

# Biotech Daily

Thursday December 4, 2014

Daily news on ASX-listed biotechnology companies

- \* ASX UP, BIOTECH DOWN: GENETIC TECHNO UP 13%, AVITA DOWN 16%
- \* META, MELBOURNE UNI, GSK, CSL, HOSPIRA SAVINGS COLLABORATION
- \* LIVING CELL PLAN RAISES \$1m, TOTAL RAISED \$4m
- \* REVA BEGINS FANTOM TRIAL
- \* VIRALYTICS CAVATAK, IPILIMUMAB CLEAR FOR MELANOMA TRIAL
- \* NOVOGEN RECEIVES \$1.5m FEDERAL R&D TAX REFUND
- \* OCEANIA, HOSKEN TAKE 5% OF ATCOR
- \* WEHI'S PROF ALAN COWMAN WINS THAI MALARIA MEDAL

## MARKET REPORT

The Australian stock market climbed 0.88 percent on Thursday December 4, 2014 with the S&P ASX 200 up 47.0 points to 5,368.8 points.

Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and three were untraded. All three Big Caps were up.

Genetic Technologies was the best, up 0.2 cents or 13.3 percent to 1.7 cents with 2.1 million shares traded, followed by Universal Biosensors up 10.3 percent to 16 cents with 156,777 shares traded.

IDT climbed 8.8 percent; Patrys was up 6.25 percent; Benitec and Bionomics were up more than four percent; Antisense, Biotron, Nanosonics and Tissue Therapies were up more than three percent; Cochlear, CSL and Resmed rose more than one percent; with Impedimed and Psivida up by less than one percent.

Avita led the falls, down 1.4 cents or 15.6 percent to 7.6 cents with 555,000 shares traded.

GI Dynamics lost 6.7 percent; Clinuvel and Oncosil were down more than five percent; Admedus and Atcor fell four percent or more; Acrux, Cellmid, Mesoblast and Phosphagenics were down three percent or more; Circadian, Prana and Prima shed more than two percent; with Alchemia, Living Cell, Sirtex and Viralytics down more than one percent.

# MANUFACTURING EXCELLENCE TASKFORCE AUSTRALIA, GLAXOSMITHKLINE, CSL, HOSPIRA

Manufacturing Excellence Taskforce Australia (META) says it has brought competitor companies together to review processes collaboratively to increase productivity. In a media release, the Federal Government-funded META said that CSL, Glaxosmithkline and Hospira were collaborating in a project initiated by the Melbourne-based Strategic Industry Research Foundation and coordinated by the University of Melbourne.

META said that the University of Melbourne's Department of Management and Marketing Prof Prakash Singh was providing a team of post-doctoral experts to work with each company to apply world-class optimization methods to the factory.

"University of Melbourne have had a strong academic focus on applied research and we are committed to seeing our academics work directly with industry to build strong and world-class standards to increase the productivity of Australian manufacturing sites," Prof Singh said.

META said that collaborative project was expected to generate a targeted three percent productivity boost with an estimated return on investment of up to \$2.4 million dollars. META managing director Zoran Angelkovski said it was his organization's first productivity focused manufacturing project "identified by the pharmaceutical industry to ensure benefits from the supply-chain optimization expertise can be leveraged to deliver major productivity improvements across a number of Australian pharmaceutical sites".

"The methodology will be shared amongst multiple pharmaceutical companies to create an exponential benefit for the industry," Mr Angelkovski said.

META said that Hospira's Mulgrave site in Victoria was the first location to engage in the project, which would ultimately achieve increases in cost competitiveness and optimization of their site manufacturing processes.

Hospira executive Andrew Hodder said that the project would "implement a full review of our manufacturing process, building up valuable knowledge and performance results relating to material flow, equipment and effective people resource utilization".

Glaxosmithkline project manager Philip Leslie said the review was "a real opportunity for a group of pharmaceutical companies who would ordinarily be competitors to come together and share techniques for increasing efficiency, productivity and ultimately savings".

"This collaborative approach to continuous improvement is the way forward for Australian manufacturers who want to be globally competitive." Mr Leslie said.

"We can all learn something from the way each of us operates and avoid trying to reinvent the wheel," Mr Leslie said.

"This way we can increase our efficiency and make us more efficient, which in turn will see us being able to compete on the world market," Mr Leslie said.

META said that the project began at Hospira in October and was expected to be completed by the end of this year.

#### LIVING CELL TECHNOLOGIES

Living Cell says its share purchase plan at 6.08 cents a share has raised by the issue of 17,564,993 fully paid ordinary shares, raising about \$1.08 million.

Living Cell said that with its \$3 million placement in October the total raised was projected to provide funding for the company's development program into 2016 (BD: Oct 8, 2014). Living Cell chief executive officer Dr Ken Taylor said the capital raise was "an excellent result and demonstrates shareholder confidence in our development path of cell therapy for neurodegenerative diseases".

Living Cell fell 0.1 cent or 1.4 percent to 7.1 cents.

