



Biotech Daily

Friday October 17, 2014

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: IMPEDIMED UP 13%, GENETIC TECHNO DOWN 7%**
- * **VIRAX TO BUY TCN-P CANCER DRUG FOR \$343k, \$2.3m SHARES**
- * **FEDERAL GOVERNMENT: \$580m NHMRC GRANTS**
- * **CALZADA NAME-CHANGE TO POLYNOVO, 3m DIRECTOR OPTIONS AGM**
- * **ACTINOGEN CORTRICINE ACQUISITION AGM**
- * **HUNTER HALL TAKES MORE PROFIT TO 11% IN SIRTEX**
- * **NUSEP APPOINTS MARK GELL DIRECTOR**
- * **ACUVAX APPOINTS NIGEL LEE FOR ACTIVISTIC FUNDS COLLECTION**

MARKET REPORT

The Australian stock market was up 0.32 percent on Friday October 17, 2014 with the S&P ASX 200 up 16.8 points to 5,271.7 points.

Sixteen of the Biotech Daily Top 40 stocks were up, eight fell, nine traded unchanged and seven were untraded.

Impedimed was the best, up five cents or 12.7 percent to 44.5 cents with 140,713 shares traded.

Prana climbed 9.5 percent; Analytica was up 6.25 percent; Patrys and Tissue Therapies were up more than five percent; Mesoblast, Pharmaxis and Uscom were up four percent or more; Neuren was up 3.7 percent; Acrux and Biotron rose more than two percent; Phosphagenics and Viralytics were up more than one percent; with Alchemia, Bionomics, CSL and Starpharma up by less than one percent.

Genetic Technologies led the falls for the second day in a row, down a further 0.1 cents or 7.1 percent to a new low of 1.3 cents with 231,000 shares traded.

Antisense, Clinuvel and Compumedics lost more than four percent; Admedus and Universal Biosensors were down more than three percent; Ellex shed 2.9 percent; Benitec was down 1.5 percent; with Cochlear and Resmed down by less than one percent.

VIRAX HOLDINGS

Virax says it will acquire Aktivite Therapeutics and its TCN-P cancer drug for \$US300,000 (\$A342,866) and \$2.34 million in shares, deepening its oncology pipeline.

Virax managing director Dr Robert Crombie told Biotech Daily that Aktivite was a vehicle used to acquire the tricitiribine or TCN-P technology, which was first developed at Cahaba Pharmaceuticals in Princeton, New Jersey.

Dr Crombie said that TCN-P was in two trials "largely funded by the US Department of Defense and the US National Cancer Institute".

Dr Crombie said that the acquisition was a strengthening of the Virax oncology pipeline and he was preparing to meet the US Food and Drug Administration to reactivate the investigational new drug application for GGTI-2418 and prepare for phase Ib dose-ranging trials for breast cancer and multiple myeloma (BD: Sep 9, 2014).

In a media release, Virax said that the Aktivite technology inhibited "the highly promising drug target AKT" and the two trials were a phase Ib/II in breast cancer and an active phase Ib in ovarian cancer.

The company said that 15 of 36 patients had been recruited to date for the phase Ib/II breast cancer trial at the Montefiore Medical Center in New York.

Virax said that a phase Ib ovarian cancer trial had begun at the Moffitt Cancer Center in Florida, with a phase I study on patients with acute myeloid leukaemia planned for 2015. The company said that, pending shareholder approval, 134,000,000 shares at one cent each would be paid upfront, with a further 100,000,000 to be paid on reaching defined clinical milestones.

"TCN-P is a highly promising asset presenting an outstanding clinical and commercial opportunity with robust [intellectual property] ... manufacturing complete, with ample drug supply and prestigious US cancer centres already dosing patients," Dr Crombie said.

"Assuming shareholders approve this acquisition on November 28, we plan to pursue the TCN-P program as a lead priority in tandem with our other complementary oncology compound GGTI-2418," Dr Crombie said.

"This acquisition has the potential to catapult up-side for Virax shareholders," Dr Crombie said.

"It also means that in the next 12 months we expect to be driving five clinical trials, under two separate IND applications with two of the most advanced trials funded by US government authorities," Dr Crombie said.

Virax said that TCN-P, or tricitiribine phosphate monohydrate, was a small molecule that blocked the AKT growth-promoting pathway that led to cancer.

The company said that AKT was the most frequently mutated pathway in cancer and played a key role in many cancers including those being pursued, breast, ovarian and leukaemia, as well as a potential treatment for other cancers.

Virax said that high AKT expression was associated with a poor outlook, resistance to chemotherapy and shortened patient survival time.

The company said that in animal studies TCN-P had been shown to suppress strongly the growth of high AKT expressing tumors and to overcome resistance to commonly used chemotherapeutic drugs, a key feature of the TCN-P drug.

Virax said that more than 100 patients had been dosed with TCN-P in trials at US cancer centres including the Lee Moffitt Cancer Center in Florida, MD Anderson in Texas and the Memorial Sloan Kettering Cancer Center in New York.

The company said that a phase I study of TCN-P in haematologic cancers, primarily acute myeloid leukemia, at MD Anderson and Lee Moffitt Cancer Centers showed encouraging anti-tumor activity.

Virax climbed 0.2 cents or 40 percent to 0.7 cents with 16.1 million shares traded.

FEDERAL GOVERNMENT, NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

The Federal Government says that the National Health and Medical Research Council will provide \$580.2 million for 848 research grants.

