



Biotech Daily

Thursday January 29, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: CIRCADIAN, ELLEX UP 13%, ALCHEMIA DOWN 17%**
- * **WEHI 'OBESE FAT TISSUE INFLAMMATION KEY TO TYPE 2 DIABETES'**
- * **ALCHEMIA REVIEW: DIVIDENDS, PROGRAM SALES, TRIAL REVIEW**
- * **ELLEX EXPECTS H1 REVENUE UP 19% TO \$31m, PROFIT UP 199%**
- * **USCOM H1 REVENUE UP 121% TO \$722k**
- * **GENETIC TECHNOLOGIES: '6 NEW US CENTRES OFFER BREVAGENPLUS'**
- * **SIMAVITA SIGNS ABENA FOR DENMARK, 1st ORDERS RECEIVED**
- * **US PATENT FOR ORTHOCELL CELGRO SCAFFOLD**
- * **NASDAQ ACCEPTS NOVOGEN COMPLIANCE PLAN, EXTENDS TIME**
- * **RESONANCE LOSES M-D LIZA DUNNE**
- * **REVA APPOINTS DR ROSS BRECKENRIDGE DIRECTOR**
- * **PHYTOTECH APPOINTS DR DAPHNA HEFFETZ ISRAEL CEO**

MARKET REPORT

The Australian stock market was up 0.3 percent on Thursday January 29, 2015 with the S&P ASX 200 up 16.7 points to 5,569.5 points. Twelve of the Biotech Daily Top 40 stocks were up, 15 fell, 11 traded unchanged and two were untraded.

Ellex and Circadian were the best, both up 12.9 percent to 17.5 cents and 35 cents, respectively, with 42,015 shares and 56,325 shares traded, respectively. Antisense climbed 10.0 percent; Neuren and Prana rose more than six percent; both Impedimed and Medical Developments were up 5.9 percent; Admedus was up 4.2 percent; Analytica and Starpharma were up more than three percent; Universal Biosensors rose 2.2 percent; with Cochlear, CSL and Sirtex up by less than one percent.

Alchemia led the falls, down 1.5 cents or 16.7 percent to 7.5 cents with 1.6 million shares traded. Genetic Technologies lost 7.1 percent; Optiscan fell 6.25 percent; Oncosil was down 5.5 percent; Psivida fell 4.5 percent; Cellmid fell 3.85 percent; Benitec, Bionomics, GI Dynamics and Pharmaxis shed more than two percent; with Anteo, Living Cell, Mesoblast, Nanosonics, Osprey and Resmed down one percent or more.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says its researchers have reversed type 2 diabetes in mice by dampening the inflammatory response in fat tissue.

The Institute said that Dr Ajith Vasanthakumar, Dr Axel Kallies and colleagues from Japan's Riken Institute discovered that regulatory T-cells played a key role in controlling inflammation in fat tissue and maintaining insulin sensitivity.

Dr Vasanthakumar said that regulatory T-cells acted as the guardians of the immune system, preventing the immune response from over-responding and attacking the body's own tissues.

"When [regulatory T-cells] numbers are reduced, inflammatory diseases such as diabetes and rheumatoid arthritis can occur," Dr Vasanthakumar he said.

The Institute said that recent studies had shown that fat tissue had its own type of regulatory T-cells, which disappeared from fat tissue during obesity.

"The fat tissue of obese people has lower numbers of [regulatory T-cells] than the fat tissue of people in a healthy weight range," Dr Vasanthakumar said.

"Without [regulatory T-cells], inflammation-causing cell levels increase and this rise in inflammation can lead to insulin resistance and high blood glucose levels, a classic hallmark of type 2 diabetes," Dr Vasanthakumar said.

WEHI said that the research team discovered that the interleukin-33 (IL-33) hormone was able to selectively boost regulatory T-cell populations in fat tissue, effectively halting the development of type 2 diabetes, or even reversing the disease in pre-clinical mouse models.

