



# Biotech Daily

Monday December 7, 2009

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: COMPUMEDICS UP 9%; LBT DOWN 12.5%**
- \* **CSIRO, CIRCADIAN COLLABORATE AT \$15m MONASH PROTEIN FACILITY**
- \* **CHEMGENEX PRESENTS 81-PATIENT DATA ON OMAPRO FOR CML**
- \* **ONDEK STARTS HELICOBACTER VACCINE DELIVERY TRIAL**
- \* **NANOSONICS \$12m PLACEMENT; SHARE PLAN**
- \* **TISSUE THERAPIES SHARE PLAN OVER-SUBSCRIBED, RAISES \$2.7m**
- \* **OMI FOUNDER INVENTOR DIRECTOR BRUCE KIEHNE RETIRES**
- \* **FEDERAL COURT APPROVES UNILIFE US-BOUND MEETINGS**
- \* **PACIFIC SUPERANNUATION DILUTED TO 8% OF AGENIX**

## MARKET REPORT

The Australian stock market fell 0.55 percent on Monday December 7, 2009 with the S&P ASX 200 down 25.7 points to 4676.5 points.

Eight of the Biotech Daily Top 40 stocks were up, 14 fell, 10 traded unchanged and eight were untraded. All three Big Caps were up.

Compumedics was best, up 1.5 cents or 8.6 percent to 19 cents with 10,000 shares traded, followed by Impedimed up five cents or 6.25 percent to 85 cents with 25,345 shares traded.

Acrux climbed 4.1 percent; Cathrx, Cellmid and Phosphagenics were up more than three percent; Circadian, Cochlear and Resmed rose more than two percent; with Pharmaxis up 1.75 percent.

LBT (formerly Labtech) led the falls, down 1.5 cents or 12.5 percent to 10.5 cents with 188,462 shares traded, followed by Sunshine Heart down 7.3 percent to 3.8 cents.

Novogen lost 5.1 percent; Clinovel and Prima were down more than three percent; Mesoblast, Prana and Viralytics shed more than two percent; with Biota, Psivida and QRX down more than one percent.

## CSIRO, CIRCADIAN, RECOMBINANT PROTEINS PRODUCTION FACILITY

The Commonwealth Scientific and Industrial Research Organisation will collaborate with Circadian on vascular endothelial growth factor (VEGF) cancer treatments.

Circadian said the collaboration coincided with the opening of CSIRO's Recombinant Proteins Production Facility at Monash University in Clayton, funded by both the Federal and Victorian Governments.

Circadian said the facility was a significant part of CSIRO's infrastructure capability that was accessible to the Australian biotechnology industry.

CSIRO's deputy chief of Molecular and Health Technologies Dr Tim O'Meara told Biotech Daily that the CSIRO funded \$4.6 million of the costs with Monash University providing \$1 million and each of the Federal and Victoria Governments providing \$2.8 million.

Dr O'Meara said that other costs brought the total value of the facility to about \$15 million.

The facility was opened by Federal Innovation Minister Senator Kim Carr and Victorian Innovation Minister Gavin Jennings, who said in a media release it would "support the creation of therapeutic cells, increase the capacity for the development of new drugs and provide a centre for national collaborative bioscience research".

The Ministers media release said recombinant proteins were created by manipulating DNA in human, plant or bacteria cells, to create combinations that do not occur naturally and had potential for biopharmaceutical products and human therapies.

Senator Carr said the facility would be "of great benefit to the clinical trials sector as it can produce recombinant proteins at levels that can support pre-clinical trials".

Mr Jennings said the facility was an impressive contribution to the world-class research capability of Monash University and would be "a significant boost to Australia's capacity to produce a range of therapeutics for combating various human diseases".

Circadian said it would provide funding and access to its technology and lead drug candidates and molecules, while CSIRO would provide access to its biological production infrastructure, process development capability and internal research expertise.

Circadian said its VEGF technology was a class of proteins that play a critical role in regulating tumor blood supply and it owned intellectual property related to VEGF-C, VEGF-D and VEGF receptor R3 and was developing antibodies to block these proteins to inhibit the growth and spread of cancerous cells or tumors.

The company said Avastin was the first cancer treatment based on this approach by blocking VEGF-A activity and had "outstanding success", so the development of antibodies targeting the VEGF proteins was "arguably one of the most promising potential new treatment approaches for cancer".

