Biotech Daily

Monday February 8, 2016

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: POLYNOVO UP 6%, OPTISCAN DOWN 13%**

*** CANCURE WANTS $7m FOR THREE ANTI-CANCER PLATFORM PROGRAMS**

*** FDA APPROVES 3 OF 5 OSPREY DYEVERT CLAIMS, SALES UP**

*** DORSAVI H1 REVENUE UP 63% to $1.3m, LOSS DOWN 22% TO $3m**

*** MEDICAL AUSTRALIA RIGHTS TO DUALCAP IV DISINFECTION SYSTEM**

*** ANATARA CEO DR PAUL SCHOBER APPOINTED M-D**

*** NOVOGEN APPOINTS JOHN O'CONNOR CHAIR, BRYCE CARMINE DEPUTY**

*** BIO-MELBOURNE WOMEN IN LEADERSHIP AWARDS OPEN**

MARKET REPORT

The Australian stock market slipped 0.02 percent on Monday February 8, 2016 with the ASX200 down 0.8 points to 4,975.4 points.

Seven Biotech Daily Top 40 stocks were up, 22 fell, nine traded unchanged and two were untraded.

Polynovo was the best, up 1.5 cents or 6.1 percent to 26 cents with 275,568 shares traded.

Orthocell climbed 4.35 percent; Admedus, Avita and Oncosil rose more than two percent; Anteo and Osprey were up more than one percent; with Resmed up 0.6 percent.

Optiscan led the falls, down 0.3 cents or 13.0 percent to two cents with 1.3 million shares traded, followed by Ellex down 11.3 percent to 74.5 cents with 107,473 shares traded and Antisense down 10 percent to 5.4 cents with 219,111 shares traded.

Opthea (Circadian) lost eight percent; Compumedics and IDT fell more than five percent; Acrux, Benitec, Bionomics, Biotron and Pharmaxis were down three percent or more; Atcor, Mesoblast, Prima and Pro Medicus shed two percent or more; Medical Developments, Nanosonics, Prana, Starpharma, Universal Biosensors and Viralytics lost more than one percent; with Cochlear, CSL and Sirtex down by less than one percent.

CANCURE

The Gold Coast, Queensland-based Cancure hopes to raise $6.75 million to take three anti-cancer platform technologies to the start of clinical trials.

Cancure director and chief operating officer Craig Miles and chief executive officer Dr Ian Nisbet told Biotech Daily that all three technologies, a cancer vaccine, immunotherapy and targeted therapies were invented by Griffith University researcher Prof Steve Ralph.

Dr Nisbet said that the lead program was the intra-dermal injection of the CNC118 cancer vaccine for melanoma, taking three patient-derived cell lines and converting the tumor cells to antigen-presenting cells to stimulate an immune response.

Dr Nisbet said that the cell lines had previously been in a 10-patient phase I trial at Brisbane's Princess Alexandria Hospital and the vaccine showed a good safety profile, apart from injection site reactions, with no serious adverse events.

He said that nine of the 10 stage IV melanoma patients, who had failed all prior treatments, completed the course of six doses, with four of the nine showing evidence of response.

Dr Nisbet said that the technology was likely to be useful in tumor types where an immune response could have an effect such as non-small cell lung cancer and prostate cancer.

He said the company was currently focussed on the manufacture of the cell-based vaccine, which he expected would take 18 to 24 months to complete pre-clinical work and be ready for a phase I/II trial in combination with a checkpoint inhibitor drug.

Dr Nisbet said that the immunotherapy technology was a galectin-inhibitor program

Dr Nisbet said that galectins were molecules that suppressed immune responses produced by tumor cells and the data showed that if galectin-1 could be inhibited it would allow T-cells to infiltrate the tumor and induce apoptosis, or programmed cell death.

Dr Nisbet said that pre-clinical work for the galectin-inhibitor was expected to take about 18 months and would have applicability with 'any solid tumor".

Dr Nisbet said that the third program was on 'mitocans', defined by Prof Ralph and his research team in an article entitled 'Classification of mitocans, anti-cancer drugs acting on mitochondria' and published by Mitochondrion in 2013 as "a class of anti-cancer drugs acting by way of mitochondrial destabilisation".

