



# Biotech Daily

Thursday April 15, 2010

*Daily news on ASX-listed biotechnology companies*

- \* **ASX THROUGH 5000, BIOTECH DOWN: QRX UP 11%; BENITEC DOWN 7%**
- \* **CIRCADIAN: VGX-100 INHIBITS SEVERAL MOUSE-MODEL TUMORS**
- \* **FDA ACCEPTS ACRUX'S AXIRON APPLICATION**
- \* **GTG'S DR MERVYN JACOBSON TRIAL ADJOURNED**
- \* **PHOSPHAGENICS LOSES FOUNDER CHAIRMAN PROF ANDREW VIZARD**
- \* **WILSON HTM INCREASES 1.5% IN IMPEDIMED**
- \* **BOSTON'S RA CAPITAL TAKES 5% OF PSIVIDA**
- \* **NUSEP EGM MOTIONS PASSED OVERWHELMINGLY**
- \* **QUEENSLAND TRIALS NETWORK RUNS NATIONAL ETHICS TRAINING**

## MARKET REPORT

The Australian stock market was up 0.14 percent on Thursday April 15, 2010 with the S&P ASX 200 up 7.2 points to 5001.9 points.

Twelve of the Biotech Daily Top 40 stocks were up, 18 fell, six traded unchanged and four were untraded.

QRX was best, up 11 cents or 11.3 percent to \$1.08 with 936,478 shares traded, followed by Compumedics up one cent or 6.7 percent to 16 cents with 50,000 shares traded.

Circadian climbed 5.7 percent; Impedimed and Prima were up more than three percent; Psivida and Tissue Therapies rose more than two percent; with Acrux, Cochlear and Heartware up more than one percent.

Benitec led the falls, down 0.3 cents or 6.8 percent to 4.1 cents with 47,766 shares traded, followed by Phosphagenics down 6.7 percent to 14 cents with 3.2 million shares traded.

Antisense, Genetic Technologies and Novogen were down five percent or more; Optiscan and Viralytics fell more than four percent; Avexa, Bionomics, Cellestis, Cellmid, Living Cell, Nanosonics and Phylogica were down more than three percent; with Biota, Chemgenex and CSL down more than one percent.

## CIRCADIAN TECHNOLOGIES

Circadian says its lead anti-cancer agent VGX-100 has improved the efficacy of other drugs in mouse models of prostate and pancreatic cancer and glioblastoma.

Circadian said if clinically validated, VGX-100 had the potential to be a useful new treatment for some types of cancer.

The company said VGX-100 was a fully human monoclonal antibody targeting the vascular endothelial growth factor C (VEGF-C), inhibiting the development of blood vessels required for tumor growth.

Additionally, VGX-100 may inhibit cancer spread or metastasis by suppressing the development of lymphatic vessels.

Circadian said that in a mouse model of human prostate cancer, treatment of mice with a triple combination of VGX-100, Avastin and docetaxel inhibited tumor growth by 83.4 percent compared to 35.8 percent in mice treated with Avastin and docetaxel alone.

The company said that mice treated with the triple combination were four times as likely to survive until the end of the study as animals treated with docetaxel alone and survival time was increased 2.7 times over animals treated with docetaxel plus Avastin.

Circadian said 40 percent of mice treated with the triple combination were tumor-free at the conclusion of the study, meaning that tumors had been eradicated, compared to none that were tumor-free among the mice treated with docetaxel and Avastin; and 20 percent among animals treated with docetaxel alone.

The company said that in a glioblastoma model, VGX-100 added to Avastin achieved a statistically significant improvement in tumor growth inhibition compared to untreated animals.

The glioblastoma tumors in mice treated with VGX-100 plus Avastin were on average 42 percent smaller than untreated control animals.

Circadian said that in a pancreatic cancer model, treatment with VGX-100 inhibited tumor growth similar to that achieved in mice treated with Avastin.

Circadian said the data would be presented at the American Association for Cancer Research annual meeting on April 19, 2010.

Circadian's head of preclinical research and development Dr Megan Baldwin said the results were "the first substantial data to directly demonstrate that blocking the VEGF-C pathway by VGX-100 can inhibit tumor growth in mouse models of cancer".

"Moreover, our data indicate that VGX-100 can act either by itself or in combination with approved drugs to significantly slow the growth of several different tumor types including prostate, pancreatic, and glioblastoma," Dr Baldwin said.

Circadian's chief executive officer Robert Klupacs said the data presented "a strong case for clinical evaluation of VGX-100" and its potential as a cancer treatment option.

"These data suggest that there may be some cancer indications for which VGX-100 is superior to Avastin - one of the world's leading anti-cancer drugs - or may be effective where Avastin isn't," Mr Klupacs said.

"It also suggests that there may be cases where adding VGX-100 to Avastin may significantly improve existing therapies," Mr Klupacs said.

Circadian said it controlled exclusive worldwide rights to an extensive intellectual property portfolio enabling it to develop antibodies targeting VEGF-C.

The company said it intended to file an investigational new drug application with the US Food and Drug Administration in the first half of 2011 to begin human clinical trials of VGX-100.

