# CyGenics Quarterly Newsletter August 2005

## Letter from the CEO

Greetings!

In the 12 months since our listing on the Australian Stock Exchange, the company has seen considerable activity. Momentum is certainly building for CyGenics. Late last year we restructured Boston-based subsidiary Cytomatrix, in March 2005 Cordlife opened a new facility for cord blood processing and storage in Hong Kong, in early June this year we occupied premises in Parkville's newly completed Bio21 Institute and in late June we formed a new subsidiary, CytoVations, to address the growing cell therapy market in the US.

The restructuring of Cytomatrix, which involved the appointment of Dr Michael Michalek to the new position of director of cellular screening services, enabled transfer of technology and technical expertise to the Australian and Singaporean stem cell facilities to aid progress of stem cell expansion and trials of the company's artificial thymus.

As a result of this restructuring, Cytomatrix has shifted from being a research company to one focused on the commercialisation of technology and the generation of revenue.

We are now an anchor tenant at the business incubator at the Bio21 Institute, the University of Melbourne, giving us a research and administrative base as we approach the initiation of two clinical trials for cancer treatment. These are planned to take place at Melbourne hospitals during 2006. Dr Anne Altmann has joined us as medical director to plan and oversee the trials.

We have maintained from the outset that CyGenics will develop into a global company that participates in every major facet of stem cell biotechnology. I believe that recent activities have confirmed our intention and gone a long way toward achieving these goals.

Steven Fang,
CEO, CyGenics

### This edition



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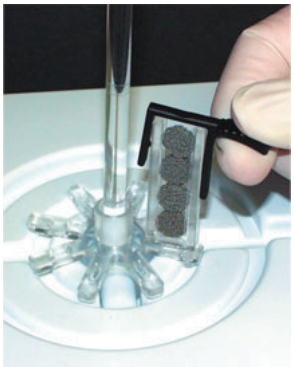
# Company highlights

## CyGenics forms new subsidiary, CytoVations



CyGenics announced the formation of a new subsidiary, CytoVations, to acquire and develop cell based technologies in June. CytoVations will assess intellectual property for the CyGenics group and assist in the subsequent development of products. Cyto-Vations will also seek suitable candidates for business partnerships and acquisitions, as well as providing management and consultancy services to various biotech and pharmaceutical companies in North America.

The company has commenced operations in New Jersey, within easy reach of more than 20 of America's top biotech and pharma companies, as well as several major state and national research and regulatory bodies.

## CyGenics strengthens Melbourne operations

In the lead up to commencement of clinical trials, we have made a number of appointments in Melbourne. Dr Anne Altmann has accepted the position of medical director and will head up the team that includes a medical consultant, a research and clinical trials coordinator and a director of regulatory affairs based in New Jersey, USA.

Dr Altmann was most recently head of the International Centre for Therapeutic Research at Servier Laboratories (Australia) Pty Ltd where she oversaw the successful completion of more than 20 international phase II and III clinical trials.

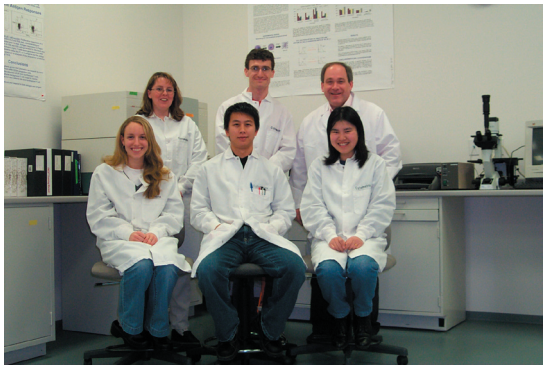
Dr Katie Allen, a paediatric gastroenterologist with positions at the Murdoch Children's Research Institute and the Royal Children's Hospital, joins CyGenics as medical consultant.

## Cordlife opens banking facility in Hong Kong


CordLife announced in late March the opening of a new facility in Hong Kong for the processing and storage of cord blood. This is a key step for growth of the company's CordLife business and is the first step in opening up access to the significant potential of the North Asia region.

Cordlife has considerable experience in doing business in the region, having successfully operated a facility in Singapore for more than three years, which processes and banks cord blood from mainly the Southeast Asia region.

## US Department of Defense renews contract with Cytomatrix



In December 2003, the US Department of Defense (DOD) entered into a contract with Cytomatrix to use the company's proprietary T cell production technology to screen vaccine prototypes under development.

In February, the DOD exercised its option to extend the contract with Cytomatrix to two years.

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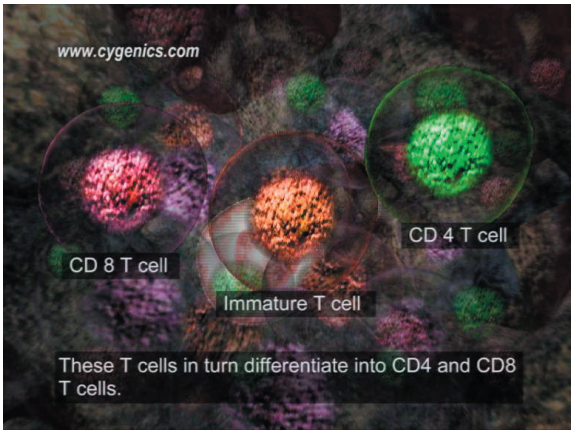
The company's proprietary T cell production technology is used to help predict how the human T cells will respond to proposed vaccines. This approach to the screening of vaccine candidates is potentially quicker and less costly than more traditional approaches that incorporate animal testing.