An abstract is available at: http://www.ncbi.nlm.nih.gov/pubmed/22846431.

Dr Nisbet said that the program was currently in a collaboration with the US National Cancer Institute for oesophageal cancer which was at the in-vitro stage and if the work was positive the Institute would continue to trial the technology in mice and undertake toxicology studies.

He said that cancer cells had high rates of reproduction and the respiratory pathway converted energy in the tumor cells, preferentially through complex 2 in mitochondria.

"Complex 2 is present in normal healthy cells but is not being used," Dr Nisbet said. "But in cancer cells it generates energy."

"The electron disruption creates reactive oxygen species that knock out key functions in the tumor cells, leading to cell death," Dr Nisbet said.

Mr Miles said that the company hoped to raise $6.75 million at 60 cents share which, with the Federal Government's Research and Development Tax Incentive program would equate to $10 million in funds for the three programs.

Mr Miles said that the funds would represent 17 percent of the company, equating to a pre-valuation of $28.8 million.

Mr Miles said the company had already raised about $12 million since inception and would require a further $15 million to complete all three programs phase I programs.

For more information go to: http://cancure.com/investors/public-documents.

Cancure is a public unlisted company.

OSPREY MEDICAL

Osprey says the US Food and Drug Administration has cleared expanded marketing claims of dye savings, image quality and reflux reduction for the Dyevert system.

Last year, Osprey fell as much as 71.6 percent to 19 cents on news that its 578-patient trial of the Avert system failed to reduce contrast-induced nephropathy (CIN) but the trial achieved three of the five expanded claims of dye savings, image quality and reflux reduction, but not contrast-induced nephropathy reduction and hospital cost savings (BD: Jul 16, Oct 19, 2015).

In December, Osprey said that further data analysis shows that its using 'standard criteria' its Avert system showed a non-significant trend for contrast-induced nephropathy reduction (BD" Dec 18, 2015).

In 2012, Osprey raised $20 million and listed on the ASX to commercialize the Baker IDI Heart and Diabetes Institute-invented Cincor cardiac contrast dye reduction and removal system (BD: Mar 1, May 2, 2012).

Today, the company said that the FDA had cleared the marketing claims of dye savings, image quality and reflux reduction.

Osprey said that the clinical results showed that Dyevert produced a greater than 45 percent average dye savings without compromised image quality.

The company said that Dyevert sales were faster than expected adoption rates and the new claims allowed it to commercialize the Dyevert and Avert systems as the only products to have received FDA claims for contrast savings without compromise in image quality through a randomized controlled multi-centre trial.

Osprey said that the expanded claims enabled physicians to comply with cardiology and radiology society guidelines to use dye sparing approaches in patients at-risk of contrast induced acute kidney injury.

The company said that the Dyevert system was a second generation product with improvements of increased dye savings and ease of use over the first generation Avert system.

Osprey said that clinical use of the Dyevert system in more than 100 patients from three different hospitals showed an average of more than 45 percent dye savings without compromised image quality, compared with typical dye savings of 30 to 35 percent for the Avert system.

The company said that commercialization of the Dyevert system began in November 2015, following the initial FDA clearance for the system.

Osprey said that in the first three months of commercial release, 24 hospitals evaluated the system with 11 placing initial orders and 13 working through the approval process to purchase the Dyevert system, significantly faster than previous experience with Avert and reflecting Dyevert's ease of use.

Osprey chief executive officer Mike McCormick said that "the FDA clearance of claims on our Dyevert system provides our sales reps with stronger marketing collateral when selling our products".

"Osprey is dedicated to supporting the efficacy of our products with tier 1 clinical evidence and as a result, we are now the only company with FDA clearance for products that reduce dye without compromising image quality," Mr McCormick said.

"These are unique and powerful claims that will allow our reps to present the Dyevert system as a product that can assist physicians in complying with Cardiology Society Guidelines that stress the need for dye reduction in patients with compromised kidneys," Mr McCormick said. "We are encouraged by our early commercial success and continue to scale up our sales force to drive adoption of the Dyevert system in 2016."

Osprey was up half a cent or 1.6 percent to 32.5 cents.

