Biotech Daily

Tuesday December 16, 2014

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHARMAXIS UP 10%, OPTISCAN DOWN 9%**

*** MELBOURNE UNI ANTIBODY DISCOVERY FOR ALL-DENGUE VACCINE**

*** FDA APPROVES OSPREY AVERT PLUS**

*** NOVOGEN: 'TRXE-009 ACTIVE AGAINST MELANOMA IN MICE'**

*** EUROPE UPHOLDS MESOBLAST OSIRIS STEM CELL PATENT CLAIMS**

*** OBJ CARTILAGE TREATMENT OPTION WITH P&G**

*** AUSINDUSTRY OK FOR ONCOSIL OFFSHORE R&D, EXPECTS $7m**

*** OBJ, P&G LAUNCH SK-II MAGNETIC EYE CARE IN HONG KONG, TAIWAN**

*** UP TO 18% OPPOSE 375k PSIVIDA DIRECTOR OPTIONS**

*** BENITEC APPOINTS DR CLAUDIA KLOTH HEAD OF MANUFACTURING**

MARKET REPORT

The Australian stock market fell 0.65 percent on Tuesday December 16, 2014 with the S&P ASX 200 down 33.8 points to 5,152.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and four were untraded. All three Big Caps fell.

Pharmaxis was the best, up 0.5 cents or 10 percent to 5.5 cents with 333,904 shares traded. Analytica and Antisense climbed eight percent or more; Acrux and Benitec were up more than six percent; Atcor and Starpharma were up more than five percent; Anteo and Impedimed climbed more than four percent; Phosphagenics was up 3.1 percent; Avita and IDT rose more than two percent; with Bionomics and Medical Developments up more than one percent.

Optiscan led the falls for the second day in a row, down 0.4 cents or 8.7 percent to 4.2 cents with 547,180 shares traded. Osprey lost six percent; Admedus, Biotron and Neuren fell more than four percent; Cellmid, Compumedics and Oncosil were down more than three percent; Alchemia, Prana, Sirtex and Universal Biosensors shed more than two percent; Clinuvel, Mesoblast and Nanosonics were down more than one percent; with Cochlear, CSL and Resmed down by less than one percent.

UNIVERSITY OF MELBOURNE

The University of Melbourne says it was involved in the discovery of a class of antibodies that could make the four different types of dengue virus non-infectious.

The University said the research with Imperial College London could lead to the development of better vaccines and tests that could reduce the incidence of dengue fever.

The University said that the research, entitled 'A new class of highly potent, broadly neutralizing antibodies isolated from viremic patients infected with dengue virus', published in Nature Immunology, outlined the first reported incidence of an antibody that could neutralize all four types of the dengue virus produced from human or mosquito cells.

An abstract is at: http://www.nature.com/ni/journal/vaop/ncurrent/full/ni.3058.html.

Co-author Melbourne's Doherty Institute for Infection and Immunity Prof Cameron Simmons said the findings could lead to vaccines targetting all strains of the dengue virus.

"This unique discovery makes the future development of vaccines that could prevent the spread of the disease a realistic goal and may also pave the way for a universal [dengue virus] vaccine," Prof Simmons said.

The University said researchers analyzed anti-dengue antibodies from patients who were infected with the virus and found a new class of antibodies that were highly effective at neutralizing the virus, which bound to a newly discovered epitope, or a unique structure that antibodies could recognize and bind to, that was present in all forms of the disease.

The University said that the geographical spread of the dengue virus continued to widen and while infection with one form of the virus led to life-long protection against that specific form but not against others.

OSPREY MEDICAL

Osprey says the US Food and Drug Administration has approved 510(k) market clearance for its Avert Plus system for cardiac contrast dye reduction and monitoring.

Osprey said that it had approval for the Avert dye reduction system but the enhanced system included a disposable smart syringe and reusable liquid crystal display monitor.

The company said that the Avert Plus monitored and displayed a physician-inputted threshold volume based on the patient's kidney function and compared it to contrast volumes injected throughout the procedure.

Osprey said the system automatically kept real-time track of the amount of dye being used and the amount diverted and allowed for a more accurate method of recording the amount of dye delivered to the patient.

Osprey chief executive officer Mike McCormick said the company was "delighted to receive FDA clearance for this addition of our contrast monitoring technology to our Avert product platform, which enables us to commercialize our full Avert Plus system in the US".

"The enhanced Avert Plus will be highly sought after for its benefits and value to physicians, patients and hospitals once we initiate our full US launch," Mr McCormick said.

Mr McCormick said that the full US launch would follow receipt of the expanded market claim for contrast induced nephropathy reduction expected by the end of 2015.

He said the company was in the process of incorporating the Avert Plus into its commercializsation efforts by first upgrading existing customers in the coming months, followed by expansion to additional hospital accounts in Texas.

Osprey said that the Avert Plus provided a simple way for doctors and hospitals to comply with dye volume recording guidelines issued by the US cardiology community to improve the quality of care following coronary procedures such as stenting or angioplasty.

Osprey climbed six cents 12 percent to 56 cents, closing down three cents or six percent at 47 cents, with 262,559 shares traded.