#### **REVA MEDICAL**

Reva says it has implanted its first patients with its Fantom bioresorbable drug-eluting scaffold.

Reva said that the first implants were performed at Sao Paulo, Brazil's Institute Dante Pazzanese of Cardiology, by invasive cardiology director Dr Alexandre Abizaid, who was co-principal investigator for the Fantom clinical trial program.

Reva's head of clinical and regulatory affairs Jeff Anderson said that "the unique features of the Fantom scaffold were evident" in the first procedures.

"The scaffold was easily delivered and the procedure was aided by the visibility of the scaffold under x-ray, a feature that we believe provides physicians with a valuable tool for confirming proper placement during implant," Mr Anderson said.

Reva chief executive officer Bob Stockman said that the beginning of the trial was "an important and valuable milestone for the company".

In March, Reva closed its Rezolve program for the Fantom stent, reducing personnel and costs, saying the Fantom stent was less complex to manufacture and the scaffolds were half the thickness and stronger than Rezolve stents (BD: Mar 27, 2014).

Reva was up seven cents or 17.1 percent to 48 cents.

# **VIRALYTICS**

Viralytics says the Portland, Oregon-based Providence Cancer Centre has approved a 26 patient phase Ib trial of Cavatak in combination with ipilimumab for late-stage melanoma. Viralytics said that the company-sponsored, open-label study was designed to evaluate the safety and tolerability of Cavatak (Coxsackievirus A21) with ipilimumab, marketed as Yervoy, in late-stage melanoma patients for whom Yervoy was the standard of care. The company said it expected to begin the trial by April 2015.

Viralytics said that investigators would assess evidence of anti-cancer activity, including response rates and bio-markers of anti-tumor immunity.

The company said that the lead investigator was Providence Cancer Center biotherapy program director Dr Brendan Curti, who was also an investigator in the ongoing phase II Calm trial assessing Cavatak as a monotherapy in late-stage melanoma patients.

Viralytics said that combining Cavatak and the mouse homologue of ipilimumab produced superior efficacy outcomes in a mouse model, compared to either agent alone.

The company said that ipilimumab was an immune checkpoint inhibitor and launched by Bristol-Myers Squibb in 2011 for the treatment of late-stage melanoma, Yervoy had sales of almost \$US1 billion in the first nine months of 2014.

"While the checkpoint inhibitors represent a major advance in the treatment of melanoma, there remains considerable potential to both improve response rates and enhance the durability of response in patients," Dr Curti said.

Viralytics managing director Dr Malcolm McColl said the results of the preclinical studies "provide encouragement that the combination of Yervoy with Cavatak may provide significant clinical benefits to patients".

"Checkpoint inhibitors are forecast to form the future backbone of cancer treatment, however there remains a need and considerable commercial opportunity to enhance their performance through the development of combination therapies," Dr McColl said. Viralytics said that the phase Ib study was the first step and a prerequisite to a

randomized phase II combination study.

The company said that intra-tumoral Cavatak would be combined with intravenous

ipilimumab.

Viralytics fell half a cent or 1.6 percent to 30.5 cents.

#### **NOVOGEN**

Novogen says it has received \$1.54 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Novogen said the rebate related to research and development expenditure for the year to June 30, 2014

The company said the funds would be used for working capital and to bring Cantrixil to its first-in-woman study in late stage ovarian cancer.

Novogen was unchanged at 8.6 cents.

#### ATCOR MEDICAL

Oceania Capital Partners and related bodies corporate have become substantial shareholders in Atcor with 8,602,150 shares or 5.11 percent of the company.

The Bellrose, New South Wales and Cape Town South Africa-based Oceania and Hosken Consolidated Investments said they bought the shares for \$800,000 or 9.3 cents a shares on December 3, 2014 "by way of subscription".

Last week, Atcor raised \$1 million from institutional and sophisticated investors at 9.3 cents a share.

Atcor fell 0.4 cents or four percent to 9.6 cents.

## THE WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

The Walter and Eliza Hall Institute says that Prof Alan Cowman has won the Sornchai Looareesuwan Medal for research on the malaria parasite and the search for vaccines. WEHI said that Prof Cowman would receive the award at the International Tropical Medicine Meeting in Bangkok, Thailand, today.

The Institute said that Prof Cowman was the head of the infection and immunity division and his team had "spent decades probing the inner workings of the most deadly malaria parasite Plasmodium falciparum".

WEHI said that Prof Cowman's work had led to the creation of two potential malaria vaccines, one in clinical trials and another in preclinical development.

The Institute said that Prof Cowman had made important discoveries about the biology of the malaria parasite, including how it evaded the immune system, infiltrated and remodeled red blood cells to replicate and spread, and how it communicated with other parasites to trigger the next stage of infection.

Prof Cowman said the work had the potential to aid the quest to eradicate malaria. WEHI said that the Sornchai Looareesuwan Medal was awarded by the Faculty of Tropical Medicine at Mahidol University, Thailand, and recognized a researcher who had focused their efforts on malaria and made a significant contribution to the field.