

Biotech Daily

Wednesday November 5, 2014

Daily news on ASX-listed biotechnology companies

- * ASX EVEN, BIOTECH DOWN: GI DYNAMICS, OPTISCAN UP 7% IDT DOWN 15%
- * GENETIC TECHNOLOGIES DR MERVYN JACOBSON 'GUILTY'
- * PHOSPHAGENICS \$6m THEFT SENTENCING ADJOURNED
- * FEDERAL GOVERNMENT: \$354m FOR 941 ARC GRANTS
- * IMUGENE PLACEMENT FOR \$2.25m, SHARE PLAN, HER-VAXX TRIAL
- * BIOPROSPECT, UNSW HEART RATE FOR DEPRESSION DIAGNOSIS TRIAL
- * BIOTRON RIGHTS ISSUE RAISES \$4m
- * PHYLOGICA EXPECTS \$1.9m FEDERAL R&D TAX REFUND
- * VERITAS TAKES 6.6% OF COCHLEAR
- * DORSAVI APPOINTS DAVE WILDERMUTH CHIEF MARKETING OFFICER

MARKET REPORT

The Australian stock market slipped 0.04 percent on Wednesday November 5, 2014 with the S&P ASX 200 down 2.0 points to 5,517.9 points. Ten of the Biotech Daily Top 40 stocks were up, 13 fell, 13 traded unchanged and four were untraded.

Both GI Dynamics and Optiscan were up 7.14 percent to 30 cents and three cents, respectively, with 82,345 shares and 1,000 shares traded, respectively.

Patrys was up 4.8 percent; Cellmid climbed 3.85 percent; Acrux and Neuren rose more than two percent; Ellex, Living Cell and Tissue Therapies were up more than one percent; with Resmed and Sirtex up by less than one percent.

IDT led the falls for the second trading day in a row, down 3.5 cents or 15.2 percent to 19.5 cents with 255,609 shares traded.

Both Analytica and Antisense lost 9.1 percent; Admedus shed eight percent; Pharmaxis fell 5.6 percent; Anteo was down 3.7 percent; Medical Developments and Mesoblast shed more than two percent; Alchemia, Clinuvel, Cochlear, Nanosonics and Viralytics were down more than one percent; with Impedimed and CSL down by less than one percent.

GENETIC TECHNOLOGIES

Genetic Technologies founder and former chief executive officer Dr Mervyn Jacobson has been found guilty on two charges of conspiracy and 33 charges of market manipulation. An officer of the Supreme Court of Victoria told Biotech Daily that the jury returned the verdicts late this afternoon, finding Dr Jacobson guilty on all counts.

When the case opened before Justice Stephen Kaye in September, Dr Jacobson pleaded not guilty to two counts of conspiracy and 33 counts of market manipulation between May and November 2006 (BD: Sep 8, Oct 29, 2014).

Dr Jacobson was charged with two counts of conspiring to take part in transactions which were likely to have the effect of creating an artificial price or maintaining a price at a level that is artificial, contrary to Section 11.5 of the criminal code and Sections 1041A and 1311 of the Corporations Act 2001.

Dr Jacobson was charged with 33 counts of taking part in transactions that were likely to have the effect of creating an artificial price or maintaining a price at a level that that is artificial, contrary to Section 1041A and Section 1311 of the Corporations Act 2001. Justice Kaye adjourned the matter to November 19, 2014 for pleadings and extended Dr Jacobson's bail.

Genetic Technologies was untraded at two cents.

PHOSPHAGENICS

The sentencing of Phosphagenics former chief executive officer Dr Esra Ogru, Dr Robert Gianello and Dr Woei-Jia Jiang has been adjourned to November 7, 2014.

Justice Felicity Hampel told the Melbourne County Court that she needed more time to understand Dr Gianello's involvement in three charges of obtaining a financial advantage by deception to be satisfied with her sentencing (BD: Aug 20, 21, 22, 29; Oct 9, 2014). Justice Hampel said the questions raised were related to whether separate charges were continuing conduct and Dr Gianello's personal benefit of about \$100,000 in relation to those charges.

