



Biotech Daily

Tuesday November 24, 2015

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH UP: GENETIC TECHNOLOGIES UP 21%; MESOBLAST DOWN 8%
- * CAPITAL RADIOLOGY BECOMES 1st 3D MEDICAL MACH7 CUSTOMER
- * D3, MEDICINES DEVELOPMENT MOXIDECTIN FOR RIVER BLINDNESS
- * PRESCIENT SHARE PLAN RAISES \$927k
- * REGENEUS LICENCES MACQUARIE STEM CELL SELECTION SYSTEM
- * MEDIBIO, JOHNS HOPKINS HEART RATE DEPRESSION TRIAL APPROVED
- * JAPAN PATENT FOR CELLMID MIDKINE FOR HAIR LOSS
- * AVITA APPOINTS MEDICAL Z, IDEAL MEDICAL FRENCH, UK DISTRIBUTORS
- * NOVOGEN HIRES NOVOTECH AS CRO FOR CANTRIXIL CANCER TRIAL
- * PRIME CONVERTIBLE LOAN REDUCES NUSEP TO 55%
- * CORRECTION: PARADIGM
- * UP TO 17% DISSENT AGAINST CLINUVEL 37.5% DIRECTORS POOL HIKE
- * PHARMAUST APPOINTS FLORIDA'S REDCHIP FOR INVESTOR RELATIONS
- * NY EMPERY TAKES % OF ORTHOCELL
- * JK, KIM HOGAN TAKE 6% OF ONCOSIL
- * DAVID FRANKLYN REPLACES SUN'S HOWARD DIGBY, DR ANTON UVAROV
- * BUCHAN HOSTS SYDNEY WOMEN'S HEALTH EVENT

MARKET REPORT

The Australian stock market fell 0.95 percent on Tuesday November 24, 2015 with the ASX200 down 50.0 points to 5,226.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 13 fell, 11 traded unchanged and one was untraded. All three Big Caps fell.

Genetic Technologies was the best, up 0.5 cents or 20.1 percent to 2.9 cents with 33.2 million shares traded. Oncosil and Tissue Therapies climbed more than nine percent; Circadian was up 8.5 percent; Compumedics improved 6.1 percent; Biotron was up 4.35 percent; Impedimed and Prana were up more than three percent; Acrux, Atcor and Universal Biosensors rose more than two percent; Orthocell and Psivida were up more than one percent; with Nanosonics and Pro Medicus up by less than one percent.

Mesoblast led the falls, down 14 cents or 8.1 percent to \$1.58 with 3.4 million shares traded. Clinuvel fell 6.7 percent; Actinogen lost 3.85 percent; Benitec, Bionomics, Optiscan, Prima, Starpharma and Uscom shed two percent or more; Admedus and IDT were down more than one percent; with Cochlear, CSL, Ellex, Pharmaxis, Resmed and Sirtex down by less than one percent.

3D MEDICAL

3D Medical says that with distribution partner Telstra Health it has implemented the first Mach7 vendor neutral archive in Australia at Melbourne's Capital Radiology.

3D said that Capital signed a four year contract in July as the foundation customer and the system had been implemented and deployed at 55 of Capital's 72 clinics.

The company said that vendor neutral image and data management service provided radiologists with the ability to view x-rays, magnetic resonance imaging and other radiology studies, regardless of location or the system used to capture the image.

3D said the service bundled vendor neutral archiving with storage and Telstra's network and the combination allowed large studies to be rapidly fetched from the archive by any site in the network, reducing time and improving efficiency.

3D Medical said that it and Mach7 Technologies generated licence fee income based on the number of radiology studies archived within the software system and Capital Radiology was expected to generate more than one million radiology studies a year.

3D chairman Dr Nigel Finch told Biotech Daily the terms of the contract were confidential.

In a media release, Dr Finch said the "on-time delivery within Capital Radiology's expansive network provides a valuable reference site to assist in generating further licence sales ... and also validates our business model for generating licence fee income for the management of medical image data".