# Clinical trial update

## CYN105 RegenImmune™ technology



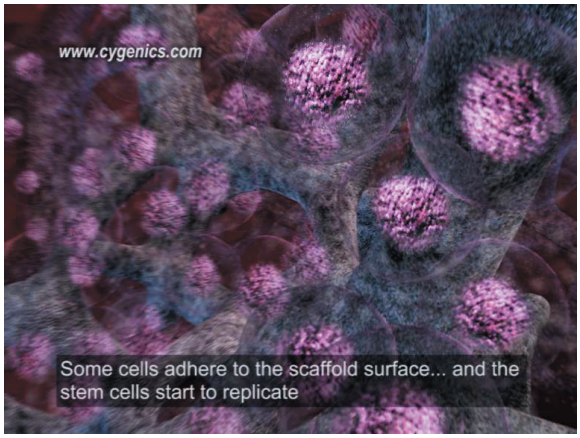

The target patient group for the RegenImmune™ technology includes cell and organ transplant recipients and those with melanoma, breast and prostate cancers, HIV, hepatitis, herpes, cytomegalovirus, Epstein-Barr virus and autoimmune disease.

The T cells found in the body which play an critical role in the immune system can be lost or damaged due to cancer, other diseases and chemotherapy. Clinical trials of RegenImmune™ technology are planned to commence in Australia in 2006. A population of normal human T cells is grown from adult stem cells using CyGenics' 3D scaffold to simulate the environment of the thymus. The T cells are able to replace those lost in human diseases and may boost the immune response to a range of diseases. The technology has particular application to patients whose immune system has been suppressed eg those receiving a cell or organ transplant or those undergoing chemotherapy. The technology is being developed for marketing to hospitals as a kit.

**Status of clinical trials**

- Technical dry runs of trial procedures in 2005
- Phase I safety trial 2006
- Out-licensing discussions to begin in 2007

## CYN205 TransCord™ technology




The target group for the TransCord™ technology includes recipients of cell and organ transplant recipients and patients receiving chemotherapy who would benefit from the addition of stem cell therapy.

The haemopoietic stem cells from bone marrow which give rise to all blood cells can be lost due to cancer, other diseases and chemotherapy. Clinical trials of TransCord™ technology are planned to commence in Australia in 2006. TransCord™ uses CyGenics' proprietary 3D scaffold for the growth of adult stem cells from umbilical cord blood, peripheral blood or bone marrow for transplantation. A limitation of potential cell-based therapy is the number of cells available per treatment.CyGenics' TransCord™ technology is under development to enable regimens involving not only more cells but also multiple treatments.

**Status of clinical trials**

- Validation of reagent 2005
- Preparation of documents for submission to FDA 2005
- Phase I safety trial 2006
- Out licensing discussions to begin in 2007

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## Interview with Dr Anne Altmann, Medical Director of CyGenics

Dr Anne Altmann (AA) has recently been appointed as Medical Director to manage the clinical trial activity of Cytomatrix for CyGenics. Here she answers some questions about her new role.

*Why has CyGenics appointed a medical director at this stage?*

AA: The company is about to enter a period of increased activity in the clinical area. The first clinical trial is of RegenImmune™, a system that will grow and develop a patient's immune T-cells. This study will look at the safety of these cells when given to patients with low immunity post chemotherapy for cancer and is being planned for commencement early in 2006. The RegenImmune™, will be run at the Peter MacCallum Cancer Centre. We are also working with the Murdoch Childrens Research Institute preparing for a trial of the novel system TransCord™ to expand haematopoietic stem cells.

*What exactly are the responsibilities of a medical director?*

AA: My role is to look at the best pathway for products under development. I am assessing the most effective, worthwhile and cost-effective means of achieving registration of new products.

I also have the role of coordinating opinions gathered from experts around the world to identify the best opportunities for application of our technology.

On a day-to-day basis, I am working with the principal investigator of the clinical trial and manage the many different elements that have to come together before the trial begins. In the lead up to, during and after the trial, it is my role also to liaise with the contract organisation that we have engaged to manage the trials. They will collect and analyse the data and write the report. I will also, during the conduct of the trials, oversee the medical data being generated to ensure that the safety of the patients remains the foremost priority.

*It's always good news for investors that a company is preparing to undertake a clinical trial. On the other hand, it seems to take a long time before the results are in. Why is this?*

AA: That's a good question. Most people have only a general understanding of the complexities of the requirements we have to satisfy before starting a clinical trial and the number of variables that contribute to the time involved. First of all, there is a lot of regulatory documentation needed. We must make detailed submissions to the research ethics committee at the institution where the trial will take place and the regulatory agencies of the countries in which we wish to register the product, such as the TGA in Australia and the FDA in the US. Approval is not automatic. We often have to modify applications for a second round of consideration. These are the normal processes companies go through.

All laboratories connected with the trial – those that manufacture the product, undertake the manipulations needed for the trial and perform the myriad of tests – must meet the criteria for compliance with regulations covering products for use in humans. In addition we need to train the relevant staff involved in the many aspects of the study and enlist the appropriate number and type of patients. Finding the right patients can be time-consuming due to the need to screen them against several criteria for inclusion and exclusion.

*Are there other trials in the discussion stage?*

AA: Yes, we are talking to the Johns Hopkins University in the US about various possibilities for use of our technology for the expansion of haematopoietic stem cells. There is much activity in the area of storing umbilical cord blood at birth as a source of stem cells, but it may not be widely known that cord blood yields only small numbers of cells. There may be enough cells to treat small children, but often insufficient for larger adults. Other opportunities are in the air for the use of the Cytomatrix cell growth scaffold in the area of hepatocyte's or liver cells.

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**For more information, please visit www.cygenics.com**