



Biotech Daily

Wednesday November 19, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: USCOM UP 14%, OPTISCAN DOWN 28%**
- * **GENETIC TECHNOLOGIES DR MERVYN JACOBSON - GAOL LIKELY**
- * **QUEENSLAND WELCOMES STAFFORD FOX \$2.5m FOR BRAIN INSTITUTE**
- * **BONE TERMINATES FOUNDER PROXIMA DEAL – REVIEWING OPTIONS**
- * **WEHI SHOWS OATS TO COELIAC LINK**
- * **GENETIC TECHNOLOGIES SELLS ‘HERITAGE’ BUSINESS FOR \$2m**
- * **CLJE TAKES 7% OF ADVANCED SURGICAL**

MARKET REPORT

The Australian stock market fell 0.57 percent on Wednesday November 19, 2014 with the S&P ASX 200 down 30.9 points to 5,368.8 points.

Fourteen of the Biotech Daily Top 40 stocks were up, 11 fell, nine traded unchanged and six were untraded.

Uscom was the best, up 2.5 cents or 14.3 percent to 20 cents with 26,581 shares traded.

Benitec climbed 9.6 percent; IDT was up 6.1 percent; Anteo and Neuren were up more than four percent; Antisense and Universal Biosensors were up more than three percent; Circadian, Clinuvel and Resmed rose more than two percent; Alchemia, Biotron, Cochlear, Impedimed and Nanosonics were up more than one percent; with Medical Developments up 0.85 percent.

Optiscan led the falls, retreating from its more than 100 percent rise, down 3.1 cents or 28.2 percent to 7.9 cents with 28.9 million shares traded.

Pharmaxis lost 7.3 percent; Genetic Technologies fell 6.7 percent; Patrys was down 5.3 percent; Admedus, Bionomics and Oncosil fell more than four percent; Acrux and Living Cell were down three percent or more; Prana shed 2.7 percent; with CSL and Sirtex down by less than one percent.

GENETIC TECHNOLOGIES

The Victoria Supreme Court has been told that Genetic Technologies founder Dr Mervyn Jacobson must serve a term of imprisonment.

Prosecuting for the Commonwealth Department of Public Prosecutions on behalf of the Australian Securities and Investments Commission, Jeremy Rapke QC told Justice Stephen Kaye that the sentence "must be a term of imprisonment that will have to be served by the accused".

The barrister defending Dr Jacobson, Sam Tovey told the court that "imprisonment is appropriate" but suggested it might not be served immediately, effectively requesting a suspended sentence.

The plea hearing was adjourned for about 30 minutes to allow arrangements to be made for Dr Jacobson to undergo a medical examination and to ensure that the surety continued for his bail arrangements.

Justice Kaye extended Dr Jacobson's bail and adjourned the plea hearing until Monday November 24, 2014.

QUEENSLAND GOVERNMENT

Queensland Science Minister Ian Walker says a \$2.5 million donation from the Stafford Fox Medical Research Foundation will establish a fellowship in stroke-induced dementia. Mr Walker said that the donation was "one of Australia's largest private donations for research into the debilitating condition".

"Queensland Brain Institute will use the funds to establish a five-year senior research fellowship in stroke-induced dementia based at QBI's Clem Jones Centre for Ageing Dementia," Mr Walker said.

"This is a coup for the Clem Jones Centre, which the Queensland Government committed \$9 million towards to drive an all-out assault on dementia, one of the big health issues facing Australia," Mr Walker said.

A Queensland Government media release said that stroke-induced dementia, also called vascular dementia, was the second most common form of dementia after Alzheimer's disease, with the number of Queenslanders with dementia expected to rise from 48,674 in 2011 to 215,272 in 2050.

The Government said that about 10,000 Queenslanders had a stroke in 2012, and about 85,000 Queenslanders were living with the effects of stroke.

"People who have had a stroke are nine times at greater risk of dementia than people who have not had a stroke," Mr Walker said.

"This is an insidious and terrible affliction often caused by small strokes so tiny that people do not even notice," Mr Walker said. "The cumulative effect is brain damage."

"Treatment now is limited to preventing further strokes and post-stroke rehabilitation," Mr Walker said. "But there is nothing to try to repair brain damage and this will be the research focus."