Circadian said this was subject to completing the VGX-100 animal toxicology studies to evaluate whether VGX-100 was safe to be studied in humans.

Circadian was up four cents or 5.7 percent to 74 cents.

## ACRUX

The US Food and Drug Administration has accepted Acrux's new drug application for the Axiron testosterone therapy for hypogonadism in men for substantive review.

Acrux chief executive officer Dr Richard Treagus told Biotech Daily the application was filed in January 2010 and the FDA had 60 days to review the package to ensure it was complete prior to the substantive review and a further 14 days to respond.

In March 2010, Acrux and Eli Lilly announced an exclusive global licencing agreement, in which Eli Lilly acquired worldwide rights to commercialize Axiron.

Dr Treagus said that his company was making the application but Eli Lilly was providing support for the process.

Acrux said the upfront payment of \$US50 million (\$A53.5 million) had been received.

In the media release to the ASX Dr Treagus said the acceptance was "another important milestone for Axiron and Acrux".

Acrux was up four cents or 1.8 percent to \$2.29.

## GENETIC TECHNOLOGIES

The trial of Genetic Technologies co-founder and former chief executive officer Dr Mervyn Jacobson and his daughter Tamara Newing has been adjourned until May 24, 2010.

In a procedural hearing in the County Court today, the Australian Securities and Investments Commission case of 319 charges of market manipulation against Dr Jacobson and 353 charges against Ms Newing was adjourned for further directions with no change to bail conditions (BD: Feb 1, 4; Mar 18, 2010).

Genetic Technologies fell 0.2 cents or 5.4 percent to 3.5 cents.

## PHOSPHAGENICS

Phosphagenics founding chairman Prof Andrew Vizard will retire at the end of the company's annual general meeting on May 21, 2010.

Prof Vizard told Biotech Daily that he was with the predecessor company Vital which listed in 1999 and morphed into Phosphagenics.

He was appointed chairman in 2000.

Prof Vizard will also retire as a director of the company.

Phosphagenics said Jonathan Addison would be appointed chairman of the board from the conclusion of the annual general meeting.

The company said Mr Addison holds a Bachelor of Economics degree, has been a director since November 2002 and is chairman of the audit, compliance and corporate governance committee.

Phosphagenics fell one cent or 6.7 percent to 14 cents with 3.2 million shares traded.

## IMPEDIMED

Wilson HTM Investment Group has increased its substantial shareholding in Impedimed from 7,713,797 shares (7.09%) to 9,406,075 shares (8.65%).

In the substantial shareholder notice Wilson HTM said it sold 37,500 shares for \$32,940 or an average price of 87.8 cents between March 10 and 12, 2010 and bought 460,000 shares for \$299,000 or an average price of 65 cents in the placement that closed last week (BD: Apr 9, 2010).

Impedimed was up 2.5 cents or 3.8 percent to 69 cents.

### PSIVIDA

RA Capital Management of Boston Massachusetts has become a substantial shareholder in Psivida with a holding of 947,930 shares or 5.1 percent.

The substantial shareholder notice said the shares were held by RA Capital Management and RA Capital Healthcare Fund.

Psivida was up 14 cents or 2.7 percent to \$5.25.

### NUSEP

Nusep says all 13 resolutions to its extraordinary general meeting were passed by overwhelming majorities.

The closest vote saw 99,217 proxy votes against and 10,466,803 proxy votes in favor.

The resolutions included ratification of a previous share issue, approval of a capital raising, the issue of shares for an underwriting agreement, the provision of shares and options to directors and minor name change to Nusep Holdings.

Nusep was up three cents or 14.3 percent to 24 cents.

### QUEENSLAND CLINICAL TRIALS NETWORK

The Queensland Clinical Trials Network is running an Australian health and medical research ethics roadshow

The Queensland Government funder industry association said the roadshow would be delivered by current and previous members of the National Health and Medical Research Council's Australian health ethics committee, including the past chair Prof Colin Thomson and would provide "essential training for researchers, sponsors and ethics committee members, with the content relevant for all states and territories".

Queensland Clinical Trials Network training and human research ethics committee manager Melissa Hagan said the roadshow content was "essential given the current overhaul and harmonization of clinical trial review".

Ms Hagan said the first workshop held in Perth in March was "both well-attended and well-received".

"We've developed the course so the content is relevant to anyone working in health and medical research, whether they're a study coordinator, ethics committee member, clinical research associate or a researcher," Ms Hagan said.

"We cover human research ethics and regulatory requirements, preparing good submissions, preparing good patient information, safety reporting, contracts, indemnity and insurance and legislative issues," Ms Hagan said.

Other speakers at the two-day workshops are Sir Charles Gairdner Hospital's Dr Nikolajs Zeps and Peter MacCallum Cancer Centre ethics coordinator Jeremy Kenner.

The Queensland Clinical Trials Network said the workshops would be held in Melbourne on May 10-11, 2010; Sydney on May 12-13; Adelaide August 9-10; and Brisbane September 14-15.

For more information go to [www.qctn.com.au](http://www.qctn.com.au).