CRC for Cell Therapy Manufacturing

Annual Report 2015
The CRC
The CRC for Cell Therapy Manufacturing is facilitating the cost-effective manufacture and rapid translation of cell therapies into clinical practice.

CTM CRC has a total of $60M in cash and in-kind resources, including a $20M grant from the Australian Government over six years. CTM CRC is providing new treatments and developing new materials-based manufacturing technologies for the treatment of conditions such as diabetes, chronic wounds, cardiovascular and immune-mediated diseases.

Headquartered at the University of South Australia’s City West campus, the CRC brings together the spectrum of skills and facilities required to turn a promising cell into a viable cell therapy. The CRC’s national and international participants include research providers, manufacturers, cell therapy companies, hospitals and charities.

Underpinning this partnership is a newly established cGMP manufacturing facility, designed to deliver cell-based therapeutics for the CRC’s Phase I human clinical trials.

Vision
To provide new treatments and develop new materials-based manufacturing technologies to increase the accessibility, affordability and efficacy of cell therapies.

CRC board
Dr Leanna Reid (Chair)
Dr Stephen Livesey
Dr Alexander Gosling AM
Mr Charlie Latham
Mr Ray Wood
Dr Sherry Kothari

Participants
Athersys, Inc.
Cell Therapies Pty Ltd
Exylika Pty Ltd
Medvet Science Pty Ltd
NextCell Pty Ltd
Queensland University of Technology
The Royal Adelaide Hospital - a division of Central Adelaide Local Health Network, Inc.
Royal Prince Alfred Hospital (Sydney Local Health District)
St Vincent’s Institute of Medical Research
SA Pathology - a division of Central Adelaide Local Health Network, Inc.
Terumo BCT, Inc.
University of South Australia
University of Sydney
Women’s and Children’s Health Network Inc.
South Australian Health and Medical Research Institute (SAHMRI) Ltd

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glossary of terms
I hereby certify that the information provided to the Department of Industry by the CRC for Cell Therapy Manufacturing in:

- the written annual report for the 2014-15 financial year;
- the CRC’s online milestone tables for the 2014-15 financial year;
- the CRC’s online financial tables for the 2014-15 financial year;
- the CRC’s online MDQ for the 2014-15 financial year; and
- the four quarterly reports provided online for the 2014-15 financial year

is accurate and provides a true and fair view of the matters reported on therein.

I certify that the Commonwealth Funding and Participant Contributions were applied for the Activities of the CRC as specified in the Commonwealth Agreement and that Commonwealth Funding has been expended only for the Activities and otherwise in accordance with this Agreement.

I certify that the CRC has met its obligations in relation to the treatment of intellectual property.

I certify that the chair of the board meets the requirements of independence set out in the Commonwealth Agreement and that the majority of board members are independent of the CRC’s research providers.

I certify that the CRC has adhered to the requirements for proper use of the CRC Program indicia, publicity and support as specified in the Commonwealth Agreement.

I am aware that giving false or misleading information is a serious offence and could lead to prosecution under the Criminal Code 1995.

Dr. Sherry Kothari
CEO & Managing Director, CRC for Cell Therapy Manufacturing
29 October 2015
Chair’s report

Time goes quickly. It is hard to believe that CTM CRC has now completed its second – and again very successful – year! I noted in our first annual report that it was an exciting time to be entering the cell therapy field. This is even more so in 2015, with over 500 therapies in clinical development worldwide.

CTM CRC is positioned to address one of the most important challenges of this fledgling industry – how to make cell therapies cost effective and accessible to mainstream medicine.

Notwithstanding the clear industry recognition of this challenge, it has been surprising to learn that CTM CRC is one of the few organisations globally that is addressing this issue head-on.

This is generating great interest in the CRC, as well as opportunities to establish strategic alliances with a wide range of international leaders in the field, as well as a number of industry partners.

The CRC participant organisations and researchers have continued to cooperate very effectively. A highlight of the year has been the addition of Royal Prince Alfred Hospital (RPA), Sydney, as a new participant. RPA’s strong translational capability will be instrumental in accelerating clinical uptake of CRC technologies.

The CTM CRC Board has operated effectively and cohesively in its second year. I am delighted to welcome our new board member, Ray Wood, as a non-executive director. Ray’s many years of experience in cell therapy manufacture complements perfectly the expertise of the continuing board members. Ray founded Cell Therapies Pty Ltd, an essential participant in CTM CRC, and served as the company’s managing director for over 12 years. Under his tenure, Cell Therapies Pty Ltd developed into a leading manufacturer and distributor of cellular therapies in the Asia Pacific. I would also like to give my personal thanks to all the board members for their remarkable insight and contributions to the CRC.

Another pleasing development has been the appointment of Suzanne Ridding as an independent member of our newly established Audit and Risk Committee that is chaired by board member, Charlie Latham. Suzanne’s extensive experience in financial and risk management, audit, governance and sustainability will be increasingly important as the CRC progresses towards succession from Commonwealth funding.

The CTM CRC Board and Management have taken a highly strategic approach over the year, particularly regarding the following priorities:

- Consistent with the strong commercial focus of CTM CRC, the board is actively monitoring the progression of projects towards tangible outcomes, as well as the opportunities for intellectual property protection and relationships with commercial partners
- The filing of two new provisional patents as well as the accelerated development of a cell delivery device for the treatment of diabetic foot ulcers are two examples of the excellent progress. The pending completion of the NextCell manufacturing clean room facility for cGMP manufacture of cell therapies is another important milestone
- The opportunity to train research staff and students in business management and entrepreneurship is one of the key benefits of the CRC Programme. In this regard, it was very encouraging to see the roll-out of our entrepreneurial PhD program during the year as well as the delivery of training on intellectual property for all CRC staff
- Feedback from students undertaking the first, four-day ePhD module ‘Commercialising Biomedical Technologies’ has been extremely positive
- Even though CTM CRC has completed only two years of operations, the board and management are already developing strategies for succession from Commonwealth funding. This includes analysis of the key competitive advantages of the CRC against industry trends, identification of the most promising opportunities and any capability gaps, as well as the priority strategic partnerships to pursue

The coming year will be an important one for CTM CRC. By the end of our third year, we intend to identify and focus most resources on those projects with the highest probability of achieving commercial application within the short to medium term. Development of a clear strategy for succession from Commonwealth funding at the end of the CRC’s six-year term will also be well underway.

Dr Leanna Read
Chair, CRC for Cell Therapy Manufacturing
During 2015, the cell therapy industry continued on the substantial growth trajectory of the recent past. With an estimated $5bn in financings during the first half of 2015, a growth of 148% compared with the same time last year, the future looks bright for the industry. There are over 15 large pharmaceutical companies with an active interest in the cell therapy industry, and over 500 therapies in clinical development. This substantial investment is mirrored by an increase in the number of patients treated, which rose from 25,000 in 2008 to over 160,000 in 2012.

With a focus on exploring the regenerative and immunomodulation properties of particular cell types, cell therapies have the potential to provide new clinical treatment options for a wide range of medical indications. Despite the evident promise of cell therapies, challenges remain to their translation into the clinic, and as yet very few have have been manufactured at scale. Thus, to translate the technical promise of cell therapies into widespread clinical impact, there needs to be a focus on easier and more cost-effective manufacture and delivery.

Through the use of bespoke materials and functionalised surfaces, CTM CRC aims to develop improved cell isolation, expansion and delivery protocols that can be integrated into existing manufacturing platforms.

As is evident from its achievements to date, CTM CRC has had a very successful year. There has been a focus on developing solutions for specific industry needs and their subsequent integration into existing scale-up /scale-out processes. CTM CRC has also forged a number of important strategic alliances that will increase the CRC’s global footprint and ensure that it remains relevant and well connected with key cell therapy industry players.