Circadian said the alliance with the CSIRO would develop improved production systems for Circadian's molecules, molecular modeling, assay development, testing of future drug candidates as well as other projects which may be mutually agreed by the parties.

Circadian chief executive officer Robert Klupacs said that "having access to CSIRO's world class infrastructure and research expertise will greatly assist us in bringing our molecules to the clinic".

CSIRO Group Executive Dr Steve Morton said his organization was "very pleased to be working with Circadian, an Australian biotech company, to advance its product development pipeline".

"This alliance highlights that there is already industry uptake of our new protein production facility and research capability," Dr Morton said.

"CSIRO is all about partnering with and delivering to Australian industry and our new facility will be a key enabler for the biotech industry," Dr Morton said.

Circadian was up 1.5 cents or 2.2 percent to 71 cents.

## CHEMGENEX PHARMACEUTICALS

Chemgenex says data to be presented in New Orleans tonight shows that omacetaxine mepesuccinate continues to improve the lives of chronic myeloid leukemia patients. Chemgenex said a presentation entitled 'Advances in Diagnosing and Treating Leukemia and Myeloproliferative Disorders' was given at a pre-conference media conference at the American Society of Hematology annual meeting in New Orleans and showed that omacetaxine mepesuccinate (Omapro) "produced durable haematologic and cytogenetic responses in chronic myeloid leukemia patients who have failed treatment with imatinib and who have developed the Bcr-Abl T315I mutation".

Chemgenex said the deputy chair of leukemia at the University of Texas MD Anderson Cancer Center Dr Jorge Cortes, an investigator for Chemgenex's phase II/III trial of omacetaxine presented the data and concluded that Omapro was "a new potential therapy for patients with T315I+ CML".

In June Chemgenex presented data showing that of 40 patients with the T315I mutation, 85 percent had a complete haematologic response leaving them effectively asymptomatic and six patients had a major cytogenetic response, effectively clearing any detectable signs of the leukemia (BD: June 11, 2009).

Today's data reviews 81 chronic myeloid leukemia patients of which 49 were in chronic phase, 17 in accelerated phase and 15 in blast phase.

The data showed that of the chronic phase patients, 86 percent (42 of 49 patients) had complete haematologic responses with a median response duration of nine months. The company said total cytogenetic response rate of chronic phase patients was 41 percent with 27 percent having a major cytogenetic response.

Among accelerated phase patients 35 percent (six of 17 patients) had overall haematologic responses with a median duration of seven months; and of the blast phase patients, 47 percent (seven of 15 patients) had overall haematologic responses with a median duration of two months.

Chemgenex said the investigators reported that omacetaxine was safe for self-administration, was well tolerated, and that reversible and manageable myelosuppression was the most common side effect.

Chemgenex chief executive officer Dr Greg Collier said the company was "delighted with the positive data presented today that continues to show that Omapro can provide clinical benefit to patients in this very difficult to treat sub-set of CML where there are no other approved treatment options".

"These results support our regulatory filings and we look forward to working with the agencies in the US and Europe over the next several months as we seek approval for Omapro in 2010," Dr Collier said.

The company said applications for marketing approval for Omapro were under review by the US Food and Drug Administration and the European Medicines Evaluation Agency. The complete oral presentation by Dr Cortes will take place on December 7, 2009 at 4:45pm US Central Time.

Chemgenex said the abstract was Number 644 entitled 'Safety and Efficacy of Subcutaneous-Administered Omacetaxine Mepesuccinate in Imatinib-Resistant Chronic Myeloid Leukemia Patients Who Harbor the Bcr- Abl T315I Mutation - Results of An Ongoing Multicenter Phase II/III Study' in the oral session was entitled 'Chronic Myeloid Leukemia - Therapy: Managing Resistance and Residual Disease'.

Chemgenex climbed as much as 12 cents or 12.4 percent to \$1.09 before closing unchanged at 97 cents with 1.4 million shares traded.

## ONDEK

Ondek has begun a phase I clinical trial to test whether the use of Helicobacter pylori bacteria can be used to deliver vaccines.

Ondek is a private company created by Nobel Prize winner Dr Barry Marshall who discovered that Helicobacter pylori caused many stomach ulcers (BD: Jul 30, 2009).

A media release from Ondek said the technology used a modified version of the Helicobacter pylori bacteria, which could be "delivered as a capsule or potentially in a yogurt style food, to coat the stomach cells of humans which enables edible vaccines to be absorbed into the body across the stomach wall".

Ondek said that finding a way to help people easily absorb vaccines without rejection was a 'holy grail' of modern medicine.

