

# **Biotech Daily**

## Monday May 11, 2015

## Daily news on ASX-listed biotechnology companies

- \* ASX, BIOTECH DOWN: PRIMA UP 9.5%, ANTISENSE DOWN 12.5%
- \* APPLICATIONS OPEN FOR \$316k VICTORIA PRIZES
- \* ACUVAX EX-CEO DR WILLIAM ARDREY GUILTY ON 18 FRAUD CHARGES
- \* PRIMA, NEC, YAMAGUCHI IMP321 COLLABORATION FOR LIVER CANCER
- \* MEDIBIO BEGINS PIVOTAL 80-PATIENT HEART-RATE DEPRESSION TRIAL
- \* CYNATA PLEADS SCHULTZ, ROADSHOW TO ASX 22% QUERY
- \* REPRODUCTIVE IVF CONTRACTS, APPOINTS RAY RIDGE CFO, CO SEC
- \* SUN REQUESTS 'ACQUISITION, CAPITAL RAISING TRADING HALT'
- \* PHARMAUST CLAIMS 2<sup>nd</sup> BIOMARKER BACKING FOR PPL-1 FOR CANCER
- \* NARHEX HOPES TO RAISE UP TO \$4m FOR RESAPP
- \* ALLAN GRAY REDUCES TO 15% OF STARPHARMA

## \* IMPEDIMED APPOINTS CEO RICHARD CARREON M-D

#### MARKET REPORT

The Australian stock market slipped 0.17 percent on Monday May 11, 2015 with the S&P ASX 200 down 9.4 points to 5,625.2 points. Fourteen of the Biotech Daily Top 40 stocks were up, 18 fell, five traded unchanged and three were untraded.

Prima was the best, up 0.2 cents or 9.5 percent to 2.3 cents with 7.4 million shares traded. Viralytics climbed 9.2 percent; Oncosil was up five percent; Cellmid and Compumedics rose more than four percent; Nanosonics was up 3.2 percent; Atcor, Ellex and Medical Developments rose more than two percent; Avita, Benitec and Osprey were up more than one percent; with Impedimed, Mesoblast and Resmed up by less than one percent.

Antisense led the falls, down two cents or 12.5 percent to 14 cents with 317,712 shares traded. GI Dynamics lost 12 percent; Biotron, Sirtex and Starpharma fell four percent or more; Actinogen, Anteo, Bionomics, Living Cell, Neuren and Prana lost more than three percent; Optiscan and Pharmaxis shed more than two percent; Admedus, IDT, Tissue Therapies and Universal Biosensors were down more than one percent; with Acrux, Cochlear and CSL down by less than one percent.

## VICTORIA GOVERNMENT

The Victoria Government says applications are open for two \$50,000 Victoria Prizes for Science and Innovation and 12 Victoria Fellowships worth \$18,000 each.

The Victoria Government said that there was a Victoria Prize for physical sciences and a Prize for life sciences, with the Fellowships also divided equally between physical sciences and life sciences.

The State Governmetn said that the Prizes For Science and Innovation recognized "outstanding leaders in science and their research contributions to the Victorian community" while the Fellowships supported researchers in science, engineering and technology, who were in the early stages of their careers and would benefit from an international study mission.

Applications close on June 25, 2015.

For further information and to apply go to: www.veski.org.au/fellowships.

## <u>ACUVAX</u>

A Perth District Court jury has found former Acuvax chief executive officer Dr William Ardrey guilty on 18 of 19 counts of fraud.

The trial of Dr Ardrey before Justice Laurence Levy began at the Perth District Court on January 27, 2015.

An officer of the court told Biotech Daily that Dr Ardrey was acquitted on the first of the 19 charges, but the jury found him guilty on the remaining 18 charges and he was due to be sentenced on May 28, 2015.

Procedural hearings have delayed the trial which was originally set for November 18, 2013 (BD: Feb 28, Apr 20, Jul 20, Nov 30, 2012; Feb 25, Aug 7, Dec 5, 2013; Jan 28, 2015). Western Australia Police told Biotech Daily that the complainant in the matter was Phoenix Eagle a company described as a small biotechnology company involved in therapeutic cosmetics.

Dr Ardrey resigned from Acuvax in 2011 (BD: Feb 9, 2011).

Acuvax was untraded at 0.1 cents at a post-consolidation 25 cents.

## PRIMA BIOMED

Prima says it has a pre-clinical collaboration with NEC Corporation and Yamaguchi University for IMP321 in combination with a peptide vaccine for liver cancer.

Prima said that IMP321 was the lead technology acquired with the France-based Immutep last year and the peptide vaccine was developed by information technology company NEC and Yamaguchi University (BD: Oct 2, Dec 17, 2014).

