



Biotech Daily

Friday March 13, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH EVEN: GENETIC TECH UP 12%, PHARMAXIS DOWN 12.5%**
- * **WEHI EDITS GENOMES TO KILL CANCER FOR ITS 100th BIRTHDAY**
- * **UNIVERSAL BIOSENSORS NEW FEATURES FOR SIEMENS TEST**
- * **BPH ENERGY: PAPERS BACK MOLECULAR DISCOVERY HLSR**
- * **AGENIX, OKS RESOLVE 2008 THROMBOVIEW INVESTMENT CASE**
- * **HUNTER HALL TAKES 9.6% OF GI DYNAMICS**
- * **ASIA UNION DECREASES, DILUTED TO 7% OF TISSUE THERAPIES**
- * **PRATT'S THORNEY (TIGA) INCREASES, DILUTED TO 5% OF MAYNE**
- * **SIMAVITA PROPOSES WARREN BINGHAM FOR DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.61 percent on Friday March 13, 2015 with the S&P ASX 200 down 35.7 points to 5,814.5 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 12 fell, 12 traded unchanged and three were untraded. All three Big Caps fell.

Genetic Technologies was the best, up 0.5 cents or 12.2 percent to 4.6 cents with 40.0 million shares traded, followed by Viralytics up 10.5 percent to 47.5 cents with 311,390 shares traded.

GI Dynamics climbed eight percent; Admedus and Avita were up more than six percent; Analytica rose 5.6 percent; Benitec and Cellmid were up more than four percent; Tissue Therapies rose 2.3 percent; Acrux, Antisense and Nanosonics were up more than one percent; with Mesoblast up 0.5 percent.

Yesterday's best, Pharmaxis, led the falls, down 1.5 cents or 12.5 percent to 10.5 cents with 5.3 million shares traded.

Biotron lost 6.45 percent; Medical Developments fell 5.2 percent; Clinuvel and Universal Biosensors fell more than four percent; Living Cell was down 3.4 percent; Atcor and Phosphagenics shed two percent or more; Alchemia and Cochlear were down more than one percent; with CSL, Osprey, Psivida, Resmed and Sirtex down less than one percent.

THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that on its 100th anniversary it has developed a genome editing technology that can target and kill blood cancer cells.

The Institute said its researchers were able to kill human lymphoma cells by locating and deleting the MCL-1 gene which was essential for cancer cell survival.

WEHI said that the research provided a proof-of-concept for using the technology as a direct treatment for human diseases arising from genetic errors.

The Institute said that Dr Brandon Aubrey, Dr Gemma Kelly and Dr Marco Herold adapted the clustered regularly interspaced short palindromic repeats (Crispr) technology to mimic and study blood cancers.

Dr Aubrey, a haematologist at the Royal Melbourne Hospital, said the team used the Crispr technology to target and directly manipulate genes in blood cancer cells.

"Using preclinical models, we were able to kill human Burkitt lymphoma cells by deleting MCL-1, a gene that has been shown to keep cancer cells alive," Dr Aubrey said.

"Our study showed that the Crispr technology can directly kill cancer cells by targeting factors that are essential for their survival and growth," Dr Aubrey said.

The research paper, entitled 'An Inducible Lentiviral Guide RNA Platform Enables the Identification of Tumor-Essential Genes and Tumor-Promoting Mutations In Vivo' was published in the journal Cell Reports and an abstract is available at:

<http://www.cell.com/cell-reports/abstract/S2211-1247%2815%2900110-2>.

WEHI said that the Crispr system located and targeted genes of interest and could either target the gene to introduce mutations that made the gene non-functional, or introduce changes that made mutated genes function normally again.

"There is a lot of excitement and a significant amount of resources being invested worldwide to use Crispr technology for treating patients," Dr Herold said.

"In our study, we showed for the first time that it is possible for Crispr technology to be used in cancer therapy, however Crispr is a unique approach that could potentially be used for treating any disease that is caused by genetic mutations," Dr Herold said.

"The speed at which we are now able to make specific changes in the DNA will also accelerate basic research discoveries in the lab," Dr Herold said.

"It is amazing to see how far medical research has come," Dr Herold said.

"When the institute was founded DNA hadn't even been discovered, and we didn't know what a gene was [and] we now have technology that can target and switch on or off specific parts of the DNA with precision," Dr Herold said.

100 Years Of Discoveries

WEHI director Prof Doug Hilton said the centenary was an opportunity to reflect on the institute's achievements, and look ahead to the next 100 years of discoveries.

