



Biotech Daily

Thursday July 23, 2015

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: ANALYTICA, UNIVERSAL BIO UP 12.5%
- POLYNOVO DOWN 8%**
- * **UNIVERSAL BIOSENSORS H1 REVENUE UP 160% TO \$7.5m, LOSS DOWN**
- * **JOURNAL PUBLISHES MESOBLAST DIABETES TRIAL RESULTS**
- * **REPRODUCTIVE HEALTH RAISES \$1.3m**
- * **OPTISCAN RAISES \$690k, TOTAL \$1.2m**
- * **IM MEDICAL RAISES \$287k, \$345k UNDERWRITTEN SHORTFALL TO GO**
- * **HUNTER HALL REDUCES 1% IN SIRTEX TO 8.4%**
- * **SIGMA-ALDRICH TO DISTRIBUTE ANTEO'S MIX&GO**
- * **PHARMAUST CLOSES 'SUCCESSFUL' PPL-1 FOR CANCER TRIAL**
- * **AVITA \$20m EGM FOR NEW DIRECTION IN US**
- * **NUSEP WANTS BUYERS FOR ITS 68% OF SINGAPORE PRIME**
- * **COGSTATE LAUNCHES PRECISION RECRUITMENT 2.1 FOR TRIALS**

MARKET REPORT

The Australian stock market fell 0.43 percent on Thursday July 23, 2015 with the ASX200 down 24.3 points to 5,590.3 points. Nineteen of the Biotech Daily Top 40 stocks were up, 15 fell, three traded unchanged and three were untraded.

Both Analytica and Universal Biosensors were up 12.5 percent to 0.9 cents and 36 cents respectively, with 674,450 shares and 217,309 shares traded, respectively. Impedimed climbed 9.2 percent; Genetic Technologies was up 6.7 percent; Acrux was up 5.9 percent; both Bionomics and Oncosil rose 4.55 percent; Anteo, Benitec, Ellex and GI Dynamics were up more than three percent; Cellmid and Pharmaxis rose more than two percent; with Compumedics, IDT, Medical Developments and Prima up more than one percent.

Polynovo led the falls, down one cent or 8.3 percent to 11 cents with 358,402 shares traded. Biotron lost seven percent; Living Cell and Uscom fell six percent or more; Prana was down 3.1 percent; Antisense, Atcor, Avita, Nanosoncis, Neuren Optiscan and Starpharma shed more than two percent; with Admedus down 1.2 percent.

UNIVERSAL BIOSENSORS

Universal Biosensors says revenue for the six months to June 30, 2015, was up 160.3 percent to \$7,460,806 reducing the net loss after tax by 41 percent to \$4,127,593.

Universal Biosensors said that research and development expenses increased eight percent to \$9.9 million.

The company said its cash balance was down 32 percent from \$15.9 million at June 30, 2014 to \$10.7 million at June 30, 2015, with a further \$8.22 million from the Research and Development Tax incentive received on July 9, 2015.

Universal Biosensors said that it was "trending towards breakeven".

The company said it would not draw down additional funds under the loan provided by investment funds managed by Athyrium Capital Management despite meeting the conditions required to draw down an additional \$US10 million (BD: Dec 20, 2013).

Universal Biosensors was up four cents or 12.5 percent to 36 cents.

MESOBLAST

Mesoblast says the journal 'Diabetes Care' has published the results of its 61-patient phase II trial of mesenchymal precursor cells (MPCs) for type 2 diabetes.

Mesoblast previously published the results of the trial, which began in 2012, saying that a single intravenous infusion of MPCs showed the cells were safe, tolerable, and improved glycaemic control as evidenced by reduction in haemoglobin A1c (HbA1c) in type 2 diabetes patients (BD: Jan 31, 2012; Dec 4, 2013).

Today, the company said that the results had been published online ahead of full print in Diabetes Care, the journal of the American Diabetes Association.

Mesoblast has been criticized by some analysts for not publishing clinical trial data in peer-reviewed journals.

Mesoblast said the article, entitled 'Allogeneic Mesenchymal Precursor Cells in Type 2 Diabetes: A Randomized, Placebo-Controlled, Dose Escalation Safety and Tolerability Pilot Study' was co-authored by trial investigator and New Orleans, Louisiana-based Tulane University medicine professor Prof Vivian Fonseca, and an abstract was available at: <http://care.diabetesjournals.org/content/early/2015/07/01/dc14-2830.abstract>.

Prof Fonseca said she was "very encouraged by the safety profile and suggestion of efficacy of Mesoblast's cell therapy in patients with type 2 diabetes".