Today, the company said that a pre-clinical study would be conducted at Yamaguchi University and supported by NEC to investigate the use of the antigen-presenting cell activator IMP321 as an adjuvant, together with peptide antigens believed to be involved in hepatocellular cancer.

Prima chief executive officer Marc Voigt said that the use of IMP321 as an adjuvant to a vaccine was "different to the other combination approaches being used for our planned clinical trials".

"The opportunity to broaden the application of IMP321 for other uses is exciting," Mr Voigt said.

Yamaguchi University president Dr Masaaki Oka said that "the use of IMP321 together with our vaccine ... could offer a unique treatment opportunity".

Prima was up 0.2 cents or 9.5 percent to 2.3 cents with 7.4 million shares traded.

#### MEDIBIO (FORMERLY BIOPROSPECT)

Medibio says it has "processed its first participant" in an 80-patient trial of its heart rate variability test to differentiate between melancholic and non-melancholic depression. Medibio said that it expected to assess all subjects in the pivotal study, conducted by the University of New South Wales and the Black Dog institute, by October and complete the study with results published this year.

The company said that the study's two primary endpoints were that the circadian heart rate variability technology differentiated between melancholic and non-melancholic depression and could determine the effectiveness of depression treatment with the 80 participants split between those with melancholic and non-melancholic depression Medibio said that the study would "involve serial monitoring of the participants before and after treatment to validate the technology's use as an objective measure to determine the effectiveness of the treatment".

The company said that a positive finding that heart rate variability could provide "the first objective diagnostic tool between the two sub-types of depression, would be a significant finding in global mental health research".

Medibio said that validation that the technology could be used to determine the effectiveness of treatment for both melancholic and non-melancholic depression would be "a major breakthrough for those with depression ... [and] make a significant impact on the treatment of depression, both economically, and in terms of producing better patient outcomes".

There is a great deal of professional discussion of the diagnoses for major depressive disorders and criticism of differences relating to melancholic and non-melancholic diagnoses in the two most recent editions of the Diagnostic and Statistical Manual of Mental Disorders (DSM) Fourth Edition and the 2013 Fifth Edition.

Medibio said that melancholic depression was "considered a biologically based condition that responds to biologically-based treatments including antidepressant medication". "In contrast, non-melancholic depression may be associated with acute or chronic stresses, and may be related to coping strategies and personality styles," Medibio said.

The company said that University of New South Wales psychiatry professor and Black Dog Institute founder Prof Gordon Parker was the principal researcher for the study.

Medibio said that participants would be assessed by two independent Black Dog Institute clinicians with electrocardiogram (ECG) data collected over a 24 hour period to measure the circadian heart rate variability at baseline and the diagnosis would be compared to the two clinician diagnoses and other clinical and self-report assessment measures.

The company said that after four to six weeks the same participants, who might receive a new treatment plan, would be asked to return for a second measurement point designed to measure the client's current symptomology.

Medibio said that the participants would be reassessed using the same measurements as at the first time point, including interview by a Black Dog Institute clinician, self-report measures and a recording of their ECG data over a 24-hour period.

The company said that the results of the second battery of measures would be compared to the first to validate the use of circadian heart rate variability as an objective diagnostic tool and to determine the effectiveness of treatment.

Medibio said that the study had been appropriately powered to show a statistically significant conclusion and required 30 to 40 participants in each group.

The company said that unlike traditional drug trials ,the study was expected to be of a relatively short duration with each participant only needing to be assessed once initially and then once four to six weeks later.

Medibio fell 2.5 cents or 7.35 percent to 31.5 cents.

## CYNATA THERAPEUTICS

Cynata has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price climbed from 92 cents on May 6, to \$1.12, a 21.7 percent increase, on May 8, 2015, and noted "a significant increase in the volume of trading".

Cynata told the ASX that it had previously announced its intention "to invigorate its investor relations activities through a strategic [investor relations and public relations] campaign assisted in part with the engagement of a US investor relations firm". The company said it had presented to a broad range of investors in Australia, the US and

Asia during the past 10 weeks and combined with its goal of securing commercial partners for its technology and recent corporate activity in the wider stem cell and regenerative medicine space it had "attracted considerable investor interest".

Cynata fell three cents or 2.7 percent to \$1.07.

## REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says it will provide its Embryocellect genetic screening to an unnamed Australian in-vitro fertilization (IVF) provider on a fee-for-service basis. Reproductive Health said it was "close to finalizing" a pre-implantation genetic screening service agreement with Indonesian clinic Morula IVF.

The company said that Morula was working to bringing Embryocellect in-house and Reproductive would provide an interim service as Morula IVF established its own laboratory processes and equipment.