The company said that the phase I trial at Perth's Sir Charles Gairdner Hospital would help identify the Helicobacter pylori strain best suited for use in an international trial and help Ondek break into the \$4 billion global vaccine market through licencing agreements.

Ondek will give strains of the bacteria to 36 healthy volunteers aged from 18 to 65.

The company said the bacteria stimulated the body's immune system to produce antibodies and was capable of evading those antibodies and continued to reproduce in the stomach.

Ondek said it was "a way of stimulating the human system to produce antibodies to diseases such as swine flu and seasonal influenza which can be attached to the Helicobacter pylori bacteria".

The trial involves healthy volunteers taking unmodified or wild type Helicobacter pylori bacteria to see how their immune systems respond, thus characterizing the safety profile of these sample bacteria.

The trial is due to finish in the second half of 2010.

Dr Marshall said his approach would be used to develop food-like vaccines that activate an immune response to fight diseases like swine flu, malaria, cholera, hepatitis B and HIV.

The technique could potentially be used to deliver insulin for diabetics.

Ondek is a private unlisted company.

## NANOSONICS

Nanosonics says Wilson HTM has fully underwritten a \$12 million placement to institutional and sophisticated investors at 55 cents a share and a share purchase plan.

Nanosonics said the funds from the capital raising would accelerate the roll-out of its flagship product Trophon EPR into global markets; provide capital to leverage the core technology platform for other products; and support the relocation of the business to larger premises to support growth.

Nanosonics said the record date for the share plan was December 9, 2009.

The company said the offer would open on December 15, 2009 and would close on January 15, 2010.

Nanosonics requested a trading halt relating to the funding and last traded at 62.5 cents.

## TISSUE THERAPIES

Tissue Therapies says its share purchase plan raised at least \$2.7 million through the issue of shares at 11.84 cents a share.

Tissue Therapies chief executive officer Dr Steven Mercer told Biotech Daily that the share plan was heavily over-subscribed and would have to be scaled back.

Tissue Therapies was unchanged at 14.5 cents.

## OCCUPATIONAL & MEDICAL INNOVATIONS

Occupational & Medical's founder Bruce Kiehne has resigned as a director. Mr Kiehne founded Occupational & Medical in 2000 and has been a director since the company listed on the ASX that year.

In a profile on its website, Occupational & Medical said Mr Kiehne had a business background in the heavy machinery and vehicle maintenance industry.

The company's website said Mr Kiehne was "the driving force behind the OMI product range".

"As a product innovator he has spent more than a decade developing and refining his safety product range," the Occupational & Medical website said.

"He was inspired to develop these products after a relative suffered an accidental environmental needle-stick injury. This personal experience set Bruce on a quest to invent a retractable syringe," the website said.

Occupational & Medical's 2009 annual report said Mr Kiehne owned 4,245,073 shares or 9.28 percent of the company and his wife Venessa Kiehne owned 2,175,495 shares or 4.75 percent.

No reason for Mr Kiehne's departure was given in the Appendix 3Z final director's interest notice.

Occupational & Medical was untraded at 14.5 cents.

## UNILIFE MEDICAL SOLUTIONS

Unilife says the Australian Federal Court has approved security holder meetings to vote on the proposed move to the US.

Unilife said the proposed transaction would be implemented through two separate schemes of arrangement between the company and its shareholders and option holders.

The company said the share scheme meeting would be held on January 8, 2010 at the Westin Hotel, 1 Martin Place, Sydney at 10am with the option holders meeting either at 10.30am or immediately following the share scheme meeting.

The record date is January 6, 2010.

An extraordinary general meeting to approve a new employee incentive scheme for Unilife Corporation, the issue of options to directors and a new incentive package for the company's chief executive officer, Alan Shortall, will be held on January 8, 2010 at 11am or immediately following the conclusion of the scheme meetings.

Unilife was up 1.5 cents or 1.5 percent to \$1.03.

## AGENIX

Pacific Superannuation's substantial shareholding in Agenix has been diluted from 9.0 percent to 7.96 percent following the maturation of convertible notes (BD: Dec 2, 2009)

Pacific Superannuation and Pacific Superannuation Fund increased their shareholding from 22,000,000 shares to 35,627,034 shares.

Pacific Superannuation was one of the convertible note-holders and director Peter McNamara is the father of Agenix director Chris McNamara.

Agenix is in a suspension and last traded at 1.7 cents.