# Biotech Daily

Monday May 9, 2016

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH EVEN: OPTHEA UP 5.5%, ANTISENSE DOWN 5%**

*** AVITA: 'RENOVACELL, NEEDLING RESTORE SCAR PIGMENT'; ROADSHOW**

*** CYNATA: '$40m APCETH CYMERUS LICENCE OPTION'**

*** ANTISENSE DOSES 3 OF 4 ACROMEGALY PATIENTS, EXTENDS TRIAL**

*** OSPREY DATA ANALYSIS: 'AVERT REDUCES DYE, KIDNEY INJURY'**

*** UNILIFE DISCOVERS PREVIOUS CHAIRMAN, CEO 'VIOLATIONS'**

*** GI DYNAMICS ENDOBARRIER WITH LIRAGLUTIDE BEST FOR HBA1C**

*** CANOPY TAKES 15% OF AUSCANN EN ROUTE TO TW BACKDOOR**

*** PRANA RECEIVES $6.5m FEDERAL R&D TAX INCENTIVE**

*** LBT APPOINTS BRENT BARNES CEO REPLACING LUSIA GUTHRIE**

## MARKET REPORT

The Australian stock market was up 0.54 percent on Monday May 9, 2016 with the ASX200 up 28.7 points to 5,320.7 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, eight traded unchanged and one was untraded. All three Big Caps were up.

Opthea was the best, up 2.5 cents or 5.5 percent to 48 cents with 40,153 shares traded, followed by Impedimed up 5.1 percent to 93.5 cents with 339,885 shares traded.

Anteo climbed 4.1 percent; Actinogen, Clinuvel, Ellex, Mesoblast, Oncosil, Osprey and Prana were up more than three percent; Acrux, Bionomics and Pharmaxis were up more than one percent; with Cochlear, CSL, Nanosonics, Resmed and Reva up by less than one percent.

Antisense led the falls, down 0.2 cents or 4.8 percent to four cents with 100,100 shares traded.

Benitec and Orthocell fell more than four percent; Atcor, Avita, Biotron, Polynovo and Starpharma were down more than three percent; Admedus, Factor (Tissue Therapies), Prima and Sirtex shed more than two percent; Compumedics, Medical Developments and Viralytics were down more than one percent; with Pro Medicus down 0.2 percent.

AVITA MEDICAL

Avita says the combination of medical needling with its Renovacell epithelial cell suspension can restore pigment on burn scars.

Avita said that a randomized, clinical trial at the Cologne, Germany-based Malteser Hospital compared no treatment to medical needing with Renovacell and medical needling without Renovacell (BD: April 21, 2016).

The company has previously told Biotech Daily that Recell provided up to 1,920 square centimetre ($cm^2$) of coverage, Renovocell covered 640$cm^2$ and Regenercell covered 320$cm^2$.

Today, Avita said that the results of the trial had been published in the journal Burns and the article, entitled 'Combination of Medical Needling and non-cultured autologous skin cell transplantation (Renovacell) for repigmentation of hypopigmented burn scars' described the study of 20 patients with scars from deep second and third-degree burns.

An abstract is at: http://www.burnsjournal.com/article/S0305-4179(16)30072-9/abstract.

Avita said that scars were on prominent areas such as the face, neck, chest and arms, with an average treatment surface area of 94$cm^2$.

Co-author of the study Dr Matthias Aust said that "the combination of medical needling and Renovacell is a very promising approach to re-pigmenting large hypo-pigmented burn scars".

"These positive results suggest that medical needling is delivering the melanocytes of the cell suspension through the needling channels straight onto the basal membrane," Dr Aust said.

Avita fell half a cent or 3.7 percent to 13 cents.

AVITA MEDICAL

Avita's chief executive officer Adam Kelliher and chief operating officer Tim Rooney say the company has been "rejuvenated" and is ready for commercialization.

Mr Kelliher said that he and Mr Rooney were in Melbourne and would visit Sydney to meet with investors and the media to describe the changes to the company over the past 12 months.

Mr Kelliher said that company had "a lot of unrealized assets" and that the Biomedical Advanced Research and Development Authority (BARDA) funding of up to $US53.9 million was significant validation.

