



Biotech Daily

Monday December 5, 2011

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: ALLIED UP 17%, PHOSPHAGENICS DOWN 6.25%**
- * **ALLIED TISSUE STUDY SHOWS DECREASED CALCIFICATION**
- * **BIOTECH TAKES 5 OF 23 COMMERCIALISATION AUSTRALIA GRANTS**
- * **ASIA UNION BUYS 7m TISSUE THERAPIES SHARES**
- * **RESONANCE APPOINTS MIDDLE EAST DISTRIBUTOR**
- * **PROBIOTEC SELLS MILTON BRAND FOR \$6m**
- * **JM FINANCIAL SLIPS BELOW 5% IN GENERA**
- * **ANTISENSE REQUESTS ATL1103 TRIAL RESULTS TRADING HALT**

MARKET REPORT

The Australian stock market was up 0.78 percent on Monday December 5, 2011 with the S&P ASX 200 up 33.3 points to 4,321.3 points.

Seventeen of the Biotech Daily Top 40 stocks were up, 10 fell, six traded unchanged and seven were untraded. All three Big Caps fell.

Allied was the best, up 0.7 cents or 17.1 percent to 4.8 cents with 15.9 million shares traded, followed by Biota up nine percent to 78.5 cents with 917,164 million shares traded.

Patrys climbed 8.1 percent; Living Cell and Psivida were up more than seven percent; Cellmid climbed 6.25 percent; Benitec was up 5.9 percent; Clinuvel and Neuren were up more than four percent; Bionomics, Mesoblast and Nanosonics were up more than three percent; Sirtex rose 2.4 percent; with Pharmaxis, QRX, Starpharma and Tissue Therapies up more than one percent.

Phosphagenics led the falls, down one cent or 6.25 percent to 15 cents, with 522,020 shares traded.

Optiscan and Universal Biosensors lost more than five percent; Genetic Technologies fell four percent; Phylogica was down 3.6 percent; Circadian and Viralytics shed more than two percent; Alchemia, Impedimed and Resmed were down more than one percent; with Acrux, Cochlear and CSL down by less than one percent.

ALLIED HEALTHCARE GROUP

Allied Health says a preclinical trial of its Adapt-treated bovine heart valves in rats shows decreased calcification compared to commercially available heart valves.

Allied said the tissue heart valve study was jointly conducted by subsidiary Celxcel and a potential partner, an unnamed tissue heart valve manufacturer.

Celxcel chief executive officer Bob Atwill told Biotech Daily that the trial was different from one published by predecessor company Biomed in that Celxcel was using the potential partner's valves treated with the Adapt process and Celxcel's terminal sterilization.

The previous independent preclinical study of the Adapt technology also showed lower levels of calcification than commercially available cardiac patches (BD: Jun 10, 2009).

The company said the study compared the performance in terms of biocompatibility and calcification potential of the Adapt anti-cytotoxic and anti-calcification process heart valve with Celxcel's terminal sterilization method against commercially available heart valves.

Allied said calcification shortened the lifespan of implanted tissue and the study showed that all forms of the commercial heart valve tissue developed calcification over 24 weeks, but the tissue subjected to Celxcel's terminal sterilization method "showed significantly reduced levels of calcification, whilst the tissue subjected to the Adapt anti-calcification engineering process, [with] the terminal sterilization method demonstrated the lowest levels of calcification".

Allied said that calcification "often results in clinicians choosing to use mechanical valves, which requires patients to undergo lifelong and complicated anticoagulant therapy".

Allied's managing-director Lee Rodne said the results were "in line with our expectations and very positive".

"The results open up the possibility of extending the lifespan of implanted tissue valves dramatically," Mr Rodne said.

"At the moment the build up of calcification means that implanted heart valve tissue has a shorter lifespan of around 10 years when compared to mechanical valves which is over 20 years," Mr Rodne said.

Celxcel's Mr Atwill said his company was "aiming to increase the lifespan of tissue heart valves to allow them to become the product-of-choice for surgeons".

"This will allow more patients to be free of the need to be tied to complicated anticoagulant therapy for the rest of their lives," Mr Atwill said.

