



Biotech Daily

Monday November 17, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: OPTISCAN UP 117%, USCOM DOWN 7.5%**
- * **INVION ON-TRACK WITH 4 PROGRAMS**
- * **WOMEN IN SCIENCE PARKVILLE PRECINCT FOR GENDER BALANCE**
- * **CELLMID LICENCES MIDKINE TO ZOETIS FOR PETS**
- * **STARPHARMA PLEADS SUPER-SCHULTZ TO ASX 25% FALL QUERY**
- * **UP TO 17.5% OPPOSE 3m CALZADA DIRECTOR OPTIONS**
- * **BIOPROSPECT HIRES MICHAEL PLAYER FOR DEPRESSION HEART TEST**
- * **GENERATION, ASSOCIATES BELOW 5% OF COCHLEAR**
- * **CIRCADIAN COMPANIES INCREASE, DILUTED TO 9% IN ANTISENSE**

MARKET REPORT

The Australian stock market fell 0.77 percent on Monday November 17, 2014 with the S&P ASX 200 down 41.8 points to 5,412.5 points.

Nine of the Biotech Daily Top 40 stocks were up, 19 fell, six traded unchanged and six were untraded. All three Big Caps fell.

Optiscan was the best for the second trading day in a row, climbing as much as 7.2 cents or 135.8 percent to 12.5 cents, before closing up 6.2 cents or 117.0 percent at 11.5 cents with 26.9 million shares traded.

Cellmid climbed 7.7 percent; Circadian was up 6.25 percent; Admedus, Clinuvel and Oncosil were up more than four percent; Avita and Prana rose more than two percent; with Osprey up 0.8 percent.

Uscom led the falls, down 1.5 cents or 7.5 percent to 18.5 cents with 178,500 shares traded.

Benitec lost 6.2 percent; Ellex and IDT fell five percent or more; Anteo, Neuren, Sirtex and Tissue Therapies fell four percent or more; Acrux, Analytica and Biotron were down three percent or more; Antisense, Impedimed and Nanosonics shed more than two percent; Alchemia, Bionomics, Cochlear, CSL, Medical Developments and Resmed were down more than one percent; with Mesoblast and Starpharma down by less than one percent.

INVION

Invion says it is on-track to report interim data for its 136-patient phase II trial of INV102, or nadolol, for smoking cessation this year.

In an investor meeting in Melbourne, Invision chief executive officer Dr Greg Collier and chief medical officer Dr Mitchell Glass said that the company had published interim data from the US National Institutes of Health-funded 60-patient phase II titration trial of INV102 for mild asthma and expected a pre-investigational new drug application meeting with the US Food and Drug Administration by the end of 2014 to discuss INV102 as a treatment for asthma, chronic obstructive pulmonary disease and cystic fibrosis.

Dr Collier and Dr Glass said they expected to report final data for both the titration for asthma and the smoking cessation trial in 2015.

Dr Glass said that the aim of the asthma trial was not to show efficacy for mild asthma, but that by incrementally increasing doses of the INV102 beta-blocker that it could reverse epithelial airway changes through the inhibition of the beta-arrestin pathway.

Dr Glass said that if INV102 was shown to be safe to be used for mild asthma, the company would hope to advance the drug for moderate to severe asthma.

Dr Glass said that beta-agonists were widely used to decrease asthma symptoms, but they increased the heart rate with safety implications for patients with cardiac disease. He said that beta-blockers reduced the heart rate and relaxed blood vessels, but had safety constraints for lung disease.

"Every beta-blocker is contraindicated for COPD," Dr Glass said.

Dr Glass said the oral nadolol was well understood, with all toxicity studies completed and safety demonstrated by the fact that it was taken by eight million people a day.

He said that by titrating or incrementally raising the dose, the beta-blocker could selectively block beta-arrestin pathway, reversing the damage caused to the internal surface of the airways.

Dr Glass said that INV103 was being developed for Lupus and had seen that the 10mg and 30mg doses were ineffective with mild patients.

Dr Glass said that the company was trialling 100mg doses and wanted to try the drug on harder patients with more severe disease.

INV103, formerly known as XToll or Chaperonin 10 was owned by CBio when it merged with Inverseon to become Invision (BD: Jul 2, 2012).

CBio completed a phase II trial of XToll for rheumatoid arthritis which showed the 10mg dose of the drug did not meet its primary endpoint (BD: Aug 1, 2011).

Today, Dr Glass said that higher doses of the drug "could have potential for rheumatoid arthritis and psoriasis ... but we're not doing it", which he said was the same for the 300mg dose for lupus.

Dr Glass said that the company was focused on its inhaled program for the currently oral INV104 zafirlukast for asthma and bronchospasm, as well as developing an inhaled version of INV102, with the Minneapolis Minnesota-based 3M Drug Delivery Systems.

