



Biotech Daily

Thursday November 5, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: GENETIC TECHNOLOGIES UP 100%
COMPUMEDICS DOWN 8%**
- * **GENETIC TECHNOLOGIES PLEADS SCHULTZ TO ASX 58% QUERY
- POSTS BREAST CANCER GUIDELINES NEWS TO NASDAQ, NOT ASX**
- * **INVION: 'HIGH COURT DISMISSES CBIO EXECUTIVE APPEAL'**
- * **WEHI: 'MASS DRUG ADMINISTRATION FOR RELAPSING MALARIA'**
- * **REGENEUS CRYOSHOT EFFICACY FOR HORSE JOINTS**
- * **SIRTEX LOSES ASIA PACIFIC HEAD DR BURWOOD CHEW**
- * **PHYLOGICA: 'PHYLOMER-OMOMYC EFFECT IN MOUSE BREAST CANCER'**
- * **CYNATA HIRES US CRO FOR STEM CELL STUDY**
- * **IMMURON SIGNS TRAVELCARE FOR US DISTRIBUTION**
- * **AUSTRALIAN ETHICAL REDUCES TO 7% OF IDT**
- * **JP MORGAN, CREDIT SUISSE 35% MESOBLAST 'LOCK-UP' NOTICES**
- * **AUSTRALIAN ETHICAL TAKES 7% OF ATCOR**
- * **GOLDMAN SACHS ABOVE 5% OF NANOSONICS, YET AGAIN**

MARKET REPORT

The Australian stock market fell 0.94 percent on Thursday November 5, 2015 with the ASX200 down 49.3 points to 5,193.0 points. Fifteen of the Biotech Daily Top 40 stocks were up, 12 fell, eight traded unchanged and five were untraded. All three Big Caps rose.

Genetic Technologies was the best, up 1.9 cents or 100 percent to 3.8 cents with 91.6 million shares traded. Ellex climbed 9.1 percent; Biotron was up 7.8 percent; Acrux and Prana were up more than four percent; Nanosonics and Reva were up more than three percent; Bionomics, IDT, Oncosil and Pro Medicus rose more than two percent; Osprey and Starpharma were up more than one percent; with Cochlear, CSL, Medical Developments, Psivida and Resmed up by less than one percent.

Compumedics led the falls, down 2.5 cents or 7.7 percent to 30 cents with 184,206 shares traded. Cellmid and Tissue Therapies lost more than six percent; Avita fell 4.55 percent; Actinogen and Admedus were down more than three percent; Benitec shed 2.3 percent; Anteo, Antisense and Impedimed were down more than one percent; with Orthocell and Sirtex down by less than one percent.

GENETIC TECHNOLOGIES

Genetic Technologies 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 climbed from 1.9 cents on November 4 to 3.0 cents, a 57.9 percent increase, today, and noted an increase in trading volumes.

Genetic Technologies said that on November 2 director Grahame Leonard filed an Appendix 3Y director's interest statement increasing his holding by 2,000,000 shares for \$34,000 or 1.7 cents a share and chief executive officer Eutillio Buccilli commented on American Cancer Society changes to breast cancer screening guidelines in a media release to the Nasdaq, but not published to the ASX.

"These guidelines, which are aimed at women with an average risk of breast cancer, raised the recommended age for first mammogram to 45 [years] and suggested women over age 55 switch to biennial mammograms," Genetic Technologies told the Nasdaq. "However, the recommendations also create clinical ambiguity by concluding that women between ages 40 and 44 should still have the choice to get annual mammograms and that women 55 years and older should likewise have the opportunity to continue annual screenings," Genetic Technologies said.

"Brevagenplus, a clinically-validated, genetically-based breast cancer risk assessment test, can help physicians resolve this ambiguity by identifying which women without a family history still warrant earlier and/or more frequent screening," Genetic Technologies told the Nasdaq on November 2, 2015.

In February and March, the ASX questioned the company regarding similar moves, following rises on the Nasdaq (BD: Jan 29, Feb 12, Mar 31, 2015).

Last night on the Nasdaq, Genetic Technologies climbed 80 US cents or 37.91 percent to \$US2.91 with 12,175,077 ADRs traded, equivalent to 1,826,261,550 Australian shares. Today, Genetic Technologies closed up 1.9 cents or 100 percent at 3.8 cents with 91.6 million shares traded.

INVION (FORMERLY CBIO)

Invion says that the High Court of Australia has dismissed an application by former officers of the then CBio without the need for a hearing.

Invion said the proceedings related to the resignations in October 2011 of the company's then executive chairman Stephen Jones, chief executive officer Jason Yeates and chief financial officer James Greig and termination payments to them.