The paper, entitled 'The transcriptional regulators IRF4, BATF and IL-33 orchestrate development and maintenance of adipose tissue-resident regulatory T-cells' was published in the journal Nature Immunology and an abstract is available at:

<http://www.nature.com/ni/journal/vaop/ncurrent/full/ni.3085.html>.

"Treating fat tissues with IL-33 restored normal [regulatory T-cell] levels, which reduced inflammation and decreased blood glucose levels," Dr Vasanthakumar said.

"Treatments that mimic IL-33 could have the potential to reduce obesity-related inflammation and type 2 diabetes," Dr Vasanthakumar said.

Dr Kallies said the research underscored the importance of healthy fat tissue in maintaining a healthy body.

"We can no longer think of fat tissue simply as energy storage," Dr Kallies said.

"Fat tissue is increasingly being recognized as a crucial organ that releases hormones and regulates development," Dr Kallies said.

"Keeping our fat tissue healthy is important for our general wellbeing and our research highlights the important role it plays in preventing disease," Dr Kallies said.

WEHI said that more than 850,000 Australians had type 2 diabetes which was "strongly linked with ... being overweight or having high blood pressure" and the complications of type 2 diabetes included kidney, eye and heart disease, with no cure.

The Institute said that people with type 2 diabetes had reduced sensitivity to insulin, a hormone that normally triggers uptake of glucose by cells and their cells no longer responded to insulin appropriately.

WEHI said that the decrease in insulin sensitivity was thought to be a result of long-term, low-level inflammation of fat tissue in people who are obese.

The study was funded by the National Health and Medical Research Council, the Australian Research Council, the Sylvia and Charles Viertel Foundation and the Victorian Government.

ALCHEMIA

Alchemia says it will pay dividends from fondaparinux revenues, divest programs and believes it has gleaned significant information from its phase III cancer trial.

Alchemia said in an "update on its ongoing corporate and clinical review which commenced in October 2014 following the phase III trial results for hyaluronic acid-irinotecan (HA-irinotecan) for metastatic colorectal cancer.

The company said it would pay a dividend by the end of 2015 and pay shareholders all revenues from fondaparinux, less the costs of running the core business functions of a listed company.

Alchemia said that it would investigate the possible sale of fondaparinux and return proceeds to shareholders.

The company said it hoped to sell or partner its Hyact platform for further clinical development, but any capital required to support its development would be raised in an entity outside Alchemia Group, such as a demerged entity, so it does not affect dividends. Alchemia said it would target a corporate transaction for its versatile assembly on stable templates (VAST) drug discovery platform by June 30, 2015, continue to cut costs and manage its tax losses for any transaction.

The company said that further analyses of the data from its phase III trial of HA-irinotecan as part of the Folfiri regimen for second and third-line metastatic colorectal cancer has shown geographical and gender differences that might be clinically important.

Last year, Alchemia's trial failed to reach its primary endpoint of a statistically significant improvement in progression-free-survival and did not meet its secondary endpoint of an improvement in overall-survival (BD: Oct 27, 2014).

The company said that the study results were unlikely to support regulatory approval from the US Food and Drug Administration but it intended to request a meeting with the FDA, although there was a risk the FDA might not grant a meeting.

Alchemia said that the removing the Russian subset, which comprised 39.3 percent to the trial population revealed a positive trend in the HA-irinotecan arm compared to the control arm for progression-free survival (PFS) and a statistically significant improvement in median overall survival ($p = 0.019$).

The company said the analysis showed that the HA-irinotecan arm had a statistically significantly better outcome for females in both median PFS ($p = 0.047$) and median overall survival compared to standard treatment ($p = 0.016$), while in males there was a trend towards the HA-irinotecan arm providing a worse outcome than the control arm.

"One possible explanation for the observed differences in the subset analysis by gender is related to the possibility that the deposition of [HA-irinotecan] at the tumor site blocks the access of other anti-cancer drugs to the tumor for a period of time," Alchemia said.

The company said that the last drug administered in both regimens was 5-Fluorouracil, which was metabolized significantly faster in men than in women, "so the order of administration ... appears to be of importance".