Mesoblast said the phase II randomized, single-blind, placebo-controlled trial at 18 US sites evaluated the effects of a single intravenous infusion of 300,000 mesenchymal precursor cells/kilogram (MPCs/kg), 1.0 million MPCs/kg or 2.0 million MPCs/kg or placebo over 12 weeks in 61 patients with a mean diabetes duration of 10 years.

The company said that a single infusion at all doses was "safe and well tolerated, with no treatment-related adverse events, and no serious adverse events over the 12-week study period ... [with] no anti-human leukocyte antigen antibody immune responses against MPC donor antigens identified in any subject".

Mesoblast said the 2.0 million MPCs/kg showed the greatest overall HbA1c reduction, with a peak decrease of 0.4 percent at eight weeks compared with placebo ($p < 0.05$).

In 2013, Mesoblast said that the highest dose decrease fell to 0.3 percent at 12 weeks.

The company said that in "the less well-controlled subjects, as defined by a baseline HbA1c greater than 8.0 percent, a 0.6 percent decrease in HbA1c was seen at eight weeks in the high dose cohort compared with placebo" and the clinical target of glycaemic control, with an HbA1c level of less than 7.0 percent, was achieved by five of 15 subjects in the 2.0 million MPC/kg group compared to none of 15 in the placebo group ($p < 0.05$).

Mesoblast was up one cent or 0.25 percent to \$3.94.

REPRODUCTIVE HEALTH SCIENCE

Reproductive Health says it has raised \$1,308,150 through the placement of 7,695,000 shares at 17 cents a share.

Reproductive Health said that Taylor Collison placed the shares to sophisticated investors to fund the acceleration of commercialization of its Embryocollect pre-implantation genetic screening diagnostic.

The company said that the funds would be used to enhance marketing and distribution and to ensure scale up of production capabilities.

Reproductive Health was unchanged at 20 cents.

OPTISCAN

Optiscan says its fully-underwritten one-for-15 rights issue at five cents a share has raised \$690,074 (BD: June 15, 2015).

Optiscan said that the funds raised, together with the short term \$500,000 debt facility provided "important funding support".

In June, the company said the funding came "at a true transitional point ... as it nears the launch of its first imaging systems using Optiscan's latest second generation technology platform".

Optiscan fell 0.1 cents or 2.1 percent to 4.6 cents.

IM MEDICAL

IM Medical says its share plan raised \$205,000 as well as \$82,259 in a top-up placement and underwriter Patersons Securities would place the shortfall of \$345,000.

IM Medical said it had repaid outstanding converting loans in full and was debt free and funds raised would be used to supplement working capital.

In May, IM Medical said its attempt to acquire data centre service provider Syncom Australia Pty Ltd through a reverse takeover had failed (BD: Jan 18, May 22, 2015).

Previously, IM Medical had been attempting to commercialize cardiac testing.

IM was unchanged at 0.1 cents with 13.7 million shares traded.

SIRTEX MEDICAL

Hunter Hall Investment Management has reduced its substantial holding in Sirtex from 5,306,548 shares (9.39%) to 4,786,548 shares (8.38%).

In March, following the failure of the Sirflox trial to meet its primary endpoint, the Sirtex share price fell as much as 55 percent and Hunter Hall bought 1,251,375 shares for \$21,829,457 or \$17.44 a share, the first time Hunter Hall had bought Sirtex shares since May 2013 when it reached an internal maximum (BD: Mar 17, 19, 2015)

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 and has sold shares at prices ranging up to \$34 a share (BD: Mar 5, 2009).

Today, Hunter Hall said that it bought and sold Sirtex shares between Mar 23 and July 21, 2015 with the single largest sale 100,000 shares for \$3,049,514 or \$30.495 a share.

Sirtex fell five cents or 0.2 percent to \$31.60 with 185,149 shares traded.

ANTEO DIAGNOSTICS

Anteo says that the St Louis, Missouri-based Sigma-Aldrich Corp will incorporate its Mix&Go bio-molecular glue range into its product portfolio.

Sigma-Aldrich's website said it distributed 230,000 chemicals, bio-chemicals and essential products and 40,000 equipment products to more than 1.4 million customers in research and applied laboratories as well as industrial and commercial markets.

Anteo said that Sigma-Aldrich customer would have access to Mix&Go reagents, coupling and activation kits.

The company said that inclusion of its products into the Sigma-Aldrich portfolio followed an evaluation of Mix&Go for a variety of applications over the past year.

Anteo head of business development Dr Tina Baumgartner said that "acceptance of Mix&Go by such a respected party as Sigma-Aldrich provides great commercial validation of Anteo's technology".

"This is an encouraging first step in what is an important relationship, one which is envisaged to generate additional products for sale going forward," Dr Baumgartner said.