3D fell 0.3 cents or 4.2 percent to 6.9 cents with 1.1 million shares traded.

D3 MEDICINE

D3 says it will advise Medicines Development for Global Health on development and regulatory strategy of moxidectin for onchocerciasis or river blindness.

D3 said that the Melbourne-based Medicines Development for Global Health was a not-for-profit bio-pharmaceutical company, which had acquired moxidectin from the World Health Organisation's Special Programme for Research and Training in Tropical Disease and the collaboration was based on a risk-share agreement.

The company said that river blindness was a disease caused by the filarial worm *Onchocerca volvulus*, which was transmitted through the bites of infected blackflies.

D3 said that each adult female worm could live for up to 15 years in the human body, producing millions of microscopic offspring, or microfilaria, that migrated through the skin, eyes and lymph nodes.

The company said that the microfilariae were the main cause of disease symptoms, which included severe skin inflammation and intense itching, enlarged lymph nodes and in some patients, visual impairment that could lead to blindness.

D3 said that in sub-Saharan Africa, the disease affected more than 37 million people with about 115 million people at risk of infection.

The company said that control and elimination of the disease relied on mass annual or biannual drug administration with ivermectin, the current standard of care.

D3 said that in phase II and phase III clinical trials, moxidectin was shown to be superior to ivermectin and in March 2015, the US-based Global Health Investment Fund invested in Medicines Development to complete the registration of moxidectin for onchocerciasis, the first new therapy for in about 30 years.

Medicines Development for Global Health founder and managing-director Mark Sullivan said his group was "committed to realize the potential of moxidectin in the management of onchocerciasis and subsequently for a number of other important neglected diseases".

D3 is a private company.

PRESCIENT THERAPEUTICS

Prescient says it raised \$927,421 in a share purchase plan at 5.4 cents a share that was fully underwritten to \$1.03 million.

In October, Prescient said the share plan was “fully underwritten by Patersons Securities up to the target amount of \$1.03 million” and although it had subscriptions for \$1,201,500 in shares it had to scale back applications as it “was only permitted to accept a maximum of 30 percent of its issued capital prior to the offer” (BD: Oct 29, 2015).

The company said in October that the funds would provide a 12-month runway.

Prescient fell 1.2 cents or 16.7 percent to six cents with 1.7 million shares traded..

REGENEUS

Regeneus says it has the rights to commercialize a cell identification and selection technology to identify and select high potency secreting stem cells for cell therapies.

Regeneus said that the technology was developed by researchers at the Centre for Nanoscale Bio-Photonics at Macquarie University and uses cell labelling technologies to identify and select cells based on the molecules that they are secreting rather than their surface markers.

The company said that cells secreted molecules such as cytokines and growth factors that drove the function and therapeutic effect of cells, but the current technology was not sensitive enough to allow analysis of secretion molecules in individual live stem cells.

Regeneus said that the Centre’s technology was “extremely sensitive and allows researchers for the first time to identify as well as select individual live stem cells based on their capacity to secrete high levels of therapeutically powerful cytokines”.

Regeneus chief scientific officer Dr Graham Vesey said the identification and selection technology “opens the door to better understand and control a whole host of diseases”.

“It holds the potential for what may be called designer cells, where a cell line is developed that is enriched for a secretion capacity which is uniquely matched to the needs of the disease in question,” Dr Vesey said.

Regeneus said that it would provide funding for further collaborative development of the technology and its applications at the Centre and Macquarie University had granted Regeneus an exclusive licence over key applications of the technology for the human and animal health markets.

Regeneus said it would pay Macquarie a royalty on revenues generated from the commercialisation of the technology.

The company said that was a range of significant commercial opportunities for the technology, including analysis kits for the research and diagnostics markets.

Regeneus was up one cent or 11.1 percent to 10 cents with two million shares traded.

MEDIBIO

Medibio says its circadian heart rate for diagnosing depression study with Johns Hopkins University Medicine School has been approved to start on December 1, 2015.