Queensland Brain Institute director Prof Perry Bartlett said the fellowship meant a research group would work to unravel the molecular mechanisms that promote recovery of cognitive function following a stroke.

"By understanding the mechanisms, we hope we will be able to develop new therapies and treatments to help improve the cognition of patients who have suffered a stroke," Prof Bartlett said.

The Government said that the Foundation was established in 2013 after the death of Moyna Fox and named in honor of her husband, former BP Australia chief executive James Stafford Fox, and both Mr and Ms Fox succumbed to dementia before their deaths.

BONE MEDICAL

Bone says it will "terminate the agreements with the Proxima Group" following an evaluation of its technologies and near completion of product development studies. Bone was created by investors in Proxima and licenced Capthymone and BN006 compounds from four subsidiary companies within the Proxima Group and had the use of the Proxima Laboratory and Research Services laboratory.

Proxima co-founder and research director Dr Roger New was formerly Bone's chairman (BD: Jul 11, Sep 22, 2011; Jan 29, Apr 4, May 12, Jun 20, 2014).

Bone said it terminated the agreements with the Proxima following a nine month evaluation of Proxima's oral delivery technologies and near completion of new product development studies.

Bone said it "has concluded that it is not in the commercial interests of the company or its shareholders to continue with the Proxima Group under the current structure".

Bone said it was in discussions with one of the Group's subsidiary companies to obtain some interest in BN006 pending the outcome of the current studies and the parties agreeing terms acceptable to Bone.

The company said that following the termination of the agreements with Proxima it would reduce expenditure, maintain a healthy cash balance and continue "reviewing other opportunities both in health sciences and other sectors".

Bone said that the Capthymone oral treatment for osteoporosis had not generated meaningful parathyroid hormone levels in blood, when comparing parathyroid hormone levels from different doses of its oral parathyroid hormone Capthymone against the commercially available injectable Forteo.

The company said that parathyroid hormone was a naturally-occurring hormone that played an important role in regulating bone formation and intact parathyroid hormone peptides in the blood would permit a faster, simplified development plan for Capthymone.

Bone said that the data indicated that the oral doses did not generate meaningful parathyroid hormone blood levels as measured by two different assay methods.

The company said that last year a similar trial using a different formulation and only one assay method showed some sign of biological activity but no blood levels and the results had not been evaluated using the second assay method.

Bone said that previous studies using the second type of assay with the two available Capthymone formulations did show some evidence of positive blood levels, but it could not apply additional funds to continue testing clinical samples from prior studies without exceeding the funds allocated for new Capthymone product development studies.

Bone said that since the results from the Capthymone clinical trials conducted to date do not support the original objective of a faster, simplified development plan, the current trial would conclude its Capthymone studies and program evaluation.

The company said there had been a delay in the development of BN006 for rheumatoid arthritis and the contract laboratory performing the experiments needed to repeat certain parts of the study program and was doing so at the laboratory's expense.

Bone said this resulted in a delay for the final study data, which was expected shortly.

The company said that its collaboration with the William Harvey Research Institute investigating the mechanism of action of BN006 had been completed.

Bone said that the experimental work was to clarify how BN006 appeared to exert a selective anti-inflammatory effect with considerably less reduction in the inflammatory agent that contributed to the disease.

The company said that a particular hypothesis was tested and further follow-up mechanism of action work was needed to more fully understand how BN006 worked.

Bone fell 0.4 cents or 36.4 percent to 0.7 cents with 21.65 million shares traded.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it has identified why some people with coeliac disease show an immune response after eating oats.

The Institute said that its researchers identified the key components in oats that triggered an immune response in some people with coeliac disease and the findings might lead to better tests for oat toxicity and have implications for new treatments being developed for coeliac disease.

WEHI said that as many as one in 60 women and one in 80 men in Australia had coeliac disease, an autoimmune condition caused by consuming gluten, a protein found in wheat, rye and barley.

The Institute said that the abnormal immune response to gluten damaged the small intestine and was associated with gastrointestinal symptoms including vomiting and diarrhoea, lethargy and an increased risk of osteoporosis and cancer.