He said that the 30-patient BARDA Recell burns trial should complete the 52-week follow-up by April 2017 and file for approval for October 2017.

Mr Kelliher said that BARDA also ensured that the company was prepared for commercialization and production of kits to supply the potential demand.

"A key part is the education of surgeons and in a way it is sort-of marketing, taking Recell to burns surgeos," Mr Rooney said.

Mr Rooney said that it took about one hour to teach surgeons how to use Recell.

Mr Kelliher said that while distributors were being engaged in Europe to add to those already appointed for the UK, France and Germany, in the US the company was considering a direct sales force to reach the 300 burns surgeons.

Mr Kelliher said that the company was hoping to start a pivotal trial for venous leg ulcers by the end of 2016 and begin a feasibility study for diabetic foot ulcers at the same time.

He said the company had committed "a whole body of work getting the product right, the marketing right, sales and the regulatory process".

Mr Kelliher said that Avita had $6.2 million in cash at March 31 which was sufficient to last until the end of 2016.

## CYNATA THERAPEUTICS

Cynata says it has a licence option agreement with Apceth GmbH to use its Cymerus stem cell technology with genetic modification for new indications including cancer.
Cynata said that the agreement with the Munich, Germany-based Apceth included an undisclosed up-front cash payment, along with milestones, “which could potentially total more than $40 million” and royalties on product sales.
The company said that the relationship intended to address “substantial unmet medical needs … [with] the potential for substantial revenues”.
Cynata said that Apceth was evaluating its technology in its in-house cell culture and genetic modification systems as part of an initial collaboration, expected to conclude by the end of 2016.
The company said that further development by Apceth would be under a development plan to be incorporated into the definitive licence agreement.
Apceth chief executive officer Dr Christine Günther said that Cymerus was “a very innovative therapeutic mesenchymal stem cell] technology” for development and commercialization in combination with genetic modification techniques.
“With access now to Cymerus, a truly scalable manufacturing technology for therapeutic [mesenchymal stem cells], we are very excited about future off-the-shelf therapeutic products,” Dr Günther said.
Cynata was up two cents or 5.2 percent to 40.5 cents with one million shares traded.

## ANTISENSE THERAPEUTICS

Antisense says it has completed dosing of three of the four adult acromegaly patients in its open-label study of ATL1103 at up to 300mg twice weekly for 13 weeks.
Antisense said the study was investigating the safety, tolerability and pharmacokinetics of ATL1103, as well as its efficacy through the effect on reducing serum insulin like growth factor I (sIGF-I).
The company said that the three dosed patients received all 26 doses of ATL1103, two patients had completed their eight-week follow-up and there were no reports of any serious adverse events related to dosing with ATL1103.
The company said that Royal Adelaide Hospital principal investigator  Dr David Torpy had requested that the third patient continue dosing with ATL1103 as the patient responded well to treatment, where previous treatment with surgery, radiotherapy and available first line pharmaceutical therapies had not lead to disease control.
Antisense said that a protocol amendment had been approved for on-going dosing of this patient for an additional 12 weeks.
The company said that as well as the potential benefit to the patient, the additional treatment period would provide valuable data on the longer dosing with ATL1103.
Antisense said it expected to submit an amendment to the study protocol for approval to conduct an interim analysis on all three patients who had completed the initial 13 weeks of dosing, which would assess the change from each of the patient’s baseline sIGF-I levels to their levels post dosing.
The company said that whether a fourth patient was enrolled would depend on the outcome of the interim analysis.
Antisense said that it did not expect any additional material expense for undertaking the extended dosing of the third patient and the conduct of the interim efficacy analysis beyond what it was to receive in previously agreed financial reimbursement for the conduct of the study.
Antisense fell 0.2 cents or 4.8 percent to four cents.

OSPREY MEDICAL

Osprey says that a further analysis of its Avert trial shows a significant reduction of contrast-induced acute kidney injury in patients with pre-existing stage 3 disease.

Last year, Osprey's share price tumbled on news that its 578-patient trial of the Avert dye-reduction system failed to reduce contrast-induced nephropathy (CIN), with 76 CIN events in the Avert arm and 74 in the control arm (BD: Oct 19, 2015).