NOVOGEN

Novogen says that lead candidate TRXE-009 originally developed for brain cancers, has been shown also to be highly active against melanoma in mice.

Novogen said that the preclinical research confirmed that TRXE-009 was an important potential treatment for melanoma, including secondary brain cancers due to melanoma, for which there currently were no effective therapies and it offered evidence, for the first time, of an hypothesized link between brain cancer and melanoma.

The company said that the link had long been considered a possibility because nerve cells and melanocytes, the melanin pigment-bearing cells in skin that lead to melanoma, had a common origin in the embryo known as the neural crest.

Novogen said that the primitive tissue gave rise to the neural cells that form the brain, spinal cord and peripheral nerves, as well as cells that form the structures of the skull; and melanocytes also come from this embryonic tissue.

The company said that until now, no functional link had been found between brain cells and melanocytes, or between brain cancer and melanoma.

Novogen said that TRXE-009 was the first compound to demonstrate the possibility of a common link, suggesting that it was the first drug with the ability to identify cancers arising in cells that had the neural crest as their common origin.

The company said that TRXE-009 had been confirmed as a potential new treatment for both adult and paediatric neural cancers and it had previously claimed a world-first in having exceptionally high killing activity against adult brain cancer, or glioblastoma multiforme, stem cells and against the paediatric brain cancers, or medulloblastoma and diffuse interstitial pontine glioma, all tumors that were highly resistant to chemotherapies.

Novogen said that the same high potency was confirmed against melanoma cells, with activity unaffected by the tumor's BRAF gene status.

Novogen chief executive officer Dr Graham Kelly said the finding "brings the value of TRXE-009 into true perspective for us".

"We initially developed the compound for brain cancer," Dr Kelly said. "We saw it as the first chemotherapy with the potential to make a meaningful difference to the survival prospects of patients, both adult and children, with primary brain cancer."

"From there we looked at its ability to kill other cancers of neural origin, and discovered that the same potency against brain cancer cells extended to neuroblastoma cells, a potential deadly cancer in children that arises in peripheral nerve tissue outside of the brain," Dr Kelly said.

"With the realization that we arguably had the first anti-cancer drug capable of recognizing cancers arising in tissues with a common neural crest origin, it was an obvious next step to look at melanoma," Dr Kelly said.

Novogen said it would deliver TRXE-009 as a proprietary construct known as Trilexium, developed to maximize the bio-availability of the drug to cancer cells in the body, with animal xenograft studies of human cancer confirming the efficacy of Trilexium.

Dr Kelly said the new finding "completely changes the outlook for this drug candidate".

"From a drug that was due to come into the clinic specifically for the treatment of adult and childhood neural cancers, we now are presented with a prospective treatment for malignant melanoma, including the treatment of secondary brain cancers due to melanoma for which there currently is no effective therapy," Dr Kelly said.

"We naturally are keen to bring Trilexium into the clinic as soon as possible, but our entire focus at the moment in terms of a clinical program is the product candidate, Cantrixil," Dr Kelly said. "Trilexium will enter the clinic only when we have been successful in raising funds specifically ear-marked for this project."

Novogen climbed 8.1 cents or 96.4 percent to 16.5 cents with 15.7 million shares traded.

MESOBLAST

Mesoblast says that the European Patent Office has upheld claims covering the use of mesenchymal stem cells for inflammatory bowel diseases, multiple sclerosis, and autoimmune encephalomyelitis.

Mesoblast said that the European patent was number 1727892 (B1) described by the European Patent Office as 'Mesenchymal stem cells and uses therefor' cited inventors as Mark Pittenger and Sudeepta Aggarwal, with Osiris Therapeutics as the applicant.

Last year, Mesoblast acquired the mesenchymal stem cell assets of the US-based Osiris for up to $US100 million in cash and scrip (BD: Oct 11, 2013).

Today, Mesoblast said that European Patent Office opposition division based in Munich, Germany, rejected all grounds of the opposition mounted by a third party opponent.

The company said that its patent claims were found to be valid in their originally granted form.

Mesoblast said that the opponents challenged the patent as a whole and supported its arguments and notice of opposition with 29 documents.

The company said that the opposition division upheld the patent without amendment against all allegations of added matter, lack of priority, lack of novelty, lack of inventive step and insufficient disclosure.

Mesoblast chief executive Prof Silviu Itescu said the company would "vigorously defend our robust intellectual property estate and commercial rights and are pleased that our patent position in the use of [mesenchymal stem cells] for inflammatory bowel diseases and demyelinating nerve diseases has been validated".

"Management of our intellectual property, which comprises more than 60 patent families, has high priority as part of our ongoing efforts to maintain and augment the value of our advanced pipeline of novel cell-based product candidates," Prof Itescu said.

Mesoblast fell eight cents or 1.9 percent to $4.10 with 697,565 shares traded.

OBJ

OBJ says that wholly-owned subsidiary Bodyguard Life Sciences has an evaluation and option agreement for its cartilage degeneration treatment with Procter and Gamble.

OBJ said that Bodyguard and Procter and Gamble would work together to evaluate the clinical efficacy, consumer appeal and commercial potential of the Bodyguard range of products and technologies.

