

Biotech Daily

Tuesday March 22, 2016

Daily news on ASX-listed biotechnology companies

* ASX, BIOTECH EVEN: ONCOSIL UP 7%, BIOTRON DOWN 6%

- * NHMRC \$3.3m FOR WINDFARM HEALTH IMPACTS
 - AMA POSITION, BIOTECH DAILY COMMENT
- * ACTINOGEN APPLIES FOR PHASE II XANAMEM FOR ALZHEIMER'S TRIAL
- * BIOPHARMACEUTICALS AUSTRALIA: \$250k PARANTA GRANT 'PIVOTAL'
- * IMPEDIMED SHARE PLAN RAISES \$74k OF HOPED-FOR \$7.5m
- * ONCOSIL POSTPONES LOAN SHARE EGM

MARKET REPORT

The Australian stock market was unchanged on Tuesday March 22, 2016 with the ASX200 even at 5,166.6 points.

Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, seven traded unchanged and three were untraded.

Oncosil was the best, up one cent or 6.7 percent to 16 cents with 3.8 million shares traded.

Anteo and Clinuvel climbed more than six percent; Medical Developments was up 4.4 percent; Tissue Therapies and Uscom rose more than two percent; Bionomics, Cochlear, Compumedics, CSL, Ellex, Nanosonics, Opthea, Orthocell, Osprey and Universal Biosensors were one percent; with Reva up 0.9 percent.

Biotron led the falls, down half a cent or 6.25 percent to 7.5 cents with 692,229 shares traded.

Cellmid lost 5.3 percent; Benitec fell four percent; Acrux, Actinogen, Living Cell and Polynovo were down more than three percent; Impedimed, Pharmaxis, Prima and Pro Medicus shed more than two percent; Admedus and Mesoblast were down more than one percent; with Resmed, Sirtex and Starpharma down by less than one percent.

NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

The National Health and Medical Research Council says it has awarded two grants worth \$3.3 million to study the effects of wind farms on human health.

The Council's chief executive officer Prof Anne Kelso said that further research was needed to explore the relationships between wind farms and human health.

"Existing research in this area is of poor quality and targeted funding is warranted to support high quality, independent research on this issue," Prof Kelso said.

The council said that research at South Australia's Flinders University would explore relationships between noise from wind farms and effects such as annoyances and reduced sleep and quality of life, while research at the University of New South Wales would investigate "the broader social and environmental circumstances that may influence the health of people living near wind farms".

Prof Kelso said the grants would support "only high quality, well designed research proposals ... NHMRC supports only the most outstanding research".

"Each application for this funding underwent the same stringent independent review process we apply to all NHMRC grant applications," Prof Kelso said.

The Council said that the grants were awarded in response to the 2015 Targeted Call for Research into Wind Farms and Human Health, following the release of the February 2015 NHMRC Statement: Evidence on Wind Farms and Human Health.

That report said: "There is no direct evidence that exposure to wind farm noise affects physical or mental health."

"While exposure to environmental noise is associated with health effects, these effects occur at much higher levels of noise than are likely to be perceived by people living in close proximity to wind farms in Australia."

Australian Medical Association

In 2014, the AMA categorically rejected the health claims, saying: "The available evidence does not support the view that the infrasound or low frequency sound generated by wind farms ... causes adverse health effects on populations residing in their vicinity." "The infrasound and low frequency sound generated by modern wind farms in Australia is

well below the level where known health effects occur, and there is no accepted physiological mechanism where sub-audible infrasound could cause health effects." "Individuals residing in the vicinity of wind farms who do experience adverse health or well-being, may do so as a consequence of their heightened anxiety or negative

perceptions regarding wind farm developments in their area. Individuals who experience heightened anxiety or diminished health and well-being in the context of local wind farms should seek medical advice."

The AMA said that the reporting of health scares and misinformation could contribute to heightened anxiety and community division.

"Electricity generation by wind turbines does not involve production of greenhouse gases, other pollutant emissions or waste, all of which can have significant direct and indirect health effects."

Biotech Daily Comment

Biotech Daily is astounded that the NHMRC has co-operated with what is clearly a political move from some members of the Liberal National Party Government to restrict what they call "unsightly" wind farms in favor of the apparently more attractive open-cut coal mines. There have been a plethora of reports on wind farm noise and indeed this writer has occasion to stay very close to a major wind farm. There is no noise. The NHMRC is wasting scarce grant funding on a political stunt. **David Langsam**

ACTINOGEN MEDICAL

Actinogen says it is preparing for its 200-patient 'Xanadu' pivotal phase II trial of Xanamem for mild Alzheimer's disease.