Medibio said the 100-subject study, at the Baltimore, Maryland-based University was designed to validate the use of the heart rate technology to differentiate between depressed and non-depressed people and support US Food and Drug Administration certification of the algorithm as an objective method to diagnose depression.

The company said that the study population would be divided between participants with major depressive disorder and participants without a mental health disorder.

Medibio fell one cent or 2.6 percent to 38 cents.

CELLMID

Cellmid says that the Japanese Patent Office has granted a patent entitled 'Method of treatment or prevention of hair loss or for the enhancement of hair growth'.

Cellmid said that the patent protected the use of midkine and the closely related protein pleiotrophin for use as hair loss and/or hair growth treatments.

The company said that the granted claims covered topical formulations, including shampoos, conditioners, creams and lotions with protection until 2031.

Cellmid said that the patent was the third member of the midkine patent family for hair growth to be accepted, following the granting of the UK and Australian patents.

Cellmid was unchanged at 2.7 cents with 2.6 million shares traded.

AVITA MEDICAL

Avita says it has appointed specialist wound-care distributors Medical Z for France and Ideal Medical Solutions for the UK for its full product range in each territory.

Avita said the Tours-based Medical Z was "a leader in compression garment technology" with recognition for therapeutic garments to treat burn victims and plastic surgery patients, while the Surrey-based Ideal Medical Solutions specialized in the distribution of medical devices, mainly for the burns, plastics, reconstructive, aesthetic surgery sectors.

The company said that with Conformité Européenne (CE) mark approval, it would look to extend its European reach into other countries.

Avita was unchanged at 9.4 cents.

NOVOGEN

Novogen says it has hired the Sydney-based Novotech as the contract research organisation for a phase I study of Cantrixil for cancer to begin in 2016.

Novogen said the first-in-human study would investigate the safety and feasibility of Cantrixil administered through the intra-peritoneal route for patients with refractory and/or recurrent peritoneal malignancies with malignant ascites.

Novogen clinical and regulatory affairs manager Dr Kimberley Lilischkis said the study would be weighted towards ovarian cancer patients with the selection of a gynaecological oncology site, but patients with other cancer types would be eligible to enrol in the first study "since early preclinical data suggests the drug candidate may benefit patients with a range of cancer types".

Novogen climbed half a cent or 3.85 percent to 13.5 cents with 2.5 million shares traded.

NUSEP HOLDINGS

Nusep says that Singapore subsidiary Prime Biologics has converted a bridging loan of \$S8.8 million (\$A8.6 million) provided by class A shareholders, Xeraya and JP Capital.

Nusep said that Prime had received all remaining funding tranches under the agreement for a total investment of \$S19,999,710 from Xeraya and JP Capital.

The company said that as a result of the conversion a further 32,572 Preference A shares have been issued, reducing Nusep's share in Prime from 68 percent in July to 55.1 percent of the 174,073 shares on issue (BD: Jul 27, 2015).

Nusep said that its stake in Prime might decrease further subject to the conversion of interest on the bridging loan, with the interest payment a matter of dispute between Nusep and Prime.

Nusep was untraded at 4.1 cents.

PARADIGM BIOPHARMACEUTICALS

Last night's edition incorrectly described Paradigm's Zilosul for bone marrow oedema as a belonging to the Geretsried, Germany-based Bene Pharmachem GmbH.

Paradigm has told Biotech Daily that Zilosul, an injectable form of pentosan polysulphate, is its trademarked name, not Bene Pharmachem's as reported.

The sub-editor who made the error has confessed and apologized to Paradigm, whose chairman Graeme Kaufman pleaded for mercy.

To quote the former Governor of California: "He'll live."

Paradigm fell one cent or 2.9 percent to 33 cents.

CLINUVEL

Clinuvel's annual general meeting passed all resolutions but with dissent of up to 17.1 percent against the 37.5 percent increase in the directors remuneration pool to \$550,000.

Clinuvel said the resolution was passed with 14,134,677 votes (82.9%) in favor and 2,908,206 votes (17.1%) against, while approval of the 10 percent placement capacity, the remuneration report and the re-election of director Willem Blijdorp were passed by wider margins, with chairman Stan McLiesh re-elected overwhelmingly.