"When you reflect on the advancements in health and medicine over the past 100 years, the milestones we have achieved have been absolutely remarkable," Professor Hilton said. "We couldn't be more proud of the impact the institute's research has made."

"Our discoveries have improved the lives of tens of millions of people worldwide and, as we continue to unravel the mysteries of the body and disease, we hope to impact the lives of tens of millions more," Dr Hilton said.

The Institute said that its achievements included discovering colony stimulating factors (CSF), which boosted white blood cells after cancer treatment and had helped more than 20 million people worldwide, as well as identifying the BCL-2 protein that kept cancer cells alive, leading to the development of anti-cancer drugs, treating immune disorders by suppressing the immune system, understanding how malaria invaded and infected blood cells, pioneering the use of hen eggs to grow and study viruses for flu vaccine production and researching and developing snakebite vaccines with CSL.

UNIVERSAL BIOSENSORS

Universal Biosensors says Siemens Healthcare will make additional payments to incorporate additional features in the Xprecia Stride Coagulation Analyzer.

Universal Biosensors said that with Siemens, it expected regulatory approval and commercial launch of the additional high commercial value tests by the end of 2016.

The company said that the Xprecia was the first point-of-care coagulation testing system developed with Siemens, launched in December 2014, and further point-of-care coagulation tests were in development in collaboration with Siemens.

Universal Biosensors said it continued to advance the development of its own prothrombin time, international normalized ratio (PT-INR) test for decentralized settings and targeted product launch by the end of 2015.

The company said that reliability and clinical testing were underway and preparations were being made for final design verification and regulatory trials.

Universal Biosensors chief executive officer Paul Wright said that "following the successful development of the Xprecia Stride Coagulation Analyzer for Siemens, it's exciting to have several new point-of-care coagulation testing products coming down the pipeline".

Universal Biosensors fell 1.5 cents or 4.8 percent to 29.5 cents.

BPH ENERGY, MOLECULAR DISCOVERY SYSTEMS

BPH says that two papers support 20 percent investee company Molecular Discovery Systems' HLS5, or TRIM35, as a tumor suppressor gene.

BPH said that the papers were collaborations between Fudan University Shanghai Cancer Centre and other Chinese Institutes, including Shanghai Cancer Institute, Liver Cancer Institute, Second Military Medical University and Qi Dong Liver Cancer Institute, and focused on identifying the role of HLS5 in liver cancer, the third leading cause of cancer related deaths worldwide.

BPH said that the article entitled 'TRIM35 Interacts with pyruvate kinase isoform M2 to suppress the Warburg effect and tumorigenicity in hepatocellular carcinoma' established the means by which HLS5 suppressed the proliferation of cancer cells in liver cancer and concluded that HLS5 and PKM2 expression levels were a critical mechanism in the development of human cancers.

An abstract is at: <http://www.nature.com/onc/journal/vaop/ncurrent/full/onc2014325a.html>.

BPH said that the research demonstrated that HLS5 bound an enzyme involved in the production of energy for cancer cells, pyruvate kinase isoform M2 (PKM2) and subsequent experiments determined that HLS5 bound PKM2 to form a complex which decreased the level of activated PKM2.

The company said that the formation of this HLS5 PKM2 complex limited the cancer cell's means of energy production and its ability to proliferate.

BPH said that in the second research article, entitled 'Co-expression of PKM2 and TRIM35 predicts survival and recurrence in hepatocellular carcinoma' the expression levels of HLS5 and PKM2 were assessed for potential use as a prognostic marker for hepatocellular carcinoma, or liver cancer.

The company said that the study analyzed the liver samples of 688 patients who had liver cancer and had a section of their liver removed and found that patients who had hepatocellular carcinoma and were positive for PKM2 expression and negative for HLS5 had shorter overall survival and time to recurrence.

An abstract is available at: <http://www.ncbi.nlm.nih.gov/pubmed/25576919>.

Last year, Molecular Discoveries suspended all of its early programs (BD: Jun 4, 2014).

BPH was unchanged at half a cent with one million shares traded.

AGENIX

Agenix says it has agreed with OKS AGX Inc to settle Supreme Court proceedings arising from a \$5 million share subscription agreement from 2008.

In 2008, Agenix raised \$5 million through the placement of 41,666,666 shares at 12 cents a share to OKS-AGX, a British Virgin Islands vehicle “backed by Middle Eastern interests” but with no further information on the identity of the company (BD: Mar 19, 2008).

Agenix said at that time that OKS-AGX would own 9.78 percent of its capital and OKS-AGX representative, James Liu, would be appointed to the board and its remuneration committee.

