



# Biotech Daily

Tuesday September 21, 2010

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: NANOSONICS UP 19%, NOVOGEN DOWN 7%**
- \* **WEHI IDENTIFIES IMMUNE SYSTEM SENTINEL PROTEIN**
- \* **GE HEALTHCARE DISTRIBUTES NANOSONICS' TROPHON IN US, CANADA**
- \* **ATOS, CALZADA, METABOLIC AOD9604 WEIGHT-LOSS DEAL FAILS**
- \* **BIODIEM PLACES FURTHER \$1m RIGHTS ISSUE SHORTFALL**
- \* **SELECT VACCINES RIGHTS ISSUE TO RAISE \$1.2m; \$500k PLACEMENT**
- \* **SOUTH AFRICAN PATENT FOR MEDIGARD 3ML SYRINGE**
- \* **OMI FILES DOCUMENTS AHEAD OF NOVEMBER RETURN TO TRADING**
- \* **NOVEMBER RELISTING FOR FERMISCAN**

## MARKET REPORT

The Australian stock market fell 0.3 percent on Tuesday September 21, 2010, with the ASX200 down 13.8 points to 4617.5 points.

Nine of the Biotech Daily Top 40 stocks were up, 12 fell, 12 traded unchanged and seven were untraded.

Nanosonics was best, up 12.5 cents or 18.7 percent to 79.5 cents with 1.6 million shares traded, followed by Circadian 7.3 percent to 59 cents with 46,750 shares traded.

Psivida climbed 4.6 percent on small volumes; Genetic Technologies, Mesoblast and Viralytics were up more than three percent; Impedimed was up more than one percent; with Acrux, Cellestis and Resmed up less than one percent.

Novogen led the falls, down one cent or 7.4 percent to 12.5 cents with 17,650 shares traded, followed by Prima down 6.7 percent to 9.8 cents with 7.8 million shares traded.

Patrys lost 5.1 percent; Phylogica fell four percent; Alchemia and Virax were down more than three percent; with Chemgenex, Cochlear, Phosphagenics and Sirtex down more than one percent.

## WALTER AND ELIZA HALL INSTITUTE FOR MEDICAL RESEARCH

A protein called PU1 is essential for the development of dendritic cells, the sentinels of the immune system, Walter and Eliza Hall Institute researchers have shown.

A Walter and Eliza Hall Institute spokeswoman said the findings had the potential to improve dendritic cell-based therapies, such as those given to cancer patients who have suppressed dendritic cell function.

The Institute said in a media release that dendritic cells were immune cells that present proteins from foreign invaders, such as viruses, to the killer T cells of the immune system, allowing a full immune response to be mounted against the invaders.

In an article entitled 'The Transcription Factor PU.1 Controls Dendritic Cell Development and Flt3 Cytokine Receptor Expression in a Dose-Dependent Manner' published in the journal *Immunity*, the researchers from WEHI's immunology division said PU1 played "multiple context and concentration dependent roles in lymphoid and myeloid cell development".

"Here we showed that PU1 ... was essential for dendritic cell development in vivo and that conditional ablation of PU1 in defined precursors, including the common [dendritic cell] progenitor, blocked Flt3 ligand-induced [dendritic cell] generation in vitro," the article said.

"PU1 was also required for the parallel granulocyte-macrophage colony stimulating factor-induced [dendritic cell] pathway from early haematopoietic progenitors. Molecular studies demonstrated that PU1 directly regulated Flt3 in a concentration-dependent manner ...

"These studies identify PU1 as a critical regulator of both conventional and plasmacytoid [dendritic cell] development and provide one mechanism how altered PU1 concentration can have profound functional consequences for haematopoietic cell development".

An abstract is at <http://www.cell.com/immunity/abstract/S1074-7613%2810%2900171-8>.

WEHI said the researchers had been studying dendritic cells and how different molecules regulated their development.

One of the researchers Dr Li Wu said that one of the molecules that was known to be important to this development was the protein Flt3 which was a cytokine receptor found on the surface of blood stem cells and the parent cells that give rise to dendritic cells (DC).