WEHI said that people with coeliac disease must adhere to a lifelong gluten-free diet that excluded wheat, barley and rye.

The Institute said that the question of whether oats were toxic for people with coeliac disease was controversial, but because oats contain proteins, called avenins, that were similar to gluten, oats were excluded from the gluten-free diet in Australia.

WEHI said its researchers with colleagues from Monash University and the Cambridge Massachusetts-based Immusant led the 10-year study.

Immusant's chief scientific officer and co-founder Dr Bob Anderson identified the first potential vaccine for coeliac disease while working at the Walter and Eliza Hall Institute (BD: May 9, 2011; Jan 22, 2012).

WEHI said that the research showed that oat consumption triggered an immune response in eight percent of the 73 participants with coeliac disease.

The article, entitled 'Ingestion of oats and barley in patients with celiac disease mobilizes cross-reactive T cells activated by avenin peptides and immuno-dominant hordein peptides' was published in the Journal of Autoimmunity and an abstract is available at:

<http://www.sciencedirect.com/science/article/pii/S0896841114001474>.

WEHI researcher Dr Melinda Hardy said the study was the first of its kind to comprehensively profile immune responses to oats in people with coeliac disease.

"The significance of previous studies performed in test tubes was unclear," Dr Hardy said.

"By studying people with coeliac disease who had eaten oats, we were able to undertake a detailed profile of the resultant immune response in their blood stream," Dr Hardy said.

"Our study was able to establish the parts of oat avenins that cause an immune response in people with coeliac disease," Dr Hardy said.

WEHI's head of coeliac research Dr Jason Tye-Din and a gastroenterologist at the Royal Melbourne Hospital said the study showed oats were well tolerated by most people with coeliac disease, but in a proportion of people with coeliac disease oat consumption could trigger immune responses similar to those caused by eating barley.

"This study provides specific detail on the parts of oats stimulating immune responses, and highlights the relevance of grains other than wheat in coeliac disease," Dr Tye-Din said. "This is a vital piece of the puzzle that informs the development of targeted tests for oat toxicity and the design of new treatments for people with coeliac disease."

Coeliac Australia president Tom McLeod said the good health of people with coeliac disease depended on strict removal of dietary gluten.

"This study adds to our understanding of oats in coeliac disease, and sets the scene for definitive evaluation on what can be safely consumed by people with coeliac disease," Mr McLeod said.

GENETIC TECHNOLOGIES

Genetic Technologies says it has sold its heritage Australian Genetics business to Primary Health Care subsidiary Specialist Diagnostics Services for \$2 million in cash.

Genetic Technologies chief executive officer Alison Mew told Biotech Daily that the heritage assets were the canine, medical and paternity testing and formerly the forensic testing work for the New South Wales Police.

Genetic Technologies said the sale followed its announced plan to sell non-core assets and focus business activities on the US molecular diagnostics market and commercialization of its lead breast cancer risk test Brevagenplus (BD: Sep 15, 2014).

Ms Mew said the sale was "another material milestone in our transformation to becoming a streamlined and focused molecular diagnostics company committed to the commercialization of our flagship breast cancer risk test, Brevagenplus".

"Implementation of the restructure plans continue and are on track for completion over the next quarter," Ms Mew said.

In an October notice of meeting Genetic Technologies said that shareholders would vote to change the company's name to 'Phenogen Sciences' the name of its US Brevagen sales subsidiary at the annual general meeting on November 25, 2014.

In 2010, Genetic Technologies established the Charlotte North Carolina Phenogen Sciences to market the breast cancer test (BD: Oct 26, 2010).

Genetic Technologies fell 0.1 cents or 6.7 percent to 1.4 cents.

ADVANCED SURGICAL DESIGN & MANUFACTURE

CLJE Investments has become a substantial shareholder in Advanced Surgical with 4,600,000 shares or 7.22 percent of the company.

The Baulkham Hills, Sydney-based CLJE said it bought the shares on October 26, 2014 for five cents a share.

Advanced Surgical raised \$1 million in an under-written rights issue at five cents a share (BD: Oct 24, 2014).

The initial substantial shareholder notice was signed by director Craig Andrew Harris.

Advanced Surgical was unchanged at 5.5 cents.