In a media release, Prime Minister Tony Abbott and the Minister for Health Peter Dutton announced funding for 555 Project Grants totalling \$421.1 million, eight Partnership Projects worth \$7.3 million, 19 Centres of Research Excellence of \$47.3 million, 125 Early Career Fellowships valued at \$39.4 million, 58 Career Development Fellowships for \$24.1 million, 10 Translating Research into Practice Fellowships valued at \$1.7 million, 47 Equipment grants totalling \$6 million and 26 Independent Medical Research Institutions Infrastructure grants worth \$32.7 million.

In 2013, the Federal Government provided \$559 million for 963 NHMRC grants, down 14.3 percent on the previous year when the then Labor-Greens Government provided \$652 million for 1,141 NHMRC grants (BD: Oct 19, 2012; Oct 23, 2013).

The detailed list of NHMRC grants awarded to successful researchers is available at:

<https://www.nhmrc.gov.au/grants/outcomes-funding-rounds>.

CALZADA

Calzada shareholders will vote to change the company's name to Polynovo at its annual general meeting as well as approve 3,000,000 director options.

Calzada changed its name from Metabolic following two trials showing its lead drugs AOD9604 for obesity and ACV1 for neuropathic pain did not meet their endpoints and then acquired Polynovo from Xceed Capital (BD: Feb 21, Aug 14, 2007; Jul 18, 2008).

Calzada's wholly-owned subsidiary Polynovo has been developing the Novosorb bioresorbable polymer technology which originated at the Commonwealth Scientific and Industrial Research Organisation and has been trialled for wound treatment, structural support and as a bioresorbable cardiac stent.

The company also holds the intellectual property to AOD9604, which has been at the centre of the Essendon Football Club supplements controversy (BD: Apr 26, 2013).

Today, Calzada said it was "the view of the board that the strategic direction of the company is primarily focused on the Polynovo business and as a result the directors consider that the current name is no longer appropriate".

Calzada said that shareholders would vote to issue 500,000 options exercisable at 20 cents each within three years to directors Bruce Rathie, David McQuillan, Max Johnston and Phillip Powell, with a further 500,000 options exercisable at 14 cents each within three years to Mr Johnston and Mr Powell.

The meeting will be held at Unit 2, 320 Lorimer Street, Port Melbourne on November 17, 2014, at 10am (AEST).

Calzada fell 0.1 cents or 1.1 percent to 8.9 cents.

SIRTEX MEDICAL

Hunter Hall Investment Management has again reduced its substantial holding in Sirtex from 6,770,341 shares (11.98%) to 6,038,251 shares (10.68%).

Hunter Hall bought and sold shares between August 20 and October 14, 2014 with the single largest sale of 130,000 shares for \$2,724,195 or \$20.96 a share.

Hunter Hall has been reducing its holding in Sirtex since May 2013 (BD: May 29, 2013).

Hunter Hall has been a long term shareholder in Sirtex and in 2009 increased to 16,684,884 shares (29.92%) when the company was at \$2.35 a share (BD: Mar 5, 2009).

Sirtex was unchanged at \$22.36 with 309,018 shares traded.

ACTINOGEN

Actinogen shareholders will vote on 19 resolutions, with most relating to the acquisition of the Edinburgh, Scotland-based Corticrine to develop therapies for Alzheimer's dementia. In August, Actinogen said that Corticrine was a University of Edinburgh spin-out and had licenced development and commercialization rights from the University to UE2343 for Alzheimer's disease (BD: Aug 27, 2014).

Today the company proposed 19 annual general meeting resolutions, including the adoption of the remuneration report and approval of the 10 percent placement capacity, with most resolutions relating to funding the acquisition and appointing new directors. The company said that shareholders would vote to re-elect directors Dr Anton Uvarov and Dr Brendan de Kauwe, appoint as directors Dr Jason Loveridge and Martin Rogers and authorize a director placement for Dr de Kauwe, Dr Uvarov, Dr Loveridge and Mr Rogers. The Actinogen resolutions include approval for a placement the issue of 5,500,000 'facilitator options' exercisable at two cents by November 30, 2018 to Concept Biotech, which was described as a shareholder in Corticrine; an employee share plan; 6,000,000 loan shares at two cents each for Dr Loveridge, 25,000,000 loan shares at two cents each for Mr Rogers and 2,000,000 loan shares at two cents each for the head of clinical research Vincent Ruffles.

The meeting will be held at the Level 2, 1 Walker Avenue, West Perth, Western Australia on November 19, 2014 at 10.30am (AWST).

Actinogen was untraded at four cents.

NUSEP HOLDINGS

Nusep says it has appointed Mark Gell as an independent, non-executive director.

Nusep said that Mr Gell had more than 30 years experience in the public and private sectors with a knowledge of capital markets, strategy and issues management.

The company said that Mr Gell was a director and past chairman of the Australasian Investor Relations Association and had held senior positions at Citibank, Australian National Industries, TNT, Boral, Telstra, Onesteel and Lend Lease.

Nusep said that Mr Gell held an Economics degree from the University of Sydney and a Masters of Business Administration from the Australian Graduate School of Management. Nusep was untraded at 5.9 cents.

ACUVAX

Acuvax says it has appointed Nigel Lee as a director, effective from today.

Acuvax said that the appointment of Mr Lee was "strategic and consistent with the proposed change of activities of the company via the acquisition of micro collection company Activistic" (BD: Oct 8, 2014).

Prior to the Activistic acquisition, Acuvax had been developing cancer drugs, endured board turmoil and management changes and in 2012 Paul Hopper and Dr Roger Aston hoped to use the company for a backdoor listing for the Biolife Science Her-Vaxx technology, now with Imugene (BD: Dec 20, 2012; Feb 12, 2013; Jun 24, 2014).

Acuvax was untraded at 0.1 cents.