"Despite its importance in early blood cell development and dendritic cell development, there is surprisingly little known about how Flt3 expression is controlled," Dr Wu said.

"PU1 can therefore control DC development through regulating Flt3," Dr Wu said.

Dr Sebastian Carotta said PU1 was known to be important to the development of blood cells and immune cells.

"If PU1 is poorly regulated there is a deficiency in the development of blood cells and leukaemia can result," Dr Carotta said.

"To study the role of PU1 and look at how it's regulated we developed an animal model and a new in vitro system for tracing [dendritic cell] development from their precursors," Dr Carotta said.

"These systems make it possible to switch off PU1 in the precursor cells to DC. From that we determined that loss of PU1 completely abolished DC development," Dr Carotta said.

Dr Wu said the study showed PU1 to be a master regulator of dendritic cell development.

"Although a growing number of transcription factors have been implicated in the development of specific dendritic cell populations, this is the first time a single transcription factor has been shown to be required for all DC lineages," Dr Wu said.

Dr Wu said the findings had the potential to improve dendritic cell-based therapies, such as those given to cancer patients who have suppressed dendritic cell function.

"The problem is people don't know how to develop good [dendritic cells] for these therapies," she said. "By understanding how DC development is regulated it should be possible to create different types of DC populations for therapeutic use," Dr Wu said.

## NANOSONICS

Nanosonics says GE Healthcare will have exclusive distribution rights for Nanosonics' Trophon EPR ultrasound probe disinfector and its consumables in the US and Canada. Nanosonics said the agreement provided GE Healthcare with non-exclusive original equipment manufacturer co-sales of the Trophon EPR with GEHC ultrasound consoles in other countries outside the US and Canada.

Nanosonics chief executive officer David Radford told Biotech Daily that all the financial details of the transaction were confidential.

The company said further details were still being discussed and Nanosonics and GE agreed to target the conclusion of a definitive agreement over the next 30 days.

"The proposed alliance with GE Healthcare represents Nanosonics' accomplishment, on schedule, of its next major step toward the sale of Trophon EPR and its consumables in North America, the world's largest market for ultrasound equipment," Mr Radford said.

Mr Radford said the pre-market notification 510(k) application to the US Food and Drug Administration for the Trophon EPR was on track, with its previously anticipated timelines.

"Distribution in the US market will commence following FDA clearance of the Trophon EPR and its consumable," Mr Radford said.

Nanosonics said GEHC was the leading supplier of ultrasound equipment in the US and Canada, had global leadership in obstetric and gynaecological applications and the alliance provided for "further product development opportunities [for] GEHC's customers".

Nanosonics said it was scaling-up capacity for a US-specified device.

Nanosonics was up 12.5 cents or 18.7 percent to 79.5 cents with 1.6 million shares traded.

## CALZADA

Calzada and Atos Wellness have terminated the agreement for Calzada to invest \$500,000 in Atos and provide it with Metabolic's claimed fat-busting drug AOD9604.

The two companies told the ASX the decision to terminate the proposed agreement resulted from the due diligence investigations undertaken by each party.

Metabolic closed the AOD9604 after a 536 patient phase IIb trial showed "that weight loss compared to placebo at the primary and secondary endpoints of 12 or 24 weeks of treatment, was too low to reach statistical significance" (BD: Feb 21, 2007).

Metabolic Pharmaceuticals Pty Ltd is a wholly owned subsidiary of Calzada and the agreement proposed to provide all the intellectual property associated with Metabolic's drug development assets into Atos Wellness.

Calzada executive chairman David Franklyn said that his company would "continue to look for opportunities to restore value to its Metabolic asset portfolio, primarily AOD9604, in a manner which does not place a significant financial burden on the company".

Calzada was up 0.1 cents or 4.35 percent to 2.4 cents.

## BIODIEM

Biodiem says that further to its rights issue which closed on June 21, 2010, it has placed 5,555,555 shares to the value of \$1 million with sophisticated investors.

Biodiem said that in addition to the shares the investors would receive 2,777,778 options exercisable at 23 cents before May 31, 2012.

In June, Biodiem said its 11-for-six non-renounceable share rights offer at 18 cents a share raised \$3,506,842.62 of the hoped for \$7,548,000 (BD: Jun 24, 2010).

