

# RISS



RESEARCH  
INFRASTRUCTURE  
SUPPORT SERVICES

## ANNUAL REPORT 2009-2010



National Collaborative Research  
Infrastructure Strategy

## WHO WE ARE, WHAT WE DO

Research Infrastructure Support Services (RISS) Ltd is a not-for-profit charitable institution established in July 2007 as part of the Australian Government's National Collaborative for Research Infrastructure Strategy (NCRIS).

Our aim is to facilitate and grow investment in research and research infrastructure for the manufacture of human cells and cellular based products for transplant.

We do this via the administration of an Australian government grant funded through the Department of Innovation, Industry, Science and Research (DIISR) which is distributed to hospitals, research institutes and researchers for project grants of up to \$100,000 in three programs:

- > Therapeutic Goods Administration (TGA) Code of Good Manufacturing Practice (CgMP) Compliance Licence Maintenance
- > Quality Consulting, and
- > Researcher Access.

Projects funded under the Researcher Access program are subject to a merit-based assessment of grant applications by RISS Ltd's Expert Advisory Committee. All projects funded by RISS Ltd require co-funding or in-kind support.

The funding awarded through RISS Ltd under the NCRIS has contributed to Australia's capacity to undertake groundbreaking research which translates scientific discoveries that improve human health into practical applications in the clinical setting - in other words, from 'bench to bedside'.

It helps make Australia a leader in cell research and breakthrough treatments that will save lives and realise the potential for new treatments for a wide range of diseases including autoimmune, cardiovascular, circulatory, respiratory, infectious, metabolic and neurological diseases as well as injuries, eye disorders and cancers.

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## OUR MISSION

Improve human health through facilitating and promoting translational health capability in cell therapy.

## OUR OBJECTIVES

- To promote the NCRIS philosophy by fostering collaborative relationships in the field of manufacture of human cell and cellular based products for transplantation.
- To manage the distribution of NCRIS funding and any co-funding in the field in accordance with the conditions imposed by either the Australian Government or the co-funder.
- To assist persons operating in the field to obtain or enhance their cGMP compliance.
- To assist persons operating in the field to establish, maintain or improve their quality systems.
- To subsidise access by researchers to facilities with a TGA cGMP licence, on terms which are more commercially favourable than would otherwise normally be available to that party.
- To facilitate Infrastructure Access Agreements (and other agreements as may be required).
- To support growth in infrastructure of Australian research in the field through conferences, forums, workshops and meetings.

## OUR PHILOSOPHY

RISS supports medical research and clinical practices at the highest ethical and medical standards that makes new discoveries in cell therapy which can be translated to the clinic for the health and well-being of all people.

## RUNS ON THE BOARD

### 2009-10 Highlights

► The research infrastructure supported by RISS Ltd has facilitated clinical trials in:

- Acute Myeloid Leukaemia
- Bone repair
- Breast cancer
- Cardiac regeneration
- Diabetes
- Haematological malignancies
- Hepatitis C
- Lung cancer
- Myeloma
- Osteoarthritis
- Ovarian cancer

► 75% increase in applications for funding across the Researcher Access and Quality Consulting programs



- 40% increase in approved projects under the Researcher Access program
- 140% increase in approved projects under the Quality Consulting program
- All six sites hold TGA cGMP licence and funded for licence maintenance
- Funding partnerships with NSW, Queensland, WA and SA governments as well as major hospitals and research institutes in each of NSW, Victoria, Queensland, WA and SA
- Collaborative partnerships formed between facilities funded by RISS Ltd as well as with overseas facilities in Asia, Europe and North America
- Total value of infrastructure provided over three years of RISS Ltd - \$21.65m



## CHAIRMAN'S REPORT

While Australia has a proud record in discovering the causes of, and potential cures for, many of the world's diseases, one of the major impediments to further advancement has been the lack of financial support necessary to run laboratories which form the necessary infrastructure for scientists and medical researchers to do their work. For every dollar a medical research institute or university receives for research, approximately another 70 cents per day is needed for operating expenses.

The Australian Government has sought to address this anomaly, in part, through its seven year \$542 million NCRIS which concludes in 2010-11.

The establishment of RISS Ltd has been an important strategic component of the NCRIS, as Australia improves its capability to enable research into cellular therapies which could be vehicles for improvements in health outcomes with the potential for significant opportunity for Australian industry in the health sector.