The company said it sought orders requiring the repayment of termination payments, alleging the payments were in breach of fiduciary duties and contravened the statutory duties imposed on them by sections 180, 181 and 182 of the Corporations Act 2001. Invion said that the Supreme Court of Queensland determined that the defendants should repay \$1,071,482 and dismissed a counterclaim by the defendants seeking damages from Invion for allegedly breaching an agreement that bonus payments should have been paid after their resignations.

The Supreme Court ordered that they repay the company \$1,306,283, including interest (BD: Jun 4, 23, Jul 3, 2014).

In June, the Queensland Supreme Court's Court of Appeal dismissed an appeal by former officers of the then CBio and ordered costs against them (BD: Jun 12, 2015).

In 2011, the then CBio saw a board spill following the failure of its phase IIa trial of XToll or recombinant chaperonin 10 to meet its primary endpoint (BD: Aug 1, 2011).

Today, Invion said it would "use all avenues available ... to recover the judgment debt".

Invion was unchanged at 1.1 cents.

[THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH](#)

The Walter and Eliza Hall Institute says that most childhood Plasmodium vivax malaria infections in endemic areas are the result of relapsed, rather than new, infections.

The Institute said that four of five children in Papua New Guinea aged five to 10 years old were susceptible to recurring infection with the malaria parasite Plasmodium vivax, which could hide undetected in the liver.

WEHI said that Plasmodium vivax was the most widespread malaria parasite and the predominant cause of malaria in the vast majority of countries outside Africa.

The Institute said that the discovery had significant repercussions for malaria control programs.

WEHI said the research, entitled “Strategies for Understanding and Reducing the Plasmodium vivax and Plasmodium ovale Hypnozoite Reservoir in Papua New Guinean Children: A Randomised Placebo-Controlled Trial and Mathematical Model”, ‘was published by the Public Library of Science and an abstract was available at:

<http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001891>.

The abstract concluded that mass drug administration “campaigns combining blood and liver stage treatment are predicted to be a highly efficacious intervention for reducing Plasmodium vivax and Plasmodium ovale”.

The Institute said the research was led by its Dr Leanne Robinson and Prof Ivo Mueller with the Papua New Guinea Institute of Medical Research and the Barcelona Centre for International Health Research.

Dr Robinson said the research showed relapsing infections with Plasmodium vivax were responsible for 80 percent of infections in Papua New Guinea children aged five to 10 years and “one of the biggest problems in realising malaria eradication is relapsing ... infections, which are critical for sustained transmission in the region”.

“Children treated with drugs that targeted the liver and blood stages of infection had 80 percent fewer malaria infections than those treated with drugs that only targeted the blood stage of infection,” Dr Robinson said.

“Plasmodium vivax parasites are able to hide in the liver for long periods of time before reawakening to cause disease and continue the transmission cycle,” Dr Robinson said.

“Mass drug administration that includes a drug that kills parasites in the liver is likely to be a highly effective strategy for eliminating malaria,” Dr Robinson said.

Prof Mueller said that mathematical modelling showed current programs would be unable to achieve elimination because the programs could not identify and treat children with dormant liver infections.

“We need a better way of identifying children who are chronically infected with malaria so that they can be treated,” Prof Mueller said.

“It is the only way to stop the malaria transmission cycle in [Papua New Guinea] and is likely to be the case for eliminating malaria in other parts of the Asia-Pacific and Americas,” Prof Mueller said.

WEHI said that the researchers had a \$1.15 million grant through the Global Health Innovative Technology Fund to accelerate development of a test that identified people with dormant malaria parasites in their liver.

The Institute said that the fund was a public-private partnership between Japanese pharmaceutical companies, the Government of Japan and the Bill and Melinda Gates Foundation to leverage Japanese biotechnology capabilities to fight neglected disease.

WEHI said the team would work with Japan’s Ehime University, Switzerland’s Foundation for Innovative New Diagnostics, and Japanese biotechnology company Cellfree Sciences Co to develop biomarkers for Plasmodium vivax malaria that could drive the development of new diagnostic tools, the second diagnostic project supported by the GHIT Fund.

REGENEUS

Regeneus says that interim trial results show that its Cryoshot allogeneic off-the-shelf stem cell product is effective in early orthopaedic developmental disease in horses. Regeneus said that the trial of Cryoshot in 18 yearling thoroughbreds compared favorably to the use of conventional therapies like corticosteroids.

The company said that the preliminary results from the on-going trial were presented by Randwick Equine Centre surgeon and principal investigator Dr Chris O'Sullivan at the American College of Veterinary Surgeons conference in Tennessee.