Reproductive Health said that the training and relationship with Morula IVF had provided feedback on the ease of use of Embryocellect by clinics new to molecular biology and microarrays and "cements Morula IVF as a lead adopter" as the first clinic to offer preimplantation genetic screening in Indonesia.

The company said it was in discussion with other Australian private IVF providers that had expressed interest in a similar arrangement for the provision of pre-implantation genetic screening for their patients later in 2015.

Reproductive Health said it had appointed Ray Ridge as a part--time in-house chief financial officer and company secretary, effective from May 4, 2015.

The company said that Mr Ridge had held senior management positions in finance, compliance and commerce across a range of industries and was currently the chief financial officer and company secretary for Thor Mining Plc as well as chief financial officer for Southern Gold.

Reproductive Health said that previously Mr Ridge held executive positions with Parsons Brinckerhoff, Elders and Arthur Andersen.

Reproductive Health was up two cents or 14.3 percent to 16 cents.

## SUN BIOMEDICAL

Sun Biomedical has requested a trading halt "pending an announcement regarding an acquisition and a capital raising".

Sun has been attempting to commercialize workplace saliva-based drug tests and said it was collaborating with the Telethon Kids Institute in Subiaco Western Australia on a genetic diagnostic for asthma.

Trading will resume on May 13, 2015 or on an earlier announcement. Sun last traded at 1.1 cents.

#### PHARMAUST

Pharmaust says that analysis of the cancer marker, phosphorylated 4E binding protein 1 (p-4E-BP1), in patients in its trial of PPL-1 for cancer has shown a meaningful reduction. Pharmaust said that four of five patients treated with PPL-1 in the trial at the Royal Adelaide Hospital had a reduction in the cancer biomarker in the white blood cells.

The company said that malignancy was often characterized by changes to cancer markers and they were used to help detect, diagnose and manage various types of cancer. Pharmaust said that a decrease in the level of a tumor marker might indicate that the cancer was responding to treatment, whereas no change or an increase might indicate that the cancer was not responding.

The company said that published research had shown that p-4E-BP1 expression in breast, ovarian, and prostate tumors was associated with malignant progression and an adverse prognosis for the patient and the marker had been claimed to be a highly relevant molecular marker of malignant potential.

Pharmaust said that p70S6K and p-4E-BP1 were frequently up-regulated in cancer and had been assumed to be driving forces in tumor genesis, with p-4E-BP1 expression correlated with later tumor staging and was a prognostic factor of survival time after surgery.

PPL-1 inventor and surgeon Prof David Morris said the observation "provides further confirmation of the biological activity of PPL-1 in man by inhibiting a key cancer growth marker p-4E-BP1".

"This finding supports our studies on p70S6K in cancer cells and in animal models," Prof Morris said.

Pharmaust was up 0.1 cents or 8.3 percent to 1.3 cents with 6.8 million shares traded.

#### NARHEX LIFE SCIENCES

Narhex says it will raise up to \$4,000,000 through the issue of 200,000,000 shares at two cents each to acquire Resapp from the University of Queensland's Uniquest. Previously, Narhex said that Resapp had an exclusive licence from the University of Queensland to develop mobile telephone medical applications for the diagnosis and management of respiratory diseases (BD: Oct 2, 2014).

Today, the company said that the minimum to be raised would be \$2,500,000. Narhex said that it would be renamed Resapp, there was an offer of 18,749,999 postconsolidation shares to the facilitators and 93,750,000 post consolidation shares and performance shares to the vendors and Uniquest, the consolidation would be three-foreight shares and the offer was expected to open on May 16 and close on June 12, 2015. Narhex fell 0.1 cents or 11.1 percent to 0.8 cents.

#### **STARPHARMA**

Allan Gray Australia has reduced its holding in Starpharma from 49,848,435 shares (15.91%) to 47,381,272 shares (14.85%).

Allan Gray said it had bought and sold shares in a number of transactions between October 21, 2014 and May 6, 2015, with the single largest sale relating to "a ceasing of association" of 3,058,687 shares for \$1,545,593 or an average of 50.5 cents a share. Last year, Allan Gray bought 8,529,403 shares between May 30 and September 22, 2014 for \$5,392,383 or an average price of 63.2 cents a share with the majority acquired in a placement at 65 cents a share (BD: Sep 22, Oct 1, 2014).

Starpharma fell three cents or 4.1 percent to 70 cents.

#### **IMPEDIMED**

Impedimed says that chief executive officer Richard Carreon has been appointed as managing director, effective from May 9, 2015. Impedimed was up half a cent or 0.6 percent to 85 cents.