Allied said that all groups in the study, de novo commercial valves and those treated with Adapt with and without terminal sterilization, were subjected to similar simulated flow and pressure dynamics and were exposed to a standardized physiologic phosphate high calcium solution.

The company said that macroscopic assessment with high contrast color stain revealed a significant reduction of visible calcification on the tissue valve leaflets treated with Adapt.

Allied said that digital x-rays and independent histology reports confirmed the independent assessors evaluation of a significant reduction in leaflet calcification by the Adapt technology and Adapt treated valves had significantly lower extractable calcium than the commercial valves without Adapt treatment.

Allied said it had begun discussions on partnering and distribution opportunities for Celxcel's lead product Caridocel, a cardiovascular patch to treat congenital heart disease.

The company said Celxcel was also evaluating how the Adapt process could be used in other surgical applications, such as general surgery including hernia repair, urogynaecology including pelvic floor reconstruction, orthopaedics, cardiovascular repair and as a biological scaffold to grow and deliver stem cells.

Allied was up 0.7 cents or 17.1 percent to 4.8 cents with 15.9 million shares traded.

COMMERCIALISATION AUSTRALIA

Innovation Minister Senator Kim Carr says Commercialisation Australia has funded 22 projects with more than \$10 million, of which four are biotechnology-related.

Senator Carr said the Australian Government was “committed to backing Australian inventors who push the envelope and strive to create new and better products”.

Senator Carr said the inventions included five health-related projects to manage stress, create drugs with fewer side effects, produce healthier foods, combat hearing loss and enhance micro-scale blood storage.

Of the 22 projects provided \$10,124,409 in funding, five were biotechnology-related attracting a total of \$598,480.

The largest biotechnology grant was \$300,000 for the New South Wales-based Clarity Pharmaceuticals with \$50,000 for a “skills and knowledge” grant and a \$250,000 proof of concept grant for a process for medical imaging.

Clarity Pharmaceuticals said it would trial radiopharmaceutical products with positron emission tomography imaging to track the path of biopharmaceuticals inside the body. Clarity said the funds would cover expert regulatory advice and undertake an imaging validation study to expand its imaging service, currently limited to animal studies, to include human clinical trials.

Western Australia’s Invatec Health received \$252,987 for a method of identifying and managing chronic stress through “an innovative stress monitoring and management system known as the Stress Fit System”.

Invatec said the Stress Fit System identified harmful levels of prolonged stress using biological data and the funding would enable real-time testing of the system.

Victoria’s Otifex Therapeutics was granted \$200,000 for its nasal spray for the treatment of fluid in the middle ear to reduce the need for grommet operations.

The company said the funds would help support an executive to manage the trials and develop the commercialization strategy.

The University of Tasmania’s Dr Robin Fieldhouse received a grant of \$49,680 for the Millisport functional porous polymer medium for the storage of dried blood spots as an alternative to conventional paper based media.

Dr Fieldhouse said Millisport had improved accuracy of analyses over paper media and simpler, more reliable customer workflows.

Dr Fieldhouse said Millisport was “projected to enable the pharmaceutical industry to realize the full range of potential benefits of [dried blood spots] technology over traditional wet blood techniques, which include less invasive sampling and easier transportation”.

Victoria’s Nexvet Biopharma received \$48,800 to develop biological drugs for companion animals that were “specific equivalents of blockbuster human biopharmaceuticals”.

Nextvet said the therapeutic focus was on pain, cancer and inflammatory diseases for dogs, cats and horses.

TISSUE THERAPIES

Asia Union Investment has increased its holding in Tissue Therapies from 16,000,000 shares (11.58%) to 23,010,000 shares (13.64%).

The Sydney-based Asia Union said it bought shares including 4,860,005 shares at 50 cents each in a placement rights issue on May 11, 2011 and 2,000,000 shares for \$740,000, or 37 cents a share, on November 30, 2011.

Last week, Australian Ethical Trusts sold its holding in Tissue Therapies, including 7,257,151 shares at 37 cents a share on November 30 (BD: Dec 1, 2011).