Since the inception of the company in 2007, RISS Ltd has made significant inroads into establishing itself as a vital part of translational health capability through administration and distribution of the Australian Government's funding grants under NCRIS of \$7.6 million.

I am pleased to report that, with the completion of RISS Ltd's third year of operation in 2009-10, we have moved from the establishment of our programs to full scale implementation of our important agenda to contribute to the advancement of scientific and medical research in cell therapy through:

- the development of new infrastructure
- the maintenance of existing infrastructure, and
- improved access to available infrastructure by Australian researchers.

While the highlights and specific achievements of 2009-10 are set out elsewhere in this report, it is valuable to look at some of the key strategic initiatives of RISS Ltd over the three years since its establishment. Of course this needs to be seen from the perspective of RISS Ltd's operations as a small start-up company with a specific public policy focus and very modest administrative resources. In that time, RISS Ltd has:

- secured State Government funds for stakeholders following extensive consultation of
  - \$1.315 million from NSW (greater than 1:1 co-funding), and
  - \$890,000 of investment from Queensland (1:1 co-funding) with the potential for greater investment in the coming years
- attracted infrastructure investment from a cell therapies company to assist with operational costs in a NSW facility
- approved funding to a new site in NSW which has attracted a further \$12 million in co-investment through development of a new research hub, the Sydney Centre for Cell and Gene Therapy. This also fostered development of a new collaborative initiative at the site and brought several leading research groups together for the first time
- extended our infrastructure research facilities base with the inclusion of new facilities in NSW (Children's Hospital at Westmead), Victoria (Monash Institute of Medical Research, The Alfred and St Vincents Institute) and SA (Mawson Institute)
- facilitated enhanced collaboration in Queensland through the development of a Centre of Excellence in Cellular Therapies
- developed links with numerous philanthropic organisations in regard to further leveraging Australian Government funds in line with our charitable status
- conducted a thorough independent review of the current capabilities of Australia's cellular therapies sector
- encouraged development of an Australian subsidiary of a United States cell therapy company through development of a suitable manufacturing site at Westmead Children's Hospital.

Our major strategic initiative over the coming twelve months is to expand the base of funding sources for the crucial work of RISS Ltd from both the government and non-government sectors.

The paradox of public policy is that while, on the one hand, there is continuing pressures on public funding of programs which do not deliver direct services, on the other hand, investments in science and medical research hold the hope of breakthrough advancements in medical technology and life changing treatments and therapies. This tension is healthy and the debate will continue.

Hence, the Board believes that to leverage the current NCRIS investment in research infrastructure to the maximum extent practicable, it is vital the opportunities generated from the additional access generated by RISS Ltd programs is translated into new treatment modalities. This will require the identification of alternative, sustainable funding sources.

The Board would like to express its gratitude for the support and encouragement it has received from the Australian Government Department of Industry, Innovation, Science and Resources; the Chair and secretariat of NCRIS steering committee; our stakeholder groups; and State and Territory Governments.

The Board also wishes to record its appreciation to its CEO, Dr Stewart Hay, for his outstanding commitment, leadership and contribution to the success of RISS Ltd.

With the continuing support of government, I am confident that the research and research infrastructure supported by RISS Ltd will continue to contribute positively to improved health outcomes from bench to bedside as work in the laboratory translates to, and is integrated with, the delivery of clinical care.

Terry Slater  
Chairman

## CEO'S REPORT

The past year has been a productive year for RISS Ltd.

I am pleased to report that we have consolidated our performance and continued growth in our three core programs of TGA Licence Maintenance, Quality Consulting and Researcher Access, as well as re-introduced the successful and popular Smart Surface seminar series.

We are on track to fully disburse the funds made available to us under NCRIS by the end of the funding period in June 2011, and have already realised substantial achievements in improving research infrastructure enabling quality manufacturing of material for clinical trials as well as new and strengthened collaborations within the sector.

RISS Ltd's contribution to the NCRIS cell therapy consortium has not only involved the application and management of funding subsidies, but has also focussed on building the sustainability and improving the utilisation of facilities. In 2009-10 these endeavours have included:

- attracting international clients
- creating improved pricing systems
- marketing activities including the profiling of success stories
- attracting funding from State governments and industry, and
- technology assessments.