Achievements

Awards
- Professor Tony Weiss- Federation of Asian and Oceanian Biochemists and Molecular Biologists Entrepreneurship Prize
- Professor John Rasko- Fellow of Australian Academy of Health and Medical Sciences
- Dr Alexander Gosling- Member of the Order of Australia
- Dr Sherry Kothari- Woman in Innovation and Technology award winner, Health & Science category
- Dr Leanna Read appointed as Chief Scientist for South Australia

Research & collaboration
- Royal Prince Alfred Hospital, Sydney, joined as a new participant
- Terumo BCT Quantum® cell expansion system installed and commissioned for commercial scale testing of cell therapies at the UniSA Mawson Lakes campus
- A novel process to expand therapeutic cells using hollow fibre bioreactor systems successfully developed
- Prototype devices to capture therapeutic cells and deliver them to wounds successfully developed
- A framework to ensure CTM CRC project activities are aligned with globally recognised therapeutic product development standards established
- A number of strategic international linkages established, including with the Centre for Commercialization of Regenerative Medicine (Canada), University College London (UCL) and the Cell Therapy Catapult (UK)
- A collaboration agreement with the Wound Management Innovation CRC executed

Commercialisation & utilisation
- CTM@CRC Ltd filed two new provisional patent applications
- NextCell manufacturing clean room facility fully staffed and ready to be commissioned for cGMP manufacture of cell therapies
- Commercial negotiations with end users in the areas of cancer immunotherapies and induced pluripotent stem cells on-going under non-disclosure agreements

Education
- First, four-day ePhD module delivered: ‘Commercialising Biomedical Technologies’
- Partnership established with the Playford Trust to sponsor two new PhD scholarships
- Full day training on intellectual property fundamentals delivered to staff and researchers across CTM CRC
- Four new PhD students and one honours student commenced

Communications
- ‘Affordable Cell Therapies: FACT OR FICTION?’ public engagement event held with industry, government and end user representatives, addressing the challenges of cell therapy manufacturing
- First edition of CTM CRC’s ImpaCT magazine published and distributed to external audiences

Dr Sherry Kothari - CEO & Managing Director
First year review
In response to recommendations from the Cooperative Research Centres Committee following the CTM CRC first year review:

- An audit and risk committee was established, with an independent external member
- CTM CRC instigated the Participant Listening Program to gather participant feedback annually
- Mr Ray Wood was appointed to the CTM CRC Board as a non-executive director. Mr Wood has more than 35 year’s experience in bringing Australian innovation and technology to market

Risks and impediments
The CTM CRC Audit & Risk Committee was established to assist the board in exercising due care, diligence and skill in discharging its oversight and monitoring responsibilities in relation to risk management, internal and external audit, financial statements and any other matter that the CTM CRC Ltd Board requests the committee to review.

The committee has developed and formalised a risk management framework, on which it reports at each committee meeting. The framework ensures that the following risks are measured, and that the appropriate risk mitigation strategies are developed:

- Financial management
- Projects and partner management
- Legal liability
- Information management
- Workplace health and safety (WHS)
- Procurement/contract management
- Human resource management
- Social/Political

At the research project level, all project leaders are required to identify risks at the beginning of the project and report quarterly on risk status and mitigation activities.

End-user environment
The cell therapy industry environment was very positive during the reporting period, especially in the area of T cell-based immunotherapy. A number of large pharmaceutical companies and venture capital funds invested heavily in smaller cell therapy companies. Total capital raised in the area of regenerative medicine more than doubled from $3bn in 2013 to $6.3bn in 2014.

Many countries and regions are establishing initiatives to ensure they remain competitive and to better address the challenges facing development of cell-based therapies.

Challenges include the high cost of manufacture, evolving regulatory framework, manufacturing and supply logistics.

The Cell Therapy Catapult and the Centre for Commercialization of Regenerative Medicine are examples of such initiatives in Europe and North America. CTM CRC has recently established strategic alliances with both centres in order to foster global collaborations across these continents.

The CTM CRC Board and its management team conduct regular strategic discussions to stay abreast of developments in the field. Furthermore, CTM CRC maintains links with key opinion leaders through its activities at national and international conferences and through sponsoring/hosting networking forums. This has led to a number of Australian and overseas organisations expressing an interest in collaborating with CTM CRC.

CTM CRC end-users comprise:

- Cell therapy companies with a proprietary cell or those targeting a specific clinical indication e.g. Athersys, Inc.
- Cell therapy tools companies, including those providing reagents and hardware e.g. Terumo BCT, Inc.
- Companies that specialise in scale-up, automation and large-scale manufacture e.g. GE Healthcare, Livetech
- SMEs that are positioned to exploit technological platforms e.g. Cell Therapies Pty Ltd
- Clinics, hospitals and patients

Impacts
CTM CRC introduced a change to its project management and oversight of research activities. Dr Tony Simula, in his role as R&D Program Manager, has embedded himself within project teams to provide development and commercialisation input. This change has led to significant progress in a short period.

Progress has been made towards the development of a delivery device for the treatment of diabetic foot ulcers. CTM CRC also lodged two new provisional patent applications during the reporting period. Protection of IP is critical to CTM CRC attracting commercial interest in its technologies and achieving its expected impact both on the global cell therapy industry and on the Australian cell therapy manufacturing industry. To that end, CTM CRC has set a goal of lodging at least one new patent application for each of its major development projects by the end of the third year of the CRC.

As a result, key milestones from years four and five of the CRC may be brought forward by as much as two years.

CTM CRC and Athersys, Inc., are in discussions about clinical entry, which would have a significant impact on the value of the technology to CTM CRC participants.

The inclusion of the RPA as a new participant has increased CTM CRC’s translational capabilities.

This will facilitate the transfer of therapeutic technologies developed by CTM CRC researchers into the clinic.

Furthermore, the collaborations CTM CRC has established with equivalent centres in Europe and North America will provide access to a network of cell therapy organisations that can be leveraged to facilitate the successful adoption of CTM CRC technologies within the global cell therapy industry.

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CTM CRC remains focused on its vision to develop innovative technologies and materials-based solutions to increase the accessibility, affordability and efficacy of cell-based therapies.

Owing to its continued progress and tangible outcomes over the last 12 months, CTM CRC is in a strong position to become a key contributor to the local and global cell therapy industries. 

Performance against activities

Two new projects commenced, increasing the total number of CTM CRC projects to nine. One project was completed, and all remaining projects are progressing well.

A quarterly regulatory review of all projects has been implemented to identify the regulatory and technical requirements for each project. The process aims to identify project risks and develop strategies to progress projects to clinical testing. The outcome will be a ‘roadmap’ for the manufacturing and clinical development of any CTM CRC therapeutic or device.

23 milestones were due for completion. All four milestones outstanding from the previous reporting period were completed, and 17 of the 19 milestones from this reporting period were also completed. The remaining in-progress milestones are expected to be completed in the next reporting period. One in-progress milestone relates to the publication of research outcomes. Research data publication was delayed to allow for provisional patent applications, data will be submitted for publication in the next reporting period. The other in-progress milestone was due to a delay in commissioning the NexCell cGMP facility, which will be completed in the next reporting period.

Research Program 1: Materials & Bioprocessing

Research Program 1 involves the development of new materials and surfaces to facilitate the cost-effective manufacture and delivery of therapeutic cells. Focusing on open and closed bioprocessing systems, the program is investigating platform technologies to improve the isolation, expansion and delivery of cells. The program’s key research includes the design and development of:

- New surface coatings for bioreactors to improve the expansion of cells
- Novel capture technologies to facilitate target cell isolation and expansion
- New biomaterials and advanced surface coatings to deliver cells to the site of injury, such as wounds
- Scaffolds for the co-culture and delivery of combinations of therapeutic cells

Activities in Research Program 1

Improving cell yields from hollow fibre bioreactor systems

Cell expansion is a major cost in the manufacture of a cell therapy and can be an impediment to successful clinical translation. By investigating multiple techniques to modify bioreactor surfaces, CTM CRC researchers have successfully developed an improved process for expanding therapeutic cells. 

The process is adaptable to multiple cell types and bioreactor systems and has the potential to reduce the cost of goods for cell therapies. The project’s lead industry participant has installed equipment at CTM CRC’s research facility to facilitate integration of the new process into existing production infrastructure.

Expansion surfaces for human regulatory T cells and endothelial progenitor cells

Human regulatory T cells (Tregs) and endothelial progenitor cells (EPCs) have the potential to be used as adjunct therapies in organ and cell transplantation. However, significant challenges remain in using these cell types clinically. Target cells need to be isolated from an individual patient for autologous use. Following isolation, cells must be expanded significantly over a short period of time, often starting from low numbers.

By combining novel manufacturing techniques, surface optimisation and high-throughput screening, CTM CRC researchers have developed prototype materials that induce the rapid expansion of T cells such as Tregs and killer T cells. These materials have the potential to reduce the cost of manufacture of T cell-based therapies and can be scaled in a variety of bioreactor platforms. High-throughput screening techniques have also been used to identify a number of key bioactive molecules with the potential to selectively expand therapeutic cells. Future work will focus on developing functionalised surfaces with the potential for either selective isolation or targeted capture of these cells for rapid revascularisation of implants.

Engineer of a cell delivery device for the treatment of wounds

Chronic wounds are a significant burden on healthcare costs due to an ageing population. During the reporting period, CTM CRC researchers successfully developed prototype devices to capture therapeutic cells and deliver them to wounds. Rapid progress on the project has resulted in a provisional patent application being filed in early 2015.

In collaboration with the project’s commercial participant, CTM CRC researchers are further developing the product concept to ensure smooth transition to the clinic. This includes the evaluation of the safety and efficacy of the device in preclinical studies within Research Program 2.

Scaffolds for the transport and delivery of human islets to treat diabetes

The number of cases of Type 1 diabetes in Australia is expected to double over the next 20 years. Donor islet transplantation is a promising treatment and a potential cure for sufferers of diabetes. Existing methods for isolating islets from pancreatic tissue yield low numbers of viable islets. CTM CRC researchers are developing novel devices that aim to maximise islet survival during the critical 24-hour period following isolation.