The company said at that time that the trial achieved three US Food and Drug Administration expanded claims of dye savings, image quality and reflux reduction, which were granted this year (BD: Jul 16, 2015; Feb 8, 2016).

In December 2015, Osprey said that further data analysis showed that its using 'standard criteria', its Avert system showed a non-significant trend for contrast-induced nephropathy reduction and its physician steering committee reviewed the data set to investigate the contrast-induced nephropathy co-primary endpoint and noted that the FDA-directed criteria for CIN measurement of serum creatinine increase of more than 0.3mg/dl captured subtle changes in kidney function and based on the FDA criteria, it was not able to show a reduction of CIN events (BD: Dec 18, 2015).

Osprey said the FDA criteria was a more recent methodology that captured subtle changes in kidney function and the standard criteria for CIN of a serum creatinine increase of more than 0.5mg/dl or more than 25 percent was "the classic measurement which captures significant changes in kidney function".

Today, Osprey said that data presented at the Society for Cardiovascular Angiography and Interventions meeting in Orlando, Florida on May 4, 2016 "highlighted the significance of post-trial analysis" directed by the Physician Steering Committee.

The company said that the post-trial analysis, presented by Avert principal investigator, Dr Roxana Mehran, showed a significant reduction of contrast-induced acute kidney injury (CI-AKI) in patients with pre-existing stage 3 kidney disease (eGFR 40-60).

Osprey said that using the "standard criteria" for detection of CI-AKI, a per-protocol analysis of 470 patients showed that all patients had a mean reduction in CI-AKI of 20.5 percent, but the 264 patients with pre-existing stage 3 kidney disease had a mean reduction of 49.5 percent.

Dr Mehran said it was "an important finding, as numerous other medical devices and/or drug therapies have not been successful in demonstrating a significant reduction in CI-AKI through a randomized controlled trial".

Osprey said that stage 3 kidney disease referred to patients who had lost half or more of normal kidney function and the patient group was its primary market focus.

Osprey chief executive officer Mike McCormick said that the reduction in CI-AKI in a sub-population was "encouraging and feedback from key opinion leading physicians at the conference suggests these findings are important when considering care options for patients with compromised kidneys".

The company said that the trial results had led to the Avert system and its second generation Dyevert System receiving US Food and Drug Administration clearance for dye savings, image quality and reflux reduction claims.

Osprey said that increased dye savings in more complex procedures post-trial analysis also showed that Avert facilitated dye reduction in Percutaneous Coronary Intervention or stenting procedures, showing that as procedure complexity increased so did the amount of dye savings.

The company said that the analysis also showed that dye reduction did not affect image quality and physicians reported adequate image quality in more than 99.3 percent of procedures.

Osprey was up one cent or 3.8 percent to 27.5 cents.

## UNILIFE

Unilife says it has discovered “violations of company policies and procedures and possible violations of law” by the former chief executive officer and chairman.

Unilife said it was delaying a quarterly conference call scheduled for today, Monday, May 9, 2016 at 10pm (AEST) but did not specify the person or persons involved saying that the “former chief executive officer and … the former chairman … resigned in 2015”.

In March, Unilife said that executive chairman and chief executive officer Alan Shortall would receive $US1,486,802 ($A1,980,584) in termination pay (BD: Mar 15, 2016).

Today, the company said it was “investigating these matters and their potential impact on financial reporting and internal controls over financial reporting, related to previously-issued financial statements, current interim financial information and management’s certifications”.

“The investigation has just commenced due to the recent discovery by current management but has not to date discovered any financial loss to the company,” Unilife said.

Unilife said it expected to delay filing its quarterly report for the three months to March 31, 2016 to the US Securities and Exchange Commission and would hold its special meeting of shareholders as scheduled on May 9 at 4pm (USEDT), May 10 2016 at 6am (AEST).

Unilife closed down 3.8 cents or 30.4 percent to 8.7 cents with 11.2 million shares traded.

## GI DYNAMICS

GI Dynamics says the combination of its Endobarrier with the GLP-1 receptor agonist liraglutide was more effective in reducing blood sugar levels than either alone.

