

# Milestones achieved, positioned for revenue growth

## Company calendar

The past few months have been an active time for the company with attendance at road shows, conferences, investor relations and stakeholder activities. Please find an update on Allied's company calendar below:

### RECENTLY ATTENDED

- **Biotech Showcase January 7-9:** Biotech Showcase held alongside JP Morgan 2013 Healthcare Conference was an investor and partnering conference devoted to providing companies with an opportunity to present and meet with investors and biopharmaceutical executives.
- **Society of Thoracic Surgeons Annual Meeting January 26-30:** The meeting promoted the exchange of information regarding the research in, and diagnosis and treatment of, cardiovascular and thoracic disease.
- **6th World Congress Paediatric Cardiology & Cardiac Surgery February 17-22:** A major international scientific event and an opportunity to highlight and review research and technological developments in basic sciences, clinical research and therapeutic interventions.

### UPCOMING

- **AATS Annual Meeting May 4-8:** The AATS Annual meeting is the annual conference for the American Association for Thoracic Surgery, an international organization of over 1,300 of the world's foremost cardiothoracic surgeons. The meeting will bring together the world's leading figures in cardiothoracic disease to discuss the latest information regarding management guidelines, imaging, pathology, minimally invasive approaches, percutaneous approaches, surgical techniques, devices, and long term results.
- **AusBiotech Asia Biotech Invest Hong Kong June 3-5:** The conference will bring cutting-edge biotech innovators together with Asia's investment community to discover and fund the future of biotech.

**For more information, please contact:**
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Dear Shareholder,

Welcome to Allied Healthcare Group's first investor newsletter for 2013. It is with great pleasure that I provide this progress update, to touch on the major milestones we have achieved in recent months and also our exciting plans for the year that is ahead.

Our tissue regeneration division, with its lead product in CardioCel®, and our DNA vaccines division have both made significant headway. For CardioCel®, we are also beginning to see the potential of this novel technology translate into real benefits for patients and create a new source of revenue for the Company.

CardioCel®, which is now in use to repair congenital heart disease (CHD) in Australian children, is expected to become revenue generating in 2013. A recent review of patients involved in an ongoing Phase II extension trial also found no sign of calcification related to the CardioCel® implant four years post-surgery. This provides further strong support for our claim that CardioCel® can reduce the life-time need for follow-up surgery in CHD patients.

The DNA vaccines division, development of a next-generation vaccine for Human papillomavirus (HPV) is also progressing well, with an early animal model trial showing the vaccine does induce the required immune response. A Phase I clinical trial of a vaccine for Herpes simplex virus (HSV) is scheduled to commence this financial year.

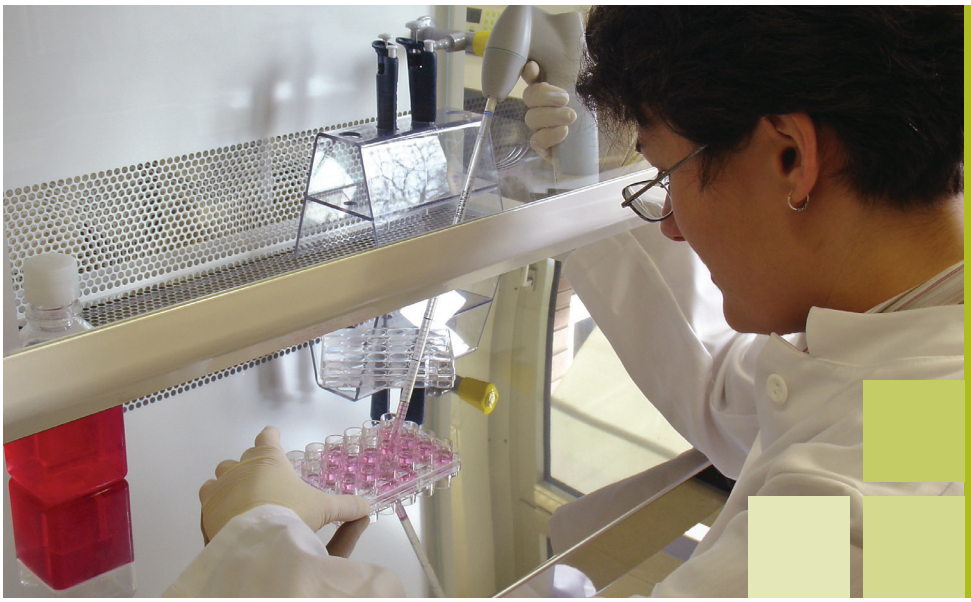
We also begin the year in a strong cash position so we are well placed to increase this positive momentum and progress towards the Company's clinical development and marketing objectives.