The company said it had filed a US patent application to protect this unexpected outcome.

Alchemia said that in some subsets, improvement in overall survival was substantially greater than the improvement in progression-free survival and these observed differences could relate to the mechanism of action of HA-irinotecan.

Alchemia said that the future of HA-irinotecan and the Hyact platform was uncertain, although two further trials were underway, the combination trial of combination of HA-irinotecan with Erbitux (cetuximab) for metastatic colorectal cancer in collaboration with Merck Serono which was placed on hold following the phase III trial results and a small cell lung cancer trial.

Alchemia fell 1.5 cents or 16.7 percent to 7.5 cents with 1.6 million shares traded.

ELLEX MEDICAL LASERS

Ellex says revenue for the six months to December 31, 2014 is expected to be up 19.2 percent to \$31 million, compared to the prior corresponding period.

Ellex said it expected to report a profit before tax of about \$1.3 million for the six months up 198.8 percent compared to \$654,000 for the six months to December 31, 2013.

The company said the increase in revenue was attributable to strong sales of the Ultra Q Reflex laser for vitreous floaters, initial sales of the Integre Pro retinal laser, the lower value of the Australian dollar against the US dollar, the acquisition of the Canaloplasty glaucoma surgery business and increased demand in Australia and Asia, but despite the sales, it expected the operating result would be negatively impacted by the restructure of the Japanese business and a higher product development amortisation expense.

The company said it expected to report its half-year results by the end of February 2015. Ellex was up four cents or 12.9 percent to 35 cents.

USCOM

Uscom says that receipts from customers for the six months to December 31, 2014 was up 120.9 percent to \$722,481, compared to the previous corresponding period.

Uscom said that revenue for the three months to December 31, 2014 was up 101.4 percent to \$460,220 compared to the corresponding quarter.

Uscom was unchanged at 20 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says it expects up to six new US breast diagnosis and treatment centres to begin offering Brevagenplus by March 2015.

Genetic Technologies said there were a growing number of additional new breast and imaging centre customers expected to follow later in the year 2015 and as a result the company expects sales growth to accelerate in the second half 2015 and beyond.

The company said it had revised its sales strategy to focus on large comprehensive breast treatment and imaging centres, along with its ongoing approach to independent physician and women's healthcare providers.

Genetic Technologies said that the large breast centres were more complex entities with a longer sales cycle, but with higher potential, which was expected to lead to significant acceleration in growth and less volatile test volumes than experienced to date.

Genetic Technologies fell 0.1 cents or 7.1 percent to 1.3 cents with 2.5 million shares traded.

SIMAVITA

Simavita says that Abena A/S will distribute its smart incontinence management (SIM) system in Denmark and the company has received its first orders.

Simavita said that Abena delivered incontinence products to 51 municipalities, including nursing homes and home care, and all the hospitals in Denmark.

The company said that the exclusive five-year distribution agreement with Abena followed the establishment and operation of a showcase site in Copenhagen and SIM assessments conducted at the site were being compiled into a report for review by the Danish

Government, for consideration as a best practice approach to incontinence management.

Simavita fell half a cent or 1.15 percent to 43 cents.

ORTHOCELL

Orthocell says it has been granted a US patent for its Celgro soft tissue reconstruction scaffold technology.

Orthocell said that the patent, entitled 'A Collagen Scaffold for Cell Growth and a method producing the Same', provided important protection to the Celgro product in the US as Orthocell prepared for registrations and commercialization.

Orthocell managing director Paul Anderson said the patent strengthened the company's intellectual property position for its soft tissue reconstruction technology "and comes at a perfect time for the company as we move our products through international registration processes as well as commercial partnerships".

Orthocell said it planned to file the first registration for approval of Celgro by October 2015 and was expanding production capacity to support sales.

Orthocell fell half a cent or 1.2 percent to 40 cents.

NOVOGEN

Novogen says the Nasdaq has approved its plan evidencing its ability to achieve and sustain compliance with the minimum stockholders' equity rule.