Regeneus said that joint lesions, subchondral lucencies of the medial femoral condyle of the stifle joint, were identified and assessed under arthroscopic guidance.

The company said that the joint lesions were an indicator of early orthopaedic developmental disease in yearling thoroughbreds and could lead to bone cysts.

Regeneus said that the smaller lesions with less loose cartilage were subsequently injected with Cryoshot Equine alone (group 1), whereas the larger lesions, also treated with Cryoshot were stabilized surgically with polydioxanone pins to prevent cartilage movement (group 2).

The company said that nine of the 10 lesions in group 1 improved with a large reduction in size of the lesion, while seven of eight lesions in group 2 improved, with similarly large reductions in size of the lesion.

Regeneus said that one lesion in each group progressed to bone cyst and the results compared favorably with conventional therapy "where only 55 percent improve and up to 25 percent progress to bone cyst".

The company said that up to 15 percent of yearling thoroughbreds developed abnormal subchondral lucencies in the stifle joint, with the current treatment of choice, an injection of corticosteroids under arthroscopic guidance.

Regeneus said that although two in three improve with corticosteroids, one in five of these lucencies still progress to form a bone cyst which are a potential cause of future lameness and were associated with a reduced ability to start a race.

The company said the treatment could have a significant economic impact in the industry since horses that develop a bone cyst or having a significant lucency of the medial femoral condyle typically sell for 30 to 40 percent of the estimated value, which ranged up to \$290,000.

Regeneus head of veterinary business Dr Duncan Thomson said that stem cells had anti-inflammatory effects, but "these results indicate that in orthopaedic developmental disease, early use of mesenchymal stem cells, even before clinical signs are evident, can have a positive effect upon healing and disease progression".

"The horse is often touted as a good model for human joint and bone diseases," Dr Thomson said. "These results encourage us to explore earlier use of cell therapy for people with developmental orthopaedic diseases."

Regeneus was unchanged at 12 cents.

SIRTEX MEDICAL

Sirtex says that Asia Pacific chief executive Dr Burwood Chew "will depart the company, effective immediately".

Sirtex said it thanked Dr Chew for his contribution.

The company said that Europe Middle East and Africa chief executive Nigel Lange had assumed overall management responsibility for the Asia Pacific business, pending the appointment of a replacement.

Sirtex fell 32 cents or 0.8 percent to \$38.18 with 289,683 shares traded.

PHYLOGICA

Phylogica says an expanded breast cancer study in mice confirms its peptide-Omomyc fusion “significantly reduces tumor size” with sustained tumor inhibition.

Phylogica said that the study by the Perth-based the Harry Perkins Institute of Medical Research’s Prof Pilar Blancafort reproduced findings in an animal model of breast cancer undertaken earlier this year (BD: Mar 30, 2015).

The company said that the Myc transcription factor was “a highly validated intracellular cancer target, expressed in many common cancers that had proven to be undruggable with conventional therapies”.

Separate research said that Omomyc interfered with the action of Myc.

Phylogica said the aim of the expanded study was to show that Omomyc fused to cell penetrating Phylomer 1746 could be efficiently delivered inside cells to treat cancer.

The company said the mouse model used triple negative breast cancer cells which were typically resistant to treatment with conventional drugs and there was a statistically significant reduction in the size of tumors injected directly with the 1746-Omomyc fusion compared to controls.

Phylogica said the experiment provided the proof of concept for the ability to deliver a biologic cargo into the intracellular environment and Prof Blancafort observed that inhibition of tumour growth was sustained after cessation of treatment.

Prof Blancafort said he was “very pleased to observe such strong effects of the 1746-Omomyc fusion against a particularly aggressive multi-drug resistant tumor”.

“The fact these effects were sustained in the absence of drug combined with the lack of evidence for drug-related toxicity in animals treated with 1746-Omomyc is very encouraging, Prof Blancafort said.

Phylogica chief executive officer Dr Richard Hopkins said that drugs against Myc were “highly sought after given its critical role in most common human cancers”.

Phylogica was up 0.1 cents or 8.3 percent to 1.3 cents with 14.6 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has hired the London-based Clinical Trial Company as the contract research organisation for its phase I study of CYP-001 for graft versus host disease.

In February, Cynata hired the Wilmington, North Carolina-based Pharmaceutical Product Development to begin planning and logistics development for a phase I stem cell study (BD: Feb 16, 2015).

Cynata said at that time that Pharmaceutical Product Development was responsible for the initial planning for the phase I trial.

Today, the company said that graft versus host disease was a complication of bone marrow transplantation and related procedures and was a debilitating condition, in which transplanted cells attack the recipient.

Cynata said that steroids were the first-line treatment, but when that was ineffective, the prognosis was extremely poor, with mortality rates of up to 80 percent.

