

# **Biotech** Daily

# Friday December 7, 2012

Daily news on ASX-listed biotechnology companies

\* ASX UP, BIOTECH DOWN: OPTISCAN UP 14%, LIVING CELL DOWN 8%

- \* NOVOGEN BACK TO CANCER FUTURE WITH CEO PROF GRAHAM KELLY
- \* WEHI IMMUNE 'KILL SWITCH' NLRP1 COULD BE CHEMOTHERAPY TARGET
- \* PROCTOR & GAMBLE, OBJ MAGNETIC TRANSDERMAL TRIALS
- **\* BIONICHE DIRECTOR NICK PHOTIADES RETIRES**

## MARKET REPORT

The Australian stock market was up 0.94 percent on Friday December 7, 2012 with the S&P ASX 200 up 42.5 points to 4,551.8 points.

Ten of the Biotech Daily Top 40 stocks were up, 14 fell, 11 traded unchanged and five were untraded. All three Big Caps were up.

Optiscan was the best, up 1.2 cents or 13.6 percent to 10 cents with 90,333 shares traded.

Antisense climbed 8.3 percent; Mesoblast was up 6.4 percent; Acrux was up 4.6 percent; Anteo and Sunshine Heart were up more than three percent; CSL, Patrys, Prana, Reva and Starpharma rose two percent or more; Resmed was up 1.5 percent; with Cochlear up 0.6 percent.

Living Cell led the falls, down 0.4 cents or eight percent to 4.6 cents with 226,504 shares traded.

Allied Health and Phylogica fell four percent or more; GI Dynamics, Phosphagenics and Psivida lost more than three percent; Neuren and Genetic Technologies shed more than two percent; Bionomics, Sirtex, Tissue Therapies and Universal Biosensors were down one percent or more; with Heartware and Pharmaxis down by less than one percent.

#### <u>NOVOGEN</u>

Novogen has acquired Triaxial Pharmaceuticals to return the company to isoflavone based development with former director Prof Graham Kelly as chief executive officer. In 2006, Prof Kelly resigned as a Novogen director and chairman of its US subsidiary Marshall Edwards, now MEI Pharma, (BD: Oct 30, 2006).

In 2010, Novogen's share price collapsed, following the release of non-significant results for its 142-patient phase III phenoxodiol ovarian cancer trial, and later that year, the company sold the isoflavone technology to Marshall Edwards (BD: Jun 2, Sep 9, 2010). Today, Prof Graham Kelly said that with incoming chief scientific officer Dr Andrew Heaton, changes had been made to the original Novogen technology to enable it to avoid problems of delivery and potency, as well as passing through the blood-brain barrier to target brain cancers.

Prof Kelly said that one of the earlier issues was that isoflavonoids would become coated with sugar in the bloodstream and by the tumors they were targeting "and once coated with sugar they can't attach to the target cancer cell".

Prof Kelly said that changes to the small molecules and a new method of manufacture meant that the compound had "a log-fold increase in anti-cancer activity".

Prof Kelly said that attaching new chemical entities to the molecule protected the drug from being coated.

Prof Kelly said that having achieved a more effective molecule, Triaxial turned from ovarian cancer to crossing the blood-brain barrier.

He said that appeared to cross the blood-brain barrier and was "highly effective against glioma [tumor] cells in test tubes".

Prof Kelly said the company was conducting in-vitro and in-vivo preclinical work on the compounds and was aiming for human clinical trials in 2014.

Prof Kelly said that Novogen had less than \$1 million in cash and would be hoping to raise funds in 2013.

In a media release, Novogen said it acquired 100 percent of Triaxial for \$1,885,000 consisting of 15.4 million Novogen shares and a \$1.5 million loan payable to the Triaxial shareholders.

Outgoing Novogen chairman William Rueckert said the acquisition of Triaxial "completes the restructuring of Novogen that was undertaken three years ago".

"It is fitting that Dr Kelly will bring back to Novogen his vision and expertise in creating new and exciting drug candidates to treat some of our most difficult diseases," Mr Rueckert said.

Mr Rueckert said that Novogen had "separated itself entirely from MEI Pharma, the company that it previously founded and has controlled for the last decade".

Prof Kelly said the technology platform was an innovative method of drug design and manufacture that permitted the creation of structures not previously achievable.

"These are known as super benzopyrans and they offer an opportunity to create anticancer drugs with greatly enhanced levels of potency and bioavailability," Prof Kelly said. "The company's first drug, CS-6, has been designed specifically to cross the blood-brain barrier and to attack primary brain cancer cells," Prof Kelly said.

"Our immediate goal is the first truly effective drug against a disease which sees 10,000 new cases diagnosed each year in the US and which have poor treatment options," Prof Kelly said.

Prof Kelly said the new Novogen board consisted of John O'Connor, Stephen Coffey, Prof Kelly, Dr Heaton and Robert Birch.

On the Nasdaq last night, Novogen rose \$US1.29 or 17.3 percent to \$US8.75.

On the ASX, Novogen was up half a cent or 5.3 percent to 10 cents.

# THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers have discovered an immune system 'kill switch' that destroys blood stem cells when the body is under severe stress. The Institute said the discovery of the activity of cell receptor NLRP1 could have implications for protecting the blood system during chemotherapy or in diseases associated with overwhelming infection, such as sepsis.

The Institute said the signaling system was triggered when immune cell signals protecting the body from infection over-responded in a way that caused problems for the patient. WEHI said that Dr Seth Masters, Dr Motti Gerlic, Dr Benjamin Kile and Dr Ben Croker led a research project that found blocking these internal signals, in particular a cell receptor called NLRP1, could stop blood stem cells from self-destructing, preventing death after chemotherapy and boosting recovery from infection.

The research, entitled 'NLRP1 Inflammasome Activation Induces Pyroptosis of Hematopoietic Progenitor Cells' was published in the journal Immunity and an abstract at: <u>http://www.sciencedirect.com/science/article/pii/S1074761312005067</u>.

The Institute said that NLRP1 was part of a family of immune receptors that acted as a protective mechanism, instructing immune and blood stem cells to die because it has sensed infection or severe stress-related damage.

Dr Masters said the protective mechanism could "go too far".

"One theory is that when stem cells are infected with a bacteria or virus, they can effectively pass the infection on to all their blood cell offspring, helping to spread the pathogen throughout the body," Dr Masters said. "So the body has evolved to activate this pathway to kill the infected stem cell, reducing the risk of infection."

"However, in the case of sepsis, or in a cancer patient who contracts an infection, the NLRP1 receptor inappropriately instructs blood stem cells to die, and too many are killed, until the patient can't recover their immune cells, leaving them at much higher risk of death," Dr Masters said.

Dr Croker said it was the first time that immune receptor-mediated killing of blood stem cells had been suggested to be a critical factor in sepsis, a severe inflammatory disease that kills one person every few minutes worldwide.

"Sepsis is the leading cause of death in critically ill patients, leading to shock, organ failure and death," Dr Croker said.

"People with sepsis have very low numbers of immune cells in the blood and the ability of the immune system to recover and immune cells to repopulate the body is strongly linked to the patient's chance of survival," Dr Croker said.

The Institute said that most research has focused on the 'cytokine storm' theory of sepsis, which said that an excess of inflammatory signals sent out by immune cells caused the severe symptoms.

Dr Croker said all the clinical trials based on this theory had failed.

"Our research provides a different view of the disease, one in which the death of blood stem cells leaves the patient unable to repopulate their red and white blood cells, and therefore unable to recover," Dr Croker said.

Dr Masters said the research could lead to treatments for sepsis.

"We are really still just treating the infection, in a situation where most people die not from the infection, but from the body's immune response to it," Dr Masters said.

The Institute said its research team was testing inhibitors of this pathway to treat severe infections.

"It is early days, but we are optimistic that this is a pathway that could help to prevent blood cell death and treat severe cases of sepsis, as well as other conditions where blood stem cells are critically depleted, such as during chemotherapy," Dr Masters said.

# <u>OBJ</u>

OBJ says Procter and Gamble has committed to two human clinical trials of its magnetic enhanced transdermal technologies.

In May, OBJ said it had an exclusive multi-product joint development agreement with Procter and Gamble to investigate products using the magnetic transdermal technologies (BD: May 21, 2012).

OBJ said at that time that the two companies began collaborations more than one year earlier and the two companies would jointly evaluate the application of its micro-array technologies with Procter and Gamble products.

Today, OBJ said that the commitment to human clinical trials was "a solid investment by [Proctor and Gamble] and a key milestone for OBJ in the development of consumer products utilising its magnetic micro-array technologies".

OBJ director Glyn Denison said the company's technical team was in Cincinnati in November to present the results of the pre-clinical developments conducted over the last seven months.

"The success of the pre-clinical developments has enabled the two companies to finalize the design, format and protocols for two important human clinical trials aimed to start in early 2013," Mr Denison said.

Mr Denison said the clinical trials were the culmination of the research and development phases "for these first two molecules" but did not disclose the nature of the products. He said for the "two key proprietary molecules" were used by Proctor and Gamble across a number of their global product platforms

"If successful, these two clinical trials will lay the groundwork for discussions into the possible development and manufacture of products incorporating OBJ's technology," Mr Denison said.

OBJ technical director Jeff Edwards said that Proctor and Gamble's products had been optimized using the best formulation chemistry, "so opportunities for significant performance enhancement are limited".

"The attraction of OBJ's technology is that it offers a new path for performance enhancement based on physical science rather than chemistry and the potential for new levels of performance that compliments their current formulations," Mr Edwards said. OBJ was up 0.1 cents or 6.25 percent to 1.7 cents with 33.8 million shares traded.

## **BIONICHE LIFE SCIENCES**

Bioniche says that director Nick Photiades has retired.

Bioniche said Mr Photiades was appointed a director in September, 2009.

Bioniche chairman James Rae said that Mr Photiades had been provided expertise in audit, legal, financing, deal-making and strategic planning and thanked him for his service. The company said that the vacated position would not be filled at this time. According to the company's website it continues with a nine-member board.

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