Tissue Therapies was up half a cent or 1.2 percent to 42.5 cents.

RESONANCE HEALTH

Resonance says it has appointed Gulf Drug Establishment as distributor for the Ferriscan service in the United Arab Emirates, Saudi Arabia and Egypt.

Resonance said that its Ferriscan diagnostic was a non-invasive, magnetic resonance imaging-based service for the measurement of liver iron overload.

Resonance managing director Liza Dunne said the appointment of Gulf Drug Establishment was "an important step in developing a market that holds great potential for the company".

"There is a high number of patients with iron overload in the region caused by the regular blood transfusions they receive to treat their genetic blood disorders, such as thalassaemia and sickle cell disease," Ms Dunne said.

"Ferriscan is now recognized internationally as the gold standard in the measurement of liver iron concentration and iron overload," Ms Dunne said.

Resonance said that Gulf Drug Establishment was a leading player in healthcare products and services in the UAE and was one of the first companies to have started pharmacies, private clinics and healthcare marketing and distribution services in the country.

Resonance said the partnership would provide patients attending the Emirates Thalassaemia Society in Dubai with immediate access to Ferriscan.

The company said it expected the Ferriscan service would be established in other Middle Eastern countries during 2012.

"Ferriscan has had strong support from key clinicians in the region who have seen its beneficial effects on patient management through clinical trials," Ms Dunne said.

Resonance said that Ferriscan was available in more than 120 centres in more than 20 countries.

Resonance was up 0.1 cents or 8.3 percent to 1.3 cents.

PROBIOTEC

Probiotec has sold the Milton brand, including all intellectual property and business assets for the countries it has the rights to Rivadis Australia for \$6 million

Probiotec managing director Wayne Stringer told Biotech Daily that his company held the rights for the Milton antibacterial sterilization and baby care brand in Australia, New Zealand and several South East Asian countries while Rivadis had the rights "for many other countries".

Mr Stringer said that Probiotec would provide distribution, sales support and contract manufacturing services to Rivadis.

In a media release to the ASX Probiotec said the company could earn payments of \$750,000 based on achievement of sales targets.

The company said that in 2010-'11 financial year Probiotec achieved gross sales of \$2.57 million under the Milton brand.

Probiotec said that apart from the \$6 million cash proceeds it would receive payment for all stock on hand worth about \$150,000 on completion.

The company said the proceeds would go to the early repayment of several of Probiotec's existing debt facilities and was forecast to reduce its net profit after tax by \$400,000 to \$500,000 on an annualized basis as a result of lost earnings, offset by earnings from ongoing distribution and manufacturing services and the reduction in interest expense caused by the repayment of debt facilities.

Probiotec said the sale would give rise to a non-recurring profit before tax of \$2.9 million in the half year to December 31, 2011.

Probiotec was unchanged at 35 cents.

GENERA BIOSYSTEMS

JM Financial Group has ceased its substantial holding in Genera with a net reduction of 6,080 shares taking it below the five percent substantial mark.

JM Financial holds portfolios on behalf of clients and said in its substantial shareholder notice that the largest purchase was 48,259 shares for \$7,730 or 16 cents a share on July 26, 2011 and the largest sale was 50,824 shares for \$5,453 or 10.7 cents a share on November 30, 2011.

Genera was unchanged at 11 cents.

ANTISENSE

Antisense has requested a trading halt pending an announcement "in relation to reporting on the ATL1103 clinical trial".

The company has previously said the phase I trial of single ascending doses and multiple doses of ATL1103 in healthy adult male subjects was to study safety, tolerability and pharmacokinetics (BD: Oct 11, 2011).

Antisense has said that ATL1103 was designed to block the expression of the growth hormone receptor to reduce levels of the hormone insulin-like growth factor-I (IGF-I) in blood, the therapeutic endpoint in treating the growth disorder acromegaly.

Antisense said that reducing the effects of IGF-I had a potential role in the treatment of diabetic retinopathy, diabetic nephropathy and some cancers.

Trading will resume on December 7, 2011 or on an earlier announcement.

Antisense last traded at 3.2 cents.