DORSAVI

Dorsavi says that revenue for the six months to December 31, 2015, was up 62.7 percent to $1,341,938 reducing net loss after tax 21.8 percent to $3,109,328.
Dorsavi said that sales revenue for its wearable body movement sensor systems increased by 110 percent which was offset partially by a reduction in interest income.
The company said that diluted loss per share fell 32.7 percent from 3.27 cents in the previous year to 2.20 for the six months to December 31, 2015.
Dorsavi said that net tangible asset backing per share fell 33.3 percent from nine cents at December 31, 2014 to six cents at December 31, 2015.
The company said it had cash and cash equivalents of $8,919,143 at December 31, 2015, compared to $5,743,513 at June 30, 2015, mainly due to a $7,179,800 capital raising.
Dorsavi was unchanged at 36 cents.

MEDICAL AUSTRALIA

Medical Australia says it has exclusive distribution rights from Catheter Connections for its Dualcap disinfection system in Australia and New Zealand
The Salt Lake City, Utah-based Catheter Connections said that the disinfection cap system was designed for use on needle-free valves and the end of the intravenous tubing, or male luer connector, and contained 70 percent isopropyl alcohol to disinfect and protect intravenous connectors between uses.
Medical Australia did not disclose the value or terms of the distribution deal.
Medical Australia said that the Dualcap system had been clinically proven to significantly reduce instances of intravenous-associated infections and was the first disinfection system of its type approved by the US Food and Drug Administration.
The company said that the Dualcap system was approved by the Australian Therapeutic Goods Administration and was a market-leading product widely used in hospitals across the US.
Medical Australia said it would focus on marketing and promoting Dualcap to the public and private hospital sectors in Australia where it had numerous contracts and supply agreements in place, before rolling the product out into the New Zealand market.
The company said it was encouraged by the agreement, which reflected its focus on infection control, in particular hospital acquired infections.
Medical Australia chief executive officer Darryl Ellis said that infection control and hospital acquired infections were “increasingly critical for all in the healthcare sector”.
“Now that we have finalised the divestment of our interest in the Medivet business, our sole focus is on the continued growth and development of the human healthcare business,” Mr Ellis said.
“We are currently assessing a number of strategic alliances that may further strengthen our product range,” Mr Ellis said.
Medical Australia was untraded at six cents.

ANATARA LIFESCIENCES

Anatara says that chief executive officer Dr Paul Schober has been appointed as the company’s managing-director effective from today.
Anatara is developing the pineapple-stem bromelain-based Detach non-antibiotic as a treatment for pig diarrhoea, with potential use in humans.
Anatara climbed 13 cents or 8.7 percent to $1.63.

NOVOGEN

Novogen says it has appointed John O'Connor as chairman and Bryce Carmine as deputy chairman, effective immediately.

Novogen said that the two appointments replaced interim chairman Ian Phillips and interim chief executive officer Iain Ross.

The company said that recently-appointed chief executive officer Dr James Garner had been appointed as an executive director, with Mr Phillips and Mr Ross resuming their roles as non-executive directors.

The interim appointments of Mr Phillips and Mr Ross followed last year's unexpected resignation as executive chairman and later as chief executive officer of Novogen founder Dr Graham Kelly (BD: Jul 1, 22, 2015).

Today, Novogen said that Mr O'Connor had been deputy chairman since 2014 and was a long-term shareholder in Novogen, with more than 30 years' experience in the financial industry, as a fund manager and stockbroker.

Novogen was up one cent or 9.5 percent to 11.5 cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says that nominations for the 2016 'Women in Leadership' awards have opened.

The Network said that the awards launched last year and "celebrate, honor and profile outstanding women in the biotechnology, medical technology and health innovation sector".

The Bio-Melbourne Network said that applications would close on March 31 and the awards would be presented at the 'Connecting Women Lunch' on May 20, 2016.

The Network said that CSL continued as the premier sponsor, with Johnson & Johnson Innovation and the State Government of Victoria continuing as major sponsors, along with Trajan Scientific and Medical as a new major sponsor.

The industry organization said that continuing supporting sponsors were Phillips Ormonde Fitzpatrick, Brooker Consulting and Starpharma.

Bookings for the Connecting Women Lunch open on March 15 and for details go to: www.biomelbourne.org/moxiefiles/files/Women_in_Leadership_Awards_Kit_2016.pdf