

Biotech Daily

Tuesday August 11, 2015

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: AVITA UP 10%, ANALYTICA DOWN 12.5%
- * COCHLEAR POSTS \$926m RECORD REVENUE, PROFIT UP 33% to \$146m
- * ANALYTICA RAISES FURTHER \$65k
- * HEARTWARE COMPLETES ENDURANCE 2 DESTINATION ENROLMENT
- * ACTINOGEN XANAMEM PHASE I TRIGGERS 5m MARTIN ROGERS SHARES
- * CB CO, CURRAN SUPER FUND REDUCES, DILUTED TO 8.6% OF ATCOR
- * ROD GIBSON, ROSHERVILLE TAKE 6% OF REPRODUCTIVE HEALTH
- * CLINICAL GENOMICS: HOWARD CHANDLER 'EMERITUS SCIENTIST'
- * UNIVERSAL BIOSENSORS LOSES DIRECTOR CHRIS SMITH TO COCHLEAR
- * PORK CRC TO ASSIST ANATARA DETACH PIG DIARRHOEA TRIALS

MARKET REPORT

The Australian stock market fell 0.65 percent on Tuesday August 11, 2015 with the ASX200 down 36.0 points to 5,473.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 17 fell, nine traded unchanged and three were untraded.

Avita was the best, up 0.7 cents or 10.3 percent to 7.5 cents with 29,682 shares traded.

Actinogen climbed 4.8 percent; Genetic Technologies was up 3.85 percent; Antisense and Medical Developments rose more than two percent; Clinuvel, Compumedics, Ellex, Polynovo, Resmed and Tissue Therapies were up more than one percent; with Nanosonics up 0.9 percent.

Analytica led the falls, down 0.1 cents or 12.5 percent to 0.7 cents with 9.8 million shares traded, followed by Benitec down 11.5 percent to 77 cents with 292,701 shares traded.

Cochlear and Universal Biosensors lost seven percent or more; Reva was down 6.1 percent; Prima fell 4.2 percent; both Biotron and Neuren were down three percent; Atcor, Cellmid, Pharmaxis, Starpharma and Viralytics shed more than two percent; Clinuvel and Psivida were down more than one percent; with Acrux, Admedus, CSL, Impedimed, Mesoblast and Sirtex down by more than one percent.

COCHLEAR

Cochlear says total revenue for the 12 months to June 30, 2015 was up 15.0 percent to \$925,630,000 with a net profit after tax up 33.2 percent to \$145,840,000.

In his last full year results teleconference before retiring from the company, Cochlear chief executive officer Dr Chris Roberts said that a share price fall could be attributed to higher profit expectations for the year to June 30, 2015 as well as the guidance for the coming financial year.

Dr Roberts said that "one of the highest NPAT numbers in the consensus has a sell on us".

"How intellectually honest is that?" Dr Roberts asked.

Dr Roberts said that Cochlear did not normally give guidance numbers but following the publication of ASX Guidance Note 8, the company thought that the 2014-'15 "analysts were rather high and we thought we'd take control of that".

Dr Roberts said the guidance for the net profit after tax for the coming year to June 30, 2016 was expected to be in the order of \$165 million to \$175 million, depending on foreign exchange rates.

Dr Roberts said that tens of thousands of the new wireless system had been sold allowing direct input from computers, telephones and televisions to the hearing controller.

Dr Roberts said that sales were up in all regions with total sales up three percent to 26,838 units.

Asked to reflect on his contribution to the company, Dr Roberts said that "eight times the number of people [had Cochlear] implants" between his arrival at the company and today. Cochlear's accounts said that record sales of \$941.9 million had been impacted by \$16.3 million in foreign exchange losses, providing the record revenue of \$925.6 million.

Cochlear said that the investment in research and development was up 0.3 percent to \$127,985,000 or 13.8 percent of total revenue, down slightly from 15.85 percent of

revenue in the year to June 30, 2014 and 16.0 percent for the year to June 30, 2013. The company said the final 100 percent franked dividend was down 21.3 percent to \$1.00 to be paid on October 1, 2015, based on a record date of September 10, 2015, taking the full year dividend to \$1.90 compared to the previous year's \$2.54.