Prototype transport devices with features that allow for the greatest proportion of islets to retain their function of producing insulin after transplantation are currently under investigation. The knowledge gained from these studies will inform the development of more advanced transplant devices.

Development of a T cell-based immunotherapy

A four-month pilot study was undertaken to investigate a novel cancer treatment, which is the subject of a provisional patent application held by CTM CRC. The basis of the new treatment is a chimeric antigen receptor T cell directed against a specific cancer target.

The project was completed during the reporting period, with encouraging results. On the basis of these results, CTM CRC is exploring further funding opportunities to continue development of the technology and commercial transfer.
Research Program 2: Clinical Translation

This program is focused on further development and clinical translation of technologies from Research Program 1 and include:

- Preclinical safety and efficacy studies to generate data packages for entry into human clinical trials
- Establishment of a cGMP facility for manufacturing cell therapies for human clinical testing
- Consistency with therapeutic regulatory requirements for product/technology developed in Research Program 1
- Manufacture of investigational clinical material to cGMP standards
- Initiation of two Phase I human clinical trials

Activities in Research Program 2

Generation of preclinical data

Conducting preclinical trials using appropriate models of disease is essential in developing a cell therapy. These trials generate the data necessary to demonstrate the safety and efficacy of a product prior to its approval for use in humans.

CTM CRC researchers are developing two animal models for preclinical testing. The first is to test cell delivery devices for the treatment of chronic wounds. Significant progress has been made with prototype wound patches, the data set is now being generated for a Phase I clinical trial. The second is to establish a model that replicates the human immune system, to investigate its response to foreign materials such as cells and devices.

Establishment of a cGMP manufacturing capability

A facility for process development and manufacture of cell therapies for human clinical trials is critical for the rapid translation of CTM CRC research. To ensure access to an appropriate facility, CTM CRC participant NextCell Pty Ltd is establishing a cGMP manufacturing facility. Commissioning of the facility has commenced and is expected to be completed in the first quarter of the next reporting period.

Isolated human islets

The facility is also available to CTM CRC researchers for non-cGMP activities, to assist with their translation into the cGMP facility. All staff required to manage the commissioning have been appointed. The NextCell Pty Ltd team has also integrated Cell Therapies Pty Ltd’s quality management system into the facility, which is approved by all major regulatory agencies.

Alignment of projects with regulatory requirements

CTM CRC has instigated a regulatory review program to provide guidance to researchers on therapeutic product development. Projects are reviewed on a quarterly basis to identify and plan for relevant regulatory requirements. Staff from NextCell Pty Ltd and Cell Therapies Pty Ltd, who are experienced in dealing with regulatory agencies in all major jurisdictions, are closely involved in the review program. NextCell Pty Ltd staff also provide CTM CRC researchers with technical support and resources.

A knowledge management system has also been implemented to manage CTM CRC project data. All electronic files and data related to CTM CRC projects are centralised in a secure electronic storage facility, which is backed up daily.

Dr Giles Kirby - CTM CRC researcher
education & training

CTM CRC’s education and training program aims to advance the emerging cell therapy industry in Australia by cultivating a workforce with the necessary skills.

**ePhD Program**

Through CTM CRC’s flagship ‘entrepreneurial PhD (ePhD) Program’, graduates are equipped with skills that will allow them to pursue a broad range of careers in the biomedical sector.

The training focuses on creating an industry-ready workforce possessing valuable transferrable skills, an understanding of research translation and commercialisation, and an entrepreneurial mindset.

Activities consist of four, in-residence sessions at CTM CRC, each two- to four-days in length, and a capstone project or industry placement in the final year. Students are also included in other professional and social opportunities presented by the CRC to increase face-to-face engagement, enhance linkages to CRC participants, and develop networks of professional contacts.

The CRC anticipates educating twenty PhD students through the ePhD Program. Students are provided with research opportunities, and supported through a top-up stipend and project operating funds. To date, CTM CRC has awarded eleven PhD scholarships and one honours scholarship, and officially launched the ePhD Program with the delivery of its first training module.

**Student engagement**

During the reporting period, four new PhD students joined CTM CRC. As a result, CTM CRC has surpassed its student engagement Commonwealth milestones for the reporting period.

Two new PhD opportunities for students commencing in 2015 were created as a result of generous support received from the Playford Memorial Trust. CTM CRC/Playford Trust PhD scholarships are awarded to high-achieving scholars who are committed to using their skills and research for the future development of industry in South Australia. Ms Hannah Thomas and Mr Sebastian Stead were the 2015 recipients, and were formally recognised at an awards ceremony on 29 April 2015.

To further facilitate recruitment into the ePhD Program, CTM CRC introduced honours stipends. Attracting the best honours students provides a pathway to undertaking further research and study with CTM CRC. One student was awarded CTM CRC’s first honours stipend during the reporting period.

In addition to CTM CRC’s PhD and honours students, CRC researchers also recruited and supervised a number of visiting scientists from Australia and abroad conducting research as part of their bachelor’s and masters degrees. During the reporting period, five students from Australia, France and Brazil joined the CRC on internships ranging from several weeks to six months.

**Events**

**Commercialising Biomedical Technologies**

The ePhD Program was created by CTM CRC to generate an industry-ready workforce through industry-relevant education modules embedded in traditional doctoral research.

The first of the four ePhD Program modules entitled ‘Commercialising Biomedical Technologies’ was held on 14-17 April 2015 in Adelaide.

The four-day program exposed students to the process of biomedical technology discovery, development and path to market.

Creating and launching a new venture and exploring career opportunities in the biotechnology and pharmaceutical sectors were also addressed. The course was delivered by topic experts, comprising CTM CRC staff and guest speakers from the biotech community. To maximise student engagement and participation, it was delivered through a combination of lectures, case studies and workshop exercises.

**ImpaCT Day**

CTM CRC’s annual ImpaCT Day was held on 30 October 2014 and brought together students from Adelaide, Sydney and Brisbane for the first time. Students were asked to deliver a three-minute presentation tailored to a non-specialist audience, modelled on the 3-Minute Thesis to hone communication skills. Six PhD students presented, and Mr Lewis Martin and Ms Kristen Malatesta were recognised for the best student presentations.

A half-day tour of Mayne Pharma, a specialty pharmaceutical company based in Adelaide that develops and manufactures branded and generic pharmaceuticals, provided valuable context to the module. Students attended a tour of the production facilities and participated in discussions on drug versus biologic manufacturing practices.

Nine PhD students participated and each received a certificate of completion for the module.

More detail about CTM CRC’s ImpaCT Day on page 26.
Industry development
Bridging the gap between industry and researchers is an important facet of the education program.
CTM CRC has identified strategic areas where CRC staff would benefit from professional development and anticipates presenting workshops and seminars on an as needs basis to improve research outcomes.
In June 2015, CTM CRC conducted its first staff development workshop for all CRC researchers on the topic of intellectual property. The one-day training program was delivered by CTM CRC’s General Manager, Dr Justin Coombs, who is an experienced patent and trademarks attorney. Staff were educated on the fundamentals of intellectual property, with an emphasis on patents, and were provided with valuable insights into CTM CRC’s commercialisation strategies. Twelve researchers attended, including project leaders.
CTM CRC intends to expand its training programs to academic and industry professionals from related biomedical and manufacturing facilities. These initiatives will focus on transferring the specialised knowledge and skills required for the commercial success and viability of cell therapies, in particular cGMP manufacture and regulatory challenges. Collectively, the ePhD Program and industry training program will foster the commercialisation and growth of Australia’s expanding biomedical and cell therapy industries.

External engagement
The education program regularly communicates with a wider audience through events and community engagement. CTM CRC’s Education Program Manager, Dr Monica Kerr specialises in career and professional development of PhD students and scientists.
During the reporting period, she spoke to local high school students about CTM CRC and cell therapies as part of an outreach event hosted by CRC CARE. She also spoke to a group of young women as part of a STEM mentoring program sponsored by South Australia’s Department of State Development. She delivered a further presentation ‘Developing entrepreneurial research students’ at the forum Entrepreneurial Ecosystems: Great Places to Create Business, hosted by the University of Adelaide on 3 February 2015. Dr Kerr was invited by the Chief Scientist of South Australia to join the STEM Expert Network, established in conjunction with the South Australian Science Council to provide input into the council’s policy recommendations in the important area of STEM education.

These external engagements increase the visibility of CTM CRC, and help promote pathways and career opportunities in the biomedical and STEM job sectors, particularly where they interface with industry.