Cynata head of product development Dr Kilian Kelly said the trial was “a critically important milestone in the development of the Cymerus platform technology”.

“Cynata has further meetings scheduled with regulatory bodies and subject to the outcome of those meetings we expect to commence the trial in the first half of 2016,” Dr Kelly said.

Cynata fell two cents or 6.5 percent to 8.2 cents.

IMMURON

Immuron says that the Lone Tree, Colorado-based Travelcare Worldwide will sell Travelan for travellers diarrhoea throughout its travel medicine network.

Immuron said the terms and conditions were confidential but Travelcare was a group purchasing organization and a provider of travel medicine, immunization and vaccination services with more than 70 travel clinics and mobile healthcare services to companies, schools, churches and other organisations, saving clients time and money.

Immuron chief executive officer Thomas Liquard said the contract was “another win for Travelan in the US and a clear indication of Travelan’s outstanding value proposition”.

Immuron fell one cent or 2.2 percent to 44 cents.

IDT AUSTRALIA, AUSTRALIAN ETHICAL INVESTMENT

Australian Ethical Australian Share Fund has reduced its substantial holding in IDT from 17,661,419 shares (9.15%) to 14,272,698 shares (7.39%).

Australian Ethical said that between August 18 and November 4 it sold 3,388,721 shares for \$1,291,870 or 38.1 cents a share.

Last year, Australian Ethical became substantial in IDT with a holding of 22,766,419 shares or 12.81 percent, following the company’s \$17,016,000 raising at 15 cents a share (BD: Jan 18, 2015)

IDT was up one cent or 2.6 percent to 39 cents.

MESOBLAST

JP Morgan and Credit Suisse have filed substantial shareholder notices in Mesoblast relating to the on-going US initial public offer to list on the Nasdaq.

Earlier this week, Mesoblast filed a registration statement to the US Securities and Exchange Commission offering 5,742,510 American depositary shares (ADSs) and to list on the Nasdaq (BD: Nov 3, 2015).

Mesoblast said at that time that it had applied to list the ADSs on the Nasdaq Global Select Market under the symbol ‘MESO’, with each ADS equivalent to five Australian shares.

When the company requested a voluntary suspension for the capital raising, it closed at \$3.41, implying the US shares would be priced about \$17.05 pending discounts or premium pricing, implying a total raise of \$97,909,796.

Mesoblast said that JP Morgan and Credit Suisse were the joint book-running managers of the offer and the representatives of the underwriters.

Today, both JP Morgan and Credit Suisse said they held 127,034,176 shares under “lock-up” provisions for the capital raising.

JP Morgan said it held a total of 127,703,105 Mesoblast shares (34.49%), while Credit Suisse said it held 131,856,954 shares (35.61%).

The holding overlap and include large shareholders such as Cephalon (now Teva) with 55,785,806 shares, as well as 67,756,838 shares held by chief executive Prof Silviu Itescu and 1,059,000 shares held by director Michael Spooner.

The Credit Suisse statement said that chairman Brian Jamieson held 335,000 shares and “Brians Maserati Pty Ltd” held 275,000 shares.

Mesoblast last traded at \$3.41.

ATCOR MEDICAL

Australian Ethical Smaller Companies Trust has increased its substantial holding in Atcor from 10,277,778 shares (5.68%) to 13,802,534 shares (6.94%).

Australian Ethical said it bought and sold shares between October 14 and November 4, 2015, including the acquisition of 800,000 shares for \$168,000 or 21 cents a share, but failed to detail the cost of the remaining 2,724,756 shares.

Atcor was unchanged at 21.5 cents.

NANOSONICS

The Delaware-based Goldman Sachs Group says that, yet again, it has become substantial in Nanosonics with 14,619,538 shares or 5.16 percent.

Goldman Sachs said that between July 14 and November 2, 2015 it acquired between 50 shares and 1,344,230 shares for no cost, with the single largest purchase 194,961 shares for \$258,323 or \$1.325 a share, which the company previously reported.

Throughout October, Goldman Sachs has repeatedly increased above or reduced below the five percent substantial threshold in Nanosonics, primarily borrowing or returning shares "to the counterparty under a repurchase agreement" for no applicable consideration (BD: Oct 2, 5, 15, 16, 20, 23, 27, 28, 2015).

Previously, under a counterparty agreement, Goldman Sachs returned, lent and borrowed shares held by subsidiaries, Rothesay Life, JP Morgan Chase, RBC Dexia Australia, HSBC Custody Nominees Australia and the Bank of New York Mellon (BD: Apr 13, 2015). Nanosonics rose six cents or 3.8 percent to \$1.65.