Cochlear said net tangible assets per share at June 30, 2015 was up 33.4 percent to \$2.222 and diluted earnings per share climbed 55.2 percent to \$2.548, compared to the previous year's \$1.642.

The company said it held \$72,208,000 in cash and cash equivalents at June 30, 2015, compared to \$56,127,000 at June 30, 2014.

Cochlear fell as much as \$13.31 or 14.8 percent to \$76.73 before closing down \$6.48 or 7.2 percent at \$83.56 with 1.2 million shares traded.

ANALYTICA

Analytica says it has raised a further \$64,937 through the placement of 8,117,144 shares at 0.8 cents a share.

Last week, Analytica said its rights issue raised \$1,817,317 with the shortfall expected to raise \$982,683, taking the total raised to \$2,800,000, of the hoped-for \$3.76 million (BD: Aug 6, 2015).

Analytica said last week that the partly-underwritten, one-for-two, renounceable rights issue at 0.8 cents a share had 227,164,628 shares taken up and was undersubscribed by 242,445,222 shares and 122,835,372 shortfall shares would be taken up by underwriter Patersons Securities investors (BD: Jul 8, 2015).

Analytica fell 0.1 cents or 12.5 percent to 0.7 cents with 9.8 million shares traded.

HEARTWARE INTERNATIONAL

Heartware says that enrolment of 465 patients in its Endurance2 destination therapy clinical trial has been completed.

Heartware said that the Endurance2 was supplemental to the original Endurance trial which enrolled 446 patients between August 2010 and May 2012 and was the largest destination therapy clinical trial of a ventricular assist device conducted to date. The company said that the trial was designed to evaluate patients implanted with the

Heartware ventricular assist system for long-term use as destination therapy. Heartware said that data from the Endurance program was expected to form the basis for a pre-market approval application to the US Food and Drug Administration seeking

approval for destination therapy.

The company said it expected to file the application in 2016.

Heartware chief executive officer Doug Godshall said that "this second phase of our destination therapy trial reflects Heartware's commitment to research and to the betterment of patient outcomes".

The company said that Endurance2 was a prospective, randomized, controlled, unblinded, multi-center evaluation of the stroke incidence in patients implanted with a Heartware ventricular assist device (HVAD) pump who receive optimal blood pressure management. The company said that the primary endpoint was the incidence of neurologic injury at 12 months on the originally implanted device and the endpoint would be tested for non-inferiority compared to the control device.

Heartware said that in April 2015 the Endurance destination therapy trial met its primary endpoint, with results presented at the International Society for Heart and Lung Transplantation meeting in Nice, France (BD: Apr 17, 2015).

Last night on the Nasdaq, Heartware was up 58 US cents or 0.67 percent to \$US87.56 (\$A119.67, equivalent to \$3.42 per CDI prior to the company's departure from the ASX) with 240,424 shares traded.

ACTINOGEN MEDICAL

Actinogen says it has completed its phase I trials of Xanamem for Alzheimer's disease, on-time and on-budget.

Actinogen said that 40 healthy volunteers participated in the study, with 36 as placebocontrolled double-blinded study participants, which demonstrated the metabolism, safety and tolerability of Xanamem across the dose range of 10mg to 35mg twice daily.

The company said that the final stage of the Australian trial was designed to examine the central nervous system pharmacokinetics of Xanamem in four healthy volunteers.

The company said the trial was conducted at the Perth, Western Australia-based Linear Clinical Research at the Queen Elizabeth II Medical Centre and the samples would be analyzed at the University of Edinburgh.

Actinogen said that dosing in the final pre-clinical toxicology study was nearing completion with results expected before the end of the year.

The company said that the results would be incorporated into the documentation supporting a phase II study and enable an investigational new drug application to the US Food and Drug Administration.