Student awards
Malatesta K - Robinson Research Institute Travel Grant
Australasian Society for Immunology 2015, Canberra
Tan L - Best Presentation Award
University of South Australia 3rd Bi-Annual School of Pharmacy and Medical Sciences Symposium

New PhD & honours students

<table>
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<tr>
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<th>thesis title</th>
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<td>Kay Rhine Myo Min</td>
<td>2 - Clinical Translation</td>
<td>Honours</td>
<td>UniSA</td>
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<td>Desmoglein-2 and its role in pancreatic islet and endothelial cell cross-talk</td>
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<td>Development of an additive manufacturing technology platform based on melt electrospinning</td>
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<td>Sebastian Stead</td>
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<td>Dendritic cell target therapy utilising porous silicon nanoparticles</td>
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<td>Hannah Thomas</td>
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<td>Flightless I regulation of pericyte function in wound healing and tissue regeneration</td>
<td>2018/19</td>
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<td>Gink Yang</td>
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<td>Aus</td>
<td>Development of a novel stem cell based therapy for patients with Epidermolysis Bullosa</td>
<td>2018/19</td>
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Continuing students

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<td>Matti Hiob</td>
<td>1 - Materials &amp; Bioprocessing</td>
<td>PhD</td>
<td>Sydney</td>
<td>Aus</td>
<td>Hollow fibre reactor systems</td>
<td>2015/16</td>
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<td>Kristen Malatesta</td>
<td>1 - Materials &amp; Bioprocessing</td>
<td>PhD</td>
<td>Adel</td>
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<td>The functional Role of microRNA in human regulatory T cell subsets</td>
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<td>Adel Dallottojar</td>
<td>1 - Materials &amp; Bioprocessing</td>
<td>PhD</td>
<td>UniSA</td>
<td>Aus</td>
<td>Using high throughput screening to design cell therapy scaffolds</td>
<td>2017/18</td>
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<td>Lewis Martin</td>
<td>1 - Materials &amp; Bioprocessing</td>
<td>PhD</td>
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<td>Aus</td>
<td>Computer simulations of therapeutic peptides for immobilisation on plasma-activated surfaces</td>
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<td>Hanieh Shirazi</td>
<td>1 - Materials &amp; Bioprocessing</td>
<td>PhD</td>
<td>UniSA</td>
<td>Aus</td>
<td>Development of novel plasma polymer surfaces for adhesion, proliferation and harvesting of stem cells</td>
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<td>1 - Materials &amp; Bioprocessing</td>
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<td>UniSA</td>
<td>Aus</td>
<td>Vasculogenic mimicry: regulation and function in melanoma</td>
<td>2017/18</td>
</tr>
<tr>
<td>Emma Thompson</td>
<td>1 - Materials &amp; Bioprocessing</td>
<td>PhD</td>
<td>UniSA</td>
<td>Aus</td>
<td>The potential role of interleukin-3 (IL-3) in blood vessel development in breast cancer</td>
<td>2017/18</td>
</tr>
</tbody>
</table>
CTM CRC has a strong focus on the translation and commercialisation of its research. Meaningful SME engagement fulfills an important role in this process. For example:

- Every CTM CRC research project, where possible, is informed and guided by an industry participant. This ensures that industry end users are intimately involved with projects, and that projects produce outputs that address end user needs.
- SMEs are engaged early in a project to ensure CTM CRC and SMEs jointly create appropriate pathways to utilisation.
- End-user needs are addressed by CTM CRC to ensure SMEs remain interested. By proactively engaging SMEs in research, we assist them in building capacity for innovation, generating value and creating jobs.

SME participants are invited to participate in CTM CRC-wide activities such as the ePhD program. This ensures SME workforce needs are addressed through CRC education and training packages.

CTM CRC has engaged directly with four Australian SMEs through its research activities. Two of these SMEs, Cell Therapies Pty. Ltd. and NextCell Pty. Ltd., are actively engaged in the development of CTM CRC’s cGMP manufacturing facility.

As part of this development, they are providing regulatory and manufacturing training, as well as project-specific advice on product development to CTM CRC researchers.

CTM CRC also has an overseas SME participant, Athersys, Inc., which is instrumental in the commercial development of two CTM CRC projects.

CTM CRC maintains active engagement with all its SME and industry participants through regular project meetings, CRC ImpaCT Days and internal communication channels such as Participant Committee meetings.
Utilisation and commercialisation

Utilisation and commercialisation

Two utilisation milestones due for completion related to patent application filings:

- Patent filed: Coating for hollow fibres; and
- Patent submitted: Delivery of MSCs to wounds.

Both of these milestones were successfully completed with the filing of Australian provisional patent applications, as detailed in the registered intellectual property table.

In order to ascertain the potential novelty and inventive step of the subject technologies as soon as possible, International Type Searches under Article 15(5) of the Patent Cooperation Treaty have been requested in respect of each application.

Each of the patent applications noted above already has a commercialisation pathway in place with a defined industry utilisation partner.

One patent application is subject to the conditions of an IP transfer agreement with industry participant, Terumo BCT. This agreement will see the patent application assigned to Terumo BCT in return for a future royalty stream on sale of patent protected product by Terumo BCT.

For a second patent application, Athersys, Inc., has already been appointed as a provisional utilisation party for the subject technology. A formal commercial IP transfer agreement on this technology is expected to be finalised during the next reporting period.

Intellectual property management

CTM CRC has a strong focus on generating impact from its research activities and, as such, the protection and commercialisation of IP is critical.

CTM CRC’s general manager is a registered patent attorney with substantial experience in bioscience commercialisation. This allows CTM CRC to take a strategic approach to how IP is protected and transacted.

CTM CRC’s business model has been carefully structured from its inception to facilitate the exploitation of technology developed through its research programs, and centres around promoting the transaction of CTM CRC project IP into the hands of end users.

The legal framework for handling IP within the CRC remains unchanged from the previous reporting period, and has been structured to optimise the transaction of IP to the end-user and maximise the end-user benefit of CTM CRC research. In particular:

- All CTM CRC participants have agreed to assign CTM CRC project IP to the CRC management company, CTM@CRC Ltd.
- CTM CRC appoints a Utilisation Party (likely to be an industry participant) at the outset of each project.
- Transaction of project IP to each Utilisation Party is formalised via a Utilisation Plan, which sets out the terms and conditions for IP transaction, exploitation and returns.
- Background IP (BIP) is licensed from the IP holder solely for use in the project. If the BIP is subsequently needed for a commercial transaction, there will be a further negotiation between the Utilisation Party and the owner of the BIP.

IP identification and capture

A strategy is in place for the rapid identification of IP emerging from CTM CRC projects.

CTM CRC’s general manager and research & development manager each maintain regular contact with project teams for briefings on research outputs.

CTM CRC’s capture and exploitation of project IP is intended to provide benefit to Australia, particularly to provide new medical technologies to Australian patients (Principle 2(b)).

Ownership of all IP generated through CTM CRC collaborative projects will vest in CTM@CRC Ltd, and these ownership arrangements have been agreed to by all CRC participants in the Participant Agreements (Principle 2(c)).

CTM CRC has a clear policy position regarding the exploitation of CTM CRC project IP (Principle 2(d)).

The operational aspects of CTM CRC’s IP policy address Principles 2(e) and 2(f), specifically:

- CTM CRC’s IP policies are reflected in and disseminated to staff through the CRC’s Intellectual Property, Confidentiality and Disclosure policy.

This allows for the rapid identification of potential IP as it is generated. A substantial benefit of this strategy is that it shifts the responsibility for IP identification to management personnel who have substantial industry experience in IP identification, protection and commercialisation.

Publication guidelines also require CTM CRC researchers to submit any project-related publication to management for review prior to publication. This provides an independent secondary mechanism to identify and capture CTM CRC IP prior to any public disclosure.

National principles of intellectual property management for publicly funded research

CTM CRC’s IP management strategy has been developed and implemented in accordance with the National Principles of Intellectual Property Management for Publicly Funded Research.

With particular reference to these principles:

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Publication guidelines also require CTM CRC researchers to submit any project-related publication to management for review prior to publication. This provides an independent secondary mechanism to identify and capture CTM CRC IP prior to any public disclosure.
- CTM CRC also has specific policies in place relating to the retention of project data. These policies are documented and disseminated to researchers in the CRC’s Good Scientific Practice policy and Use of CTM CRC Lab Books policy.

- CTM CRC researchers have access to the management team for a broad range of IP and commercialisation advice.

- All individual CTM CRC researchers and students are required to personally execute a Deed Poll that, among other things, confirms CTM@CRC Ltd ownership of IP generated in CRC funded projects.

- CTM CRC’s Participants’ Agreements clearly define the basis for how any commercial returns would be divided among CRC participants.

- The agreements also include provisions to enable academic publication of CTM CRC research in a way that is compatible with protection of CRC project IP.

**Professional advisors**

To assist with its commercialisation and utilisation activities during the reporting period, CTM CRC retained the services of a range of professional advisors including: Phillips Ormonde Fitzpatrick for intellectual property as well as FAL Lawyers and Roach Corporate Law for commercial legal matters.