In November last year, the Nasdaq sent Novogen a compliance letter (BD: Nov 12, 2014).

The company said that the Nasdaq had granted it an extension of time to further demonstrate compliance with the rule.

Novogen was up half a cent or 4.55 percent to 11.5 cents.

RESONANCE HEALTH

Resonance says that managing director Liza Dunne has resigned, effective from January 30, 2015 "to pursue other interests".

Resonance said that Ms Dunne had been with the company for 11 years.

Ms Dunne said that she was "delighted to have had the opportunity to be a part of Resonance Health from its early stages soon after listing on the ASX through to the successful international commercialization of the Ferriscan technology and was privileged to lead the company as managing director for the past six years".

Ms Dunne said that the company was "in a strong position with significant opportunities ahead".

"Double digit growth in the Ferriscan business is expected to continue and a profitable full year result is anticipated," Ms Dunne said.

Ms Dunne said that the cash raised in 2014 provided the funding to commercialize the Hepafat-Scan product and accelerate investment in research and development for an imaging diagnostic tool for liver fibrosis.

Resonance chairman Dr Martin Blake said that Ms Dunne had "laid a solid foundation for the company and leaves it in the strongest position it has ever been in".

"On behalf of the board and all the staff, I wish to express our sincere thanks and appreciation to Liza for her service and dedication to the company over many years and her leadership as managing director through some difficult years," Dr Blake said.

Resonance said a search had begun for a new managing director.

Resonance was unchanged at four cents.

REVA MEDICAL

Reva says it has appointed Dr Ross Breckenridge as a non-executive director.

Reva said that Dr Breckenridge was a recognized leader in cardiovascular medicine and was currently a senior clinical lecturer at University College London and the program director for the Masters Program in Clinical and Experimental Medicine.

The company said that Dr Breckenridge's research focused on the response of the heart to low levels of oxygen, with the overall aim of identifying novel therapeutic targets for cardiac disease.

Reva said that Dr Breckenridge was also a consultant physician at University College London, Hospital and provided consultation services to investors in the biotechnology and healthcare sector.

The company said that Dr Breckenridge currently served on the boards of Senrigan Capital, Empower India and the Cornelia de Lange Society of Great Britain.

Reva said that Dr Breckenridge held a Bachelor of Medicine and Bachelor of Surgery from Oxford University, and a Doctorate of Philosophy from the University of Cambridge.

Reva was unchanged at 46 cents.

PHYTOTECH MEDICAL

Phytotech says it has appointed of Dr Daphna Heffetz as the chief executive officer of its wholly-owned subsidiary company in Israel also called Phytotech Medical.

Phytotech said that Dr Heffetz would lead development and commercialization of its cannabis-based therapeutics products in collaboration with scientists at the Hebrew University in Israel through the University's Yissum Research Development Company.

The company said that the first products to be developed would be based on proprietary oral and buccal drug delivery technologies.

Phytotech said Dr Heffetz had more than 20 years experience in establishing biotechnology companies and had experience in developing therapeutic products based on drug delivery technologies.

The company said that most recently Dr Heffetz was Alon Medtech Ventures chief executive officer and in 2000 she founded Transpharma Medical, a transdermal drug delivery company, raising \$US34 million in three financing rounds and brought more than \$US50 million from collaborations with pharmaceutical companies

Phytotech said that previously Dr Heffetz held executive positions at Healthcare subsidiary Savyon Diagnostics and was appointed as chief executive officer and a director.

The company said that Dr Heffetz held a Masters of Science, a Doctorate of Philosophy and was a post-doctoral fellow in molecular biology with the Weizmann Institute.

Phytotech said that Dr Heffetz would receive a base salary of NIS720,000 (\$A232,150), and would be entitled to a company car, pension plan, insurance and education fund, all of which were customary in Israel, and would be granted 4,500,000 unlisted options exercisable at 20 cents each, vesting over three years.

Phytotech was up three cents or 5.8 percent to 54.5 cents with 9.0 million shares traded.