The company said that Procter and Gamble would conduct market research and usability trials for the right to review the outcomes of the clinical evaluation program and would have an option to negotiate a product development agreement and licence.

OBJ said that Bodyguard was its musculoskeletal division, using the magnetic microarray technology to deliver nutritional and structural ingredients directly into the joint cavity.

The company said Bodyguard had developed a platform of lifestyle maintenance products designed to reduce joint degeneration and pain by altering the underlying cause of cartilage degeneration.

OBJ said that an evaluation earlier this year showed the Bodyguard technology and its Lubricen formulation substantially improved joint function across a range of medically diagnosed knee pathologies following 14 days of daily use (BD: Apr 28, 29, 2014).

OBJ said that the existing agreement with Procter and Gamble was limited to the beauty and grooming category and this agreement expanded it to lifestyle and consumer health.

The company said that the first product to be evaluated would be Kneeguard targeting knee cartilage degradation.

OBJ was up 0.4 cents or 4.7 percent to 8.9 cents with 7.7 million shares traded.

ONCOSIL MEDICAL

Oncosil says that the Federal Government department Ausindustry has approved its overseas research and development expenditure for the 43.5 percent Tax Incentive.
Oncosil said that the finding certified that all eligible expenditure incurred in relation to its development project would be subject to the R&D Tax Incentive and was expected to be about $6.74 million through the program.
Oncosil executive chairman Dr Roger Aston said that the finding was important “because it gives validation to our processes and the manner in which our project is being conducted”.
“It also gives an increased level of certainty to our internal cash flow projections as the approval is binding,” Dr Aston said.
“The confidence that we will receive these tax refunds each year allows us to continue to focus on our primary objectives,” Dr Aston said.
Oncosil fell 0.3 cents or 3.5 percent to 8.2 cents.

OBJ

OBJ says the SK-II ‘magnetic eye care kit’ developed with Procter and Gamble was launched in Hong Kong and Taiwan last week.
In September, OBJ said Proctor and Gamble had launched the product, incorporating its magnetic micro-array technology, in Seoul, South Korea and the SK-II was Procter and Gamble’s “fastest growing prestige skincare and cosmetic brand” (BD: Sep 30, 2014).
The company said that the SK-II Eye Wand was the first of three work plans with for Procter and Gamble (BD: Apr 28, 2014).
OBJ said that Proctor and Gamble had reported that stocks for the first two months in South Korea had sold out within the first few days and that initial quantities for the Hong Kong launch had been doubled in anticipation of the level of consumer interest.

PSIVIDA

Psivida’s annual general meeting passed all resolutions, with up to 18 percent opposition to the issue of 375,000 options to directors and chief executive officer Dr Paul Ashton.
The strongest percentage dissent was against the issue of 20,000 options to director Peter Savas with 1,613,269 votes (18.2%) against the resolution and 7,251,482 votes (81.8%) in favor.
Psivida shareholders similarly opposed the grant of 245,000 options to Dr Ashton, 30,000 options to chairman Dr David Mazzo, with 40,000 options for Dr James Barry and 20,000 options each for Douglas Godshall and Michael Rogers (BD: Oct 27, 2014).
The company said that directors Dr Ashton, Dr Mazzo, Mr Godshall, Dr Barry, Mr Rogers and Mr Savas were elected with more than 8.5 million votes in favor and up to 563,479 votes ‘withheld’.
Psivida said that the ratification of previous share issues were supported by a similar margin, but the ratification of the appointment of Deloitte & Touche as auditors attracted the strongest opposition with 1,945,499 votes against, but with the strongest supporting vote, with 17,430,482 votes in favor.
The company’s most recent Appendix 3B said that Psivida had 29,362,295 US shares and Chess depositary interests on issue, meaning that the opposition to the directors options amounted to 5.5 percent of the company and the opposition to Deloitte & Touche was 6.6 percent, sufficient to requisition extraordinary general meetings.
Psivida was untraded at $5.21.

BENITEC BIOPHARMA

Benitec says it has appointed Dr Claudia Kloth as its vice-president of manufacturing, effective from January 5, 2015.

Benitec said that Dr Kloth 14 years experience in process development and manufacturing, most recently with gene therapy vectors, including adeno-associated viruses, which Benitec was using in its hepatitis C, hepatitis B and age-related macular degeneration programs.

The company said that previously Dr Kloth led the Basel, Switzerland-based Lonza's process development group in the development, optimization and transfer of viral-based and cell therapy products to manufacturing, through scalable processes.

Benitec said that Dr Kloth was based in the US.

Benitec chief executive officer Dr Peter French said that Dr Kloth brought "a wealth of experience" to development and scale-up of the adeno-associated virus manufacturing requirements for its DNA-directed RNA-interference-based therapeutics.

"We have taken this step now as we are confident that our TT-034 program is progressing well and we are looking at the next stage, scale-up of adeno-associated virus manufacturing to service the potentially very large markets for our novel therapeutic products for [hepatitis C and B]," Dr French said.

Benitec was up 5.5 cents or 6.4 percent to 91.5 cents.