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### Registered intellectual property rights held by CTM@CRC Ltd. at 30 June 2015

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<td>provisional application</td>
<td>19/02/2015</td>
</tr>
</tbody>
</table>
marketing & communications

CTM CRC’s integrated marketing and communications strategy provides the framework for communicating the CRC’s objectives, activities, achievements and success to internal and external audiences.

During the reporting period, CTM CRC focused on two key areas: raising the external profile of research and education activities, and increasing communication and collaboration within the CRC. To achieve the desired results in these areas, CTM CRC conducted a number of internal and external engagement activities throughout the year. These included:

- Publishing the first edition of the CTM CRC ImpaCT magazine
- Hosting the inaugural ImpaCT Day
- Launching the CTM CRC ‘Participant Listening Program’
- Hosting public access and industry events
- Reviewing the CTM CRC website and social media strategy

Internal communications

During the reporting period, CTM CRC’s internal communications activities focused on encouraging and supporting collaboration amongst CTM CRC participants, including researchers and students. Strengthening the sense of community throughout the CRC was also a priority.

Internal stakeholders were engaged via communications, publications and activities that included ImpaCT Days, the Participant Listening Program, the ePhD Program, Participants Committee meetings, research project management meetings, email campaigns and quarterly reporting.

External communications

External communications activities for the reporting period included the CTM CRC ImpaCT magazine, media releases, radio broadcasts, brochures and associated marketing publications, networking events, public lectures, conference presentations, sponsorship and the CTM CRC website and social media.

CTM CRC’s first ImpaCT Day on 30 October 2014 included presentations by researchers and students, as well as general discussions about project highlights and challenges to promote information sharing.

ImpaCT Day

CTM CRC introduced its ImpaCT Day series during the reporting period. ImpaCT Days engage all CTM CRC participants and the management team in a full-day interactive forum.

Participant Listening Program

The Participant Listening Program was developed in response to a recommendation following the CTM CRC first year review. The aim of the program is to gather feedback from participants about their experiences in the CRC, and to solicit suggestions for improvement.

The Participant Listening Program commenced during the reporting period with interviews and surveys of CTM CRC’s participants. The feedback provided by participants is being used by CTM CRC management to identify and address highlighted issues.

Affordable Cell Therapies – FACT or FICTION? event

During the reporting period CTM CRC held its first large-scale external event – ‘Affordable Cell Therapies - FACT or FICTION?’ The event was held at the South Australian Health and Medical Research Institute (SAHMRI) and attracted over 100 people, including the public, national industry, government and academic representatives.

Opened by the Hon Jack Snelling, Minister for Health and Health Industries, the event included a keynote presentation by Dr Chockalingam Palaniappan, Senior Vice President at Terumo BCT. A panel discussion followed, chaired by Professor Ian Olver, CEO of the Cancer Council Australia, to address the issue of the affordability of cell therapies.

Website and social media

Website and social media are an integral part of CTM CRC’s internal and external communications strategies. The website, located at www.ctmcrc.com, hosts details about CTM CRC research and education programs, participants, news, events and publications. It serves as an up-to-date portal of information for CTM CRC and its stakeholders.

CTM CRC also has social media accounts with Facebook, Twitter and LinkedIn. Social media is used by the CRC to distribute news and achievements from CTM CRC and the cell therapy industry, as well as promote the CRC’s programs, researchers and students. Social media aids in unifying and strengthening CTM CRC’s online message and drives traffic to the website.

Social media following

<table>
<thead>
<tr>
<th>Platform</th>
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</tr>
</thead>
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<tr>
<td>LinkedIn</td>
<td>168</td>
<td>~ 133.3</td>
</tr>
<tr>
<td>Twitter</td>
<td>119</td>
<td>~ 164.4</td>
</tr>
<tr>
<td>Facebook</td>
<td>51</td>
<td>~ 142.9</td>
</tr>
</tbody>
</table>
Measurement of activity effectiveness

CTM CRC uses measurement mechanisms such as the Participant Listening Program, social media monitoring, website engagement statistics and direct feedback to determine the effectiveness of its communications strategies and to inform the development of future strategies.

Event highlights

30 October, 2014 – ‘Affordable Cell Therapies – FACT OR FICTION?’
South Australian Health and Medical Research Institute, Adelaide

30 October, 2014 – ‘CTM CRC ImpaCT Day’
South Australian Health and Medical Research Institute, Adelaide

14 – 17 April, 2015 – ‘ePhD Module 1: Commercialising Biomedical Technologies’
University of South Australia, City West Campus
Mayne Pharma (Tour)

16 April, 2015 – ‘CTM CRC Chill Out’
Jack Ruby, Adelaide

University of South Australia, City West Campus

Sponsorship

Washington, DC

20 – 22 May, 2015 – World Stem Cell and Regenerative Medicine Congress 2015
Business Design Center, London

27 – 30 May, 2015 – ISCT 2015 Annual Meeting
Caesar’s Palace, Las Vegas

Media releases & PR

12 August, 2014 – ‘Royal Prince Alfred Hospital joins Adelaide’s cell manufacturing CRC’
The Advertiser Business Journal, Adelaide
adelaidenow.com.au

12 August, 2014 – ‘CRC for Cell Therapy Manufacturing adds to its expertise with world-renowned RPA’
CTM CRC media release

29 September, 2014 – ‘CTM CRC launches new Entrepreneurial PhD Program’
CTM CRC media release

October, 2014 – ‘CRC for Cell Therapy Manufacturing – driving the CT industry in Australia’
Australasian Biotechnology Journal, Volume 24, No.3

30 October, 2014 – ‘South Australia’s growing cell therapy sector marks major milestone’
Government of South Australia - Minister for Health & Health Industries media release

4 November, 2014 – ‘CTM CRC offering entrepreneurial scholarships to boost business savvy’
The Advertiser Business Journal, Adelaide
adelaidenow.com.au

4 November, 2014 – ‘Terumo BCT inks deal with cooperative research centre at Mawson Lakes’
The Advertiser Business Journal, Adelaide
adelaidenow.com.au

December, 2014 – ‘Cell building – the biotech path’
CRCA Know How magazine

13 March, 2015 – ‘Wound CRC and Cell Therapy Manufacturing CRC collaborate to transform wound outcomes’
Wound Management Innovation CRC media release

20 March, 2015 – ‘International regenerative medicine groups form strategic alliance to commercialise cell therapies’
CTM CRC media release

26 March, 2015 – ‘International regenerative medicine groups form alliance’
bioindustryfocus.ca

1 April, 2015 – ‘CRC chat with Tony Peacock and Sherry Kothari’
666ABCCanberra (radio interview)

23 April, 2015 – ‘Cell Therapy Manufacturing Cooperative Research Centre links research and industry’
The Lead South Australia

Dr Chockalingam Palaniappan - Terumo BCT
Presentation at CTM CRC's Affordable Cell Therapies - FACT OR FICTION? event
governance

Board, committees and key staff
CTM CRC was formed in July 2013 through the Australian Government’s CRC program, which supports end-user driven research collaborations to address major challenges facing Australia. It will receive $20M from the Commonwealth Government over six years, commencing in July 2013.

Structure
A not-for-profit company limited by guarantee, CTM@CRC Ltd, was established to manage and govern CTM CRC, and to oversee all of its activities. The company has tax-exempt status, and endorsement from the ACNC and ATO as a health promotion charity. The company operates a lean management structure to maximise its spend on research activities, and has overall responsibility for the delivery of the agreed research outputs, utilisation and impacts of the CRC.

Participants of CTM CRC include companies in the cell therapy industry, research institutions, universities and hospitals. The involvement of these organisations in the CRC is governed by an Essential Participants’ Agreement between CTM@CRC Ltd and the Essential Participants, and Other Participant’s Agreements between CTM@CRC Ltd and each of the Other Participants.

CTM CRC Board
CTM@CRC Ltd is governed by an independent, skills-based board of directors. The primary responsibility of the CRC’s board of directors is to provide high-level governance for the CRC, financial accountability and oversight of compliance with Commonwealth and other appropriate laws and regulations. In addition to monitoring CTM CRC performance, the board plays an important role in the approval and regular review of CTM CRC funded projects to ensure that all CTM CRC research is aligned with its objectives. The board maintains oversight of CTM CRC finances to ensure compliance with ASIC/ACNC regulations and to ensure that funds are expended appropriately.

The Board has a minimum of three directors, including the managing director. The chair and directors are each appointed for a period of three years. Both the chair and directors can be re-elected by a special majority vote (75%) of members. Essential Participants of CTM CRC may apply to be members of CTM@CRC Ltd, and are entitled to vote at company general meetings.

Mr Ray Wood was elected as a non-executive director at the CTM@CRC Ltd AGM on 26 November 2014 by a majority vote of members.

Board members
Leanna Read PhD, FAICD, FTSE
Dr Leanna Read has broad-ranging executive, board and investment experience in technology-based enterprises, particularly biotechnology.

