# Biotech Daily

Tuesday August 26, 2014

*Daily news on ASX-listed biotechnology companies*

*** ASX EVEN, BIOTECH DOWN: OPTISCAN UP 6%, ONCOSIL DOWN 8%**

*** ST VINCENT'S ISOLATE DIABETES-CAUSING IMMUNE CELLS**

*** ACTINOGEN REQUESTS ACQUISITION, CAPITAL RAISING HALT**

*** MESOBLAST REVENUE DOWN 10% TO $26m, LOSS UP 31% TO $81m**

*** ANTEO REVENUE UP 43% TO $2.6m, LOSS UP 14% TO $2.5m**

*** PROGEN REVENUE UP 64% to $6m, LOSS DOWN 14% TO $2m**

*** US COURT RULES FOR GENETIC TECHNOLOGIES AGAINST GSK**

*** ANSTO SETTLES WITH CYCLOPHARM FOR $2.65m**

*** HARDING LOEVNER BELOW 5% IN COCHLEAR**

*** IM MEDICAL DROPS WHITE DATA FOR ADX**

*** REPRODUCTIVE HEALTH APPOINTS SUE MACLEMAN DIRECTOR**

*** MAYNE APPOINTS PROF BRUCE ROBINSON DIRECTOR**

## MARKET REPORT

The Australian stock market edged up 0.05 percent on Tuesday August 26, 2014 with the S&P ASX 200 up 2.7 points to 5,637.6 points. Five Biotech Daily Top 40 stocks were up, 16 fell, 15 traded unchanged and four were untraded.

Optiscan was the best, up 0.2 cents or 6.25 percent to 3.4 cents with 110,000 shares traded. Mesoblast climbed 5.85 percent; Bionomics was up 4.3 percent; Admedus was up 3.3 percent; CSL was up 1.1 percent; with Starpharma up 0.7 percent.

Oncosil led the falls, down one cent or 8.3 percent to 11 cents with 1.6 million shares traded.

Avita and Benitec fell four percent or more; Antisense and Biotron were down more than three percent; Neuren, Phosphagenics, Prana and Prima shed two percent or more; Clinuvel, GI Dynamics, Impedimed, Tissue Therapies and Viralytics were down more than one percent; with Acrux, Cochlear and Sirtex up by less than one percent.

## ST VINCENT'S INSTITUTE OF MEDICAL RESEARCH

Melbourne's St Vincent's Institute says that its researchers have observed the immune cells that destroy the insulin-producing cells of the pancreas, causing type 1 diabetes.
The Institute said that the researchers had isolating the cells from the pancreas of an organ donor who had the disease and they were able to show that the cells were recognizing a particular part of the insulin molecule itself.
The Institute said that type 1 diabetes occurred when the body's immune cells mistakenly destroyed the insulin-producing cells of the pancreas.
The St Vincent's Institute said that until now, it was not known exactly what components of the insulin-producing cells the immune cells targeted in humans.
The Institute said that Dr Stuart Mannering and his team studied a pancreas that had been donated by the family of a 19 year-old man who died due to complications of type 1 diabetes.
The Institute said the findings would have "an immediate impact on the design of clinical trials aimed at preventing the disease".
"We caught the immune cells at the scene-of-the-crime in the pancreas and then we were able to characterize them," Dr Mannering said.
"No one has been able to do this in humans before," Dr Mannering said.
The research article, published in the journal Diabetes today, was entitled 'Proinsulin specific, HLA-DQ8 and HLA-DQ8 transdimer restricted, CD4+ T cells infiltrate the islets in type 1 diabetes' and an abstract is available at:
http://diabetes.diabetesjournals.org/content/early/2014/08/15/db14-0858.abstract.
The Institute said that the existence of cells with exactly these properties had been predicted, but this was the first time they have been found.
"Manipulating the immune system provides a promising approach to finding a cure for type 1 diabetes which is the ultimate goal of our research program," Dr Mannering said.
The Institute said that by identifying the exact portion of insulin that the immune cells targetted in human diabetes, the study gave a new angle of attack for clinical trials looking to prevent type 1 diabetes.
St Vincent's Institute director Prof Tom Kay, a co-author on the study, said the work was a technical triumph.
"Researchers do not normally have access to a pancreas from someone with type 1 diabetes and studies have mainly relied on the blood, where such cells are much rarer than in the pancreas," Prof Kay said.
"This is just one of the many benefits of the remarkable process of organ donation and transplantation," Prof Kay said.
The Institute said that the research was supported by the Juvenile Diabetes Research Foundation, the National Health and Medical Research Council, Diabetes Australia Research Trust and the Victoria Government.
Juvenile Diabetes Research Foundation chief executive officer Mike Wilson said the "breakthrough represents another step towards preventing and potentially curing type 1 diabetes".

## ACTINOGEN

Actinogen has requested a trading halt "pending an announcement regarding a potential acquisition and capital raising".
Trading will resume on August 28, 2014 or on an earlier announcement.
Actinogen last traded at 3.9 cents.

MESOBLAST

Mesoblast says revenue for the 12 months to June 30, 2014 fell 9.7 percent to $26.0 million, with a net loss after tax up 31.3 percent to $81.0 million.