Today Agenix said that the Supreme Court proceedings made no claims concerning the conduct of any current Agenix board member or personnel.

The company said that it would provide and maintain OKS with a 10 percent shareholding for two years or until a point immediately preceding a merger or acquisition transaction by Agenix, whichever occurred first and OKS would be assigned all rights, title and interest in the Thromboview project, pending conditions, including shareholder approval.

Agenix chairman Nick Weston said that he believed shareholders would support the transaction.

“The board took the view that for Agenix to move forward it must resolve this legacy matter, bequeathed by a former board, so that it can focus on its next phase,” Mr Weston said. “The company was constrained by the 2008 OKS share subscription agreement from taking Thromboview into phase III studies on its own, and despite rigorous and extensive partnering efforts worldwide since then, was unable to find a partner for the project.”

“The settlement, if approved, does not involve a cash payment, and will remove a significant barrier to Agenix increasing shareholder value and achieving near term revenue,” Mr Weston said.

Agenix was untraded at 1.3 cents.

GI DYNAMICS

Hunter Hall Investment Management has increased its substantial shareholding in GI Dynamics from 39,882,925 shares (8.42%) to 45,536,619 shares (9.61%).

The Sydney-based Hunter Hall said it acquired the shares in 18 trades between October 13, 2014 and March 10, 2015 with the single largest purchase on March 6 of 2,595,000 shares for \$383,432 or 14.8 cents a share.

GI Dynamics share price fell 50 percent last week following a US Food and Drug Administration halt to its pivotal trial its Endobarrier gastric liner for obesity and type 2 diabetes (BD: Mar 6, 2015).

Last year, Hunter Hall increased its holding in GI Dynamics following a share price fall of 19.6 percent on a European halt to its shipments of the Endobarrier (BD: Oct 7, 2014).

GI Dynamics was up one cent or eight percent to 13.5 cents.

TISSUE THERAPIES

Asia Union Investments says it has decreased in Tissue Therapies from 21,813,991 shares to 21,115,983 shares and has been diluted from 8.29 percent to 6.98 percent.

The Sydney-based Asia Union substantial shareholder notice said that between September 18, 2014 and January 21, 2015 it sold 2,017,757 shares for \$720,155 or an average price of 35.7 cents a share and bought 1,319,749 for \$277,147 on March 6, 2015 in the placement at 21 cents a share (BD: Mar 5, 2015)

Tissue Therapies was up half a cent or 2.3 percent to 22.5 cents.

MAYNE PHARMA GROUP

Thorney International says it has increased its holding in Mayne Pharma from 9,488,557 shares to 40,300,000 shares but has been diluted from 6.31 percent to 5.14 percent. In 2010, the then Tiga Trading became a substantial shareholder in Mayne Pharma, then known as Halcyon, with the acquisition of 9,488,557 shares or 6.31 percent of the company (BD: Nov 15, 2010).

Today, the Pratt Industries-related company Thorney International said that it bought shares between 2010 and 2015 on market and acquired 12,877,310 shares in a placement at 20 cents a share on October 17, 2012, as well as 2,500,000 shares in a conditional placement on November 13, 2012 for 20 cents a share and further 4,800,000 shares in a placement at 29.5 cents on December 21, 2012 and acquired 9,159,420 shares at 61 cents a share in a one-for-3.45 rights issue on February 19, 2015. Mayne was up half a cent or 0.5 percent to 94 cents with 2.5 million shares traded.

SIMAVITA

Simavita says it proposes to appoint Warren Bingham as a director, pending Toronto Stock Exchange and shareholder approval.

Simavita said that Mr Bingham had more than 20 years experience in medical devices and technologies, health economics, regulatory and clinical affairs and business development. The company said that in 2001, Mr Bingham established the Australian subsidiary of Given Imaging, a company that developed the Pillcam ingestible pill-sized camera which monitored gastro-intestinal complaints and in 2004, he registered Pillcam Capsule Endoscopy with the Medicare Benefits Scheme.

Simavita said that Mr Bingham was the chair of the Ausmedtech national advisory group and chair of the Ausmedtech health economics expert panel.

In February, Clinical Genomics appointed Mr Bingham as its Asia-Pacific vice-president (BD: Feb 2, 2015).

Mr Bingham's LinkedIn page said that he held a Certificate in Business Administration from the Australian Institute of Management, as well as a Post Graduate Certificate and Diploma of Management from the Macquarie Graduate School of Management. Simavita was untraded at 43 cents.