Dr Read has extensive experience in the CRC sector, including previous roles as CEO of the CRC for Tissue Growth and Repair, and a board member of two other CRCs. She currently holds the position of Chief Scientist for South Australia and is a member of boards that address innovation across the government, industry and academic sectors. These include the South Australian Economic Development Board, the South Australian Science Council, the University of South Australia Council, and the board of biotechnology company Biosensis Pty Ltd.

In 2001, Dr Read founded the successful biotechnology company, TGR BioSciences Pty Ltd (a CRC spinout), and served as the company’s Managing Director and CEO until 2012. Past roles have also included membership of

boards such as the Prime Minister’s Science, Engineering and Innovation Council, the Federal Government’s IR&D Board, the Commercialisation Australia Board, and the board of the Australian Academy of Technological Sciences and Engineering.

She is a fellow of the Australian Institute of Company Directors and of the Australian Academy of Technological Sciences and Engineering. Dr Read has been the recipient of a number of prestigious local and national awards.

Sherry Kothari PhD, MBA
Dr Sherry Kothari has extensive experience working within bioscience across research, industry and academia.

Dr Kothari started her career in maxillofacial surgery, before undertaking a PhD at the University of Sheffield on healing at the bone-implant interface. After lecturing in medical materials and tissue engineering at the University of Manchester, Dr Kothari undertook an MBA, to build on her passion for entrepreneurship and translation within the biotechnology sector. She has been a founder investor in two successful university life sciences spin-out companies, Dr Kothari has since played a significant role in introducing an entrepreneurial culture within science and engineering in higher education and helped mentor and fund early start-up ventures. Dr Kothari has been on the Board of SIFE (Students in Free Enterprise), raising the capacity for invention, innovation, commercialisation, technology acquisition and new business growth.

Dr Kothari moved to Australia in 2007. Based at the University of South Australia, she established partnerships across Australia, Asia and Europe. In 2011, she took over as program leader for one of three research programs of the Wound Management Innovation CRC, before taking on her current role as CEO and Managing Director of CTM CRC.

Stephen Livesey MBBS, PhD
Dr Stephen Livesey has a career spanning medicine, medical research and commercialisation.

After graduating from his medical and postdoctoral studies at the University of Melbourne in 1985, he has held a number of positions in Australia and the US. In 1996, Dr Livesey co-founded LifeCell Corporation in the US, through a technology transfer from the University of Texas. The company was established to commercialise a cell and tissue preservation technology, which he invented (now marketed as AlloDerm™).

Following a period in Australia as a Welcome Trust Senior Research Fellow, Dr Livesey returned to the US to become Executive Vice President and Chief Science Officer of LifeCell. He was the lead scientist in securing additional funding for LifeCell, including venture capital, an initial public offering on the NASDAQ, private placements, follow-on offerings and public offerings, totaling approximately US$78m. AlloDerm has been used in more than two million surgical procedures with more than 600 peer-reviewed publications on its clinical and research use. In 2007, LifeCell Corporation was acquired by Kinetic Concepts International (NYSE:KCI) for US$1.7bn.

In 2003, Dr Livesey returned to Australia and joined the Australian Stem Cell Centre, where he served as the Chief Scientific Officer and CEO. He maintains an active
Mr Charlie Latham has strong professional and government links in South Australia, and extensive networks within the Australian bioscience industry.

Ray Wood FACD

Mr Ray Wood has more than 35 years’ experience in developing and deploying Australian innovation and technology into global markets.

Mr Wood holds a BSc(Tech) Electronic Engineering. His experience ranges from the continuous flow pathology analysers of the early 1970’s and the first automated haematology counters, through to the development and marketing of diagnostic ultrasound machines, and, more recently, delivering professional consulting services and creating biotechnology spin outs.

Mr Wood has held roles within a range of organisations, including Plessy Telecommunications, Technicon Inc, Aulonics, PA Technology, Invetech and X-ray Technologies. He has significant experience in the integration of the code of cGMP, regulatory oversight and regenerative medicine.

Mr Wood has held a number of board positions, including non-executive director of Cell Therapies Pty Ltd, director of the Victorian Clean Technology Fund and director and principal of Inedics Pty Ltd. He is a Fellow of the Australian Institute of Company Directors and the Director of the Institute of Engineers Australia (ret).

Board meetings & attendance

Board meetings were held in September, October, November, February and June. Attendances are documented in the following table:

<table>
<thead>
<tr>
<th>number of board meetings eligible to attend</th>
<th>number of meetings attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Leanne Read</td>
<td>5</td>
</tr>
<tr>
<td>Dr Sherry Kothari</td>
<td>5</td>
</tr>
<tr>
<td>Mr Charlie Latham</td>
<td>5</td>
</tr>
<tr>
<td>Dr Alexander Gosling</td>
<td>5</td>
</tr>
<tr>
<td>Dr Stephen Livesey</td>
<td>5</td>
</tr>
<tr>
<td>Mr Ray Wood</td>
<td>2</td>
</tr>
</tbody>
</table>

At the AGM on 26/11/14, Mr Ray Wood was elected as a non-executive director of the board.

Audit and Risk Committee

During the reporting period, an audit and risk committee was established in response to a recommendation following the CTM CRG first year review.

The primary function of the committee is to assist the board in exercising due care, diligence and skill in discharging its oversight and monitoring responsibilities in relation to risk management, internal and external audit, financial statements and any other matter that the CTM@CRG Ltd Board requests the committee to review.

The committee meets at least four times per year, and has a number of responsibilities, including:

- Providing open lines of communication between CTM@CRG Ltd external auditors and the board
- Overseeing processes that identify and assess general business risk, reviewing the outcomes of programmed risk assessments, and advising the board as necessary
- Reviewing the adequacy of CTM@CRG Ltd internal control systems with management and the external auditors
- Reviewing any significant risks, findings and recommendations made by external or internal auditors, together with management’s responses to them

Audit and Risk Committee members

<table>
<thead>
<tr>
<th>name</th>
<th>role</th>
<th>independent/organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr Charlie Latham</td>
<td>chair CTM@CRG Ltd</td>
<td>independent</td>
</tr>
<tr>
<td>Dr Ray Wood</td>
<td>member CTM@CRG Ltd</td>
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<tr>
<td>Ms Suzanne Riddings</td>
<td>member CTM@CRG Ltd</td>
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</table>

Suzanne Riddings MBA

Ms Suzanne Riddings is the external representative on the CTM@CRG Ltd Audit and Risk Committee. Ms Riddings is an experienced executive, sustainability consultant, banker, board director and company secretary. She has held leadership positions in private, public and not-for-profit sector organisations, internationally and in Australia. Ms Riddings has also managed her own successful sustainability consultancy business since 2008 specialising in organisation sustainability, in particular carbon management and climate change adaptation.

Ms Riddings key skills and experience include strategy and policy development, extensive risk management, corporate governance, financial management and sustainability.

<table>
<thead>
<tr>
<th>Board member key skills</th>
</tr>
</thead>
<tbody>
<tr>
<td>name</td>
</tr>
<tr>
<td>Dr Leanne Read</td>
</tr>
<tr>
<td>Dr Sherry Kothari</td>
</tr>
<tr>
<td>Mr Charlie Latham</td>
</tr>
<tr>
<td>Dr Alexander Gosling</td>
</tr>
<tr>
<td>Dr Stephen Livesey</td>
</tr>
<tr>
<td>Mr Ray Wood</td>
</tr>
</tbody>
</table>

research interest in matrix-based research for spinal cord injuries, bone marrow transplantation and cartilage repair at St Vincent’s Hospital, Melbourne.

Alexander Gosling AM, DEng, FTSE, FIEAust

Dr Alexander Gosling has been working in the field of process and product development for 40 years.

Dr Gosling holds a Masters in Engineering from the University of Cambridge and an honorary doctorate from Swinburne University of Technology. As a founding director of Invetech, an engineering and process development consultancy, he has serviced clients ranging from high tech start-ups to ‘smoke-stack industry’ global companies. He was part of the management team that led Invetech firstly to a public listing (as Vision Systems Ltd), and then to its acquisition by the US Danaher group for over $800M.

Dr Gosling is a past national president of the Australasian Industrial Research Group, a past national president of the Australia-Malaysia Business Council, a Fellow of the Academy of Technological Sciences and Engineering, a Fellow of the Institute of Engineers Australia, and a Governor of the Warren Centre for Advanced Engineering. He also sits on a number of industry advisory committees. He has been appointed a Member of the Order of Australia for services to business through innovative development consultancy, and the development of start-up companies. He is also on the board of the Innovative Industrial Research Group, a past national president of the Australian Institute of Company Directors and of the Australian Institute of Engineers Australia (ret).

Mr Charlie Latham CA, FCA (England)

Mr Charlie Latham is a Chartered Accountant with a background in science, finance and compliance. He has over 35 years professional experience across a broad range of industries including life sciences, manufacturing, engineering, investment and service industries.