Dr Collier said that the company's four strategic goals were: FDA approval of INV102 for smokers who fail to quit with severe chronic obstructive pulmonary disease; demonstrate proof of concept for severe asthma, chronic obstructive pulmonary disease and cystic fibrosis; INV104 proof of concept for asthma and bronchospasm; and to partner INV103.

Dr Collier said that since he was appointed chief executive officer in 2013 the company had raised more than \$10 million (BD: May 13, 2013).

He said that the \$17 million draw-down equity facility with the New York-based Lind Partners would allow the company to achieve its four strategic goals without needing to return to investors (BD: Nov 10, 2014).

Invion fell 0.1 cents or 1.7 percent to 5.7 cents.

WOMEN IN SCIENCE PARKVILLE PRECINCT

Five Melbourne's research institutes have launched a partnership "to tackle the problem of the under-representation of women among Australia's science leaders".

In a media release distributed by the Walter and Eliza Hall Institute, the Women in Science Parkville Precinct (WISPP) brought together researchers from WEHI, the Doherty Institute for Infection and Immunity, the Florey Institute of Neuroscience and Mental Health, the Murdoch Children's Research Institute and the Peter MacCallum Cancer Centre, which collectively employed more than 4,000 medical researchers.

The Women in Science Parkville Precinct said that the Trust Company Australia Foundation had provided \$100,000 to support its initiatives.

Murdoch Children's Research Institute director Prof Kathryn North said that women comprised fewer than one-in-five researchers at senior levels of Australian universities and research institutes, despite the majority of Australian science graduates being women.

"More women than men are lost at every level of the science career ladder," Prof North said.

"WISPP involves representatives of all career stages of medical research, from the directors of the five institutes to early career researchers and students," Prof North said.

"Many individual research organizations have implemented programs to redress the gender imbalance at senior levels of their workforce," she said.

"However, many of the issues that limit the progression of women in science are sector-wide problems," Prof North said.

"By bringing five research organizations together we can tackle bigger and broader issues than any one organization can resolve," Prof North said.

Doherty Institute for Infection and Immunity director Prof Sharon Lewin said that "as a newly formed institute we have the opportunity to establish forward thinking policies and a foundation of a positive institutional culture, one that is nourishing for the ideas and work of everybody, regardless of gender".

Walter and Eliza Hall Institute director Prof Doug Hilton said that the loss of talented female researchers was an issue that required urgent action to ensure Australia's research excellence was maintained.

"If women are not entering senior roles in research at the same rate as men, this represents a huge loss of talent from the sector," Prof Hilton said.

"For too long, many people in leadership positions have either denied that gender imbalance is a problem, or dismissed it as too hard," Prof Hilton said.

"When you speak to researchers, there is widespread support and lots of creative ideas for measures that support and encourage female scientists," Prof Hilton said. "Many are not difficult or costly to implement, but just require willingness on the part of people in leadership positions."

"I see WISPP as an important initiative for bringing momentum to broader improvements across the research sector, initiatives that require support from government and other stakeholders," Prof Hilton said.

Walter and Eliza Hall Institute laboratory head Dr Marnie Blewitt said she had found many of the institute's existing gender equity measures to be valuable.

"Initiatives such as support to continue research during maternity leave and childcare assistance have made it easier for me to advance my career while having young children," Dr Blewitt said. "It is important that gender equity goes beyond assisting mothers."

"I think it is vital that WISPP explores ways to change the culture of science to ensure more women choose to remain in the sector," Dr Blewitt said.

CELLMID

Cellmid says the Florham Park, New Jersey-based Zoetis will evaluate and has an option to licence one of its midkine antibodies for therapeutic use in companion animals.

Cellmid said that its proprietary midkine antibodies had shown to be effective in animal models of a number of diseases.

The company said that Zoetis had extensive experience in the development and commercialization of animal health products and would evaluate the performance of the midkine antibody in their proprietary models with the view to licence.

Cellmid said that the agreement was exclusive for the use of the midkine antibody in animals and included upfront and exclusivity payments until such time as the option to licence was exercised.

Cellmid was up 0.2 cents or 7.7 percent to 2.8 cents with 8.3 million shares traded.

STARPHARMA

Starpharma has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price fell 15.3 cents, from 62.5 cents on November 10 to 47.2 cents today, November 17, 2014, a 24.5 percent fall, and noted an increase in trading volume.

Starpharma said that "on the contrary, the company has a strong cash position as previously announced and has recently released a number of positive announcements" including positive preliminary pharmacokinetics results from its dendrimer-docetaxel trial, the raising of \$21.4 million in a placement and share plan, the receipt of \$4.2 million Federal Government R&D Tax Incentive, the availability of the Vivagel Ansell condom in shops and the allowance of a patent in China.