Mesoblast said that research and development expense increased 15.7 percent to $55.3 million with manufacturing costs up 19.0 percent to $27.6 million.

In a teleconference, Mesoblast chief executive Prof Silviu Itescu detailed the company's pipeline and development program.

Prof Itescu said that four lead programs were designated as "tier 1", six programs were designated as "tier 2" with other programs described as "pipeline".

Prof Itescu said that the most advanced program was the MSC-100-IV mesenchymal stem cell program acquired from Osiris for acute graft versus host disease following bone marrow transplant.

He said the evidence was "compelling" that paediatric 100-day survival was 76 percent in MSC-100-IV responders compared to 28 percent in non-responders ($p < 0.001$).

Prof Itescu said that partner JCR Pharmaceuticals planned to file for Japanese registration by the end of 2014 for a 2015 launch, with Mesoblast launching the graft versus host disease product in Canada and New Zealand in 2016.

Prof Itescu said that the company expected to conduct a US 60-patient open label phase III paediatric trial of MSC-100-IV with a phase III adult trial for registration in 2016 and a launch in the 2017.

Prof Itescu said that the 1,730 patient phase III congestive heart failure trial of mesenchymal precursor cells partnered with Israel's Teva Pharmaceuticals was expected to have a safety "early look" in 2015, with a second early look, statistically-powered for the primary endpoint of major adverse cardiac events, at a later date.

Prof Itescu said the congestive heart failure trial for patients with class II and class III heart failure was actively recruiting and treating patients, but was unable to provide specific details, saying he was bound to confidentiality by agreements with Teva.

Prof Itescu said that a separate National Institutes of Health 120-patient phase II trial of mesenchymal precursor cells for class IV heart failure was also underway, with results expected by the end of 2016.

Prof Itescu said that a phase II trial of mesenchymal precursor cells for chronic lower back pain had demonstrated both pain reduction and an increase in function and would proceed to a phase III trial by the end of 2014.

Prof Itescu said the back pain trials would probably include two studies of 300 to 400 patients each, with a 12-month follow-up. .

Mesoblast chief financial officer-elect Paul Hodgkinson told the teleconference that the tier I programs were fully-funded and the company would examine the results of the tier 2 programs before deciding whether and how to proceed.

Mr Hodgkinson said that the company was applying distinct manufacturing processes for each stem cell product at the Singapore manufacturing facility, and optimizing costs, as well as improving the intellectual property around the manufacturing processes.

The company said that net tangible asset backing per share fell 44.6 percent to 40.0 cents at June 30, 2014 compared to 72.19 cents in the previous period.

Mesoblast said that diluted loss per share was 20.3 percent to 25.34 cents compared with 21.06 cents in the previous corresponding period.

Mesoblast said it had cash and equivalents of $196.4 million at June 30, 2014 compared to $315.3 million at June 30, 2013, which was sufficient to complete its lead programs.

Mr Hodgkinson said that the cash burn of $78.2 million for the year to June 30, 2014, would be higher in the coming year.

Mesoblast was up 25 cents or 5.85 percent to $4.52 with 1.5 million shares traded.

## ANTEO DIAGNOSTICS

Anteo says that revenue for the year to June 30, 2014, was up 43 percent to $2,635,848 with net loss after tax up 14 percent to $2,492,150.
Anteo said that its net tangible asset backing per share was up 136.1 percent to 0.85 cents, with diluted loss per share constant at 0.3 cents.
Anteo said that it had cash and cash equivalents of $7,070,722 at June 30, 2014 compared to $2,621,072 at June 30, 2013.
Anteo was unchanged at 14.5 cents with 1.3 million shares traded.

## PROGEN PHARMACEUTICALS

Progen says revenue for the year to June 30, 2014, was up 63.9 percent to $5,753,570 reducing net loss after tax by 13.6 percent to $1,806,945.
Progen said that most of the revenue was derived from manufacturing by its subsidiary Pharmasynth, up 92.1 percent to $5,410,952, primarily due to contracts from Taiwan licencee Medigen and twp regular large customers.
Progen said that diluted loss per share fell 56.3 percent to 3.3 cents at June 30, 2014 and net tangible assets per share fell 17.6 percent from 17.6 cents to 14.5 cents.
Progen said it had $5,596,215 in cash at June 30, 2014, compared to $8,562,774 at June 30, 2013.
Progen fell two cents or 8.2 percent to 22.5 cents.