Mr Latham began his career with an Honours degree in zoology, before transitioning to accounting, finance and management. Over the past 25 years he has been involved as Company Secretary and Chief Financial Officer (CFO) of small ASX listed entities. He has served on a number of audit and risk committees, due diligence committees and capital raising committees, and has completed numerous acquisitions and disposals of businesses. He has also been a director and secretary of several private companies and subsidiaries of public companies.

Mr Latham has strong professional and government links in South Australia, and extensive networks within the Australian bioscience industry.

Ray Wood FACD

Mr Ray Wood has more than 35 years’ experience in developing and deploying Australian innovation and technology into global markets.

Mr Wood holds a BSc(Tech) Electronic Engineering. His experience ranges from the continuous flow pathology analysers of the early 1970’s and the first automated haematology counters, through to the development and marketing of diagnostic ultrasound machines, and, more recently, delivering professional consulting services and creating biotechnology spin outs.

Mr Wood has held roles within a range of organisations, including Plessy Telecommunications, Technicon Inc, Aulonics, PA Technology, Invetech and X-ray Technologies. He has significant experience in the integration of the code of cGMP, regulatory oversight and regenerative medicine.

Mr Wood has held a number of board positions, including non-executive director of Cell Therapies Pty Ltd, director of the Victorian Clean Technology Fund and director and principal of Inedics Pty Ltd. He is a Fellow of the Australian Institute of Company Directors and the Director of the Institute of Engineers Australia (ret).

Board meetings & attendance

Board meetings were held in September, October, November, February and June. Attendances are documented in the following table:

<table>
<thead>
<tr>
<th>number of board meetings eligible to attend</th>
<th>number of meetings attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Leanne Read</td>
<td>5</td>
</tr>
<tr>
<td>Dr Sherry Kothari</td>
<td>5</td>
</tr>
<tr>
<td>Mr Charlie Latham</td>
<td>5</td>
</tr>
<tr>
<td>Dr Alexander Gosling</td>
<td>5</td>
</tr>
<tr>
<td>Dr Stephen Livesey</td>
<td>5</td>
</tr>
<tr>
<td>Mr Ray Wood</td>
<td>2</td>
</tr>
</tbody>
</table>

At the AGM on 26/11/14, Mr Ray Wood was elected as a non-executive director of the board.

Audit and Risk Committee

During the reporting period, an audit and risk committee was established in response to a recommendation following the CTM CRG first year review.

The primary function of the committee is to assist the board in exercising due care, diligence and skill in discharging its oversight and monitoring responsibilities in relation to risk management, internal and external audit, financial statements and any other matter that the CTM@CRG Ltd Board requests the committee to review.

The committee meets at least four times per year, and has a number of responsibilities, including:

- Providing open lines of communication between CTM@CRG Ltd external auditors and the board
- Overseeing processes that identify and assess general business risk, reviewing the outcomes of programmed risk assessments, and advising the board as necessary
- Reviewing the adequacy of CTM@CRG Ltd internal control systems with management and the external auditors
- Reviewing any significant risks, findings and recommendations made by external or internal auditors, together with management’s responses to them

Audit and Risk Committee members

<table>
<thead>
<tr>
<th>name</th>
<th>role</th>
<th>independent/organisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr Charlie Latham</td>
<td>chair CTM@CRG Ltd</td>
<td>independent</td>
</tr>
<tr>
<td>Dr Ray Wood</td>
<td>member CTM@CRG Ltd</td>
<td></td>
</tr>
<tr>
<td>Ms Suzanne Riddings</td>
<td>member CTM@CRG Ltd</td>
<td>independent</td>
</tr>
</tbody>
</table>

Suzanne Riddings MBA

Ms Suzanne Riddings is the external representative on the CTM@CRG Ltd Audit and Risk Committee. Ms Riddings is an experienced executive, sustainability consultant, banker, board director and company secretary. She has held leadership positions in private, public and not-for-profit sector organisations, internationally and in Australia. Ms Riddings has also managed her own successful sustainability consultancy business since 2008 specialising in organisation sustainability, in particular carbon management and climate change adaptation.

Ms Riddings key skills and experience include strategy and policy development, extensive risk management, corporate governance, financial management and sustainability.
### Key Staff 2014-15

<table>
<thead>
<tr>
<th>Name</th>
<th>Organisation</th>
<th>CRC Position/Role</th>
<th>Time Committed (FTE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Sherry Kothari</td>
<td>CRC for Cell Therapy Manufacturing</td>
<td>CEO and Managing Director</td>
<td>1.0</td>
</tr>
<tr>
<td>Dr Justin Coombs</td>
<td>CRC for Cell Therapy Manufacturing</td>
<td>General Manager</td>
<td>0.9</td>
</tr>
<tr>
<td>Dr Tony Simula</td>
<td>CRC for Cell Therapy Manufacturing</td>
<td>Program Manager, R&amp;D</td>
<td>1.0</td>
</tr>
<tr>
<td>Dr Monica Kerr</td>
<td>CRC for Cell Therapy Manufacturing</td>
<td>Program Manager, Education</td>
<td>1.0</td>
</tr>
<tr>
<td>Ms Katrina van Zanten</td>
<td>CRC for Cell Therapy Manufacturing</td>
<td>Projects and Compliance Officer</td>
<td>0.7</td>
</tr>
<tr>
<td>Ms Natalie Watkins</td>
<td>CRC for Cell Therapy Manufacturing</td>
<td>Marketing &amp; Communications Officer</td>
<td>1.0</td>
</tr>
</tbody>
</table>

#### Justin Coombs
**MiPLaw, PhD, FIPTA**  
**General Manager & IP Counsel**

Dr Justin Coombs has overall responsibility for the operations of CTM@CRC Ltd, as well as providing in-house IP counsel to the CRC.

- Registered patent and trade marks attorney with over 12 years’ IP practice experience across legal practice, biotechnology industry and government.
- Held senior management positions in the biotechnology industry.
- Postdoctoral research experience at Cornell University in the United States.

#### Tony Simula
**MBA, PhD**  
**Program Manager, R&D**

Dr Tony Simula is responsible for overseeing the progress of the research programs and ensuring the smooth transition of research into the clinic.

- 10 years research experience.
- Over 15 years working in the biopharma industry, including product development.

#### Monica Kerr
**PhD**  
**Program Manager, Education**

Dr Monica Kerr oversees the development and implementation of education and training.

- PhD-trained scientist from Harvard Medical School committed to transforming the education and training of PhD students and scientists.
- Extensive experience managing and delivering career and professional development programs.
- Previous Harvard Medical School Instructor and New York Academy of Sciences Program Director.

#### Katrina van Zanten
**Projects and Compliance Officer**

Ms Katrina van Zanten is the contact point for project reporting and compliance. Ms van Zanten coordinates project reporting and budgets, participant compliance and CTM@CRC Ltd’s reporting obligations.

- Career history spanning medical research, project management, compliance and grants administration.
- Five years at professional services firm KPMG, consulting to clients claiming the federal government’s R&D Tax Concession.
- Seven years in medical research at Flinders University in Adelaide and Sydney’s Westmead Hospital.

#### Natalie Watkins
**Marketing & Communications Officer**

Ms Natalie Watkins is responsible for the development and implementation of marketing and communication strategies and associated activities.

- Commerce degree in International Business from the University of Adelaide.
- Five years’ experience in marketing (four years marketing for biotechnology across industry and government).
During the reporting period, Royal Prince Alfred Hospital (Sydney Local Health District) joined CTM CRC as an Other Participant.

<table>
<thead>
<tr>
<th>participant</th>
<th>participant type</th>
<th>organisation type</th>
<th>ABN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Athersys, Inc.</td>
<td>essential participant</td>
<td>industry</td>
<td>International</td>
</tr>
<tr>
<td>Cell Therapies Pty Ltd</td>
<td>essential participant</td>
<td>industry</td>
<td>15 100 285 918</td>
</tr>
<tr>
<td>Evexia Pty Ltd</td>
<td>essential participant</td>
<td>industry</td>
<td>45 158 849 980</td>
</tr>
<tr>
<td>Cell Therapies Pty Ltd</td>
<td>essential participant</td>
<td>industry</td>
<td>15 009 069 745</td>
</tr>
<tr>
<td>NextCell Pty Ltd</td>
<td>essential participant</td>
<td>industry</td>
<td>85 164 452 898</td>
</tr>
<tr>
<td>Queensland University of Technology</td>
<td>essential participant</td>
<td>university</td>
<td>83 791 724 822</td>
</tr>
<tr>
<td>The Royal Adelaide Hospital - a division of Central Adelaide Local Health Network, Inc.</td>
<td>essential participant</td>
<td>hospital</td>
<td>95 269 526 412</td>
</tr>
<tr>
<td>St Vincent’s Institute of Medical Research</td>
<td>essential participant</td>
<td>research institute</td>
<td>52 004 705 640</td>
</tr>
<tr>
<td>SA Pathology - a division of Central Adelaide Local Health Network, Inc.</td>
<td>essential participant</td>
<td>state government</td>
<td>95 269 526 412</td>
</tr>
<tr>
<td>South Australian Health and Medical Research Institute Ltd</td>
<td>other participant</td>
<td>research institute</td>
<td>54 141 228 348</td>
</tr>
<tr>
<td>Royal Prince Alfred Hospital (Sydney Local Health District)</td>
<td>other participant</td>
<td>hospital</td>
<td>17 530 269 052</td>
</tr>
<tr>
<td>Terumo BCT Australia Pty Ltd</td>
<td>essential participant</td>
<td>industry</td>
<td>87 130 046 985</td>
</tr>
<tr>
<td>University of South Australia</td>
<td>essential participant</td>
<td>university</td>
<td>37 191 313 308</td>
</tr>
<tr>
<td>University of Sydney</td>
<td>essential participant</td>
<td>university</td>
<td>15 211 513 464</td>
</tr>
<tr>
<td>Women’s and Children’s Health Network Inc.</td>
<td>other participant</td>
<td>hospital</td>
<td>64 021 748 128</td>
</tr>
</tbody>
</table>