"We expect sales to build over time," Dr Baumgartner said.

"Being included in the Sigma-Aldrich range enables unprecedented access for Anteo into Sigma-Aldrich's key markets, and removes some of the barriers to entry that often occur with a direct sales approach," Dr Baumgartner said.

Anteo was up 0.3 cents or 3.4 percent to 9.1 cents with 2.0 million shares traded.

PHARMAUST

Pharmaust says it has closed its phase I/II trial of PPL-1 for cancer with the seventh and final patient showing "meaningful suppression of key cancer marker p70S6K".

Pharmaust said that the patient was administered the 25mg/kg higher dose of PPL-1 at the Royal Adelaide Hospital.

The company said that both principal end points were successfully met with PPL-1 demonstrating "a very good safety profile as compared with many other established anti-cancer drugs and ... PPL-1 showed activity against cancer through the suppression of a key cancer marker".

Pharmaust said that three patients completed the 28-day treatment period, with one patient not included in the cancer marker results as they only received one dose.

The company said that one patient received the 25mg/kg dose with the other patients treated with 5mg/kg doses.

Pharmaust said it expected pharmacokinetic and pharmacodynamic measurements in September 2015, which would include further data on other cancer-specific markers, in addition to p70S6K, and levels of PPL-1 and its metabolites in patients' circulation.

Pharmaust executive chairman Dr Roger Aston said the company had completed the first stage of studies with PPL-1 in humans and dogs and had shown "that in both cases PPL-1 is well tolerated and importantly is active against cancer".

"The suppression of tumour marker, p70S6K, in man was highly significant when the data from seven patients is combined and analyzed at day three of treatment ($p < 0.0004$) and at day seven ($p < 0.002$)," Dr Aston said.

Dr Aston said the next stage would be combination trial.

"For the next stage of human work Pharmaust will reformulate the drug into capsules, as the main challenge faced in both canine and human trials with liquid PPL-1 was the poor palatability of the formulation and nausea from the unpleasant taste," Dr Aston said.

Pharmaust fell 0.1 cents or 12.5 percent to 0.7 cents with 24.0 million shares traded.

AVITA MEDICAL

Avita shareholders will vote to raise \$20 million to list on either the Nasdaq or the New York Stock Exchange in 2016 and support a new US commercialization direction.

Avita said it would ask for approval to raise \$20 million at no less than 80 percent of the 5-day volume-weighted average price prior to the issue or prospectus date.

According to the ASX today, Avita has a market capitalization of \$41 million.

A letter from chief executive officer Adam Kelliher said the company's objective was "to ensure access to resources required to bolster the company's commercialization strategy and support growing links in the US at a governmental level".

Other resolutions include the ratification of the prior issue of 81,327,101 shares at 6.2 cents a share, which raised \$5,042,280 and the approval of an employee share plan.

The meeting will be held at Level 12, 15 William Street, Melbourne on August 24, 2015 at 11am (AEST).

Avita fell 0.2 cents or 2.1 percent to 9.4 cents.

NUSEP HOLDINGS

Nusep says that sales of its 67.8 percent interest in the Singapore-based Prime Biologics Pte will go to the open market.

In April, Nusep said that executive chairman Alison Coutts was temporarily stepping down from her position as Nusep's representative on the Prime Biologics board "to ensure no possibility of conflict of interest whilst Nusep explores a potential transaction relating to Nusep's shareholding in Prime" (BD: Apr 13, 2015).

Today, the company said that the "sale process that was announced on the April 13, 2015 did not close [and] the open market sale process will commence immediately".

Nusep said that Prime was commissioning a plasma fractionation facility to address the \$US1 billion Asian therapeutic plasma products market and was using technology developed by Nusep in association with GE Healthcare.

The company said the sale proceeds would be used to accelerate the development of Spermsep and that both human and animal artificial reproduction was a growing industry worth about \$3 billion in the US.

Nusep was untraded at 2.8 cents.

COGSTATE

Cogstate says it has released the latest version of its Precision Recruitment 2.1, remote cognitive assessment for pre-screening participants in clinical trials.

Cogstate said that the Precision Recruitment system supported clinical trials by "more effectively recruiting participants with specific levels of cognitive impairment using remote cognitive assessment technology".

The company said that the Precision Recruitment 2.1 would enable it to begin commercial deployment into clinical trials.

The company said the \$500,000 generated by the existing Precision Recruitment system in the 2014-'2015 financial year was from limited deployment of beta versions.

Cogstate said it had two existing contracts for Precision Recruitment and another pilot study to evaluate the technology would begin in August 2015.

Cogstate was unchanged at 22.5 cents.