GI Dynamics said that liraglutide was a non-insulin medicine prescribed to lower blood sugar levels.

The company said that the 12-month safety and efficacy data from its two-year, multi-center, randomized and controlled trial were presented at the Endocrine Society’s meeting in Boston, Massachusetts by Scotland’s Greater Glasgow and Clyde National Health Service’s Dr Russell Drummond.

GI Dynamics said that the combination led to greater weight loss than for either the Endobarrier alone or liraglutide alone groups.

The company said that the blood sugar levels measured by HbA1C were reduced in the combination group from an average of 9.6 percent to 7.5 percent, with 54.2 percent of patients below 7.5 percent HbA1C compared to the liraglutide alone group reducing from an average 9.7 percent HbA1C by 1.3 percent to 8.4 percent, with 31.8 percent of patients below 7.5 percent HbA1c.

GI Dynamics said that the combination group had the greatest weight loss, reducing 11.3 percent from an average weight of 112.8kg, followed by Endobarrier alone witht a 10.8 percetn reduction and the liraglutide group reducing by 3.5 percent.

The company said that Endobarrier was safe and the combination with liraglutide was well tolerated and that all serious device-related adverse events in the Endobarrier-treated patients resolved after device removal and there was one liver abscess which did not require device removal.

The company said that the abscess was resolved with antibiotics and the patient completed the study.

Last year, a higher than expected rate of liver abscesses forced GI Dynamics to close its planned 500-patient US trial, when the fifth patient of 325 enrolled patients developed the bacterial liver infection (BD: Jul 30, 31, 2015).

GI Dynamics was unchanged at 1.8 cents with three million shares traded.

## AUSCANN GROUP, TW HOLDINGS

Auscann says it will backdoor list into TW Holdings and acquire medical cannabis intellectual property and know-how from Canada's Canopy Growth Corp.
In a media release in March 2016, TW said that it would raise at least $2.5 million or another agreed minimum and conduct a one-for-20 consolidation for the transaction.
Auscann managing-director Elaine Darby told Biotech Daily that Auscann had $3.2 million in cash for its medical cannabis program.
In a media release, TW said Auscann had an agreement with the Smiths Falls, Ontario-based Canopy, which it said was "the world's premier medicinal cannabis company".
Auscann adviser Dr Stewart Washer told Biotech Daily that Auscann would acquire the Canopy intellectual property, methods of production and commercialization pathway relating to medicinal cannabis, in return for 15 percent of Auscann.
Dr Washer's father and former Liberal Party Member of the House of Representative Dr Mal Washer is the non-executive chairman of Auscann.
TW said that Canopy would be granted a three year option to acquire a further five percent stake in Auscann and Canopy founder and executive chairman Bruce Linton would be appointed as a director.
"We have confidence that the Australian medical cannabis market will grow similarly to Canada and we think the lessons we learned in our early days will prove invaluable to the team at Auscann," Mr Linton said.
TW was up 0.15 cents or 15.8 percent to 1.1 cents with 30.8 million shares traded.

## PRANA BIOTECHNOLOGY

Prana says it has received $6,477,301 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Prana said the rebate related to research and development activities for the year to June 30, 2015 and the funds would be spent on further development of PBT2 for Huntington's disease and PBT434 for the treatment of various atypical Parkinsonian movement disorders.
Prana was up 0.3 cents or 3.95 percent to 7.9 cents.

## LBT INNOVATIONS

LBT says it has appointed Cochlear executive Brent Barnes as its chief executive officer to replace co-founder Lusia Guthrie, effective from August 8, 2016.
LBT said that Mr Barnes had been an executive with Cochlear for the past 11 years in a range of roles including operations director and as a US area sales manager.
LBT said that Mr Barnes held a Master's Degree in Project Management from the University of Adelaide and a Diploma of Commerce from the Sydney Institute of Business Technology.
The company said that Mr Barnes would start on $300,000 a year plus benefits including a potential bonus of 30 percent and 1,500,000 share options, subject to shareholder approval.
LBT was up two cents or 11.8 percent to 19 cents.