Finally I would like to take this opportunity to thank our shareholders, in particular those that recently participated in the Share Purchase Plan. We greatly appreciated your support for the Company and interest in its product pipeline.

I hope you enjoy this edition of our newsletter.

Yours sincerely,

**Christopher Catlow**
*Chairman*



**FACT:**

Congenital Heart Disease is a major cause of infant death globally. In Australia, CHD prevalence has been recorded at around eight cases per 1,000 live births.

# CardioCel® now in use in Australia

**FACT:**

CHD is a major cause of infant death globally. In Australia, CHD prevalence has been recorded at around eight cases per 1,000 live births.

It has been a very productive six months for our regenerative tissue division and our lead product CardioCel®. In October last year, Professor Tom Karl at Brisbane's Mater Hospital was granted early access to CardioCel® via an Authorised Prescriber Scheme (APS). Under this program, overseen by the Therapeutic Goods Administration (TGA) and individual hospitals, surgeons can apply to use CardioCel® for the repair of CHD in children.

Professor Karl performed the first surgeries using CardioCel® in October last year and he continues to do so. To date a number of patients have been successfully implanted with CardioCel® as part of their surgery to repair their congenital heart disease. A number of other key surgeons are making similar applications to use CardioCel®, via the APS, and the Company anticipates additional early access approvals at key centres in Australia in the coming months.

Early access approval was based on ten years of preclinical and clinical studies showing the benefits of CardioCel® compared to existing marketed products. A leading benefit being the prevention of calcification at the site of repair. Our most recent review of patients taking part in an ongoing Phase II extension study confirmed patients with a CardioCel® implant remained free of calcification at the site of repair four years post-surgery. This is a highly positive result and underscores the benefit of using CardioCel® compared to other tissue products used conventionally in cardiovascular repair, and which typically show calcification within six months post-surgery. The data continues to support our claim that use of CardioCel® can reduce the need for follow-up corrective heart surgery later in a CHD patient's life.

# CardioCel®'s regenerative properties & path to market

Our research into the additional benefits and potential of CardioCel® is ongoing. In November last year we announced the successful study findings which showed CardioCel® is suited for repair of heart valves – a high-stress area of the heart and challenging setting for the CardioCel® patch. The data also showed that CardioCel® patches facilitate the growth of native tissue at the site of repair including the growth of endogenous endothelial and muscle cells. This triggers a healing process that allows tissue to be integrated into native tissue – demonstrating the ability for CardioCel® to support tissue regeneration.

# Allied to move to e-newsletter format

In 2013 we will be moving to an e-newsletter format, with an emphasis on digital shareholder communication. This is a concerted effort by the company to cut down on unnecessary production costs, as well as to provide real-time information to interested parties.

In addition to this current newsletter, we will be releasing one more paper version mid-year. The e-newsletter version will be available in fourth quarter 2013 and will be distributed via email, as well as housed on the company website and lodged on the ASX.

If you're interested in continuing to receive Allied's company newsletter, please send your preferred email address to *investors@alliedhealthcaregroup.com.au* and please update your computershare profile by visiting *www.investorcentre.com/au* to reflect this preference change.

# Allied's ADAPT® has potential beyond cardiovascular disease

Allied's ADAPT® technology, which is used to create CardioCel® patches, has also been shown to produce tissue suited for use in surgical repair elsewhere in the body. One study showed ADAPT® treated tissues are an effective bio-scaffold substitute for abdominal hernia repairs as well as pelvic floor reconstructions. Allied is currently evaluating other applications for its ADAPT® tissue engineering platform technology, including use in orthopaedics and as a biological scaffold to grow and deliver stem cells.