“Our collaboration with CTM CRC has created the opportunity to integrate different aspects of cell therapy research and manufacturing in a way we had never done before.”

Dr Jef Pinxteren - Athersys, Inc.

“Manufacturing cell therapies cost effectively is THE hot issue for industry now. CTM CRC is tackling the right problems at the right time.”

Dr Tim Oldham - Cell Therapies Pty Ltd
The substantial progress made with research projects highlights the effective cohesion and collaboration between teams. Engagement with the CRC’s industry participants is proving very valuable, providing regulatory guidance and clarity around the feasibility of product concepts as projects move closer to clinical translation. They also provide a valuable resource regarding market trends and developments.

CTM CRC’s strategy to proactively involve end-user participation is proving successful, with prototype testing and integration into existing industry processes already underway for some projects. CTM CRC’s open and transparent approach encourages collaboration and fosters dialogue at disciplinary interfaces.

CTM CRC established strategic collaborative alliances with a number of international organisations, including the Cell Therapy Catapult, the Centre for Commercialization of Regenerative Medicine, and UCL. These collaborations are the result of CTM CRC’s capabilities in the use of innovative materials-based technologies that can be easily integrated into manufacturing processes to deliver efficiencies, cost-reduction and improvements for cell therapy manufacture.

To facilitate the translation of novel cell therapies, CTM CRC has established a cGMP facility managed by participant, NextCell Pty Ltd.

Through its new participant, the Royal Prince Alfred Hospital, CTM CRC has also gained access to process development laboratories for pre-cGMP development of candidate products.

CTM CRC, in conjunction with the Government of South Australia, has also entered into a collaborative agreement with GE Healthcare to explore the feasibility of establishing a cell therapy process development hub in Adelaide. With CTM CRC’s capabilities in advanced materials technology development and GE Healthcare’s expertise in cell processing tools, process development and infrastructure design, the hub would seek to develop more cost effective cell therapy technologies for scale-up and manufacture.
financial management

CTM@CRC Ltd. retained the services of Lee Green & Co. during the reporting period, to provide day-to-day accounting services and the preparation of regular management accounts. William Buck was also retained to provide audit services and to assist with the preparation of the financial statements.

CTM@CRC Ltd. ran a substantially balanced budget during the reporting period.

All budgeted contributions from Participants were received and total expenditure was close to budget (with research expenditure slightly above budget and operational expenditure slightly below budget). In summary, a small final accrued surplus of only $8,883 was generated.

Carrying forward the surplus from the previous reporting period, CTM@CRC Ltd had an accumulated accrued surplus of approximately $2.46M at the end of the current reporting period. It is expected that the accrued surplus will run down over the remaining period of the Commonwealth Agreement, particularly in later years where the level of Commonwealth funding is reduced relative to the current reporting period.

No other significant issues with respect to financial management were experienced during the reporting period.

Financial statements

Financial statements for CTM@CRC Ltd have been prepared in accordance with the Australian Accounting Standards and the Commonwealth Government reporting requirements for CRCs and can be made available on request.
publications & presentations

Conference Presentations

Myo Min K, Parham K, Rojas D, Coates T, Bonder C, ‘Revealing a critical cross-talk between beta islet cells and the vasculature in diabetes’ Australasian Society for Immunology student retreat, August 2015


Thompson E, Tyggorov D, Kheu-Goodall Y, Lopez A, Bonder C, ‘A critical role for desmoglein-2 in melanoma vasculogenic mimicry’ Australasian Society for Immunology - student retreat, August 2015


Rasko J, ‘Stem cells now and in the future - where are we on the road to translation?’ ARCS Scientific Congress, Sydney, May 2015

Kosobrodova E, ‘Immobolisation of tropoelastin on plasma immersion ion implanted polymer surfaces’ 5th International Symposium of Surface and Interface of Biomaterials and the 24th Australasian Society for Biomaterials and Tissue Engineering, Sydney, April 2015

Simula A, ‘Rapid development and translation of affordable cell therapies’ 5th International Symposium of Surface and Interface of Biomaterials and the 24th Australasian Society for Biomaterials and Tissue Engineering, Sydney, April 2015

Forget A, ‘Microwells as a screening platform for matrix interactions with cell spheroids’ 5th International Symposium of Surface and Interface of Biomaterials and the 24th Australasian Society for Biomaterials and Tissue Engineering, Sydney, April 2015


Barry S, ‘Unravelling the FoxP3 interacome in human Treg cells’ Australasian Society of Immunology Conference, Woodlomong, November 2014


Paliapaninn C, ‘Affordable cell therapies - FACT or FICTION?’ Affordable Cell Therapies - FACT or FICTION, Adelaide, October 2014


Rasko J, ‘Cell and gene therapy; coming to terms with it all’ 5th Malaysian Tissue Engineering and Regenerative Medicine Scientific Meeting, Malaysia, September, 2014

Thompson E, ‘The potential role of interleukin-3 (IL-3) in blood vessel development in breast cancer’ 22nd Australian Vascular Biology Society Annual Scientific Meeting, November 2014

Publications & Journal Articles


Ms Emma Thompson - CTM CRC student

2015 Australian Society for Medical Research SA Annual Scientific Meeting, June 2015

Rasko J, ‘Stem cell research’ Meritex Research Institute, 10th Annual Symposium, Hobart, July 2014
## Glossary of Terms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Explanation</th>
<th>Acronym</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABN</td>
<td>Australian Business Number</td>
<td>IP</td>
<td>Intellectual property</td>
</tr>
<tr>
<td>ACNC</td>
<td>Australian Charities and Not for Profit Commission</td>
<td>R&amp;D</td>
<td>Industry Research and Development</td>
</tr>
<tr>
<td>AGM</td>
<td>Annual general meeting</td>
<td>M</td>
<td>Million</td>
</tr>
<tr>
<td>ASIC</td>
<td>Australian Securities and Investments Commission</td>
<td>QUT</td>
<td>Queensland University of Technology</td>
</tr>
<tr>
<td>ATO</td>
<td>Australian Taxation Office</td>
<td>RPA</td>
<td>Royal Prince Alfred Hospital</td>
</tr>
<tr>
<td>BIP</td>
<td>Background IP</td>
<td>SA</td>
<td>South Australia</td>
</tr>
<tr>
<td>bn</td>
<td>Billion</td>
<td>SAHMRI</td>
<td>South Australian Health and Medical Research Institute</td>
</tr>
<tr>
<td>CEO</td>
<td>Chief Executive Officer</td>
<td>SIFE</td>
<td>Students in Free Enterprise</td>
</tr>
<tr>
<td>cGMP</td>
<td>Current good manufacturing practice</td>
<td>SME</td>
<td>Small to Medium Enterprise</td>
</tr>
<tr>
<td>CoGS</td>
<td>Cost of goods sold</td>
<td>STEM</td>
<td>Science, technology, engineering and maths</td>
</tr>
<tr>
<td>CRC</td>
<td>Cooperative Research Centre</td>
<td>TReg</td>
<td>Regulatory T cell</td>
</tr>
<tr>
<td>CRC CARE</td>
<td>CRC for Contamination Assessment and Remediation of the Environment</td>
<td>UCL</td>
<td>University College London</td>
</tr>
<tr>
<td>CT</td>
<td>Cell therapy</td>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>CTM CRC</td>
<td>Cooperative Research Center for Cell Therapy Manufacturing</td>
<td>UniSA</td>
<td>University of South Australia</td>
</tr>
<tr>
<td>EPIC</td>
<td>Endothelial progenitor cell</td>
<td>US</td>
<td>United States of America</td>
</tr>
<tr>
<td>ePhD</td>
<td>Entrepreneurial PhD</td>
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