Actinogen said that it was applying for regulatory and ethical approvals to run the trial in Australia, the UK and the US and preparing research sites for recruiting patients. The company said that Xanamem had been designed to inhibit the excess production of the stress hormone cortisol in the brain and "recent global research has consistently demonstrated that excess cortisol is associated with cognitive decline and amyloid plaque build-up and neurotoxicity in the brain, which are the hallmarks of Alzheimer's disease". The company said that an advisory board had design the trial, included the University of Edinburgh's Prof Craig Ritchie, Victoria Mental Health Research Institute director Prof Colin Masters and Neurological Institute of Cleveland Clinic's Prof Jeff Cummings. Actinogen said that worldwide there were nearly 50 million people with the disease, with a total estimated cost of treating the disease at close to \$US1,000 billion. Last year, Actinogen said that its 24-volunteer, dose-ranging, phase I trial of Xanamem

confirmed safety and tolerability up to 35mg twice daily, the drug crossed the blood-brain barrier and was effectively delivered to the brain (BD: May 12, Sep 29, 2015). Actinogen fell 0.3 cents or 3.85 percent to 7.5 cents with 1.9 million shares traded.

BIOPHARMACEUTICALS AUSTRALIA, PARANTA BIOSCIENCES

Biopharmaceuticals Australia says its \$250,000 grant to Paranta "was pivotal" for the manufacture of PB01 drug product for phase I cystic fibrosis clinical trials. The Queensland Government-owned Biopharmaceuticals Australia said the \$250,000 funded the manufacture of the recombinant human follistatin PB01drug product for Paranta's first-in- human, phase I clinical trials

Biopharmaceuticals Australia said that the first two trials were conducted at CMax in Adelaide and assessed the safety, tolerability and pharmacokinetics of single and multiple ascending doses of orally inhaled PB01.

Biopharmaceuticals Australia said that the first trial had been completed "with excellent results and dosing in the second trial [was] underway".

Last year, the Melbourne-based Paranta says it had raised \$7 million to develop recombinant human follistatin PB01 for cystic fibrosis (BD: Oct 1, 2015).

Paranta chief executive officer Ross Barrow told Biotech Daily that a three-part, phase I trial of 80 healthy volunteers was underway for the first study of inhaled PB01.

The company said the study was a randomized, double-blind, placebo controlled trial, with the first two stages at CMax, with the third stage expected to start in April 2016 in Manchester, UK to investigate the effects of a single dose of PB01 on lung inflammation.

Manchester, UK to investigate the effects of a single dose of PB01 on lung inflammation. Paranta is a private company.

IMPEDIMED

Impedimed says it share purchase plan at 95 cents a share, which was capped at \$7.5 million, has raised \$74,129 (BD: Feb 9, 2016).

Impedimed confirmed that its placement at the same price raising \$75,000,000 had been completed with shareholders approving the issue of the second tranche shares. In February, Impedimed said the capital raised would fund sales of its L-Dex

lymphoedema test and develop a chronic or congestive heart failure test.

Impedimed fell 2.5 cents or 2.8 percent to 87 cents.

ONCOSIL MEDICAL

Oncosil says it has withdrawn all resolutions for its extraordinary general meeting planned for March 24, 2016 and expects to hold a replacement meeting in May 2016.

In February, Oncosil said the meeting would vote to elect Dr Chris Roberts a director and issue him 10,000,000 loan shares, with a further 14,000,000 loan shares for chief executive officer Daniel Kenny (BD: Feb 25, 2016).

Mr Kenny told Biotech Daily at that time that the loan share price would be the market price on the day of issue following shareholder approval.

Oncosil said that shareholders would also vote on extending the vesting period and repayment for a 500,000 share tranche of loan shares for chairman Dr Roger Aston and extend the vesting period and repayment period for a tranche of 5,000,000 loan shares for director Martin Rogers (BD: Mar 21, 2014).

Oncosil said that it had previously issued 5,000,000 shares at 10 cents each to Mr Rogers, 12,000,000 at 13 cents to Mr Kenny and 2,000,000 at 13 cents each to Dr Aston. Today, Oncosil said that there would be amendments to four of the five resolutions to be put to shareholders at the meeting, dealing with the proposed loan share issues and amendments to certain loan shares already on issue.

The company said that the amendments related to the pricing of the shares given the change in the share price since the loan share issues were originally proposed and the notice of the meeting was issued.

Oncosil closed at 14.5 cents on February 25 when the meeting was announced, and at 16 cents today.

In February Oncosil raised \$10 million in a placement to Regal Funds at 22 cents a share and had been trading as high as 27.5 cents a share in January (BD: Feb 10, 2016). Oncosil said it was not the intention to issue loan shares or amend loan shares already

issued following the share price change after posting the notice of meeting.

The company said the amendments would be aligned with the interests of all shareholders.

Oncosil said that "all shareholders consulted have been highly supportive of the appointment of Dr Roberts as a director ... [but] in the interests of saving costs, the company has elected to defer all resolutions".

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