Chris Dane QC, acting for Dr Gianello and Allan Sharp prosecuting for the Commonwealth Department of Public Prosecutions agreed with Justice Hampel's understanding of the series of invoices from TABridge Pty Ltd to Vital Health Sciences and Phosphagenics. Justice Hampel asked if there had been an update on the \$3.8 million restitution that had been paid, with a total restitution expected of \$5.2 million, but there was no update available.

Justice Hampel said that the matter would be adjourned.

Counsel for Dr Ogru, Dr Martine Marich told the Court that Dr Ogru was "unaccompanied and has said her goodbyes".

Mr Dane said that there was a "sting in delay ... the inverse of false hope".

Family of Dr Gianello and Dr Jiang were in court for the sentencing along with Phosphagenics chief executive officer Harry Rosen, his wife Pauline Rosen and the company's chief financial officer Anna Legge.

Justice Hampel adjourned the sentencing to Friday, November 7, 2014.

Phosphagenics was unchanged at 7.3 cents.

FEDERAL GOVERNMENT, AUSTRALIAN RESEARCH COUNCIL

The Federal Government says that 941 projects will receive Australian Research Council grants totaling \$354 million.

The Federal Minister for Education Christopher Pyne said that the grants were part of the 2015 Australian Research Council major grants and covered a broad range of research areas, including school curriculum, three-dimensional imaging and printing, improving plant diversity and preserving indigenous heritage.

"The Australian Government has committed to building a world-class education and research sector as one of the five pillars of a stronger, more productive and prosperous Australia," Mr Pyne said.

"This Government deeply values the need for a robust and thriving research sector that drives the future development of our industries," Mr Pyne said.

A media release from Mr Pyne's office said that the grants included \$250 million for 665 projects under the Discovery Projects scheme; \$70.6 million for 200 projects under the Discovery Early Career Researcher Award scheme; \$4.4 million for 10 projects under the Discovery Indigenous scheme and \$29 million for 66 projects under the Linkage Infrastructure, Equipment and Facilities scheme.

For more information about the funding outcomes, including statistics and full project details go to: http://www.arc.gov.au/media/2015_major_grant_announcement.htm.

IMUGENE

Imagene says it has commitments for a placement of \$2.25 million at one cent a share, which will be followed by a share plan.

Imugene said the placement commitments were from sophisticated investor clients of Forrest Capital, including a subscription by director Otto Buttula for \$150,000 in shares, subject to shareholder approval.

The company said that the share plan would offer investors at the record date of November 3, 2014 parcels of shares in \$1,000 increments to a maximum of \$15,000 per shareholder, with the offer opening on November 7 and closing on November 28, 2014. Imagene chief executive Charles Walker said the funds would "support the development of HER-Vaxx and our very promising new therapy for gastric and other HER-2 positive cancers".

Imugene said that funds would be applied to the manufacture of HER-Vaxx sufficient for clinical trials, beginning the phase lb/II clinical trial in patients with metastatic gastric cancer, preclinical work, corporate costs, intellectual property prosecution and general corporate purposes.

The company said that significant progress had been made on the manufacture of clinical quantities of HER-Vaxx and manufacturing partners had been appointed and work was continuing on the clinical trial protocol.

Imugene said that it expected to organize an investigational new drug application to the US Food and Drug Administration by July, 2015 and begin the trial shortly after.

The company said that the phase Ib part of the trial would be an open label, dose-escalating trial in three cohorts of six patients each.

Mr Walker told Biotech Daily that the 68-patient, randomized, placebo-controlled, double-blinded phase II trial would evaluate HER-Vaxx or placebo, given concurrently with chemotherapy, in two arms of 34 patients each.

Imugene was unchanged at 1.1 cents.

BIOPROSPECT

Bioprospect says the University of New South Wales's Black Dog Institute will conduct a 60 to 80 patient trial of its circadian heart rate-based technology for depression.

Bioprospect said that it would be the "the first independent trial of the company's heart rate technology for the diagnosis of mental health conditions".

Bioprospect executive director Kris Knauer told Biotech Daily that previous descriptions of the technology as "heart rate variability" were not accurate and the test was based on measured differences in circadian heart rate data and measures of heart rate variability. In a media release, Bioprospect said that human heart rates, including certain tell-tale changes, were sensitive measures for depression, particularly in the early stages when traditional diagnostic interviews were less sensitive.

