed cells to die by a programmed series of events, with the difference that necroptosis occurred when something had gone wrong with the normal process of apoptosis.

"The necroptotic pathway signals that something sinister might be happening, alerting and recruiting key immune cells to the scene-of-the-crime," Mr Rickard said.

" Both types of cell death have been implicated in the development of immune disorders," Mr Rickard said. "Previous research has linked necroptosis, or inflammatory cell death, with inflammatory diseases such as psoriasis and, particularly, Crohn's disease."

WEHI said that the research team looked at how the loss of key molecules involved in either necroptosis or apoptosis affected inflammation and inflammatory disease development.

"We were surprised to discover that apoptosis was the culprit in the development of inflammatory skin disease, while more extensive, system-wide inflammation such as in the liver and spleen was driven by necroptosis," Mr Rickard said.

"This was quite unexpected, because apoptosis is not normally associated with inflammation," Mr Rickard said.

Prof Silke said that an understanding of necroptosis "could help to develop better strategies for treating inflammatory diseases".

"This work has also provided us with clues about how existing medications for inflammatory diseases such as psoriasis work, suggesting their effectiveness could be related to their inhibition of apoptosis and necroptosis cell death pathways," Prof Silke said. "These existing medications are very effective, however there are significant side-effects ... [and they] do not work for everyone and can lose their effectiveness over time".

"By further interrogating these cell death pathways and their role in inflammatory diseases, we may identify new therapeutic targets that provide relief for patients, with drastically reduced side-effects," Prof Silke said.

"We are only just beginning to understand the complex cascade of signals involved in necroptosis," Prof Silke said.

"It is clear though that necroptosis is very important in our response to infection and disease," Prof Silke said.

Prof Silke said that WEHI staff had had "great success in unravelling the many complex signals in apoptosis and developing potential treatments based on these findings".

Prof Silke said that Institute teams were "turning their attention to this new cell death pathway, to better understand how it functions in normal and diseased cells".

"We hope to have the same success and see new treatments based on these fundamental scientific findings in the future," Prof Silke said.

BIOTRON

Biotron says it has recruited all 60 patients in its phase II trial of BIT225 for hepatitis C genotypes 1 or 3 in Thailand.

Biotron said that the randomized, placebo-controlled three-month dosing study at six trial sites was designed to extend efficacy data and provide further confirmation of BIT225's safety and tolerability profile in longer term dosing using the new capsule formulation of the drug.

The company said that preliminary interim data was expected by April 2015.

Biotron managing director Dr Michelle Miller said the trial was a key study for the company, as previous data was based on four-week dosing regimes.

"It is important we provide further safety and efficacy data that demonstrates further safety and tolerability over 12 weeks," Dr Miller said.

"If successfully developed, BIT225 will most likely be used in combination with other new classes of direct-acting antiviral drugs, which currently require a minimum dosing period of 12 weeks," Dr Miller said.

"Safety and antiviral efficacy data to date has been extremely encouraging and we are confident this will be replicated in an extended dosing regime," Dr Miller said.

Biotron said trial patients were receiving 200mg of BIT225 twice daily for three months in combination with current standard of care therapies, pegylated interferon alfa 2b and ribavirin before continuing to receive standard of care out to 24 weeks for genotype 3 patients or 48 weeks for genotype 1 patients.

The company said that a previous phase IIa study showed that 100 percent of eight hepatitis C genotype 1 patients who received BIT225 400mg over four weeks in conjunction with standard of care therapies had undetectable levels of virus at the 48 week follow up, compared to seven in the 200mg group (88%) and six in the standard of care group (75%) (BD: Nov 16, 2012).

Biotron said that BIT225 showed efficacy in a phase II trial with interferon and ribavirin in patients co-infected with HIV and hepatitis C genotype 3, with all six patients who completed treatment having undetectable levels of hepatitis virus 12 weeks after ceasing all treatment (BD: Oct 10, 24, 2014).

"Despite recent advances in treatment of [hepatitis C], significant treatment gaps remain, in particular for genotype 3," Dr Miller said.

Biotron was unchanged at 9.7 cents.

UNILIFE CORP

Unilife says it has a 10 year supply agreement with an unnamed pharmaceutical company for its Depot-ject delivery system with an approved ocular injection therapy.

Unilife said that the pharmaceutical company's target therapy was approved in the US and Europe for the treatment of a high prevalence disease of the retina.

The company said it expected commercial availability of Depot-ject with the therapy after a 12 to 24 month process of customization and regulatory approval for the drug-device combination.

Unilife said that its Depot-ject was designed to allow a clinician to precisely deliver the therapy into the eye through an injection.

The company said it would begin to generate revenue from the agreement by the end of 2014 through an upfront fee and customization payments.

Unilife was up 1.5 cents or 2.6 percent to 58.5 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it hopes to raise up to $3,153,694 through a share plan at 1.35 cents a share

Genetic Technologies said shareholders eligible at the record date of December 2, 2014 would be able to apply for parcels of shares up to $7,500.

The company said Lodge Partners would be the share plan lead manager and the funds would be for commercializing its Brevagenplus breast cancer test and working capital.

Genetic Technologies was unchanged at 1.5 cents.

OBJ

OBJ says it has a development and licence term sheet with New York cosmetics company Coty Inc to use its Dermaportation magnetic delivery technology.

OBJ said that Coty would have the right to commercialize a skincare device incorporating its technology in a proprietary “Wand” device for the delivery of multiple formulations.

The company said that the agreement included milestones during the product development period and royalties payable on sales.

OBJ chairman Glyn Denison said that the commitment to licence a second technology of OBJ by another partnering company was “a very significant verification” of the technology.

OBJ was up 0.1 cents or 1.05 percent to 9.6 cents with 13.3 million shares traded.

COGSTATE

Cogstate says it has completed the sale of its Axon Sports training business to an unnamed American investment company (BD: Jun 6, 2014).

Cogstate said it would not receive any upfront payment but would be entitled to an undisclosed percentage of all revenue over the next five years.

The company said that the purchaser would assume all ongoing costs and liabilities of the Axon Sports training business, providing significant cost savings.

Cogstate was untraded at 19 cents.

CIRCADIAN TECHNOLOGIES

Circadian says it has created a clinical advisory board to develop its vascular endothelial growth factor C and D trap, OPT-302, for ophthalmic diseases.

Circadian said that the board would provide insight into the regulatory and clinical development strategy for OPT-302 as it prepared its phase I US clinical trial by July 2015.

The company said that the board would provide scientific, clinical and regulatory advice for the program as well as advice on ophthalmic drug development and commercialization.

Circadian said the board would include Arizona’s Retinal Consultants Prof Pravin Dugel, the University of Sydney’s Prof Mark Gillies, Johns Hopkins Wilmer Eye Institute’s Prof Peter Campochiaro and Harvard Medical School’s Prof Kameran Lashkari.

Circadian chief executive officer Dr Megan Baldwin said the “internationally recognized key opinion leaders ... [would] be instrumental in assisting us move this important clinical program forward”.

Circadian was up one cent or 6.25 percent to 17 cents.