Biodiem was untraded at 15 cents.

## SELECT VACCINES

Select Vaccines hopes to raise up to \$1,674,612 through a fully underwritten rights issue and placement

Select said the two-for-one renounceable share rights offer of up to 587,306,038 shares at 0.2 cents a share would raise up to \$1,174,612 and shareholders would receive one free attaching option exercisable at 0.2 cents by July 31, 2013 for every two new shares allotted.

Select said the rights issue was underwritten by Patersons Securities which would be paid an underwriting fee of five percent and a management fee of one percent of the funds raised.

The company said a placement would follow the rights issue of 250,000,000 shares at 0.2 cents a share to raise \$500,000, also through Patersons Securities.

The company said the placement would provide up to 125,000,000 free attaching options exercisable at 0.2 cents per option on or before July 31, 2013.

Select said the placement would be in two tranches, the first of 93,841,292 shares under the company's 15 percent placement capacity and the second of 156,158,708 shares, be subject to shareholder approval.

Select said it intended "to investigate acquisition and investment opportunities across a range of sectors which may take the company away from its recent biotechnology focus, and could include opportunities in other sectors".

Select said the record date for the rights issue was September 29, 2010 the prospectus would be dispatched on October 5 and the offer closes on October 19, 2010.

Select was up 0.2 cents or 50 percent to 0.6 cents with 4.3 million shares traded.

## MEDIGARD

Medigard says the Republic of South Africa has granted its patent application for its 3mL Safety Vacuum Retractable Syringe.

Medigard said the patent provided protection in South Africa until March 9, 2027.

Medigard chief executive officer Peter Emery said the while South Africa might "not be a priority market for us at present, the fact that our patent has been granted in one of the jurisdictions in which we have applied bodes well for successful applications in other jurisdictions".

Medigard fell 0.2 cents or 3.45 percent to 5.6 cents.

## OMI, SUN BIOMEDICAL

The administrators of OMI (formerly Occupational & Medical Innovations) have filed documents to the ASX in preparation for a return to trading in November 2010.

The documents said that Sun Biomedical may advance OMI up to \$130,000 and OMI's company secretary David Woodford told Biotech Daily that Sun may subscribe for shares in a capital raising to prepare OMI for a return to trading.

At an extraordinary general meeting in July, Sun Biomedical effectively took control of OMI and was expected to retain OMI in the biotechnology sector (BD: Jul 26, 2010).

Mr Woodford told Biotech Daily today that OMI had a safety syringe dispenser that was not affected by the litigation with the US-based RTI.

The US legal action went against OMI causing its suspension from trading and voluntary administration (BD: Dec 14, 2009; Jan 17, 2010).

OMI is in a suspension and last traded at 14.5 cents.

Sun was unchanged at 0.1 cents.

## FERMISCAN

Fermiscan hopes to be reinstated to trading on the ASX by the end of November 2010.

The company was developing Prof Veronica James x-ray diffraction of hair test for breast cancer and was intending to merge with Polartechnics shortly before it went into a trading halt and later a voluntary suspension (BD: Oct 26, 2009).

The company was in voluntary administration and completed a deed of company arrangement (BD: Nov 18; Dec 15, 2009).

In May 2010, Fermiscan's administrators Woodgate & Co sold the company's intellectual property and other assets for \$250,000 to the Sydney Breast Clinic-related company SBC Research (BD: May 4, 2010).

In August 2010, Fermiscan director, former Polartechnics chief executive officer Ben Dillon, told Biotech Daily the company had unfinished trials of the breast cancer test in Europe and there were exemptions for research as long as it was not for commercial purposes. (BD: Aug 16, 2010). Mr Dillon said at that time that if the company wanted to commercialize the test it would have to negotiate a licence with SBC Research.

Today, the company said it had applied to be reinstated to official quotation and the ASX advised the company of "certain conditions that are required to be complied with prior to such reinstatement".

Fermiscan said the balance of the conditions would be complied with in full within the next six to eight weeks, resulting in the company being reinstated shortly thereafter.

Fermiscan last traded at three cents.