Actinogen said the trial would be run in the US, Australia and the UK and was expected to begin by July 2016.

Separately, the company said that completing the phase I program triggered the vesting of 5,000,000 employee shares to chairman Martin Rogers.

Actinogen was up 0.3 cents or 4.8 percent to 6.5 cents with 4.3 million shares traded.

ATCOR MEDICAL

CB Co Pty Ltd for the Curran Superannuation Fund says it has reduced its holding and been diluted in Atcor from 17,800,000 shares (11.31%) to 17,170,000 shares (8.64%). The Sydney-based CB Co previously said that it acted for the Curran Superannuation Fund, which was associated with Capital Investment director Charles Paul Curran. BC Co said that between May 4 and 12, 2105 it sold 630,000 shares for \$137,400 or an average price of 21.8 cents a share.

Atcor fell half a cent or 2.2 percent to 22.5 cents.

REPRODUCTIVE HEALTH SCIENCE

Rod Gibson and Rosherville Pty Ltd say they have increased their substantial holding in Reproductive Health from 2,600,000 shares (5.48%) to 3,700,000 shares to (6.27%). The Redesdale, Victoria-based Mr Gibson said Rosherville bought 100,000 shares for \$20,000 or 20 cents a share on July 30, 2015 and told Biotech Daily that he acquired a further 1,000,000 shares through Endeavour River Pty Ltd in the placement at 17 cents a share (BD: Jul 23, 2015).

Reproductive Health was untraded at 18 cents.

CLINICAL GENOMICS

Clinical Genomics says it has appointed Howard Chandler as its 'emeritus scientist' to develop technology and products.

Clinical Genomics said that Mr Chandler was a founder of Enterix in 1997 which was taken over by Clinical Genomics in October 2013 and was "a pioneer in the field of clinical diagnostics and the inventor and developer of the patient-friendly brush form of faecal immunochemical test for bowel cancer screening".

Clinical Genomics said that Mr Chandler's technology "revolutionalized" bowel cancer screening and was used to test millions of people in the US and Australia.

Clinical Genomics chief executive officer Dr Lawrence LaPointe said that Mr Chandler's "talent to invent incredibly simple solutions to save lives and to make medical decisions easier has benefited millions of people around the world".

"More recently his work in colorectal cancer screening and monitoring kicked off the wave of modern tests we now see used in screening programs," Dr LaPointe said.

Clinical Genomics said that Mr Chandler has more than 36 issued patents and was the author of numerous scientific publications.

The company said that in the 1970s Mr Chandler invented the world's first rapid immunoassay test to diagnose the species of snake venom following a bite.

Clinical Genomics said that Mr Chandler held a Masters of Agricultural Science and Diploma of Education from the University of Melbourne.

Clinical Genomics is a private company.

UNIVERSAL BIOSENSORS

Universal Biosensors says that director Chris Smith has resigned effective from August 30 to take up his new role as Cochlear chief executive officer on September 1, 2015. Universal Biosensors chairman Andrew Denver said that Mr Smith had been a director since 2013 "and we have benefited from his commercial skills and experience as we have positioned the company for its next phase of growth".

Universal Biosensors fell three cents or seven percent to 40 cents.

ANATARA LIFESCIENCES

Anatara says the Pork Cooperative Research Centre will locate clinical trial and test sites, assist with the approval of Detach for pig diarrhoea and promote trial results.

Anatara did not state the commercial terms of the collaboration agreement with the Pork Cooperative Research Centre (CRC) but said the Centre would assist in the regulatory process with the Australian Pesticides and Veterinary Management Agency.

The company said that the Pork CRC had received about \$20million in Federal Government funding, along with \$18million from its participants and an additional \$90 million from in-kind contributions and had funding until 2019.

Pork Cooperative Research Centre

Anatara said that Detach was a pineapple stem-derived non-antibiotic treatment to treat and prevent diarrhoea in pigs and other livestock animals.

The company has said it would potentially trial Detach for humans.

Anatara fell two cents or 2.25 percent to 87 cents.