## GENETIC TECHNOLOGIES

Genetic Technologies says the US District Court for the Middle District of North Carolina has denied a motion by Glaxosmithkline to dismiss its patent infringement action.
Genetic Technologies said the action was initially brought against Glaxosmithkline and nine other companies, including Agilent Technologies, Bristol-Myers Squibb Co, Eurofins STA Laboratories, Hologic, Merial, Navigenics, Neogen Corp, Pfizer and 454 Life Sciences Corp (BD: May 26, 2011).
The company said that the action against Glaxosmithkline began in the District Court of Colorado, but was then moved at the request of GSK to the District Court for the Middle District of North Carolina.
Genetic Technologies said that both sides filed motions in support of their different legal perspectives and on June 27, 2014, Glaxosmithkline moved to have Genetic Technologies second amended complaint dismissed, arguing the relevant Genetic Technologies patent covered natural phenomena or laws of nature that were not entitled to patent protection.
The company said that on August 22, 2014, the Court issued an Order denying Glaxosmithkline motion to dismiss.
Genetic Technologies said the “significant success follows the separate success reported on March 12, 2014, when a similar motion to dismiss filed by Agilent in the Northern District of California was also denied”.
Genetic Technologies chief executive officer Alison Mew said that with the removal of “another potential reason delaying negotiations, we are keen to renew settlement discussions”.
Genetic Technologies was unchanged at 2.7 cents with 1.95 million shares traded.

## CYCLOPHARM

Cyclopharm says that the Australian Nuclear Science and Technology Orgnaisation subsidiary Petnet Australia will pay its subsidiary Cyclopet Pty Ltd $2.65 million.
Cyclopharm said that following mediations Cyclopet and Petnet agreed to settle legal proceedings.
The company said that without admission of liability ANSTO and Petnet would pay $2.65 million to Cyclopet.
Cyclopharm said that the remaining terms of the settlement were “commercial in confidence for all parties”.
In 2012, Cyclopharm claimed damages against the Australian Nuclear Science and Technology Organisation in the Federal Court of Australia, following a Productivity Commission finding in April that Petnet was “in ex-ante breach of their competitive neutrality requirements in the sale of their nuclear pharmaceuticals used in positron emission tomography” (BD: Apr 4, Jun 28, 2012).
Cyclopharm said at that time that Cyclopet was claiming damages for breach of Section 52 of the Commonwealth Trade Practices Act 1974, Section 18 of the Australian Consumer Law, Section 46 of the Trade Practices Act 1974 and Section 46 of the Competition and Consumer Act 2010 alleging misleading and deceptive conduct and misuse of market power.
Cyclopharm was up two cents or 10 percent to 22 cents.

## COCHLEAR

Harding Loevner LP has ceased its substantial shareholder in Cochlear reducing from 3,434,019 shares or 6.02 percent to 4.124 percent.
The substantial shareholder notice said the Bridgewater, New Jersey-based investment management firm bought and sold shares December 12, 2012 and August 22, 2014 with the largest and most recent sale, 535,182 shares for $39,985,531.44 or $69.44 per share.
In 2012, Harding Loevner increased its substantial shareholder in Cochlear to 3,434,019 shares or 6.02 percent when the company’s shares were trading between $63 and $77 a share (BD: Dec 12, 2012).
Cochlear fell 22 cents or 0.3 percent to $70.55 with 288,913 shares traded.

## IM MEDICAL

IM Medical says it has terminated its previous agreement with White Data and hopes to acquire ADX Management for $6.0 million of its shares at 0.2 cents a share.
IM Medical previously said it would acquire White Data for $9.1 million of its shares based on a notional issue price of two cents a share for the development and management of data centre and cloud computing services (BD: Dec 17, 20, 2013; Aug 22, 2014)
In March, IM Medical said it was finalizing the merger agreement with White Data to become a specialist data centre management company (BD: Mar 31, 2014).
Today, the company IM Medical said that ADX was a specialist management company, and manager of the Australian Data Exchange Trust and the acquisition was subject to certain conditions being satisfied.
The company said that ADX was focussed on becoming a leading provider of data centre, disaster recovery and technology products.
IM Medical was up 0.1 cents or 100 percent to 0.2 cents with 7.9 million shares traded.

## REPRODUCTIVE HEALTH SCIENCE

Reproductive Health has appointed Mesoblast's head of commercial Sue MacLeman as a non-executive director replacing Simon O'Loughlin.
Reproductive said that Ms MacLeman previously worked in development and commercialization roles with Agenix, Merck, Amgen and Bristol-Myers Squibb.
Prior to joining Mesoblast where she continues as an executive, Ms MacLeman was the chief executive officer of Eqitx, Benitec and Progen.
Ms MacLeman holds and Bachelor of Pharmacy from University of Queensland, a Masters of Marketing from the University of Melbourne and Masters of Law for Deakin University.
Reproductive Health said it was developing the University of Adelaide-based Embryocellect test kit to determine an embryo's number of chromosomes.
Reproductive Health was unchanged at 20 cents.

## MAYNE PHARMA GROUP

Mayne Pharma says it has appointed Prof Bruce Robinson as a director, effective immediately.
Mayne said that Prof Robinson was the dean of the University of Sydney Medical School which he has held since 2007, and an endocrinologist practicing at the Royal North Shore Hospital.
The company said that Prof Robinson was previously the head of the Cancer Genetics Unit at the Kolling Institute of Medical Research at the Royal North Shore Hospital since 1989.
Mayne said that since 2001, Prof Robinson has been the chairman of the Hoc Mai Foundation, a program to improve health outcomes through education and exchange in Vietnam.
Mayne was up 3.5 cents or 4.3 percent to 85.5 cents with 2.0 million shares traded.