The company said that the technology consisted of "a heart monitor that sent recordings wirelessly to the internet where a proprietary algorithm analyses and delivers a quantifiable diagnosis".

Bioprospect said the technology had the potential to be the first US Food and Drug Administration-approved objective, evidence based approach to the diagnosis of depression and other affective disorders.

The company said that the trial of non-treated major depressive disorder patients would be designed to demonstrate that the heart rate technology could provide "the first objective diagnostic tool between the two hypothesized subsets of depression: melancholic and non-melancholic depression".

Bioprospect said that the Black Dog Institute founder and University of New South Wales professor of psychiatry Prof Gordon Parker would be the study's principal researcher.

The company said that a positive finding that the heart rate technology could provide the first objective diagnostic tool between the two subtypes of depression "would be one of the most significant findings in mental health research in the past decade".

Bioprospect said that validation that the technology was "sensitive to changes in symptomology, and can be used as a means to determine the effectiveness of the treatment for both melancholic and non-melancholic depression would represent a major breakthrough".

Prof Parker said that the Black Dog Institute had been focussed on melancholia, viewing it as a separate depressive condition and therefore we have pursued measures differentiating it from other depressive conditions, its causes, and its optimal treatments". "If the diagnostic tool under study has specificity in identifying those with and without melancholia we would anticipate distinct advances in pursuing causes and in directing preferential treatments to those with melancholia," Prof Parker said.

Bioprospect said that despite intensive research over many decades, there was "still no reliable quantitative, evidence-based test for depression, or to determine the effectiveness of prescribed treatment".

The company said that the two hypothesized subtypes of depression were melancholic and non-melancholic depression, with melancholic depression a biologically based condition that generally responded to treatment by anti-depression drugs.

Bioprospect said that non-melancholic depression was associated with acute or chronic stresses and/or particular personality styles, with about half the cases of non-melancholic depression not responding to anti-depressants and having a high rate of spontaneous remission.

The company said the study would be designed to demonstrate that the heart rate technology can provide the first objective diagnostic tool between melancholic and non-melancholic depression.

Bioprospect was untraded at 0.3 cents.

BIOTRON

Biotron says its fully underwritten two-for-nine rights issue at eight cents a share closed oversubscribed, raising about \$4.06 million before costs (BD: Oct 15, 2014).

Biotron said that each new share came with an attaching listed option exercisable at 12 cents by September 30, 2016 and quoted under the ASX code BITO.

The company said that the rights issue was underwritten and managed by Patersons Securities.

Biotron said in October that the funds would be used to complete the phase II trial of BIT225 for hepatitis C genotypes 1 and 3; for studies to complete applications to the US Food and Drug Administration; drug to drug interaction studies with direct-acting anti-virals to be used with BIT225; modelling pharmacokinetic data from previous trials to determine optimal dose and frequency; in-vitro studies of BIT225 antiviral activity; for commercialization fees and costs; and for working capital.

Biotron was unchanged at 10.5 cents.

PHYLOGICA

Phylogica says it expects to receive \$1.9 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Phylogica said that the rebate related to research and development expenditure for the year to June 30, 2014.

Phylogica was up 0.2 cents or 14.3 percent to 1.6 cents.

COCHLEAR

Veritas Asset Management says it has become substantial in Cochlear with the acquisition of 3,768,439 shares (6.60%).

Veritas said it was based in Central London and the registered holders of the shares were State Street UK, Bank of New York Mellon, JP Morgan, National Bank of Australia, Northern Trust UK, Kasbank Netherlands, Citibank Ireland, Deutsche Bank, HSBC Ireland and BNP Paribas UK.

Cochlear fell 98 cents or 1.3 percent to \$72.84 with 319,631 shares traded.

DORSAVI

Dorsavi says it has appointed Dave Wildermuth as global chief marketing officer, effective immediately.

Dorsavi said that the role would play "a pivotal role in driving the global adoption of the Dorsavi technology for the clinical, professional sport and occupational health and safety markets".

The company said that Mr Wildermuth had more than 29 years of experience in medical device marketing, digital marketing and television.

Dorsavi said that most recently, Mr Wildermuth had been a senior marketing director for Medtronic and previously worked in marketing at Yahoo and had been a television journalist.

Dorsavi was unchanged at 40 cents.

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