This research is important as we continue to work towards regulatory approval and also look for potential new applications of our proprietary technology. An application for a CE mark to allow CardioCel® entry to European and other markets has also been lodged and we expect to receive European marketing approval for CardioCel® by mid-2013.

The Company is on target to lodge a 510(K) submission to the FDA for CardioCel® within the next few months.

While an increased number of Australian surgeons will soon be allowed to use CardioCel® via the APS, a global market roll out is the next major step for the product. Should this roll out proceed as anticipated then our regenerative tissue technology should begin generating revenue this year for our sales division.

Allied anticipates revenues for our sales division to increase significantly over the next 12 to 24 months with European and US approval of CardioCel®.

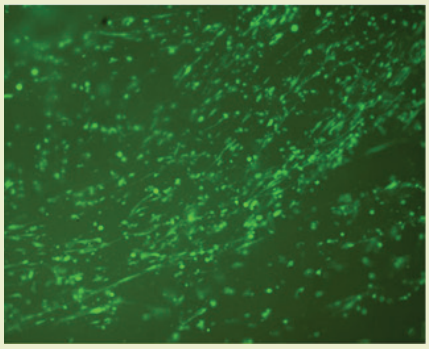
## REGULATORY PROGRESS FOR CARDIOCEL® IN 2013

- CE mark approval for Europe expected mid-2013
- 510(K) submission to the FDA on target to be lodged 1H, 2013

# Allied's regenerative tissue a platform for stem cell delivery

Another study, undertaken in conjunction with the CSIRO, showed CardioCel® provides far superior support for the seeding, growing and sustaining of a population of stem cells compared to alternative tissues.

**ADAPT® Tissue**



**Control Tissue**

Florescent green spots indicate viable mesenchymal stem cells

The CSIRO – Allied study showed that after seven days mesenchymal stem cells survived well on the ADAPT prepared tissue whereas the control tissue was unable to support stem cells over the same period (see images above). This data is important as the control tissue was manufactured under the same process currently used for gold–standard existing marketed products.

# STRONG FINANCIAL POSITION

We enter 2013 in a strong financial position. The Share Purchase Plan (SPP), which closed in January, raised $2.9M. Together with the $1.7 million placement completed in December, Allied has raised more than $4.6M over the past six months. The majority of these funds will be allocated to the preparation and market launch of CardioCel® and further building the Company's regenerative tissue franchise. Funds will also be used to invest further into Allied's DNA vaccine programs. The lead program, targeting HSV, is scheduled to enter Phase I studies this year with some initial results scheduled for release before the end of 2014. The company also generated $3.7M in revenue this financial year to December 31, up 10% on the equivalent period a year earlier. We are in a strong position at a pivotal moment in the development of the Company, and so are well placed to ensure we deliver on the potential of our upcoming milestones.

ALLIED HEALTHCARE GROUP

# Allied working on HSV, next-gen HPV vaccines

The Allied DNA vaccines program, led by Professor Ian Frazer, is progressing well. As mentioned earlier, the lead program is scheduled to begin a Phase 1 clinical trial of a vaccine for Herpes Simplex Virus (HSV). The team is also working on a next-generation therapeutic vaccine to combat human papillomavirus (HPV), which is a precursor infection to a range of anogenital, cervical and head and throat cancers.

Existing HPV vaccines (Gardasil® and Cervarix® based on work by Prof Frazer) are used to prevent an infection by the virus and are not available to people already exposed (infected) to the virus. Our next-generation HPV vaccine is designed as a therapeutic and therefore aims to target the virus thus preventing the onset of cancer in those already infected.

In November we announced the results of a study in which the vaccine was seen to successfully induce an immune response against HPV that can protect mice from developing cancer tumours associated with HPV infection.

We estimate the commercial market for a therapeutic HPV vaccine is significant. HPV infection currently affects about 2% of all women during their lifetime, and currently requires lifetime follow-up to prevent development of cervical cancer, but there is no current therapy available.

In further recognition of the importance and potential of his work, in December it was announced Prof Frazer, and his team at the University of Queensland, received a $200,000 grant from Australia's National Health and Medical Research Council (NHMRC).

HPV is one of the world's most common sexually transmitted diseases and is the causing virus in ~ 5% of all cancers globally.



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