The company's most recent Appendix 3B said that Clinuvel had 44,554,787 shares on issue meaning that the strongest opposition amounted to 6.5 percent of the company's total shares on issue, sufficient to requisition extraordinary general meetings.

Clinuvel fell 20 cents or 6.7 percent to \$2.80.

PHARMAUST

Pharmaust says it has appointed Redchip Companies for an investor relations program to expand the shareholder base in the US, Europe, Asia and Latin America.

Pharmaust said the Orlando, Florida-based Redchip provided investor relations, and financial media services as well as research for microcap, small-cap, and mid-cap stocks and had affiliates in New York, Pittsburgh, Paris and Seoul, South Korea.

Pharmaust was unchanged at nine cents.

ORTHOCELL

The New York-based Empery Asset Management has become a substantial shareholder in Orthocell with 5,325,759 shares (6.455%).

In the substantial notice, Empery managing member Ryan Lane said that the holders included himself, Marin Hoe, Empery Asset Management, Empery AM GP, Empery Tax Efficient LP and Empery Tax Efficient II LP, with Citicorp the registered holder.

The notice said the group acquired the shares on November 19, 2015 for \$2,625,599 or 49.3 cents a share, in the recent placement that raised \$4,326,862 (BD: Nov 20, 2015).

Orthocell was up half a cent or 1.1 percent to 46 cents.

ONCOSIL MEDICAL

The Fremantle, Western Australia-based JK Nominees has returned to a substantial shareholding in Oncosil with 20,000,000 shares or 5.56 percent.

In 2013, JK Nominees said the 15,000,000 shareholding was diluted from 6.46 percent to 4.96 percent in a placement at 13 cents a share (BD: Sep 13, Sep 24, 2013).

Oncosil was up 1.5 cents or 9.1 percent to 18 cents with 2.1 million shares traded.

SUN BIOMEDICAL

Sun says that Dimerix director David Franklyn has been appointed a director with executive chairman Howard Digby and director Dr Anton Uvarov resigning.

Sun said that company secretary Peter Webse had resigned effective from the close of business today and would be replaced by Dimerix chief financial officer and company secretary Ian Hobson.

Sun chairman Dr James Williams said that Mr Franklyn was “a long-time supporter of Dimerix Bioscience having been a director of the company prior to its acquisition by Sun Biomedical”.

The company said that Mr Franklyn was Entrust Funds Management managing-director between 2004 and 2015 and was previously the chairman of Calzada, now Polynovo, from 2009 to 2013, was a director of Dimerix between May 2014 and July 2015 before its merger with Sun, and was currently the managing-director of accommodation group Village National Holdings.

Sun said that Mr Franklyn would retire prior to the annual general meeting to be held on November 26 and would be entitled to stand for re-election, while the resolution to re-elect Mr Digby would be withdrawn.

Sun fell 0.1 cents or 14.3 percent to 0.6 cents with 5.6 million shares traded.

BUCHAN CONSULTING

Buchan says it will host a women's health investor event in Sydney featuring Airxpanders, Analytica, Starpharma and Virtus Health.

Buchan said that the four ASX-listed companies were using “new technologies to drive growth and provide new solutions addressing a number of common women's health issues”.

The investor relations company said that the event, entitled ‘New Technologies Driving Growth in Healthcare’ would feature a panel discussion with Virtus chief executive officer Sue Channon, Airxpanders chief executive officer Scott Dodson, Starpharma chief executive officer Dr Jackie Fairley and Analytica chief executive officer Geoff Daly and leading healthcare analysts to discuss the growth areas in women's health and the development of novel treatments for common conditions with significant unmet need and market potential.

The women's health event will be held at the Sofitel Wentworth Hotel, 61-101 Phillip Street, Sydney on December 2, 2015 from 5:30pm to 7:30pm (AEDT).

To register go to <https://asx-womens-health.eventbrite.com.au> or contact Gabriella Hold by email: ghold@buchanwe.com.au or by telephone +613 8866 1203.