Starpharma fell as low as 47.25 cents, before closing down 0.5 cents or 0.9 percent at 54.5 cents with 2.1 million shares traded.

CALZADA

Calzada's annual general meeting passed all resolutions, with up to 17.5 percent opposition to the issue of 3,000,000 director options.

The strongest dissenting was against the issue of 500,000 options exercisable at 20 cents each within three years to directors Bruce Rathie, David McQuillan, Max Johnston and Phillip Powell, with a further 500,000 options exercisable at 14 cents each within three years to Mr Johnston and Mr Powell.

The resolution was opposed by 23,405,392 votes (17.5%) with 110,191,043 votes (82.5%) in favor.

There was a smaller level of dissent against the election of directors David Williams, Mr Johnston and Mr Powell, the adoption of the employee share option plan and the amendment to the constitution.

The election of director Dr David McQuillan, the adoption of the remuneration report and the change of name to Polynovo were approved overwhelmingly.

The company's most recent Appendix 3B prior to the meeting said that Calzada had 418,509,426 shares on issue meaning that the opposition to the directors options amounted to 5.6 percent of the company, sufficient to requisition extraordinary general meetings.

Calzada fell 0.1 cents or 1.1 percent to nine cents.

BIOPROSPECT

Bioprospect says it has appointed Dr Michael Player to “a long term consulting role”, effectively acting as chief operating officer.

Bioprospect said that Dr Player was currently a research psychologist at the Black Dog Institute and working as a provisional clinical psychologist.

The company said that Dr Player completed his Doctorate of Philosophy at the University of New South Wales, investigating and quantifying objective, biological markers of depression.

Bioprospect said that the aim of his research was to find a means to test neuroplasticity in patients with major depressive disorder.

The company said that Dr Player’s research found that neuroplasticity was reduced in depression, as demonstrated by an objective test not confounded by subject effort and motivation, providing support for the hypothesis of impaired neuroplasticity in major depressive disorder.

Bioprospect said that Dr Player’s work was able to show that the biological correlate of depression normalized with effective patient treatment.

The company said that Dr Player’s research included investigations into coping techniques for low mood and depression and most recently, studies into men who had attempted suicide.

Bioprospect said that Dr Player would work for the company three days a week, allowing him to maintain his tenure at the Black Dog Institute and University of New South Wales.

The company said that Dr Player would consult on strategic direction, liaise with validation and commercial partners and be involved in clinical trial preparation and management, algorithm development, device testing and selection and research database management.

Bioprospect said that Dr Player had requested his remuneration primarily comprise a share incentive package based on Bioprospect meeting milestones allowing it to commercialize its circadian heart rate technology for the diagnosis of mental health conditions.

Dr Player said that if the circadian heart rate technology was validated “it will represent a major breakthrough in the diagnosis of, and treatment outcomes for, depression and other mental health disorders”.

Bioprospect was unchanged at 0.3 cents with 7.65 million shares traded.

COCHLEAR

The London-based Generation Investment Management has ceased its substantial holding in Cochlear reducing from 3,501,751 shares (6.14%) to 2,747,855 shares (4.81%). Generation said that it sold 753,896 shares for \$53,101,384 or an average price of \$70.44 a share.

In July, Generation increased its holding in Cochlear from 2,908,223 shares (5.10%) to 3,501,751 (6.14%) acquiring shares for an average price of \$58.89 a share and selling for or an average price of \$57.37 a share (BD: Jul 14, 2014).

At that time, Generation said it held the shares “in its capacity as investment manager for a range of client portfolios” and said the registered holders included, Citigroup, HSBC Bank Australia, JP Morgan Chase Bank, State Street Bank, Skandinaviska Enskilda Banken, Credit Agricole and Bank of New York (BD: Sep 26, 2013).

Cochlear fell 93 cents or 1.3 percent to \$71.45 with 112,076 shares traded.

ANTISENSE, CIRCADIAN

Two Circadian-related companies have been diluted in and one has increased its substantial holding in Antisense.

The total change is from 143,149,187 pre-consolidation shares (11.03%) to 14,361,583 post-consolidation shares (8.89%).

The companies were Circadian's wholly-owned subsidiary Polychip Pharmaceuticals and Polychip's 51.67 percent subsidiary Syngene.

In 2013, Antisense underwent a 10-for-one consolidation (BD: Nov 21, 2013).

Polychip retained its 101,906,497 shares consolidated as 10,190,649 shares, while Syngene increased from 41,242,690 pre-consolidation shares to 4,170,934 post consolidation shares.

Circadian has previously told Biotech Daily (BD: Feb 5, 2010) that the Packer family Consolidated Press Holdings held 19.9 percent of Syngene and the Howard Florey Institute owned about 20 percent, with the remainder owned by about 40 other holders.

Antisense fell 0.2 cents or two percent to 9.6 cents.

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