We have also worked with consortia both to represent their needs in the Super Science facilitation process (a new research infrastructure funding program of DIISR) and also in exploring the development of new consortia as a precursor for support through other funding mechanisms (such as the CRC for Cell Therapies initiative).

I am confident that, in the relatively short timeframe of three years since our establishment, RISS Ltd has made a demonstrable contribution to translational health capability. RISS Ltd has played an important role in the achievement of NCRIS objectives in the field of cell therapy by facilitating a more active, cohesive and collaborative sector.

A vital part of the work of RISS Ltd over the next year is to project what might come next, and to ensure that RISS Ltd is positioned to help drive the cell therapy sector forward and to embrace emerging challenges and opportunities.

If we look at how science and medicine has advanced in the past five years and the impact that has had on public health, what will the next five years hold and what infrastructure is needed to support the new discoveries that will emerge? What role can RISS Ltd play in improving human health through the facilitation and promotion of translational scientific and medical research in cell therapy?

I would like to thank the Chairman and the Board for the support, guidance and advice over the year.

I would also like to acknowledge the members of the Industry Advisory Committee and Expert Advisory Committee for their valuable contributions and DIISR for their commitment to advancing translational research capability in Australia through their support of RISS Ltd.

Dr Stewart Hay  
Chief Executive Officer



## PROGRAMS

### 1. TGA Licence Maintenance

The high costs associated with maintenance of TGA licensing presents a substantial impediment to external researchers from accessing facilities which are compliant with the cGMP. In the past, a share of the costs of licence maintenance has been previously passed on to the researcher.

Under the TGA Licence Maintenance program, cGMP compliant facilities can apply to RISS Ltd for NCRIS funding to subsidise the costs associated with maintaining their TGA licence. In return, facilities enter into an agreement with RISS to provide access to the facilities by external researchers.

There are currently six facilities that hold a TGA cGMP licence in an area related to the manufacture of human cells or cellular products and each of these has been received a subsidy from RISS Ltd in 2009-10 to a total value of \$300,000. The licence held differs between facilities depending on the manufacturing process that is licensed.

The facilities and licenced activities supported by RISS Ltd in 2009-10 are:

- *Sydney South West Area Health Service / Royal Prince Alfred Hospital, NSW*
  - manufacture of autologous and allogenic peripheral blood stem cells
- *Peter McCallum Cancer Institute / Cell Therapies, Victoria*
  - manufacture of autologous peripheral blood stem cells
- *Queensland Institute of Medical Research / Q-Gen, Queensland*
  - preparation and maintenance of cell banks
- *Royal Perth Hospital / Cell and Tissue Therapies, Western Australia*
  - manufacture of autologous cultured epithelial autografts - cell spray and cell spray XP
- *Orthocell, Western Australia*
  - manufacture and distribution of human tenocytes
- *SA Pathology / Institute of Medical and Veterinary Science, South Australia*
  - manufacture of autologous chondrocytes, autologous fibrin glue and allogenic and autologous haematopoietic progenitor cells - apheresis and bone marrow

## 2. Quality Consulting

The Quality Consulting program is undertaken by the ARCBS on behalf of RISS Ltd under a service level agreement, and aims to provide a mentoring and advisory service to sites that wish to attain cGMP compliance.

In 2009-10, this involved the recruitment of seven staff by the ARCBS and the conduct of seven gap analyses and provision of additional advisory services to several sites.

The outcomes of the Quality Consulting program include:

- the establishment of new cell therapy sites that will increase our national capability and the availability of infrastructure for cell therapy research
- the development of higher quality products that will lower the risk to patients enrolled in clinical trials, and
- improved understanding and knowledge by researchers of the relevant regulatory requirements.

Details of the gap analyses conducted in 2009-10 are provided below.

Institution	Consulting (hours)
Bosch Institute, University of Sydney - Retinal & Developmental Neurobiology Laboratory	130
Westmead Hospital - Pancreatic Islet Production	130
St Vincent's Institute - Human Islet Transplant Program	135
Monash Institute of Medical Research	132
Eskitis Institute, Griffith University - National Centre for Adult Stem Cell Research	130
Sir Charles Gairdner Hospital - Path Centre	38
University of South Australia - Mawson Institute	199

Since the recent deployment of this program, 13 gap analyses have been conducted. A further two gap analyses are scheduled to be conducted by June 2011.

### 3. Researcher Access

In addition to the agreement with TGA licenced facilities which enables access by researchers, RISS Ltd further assists researchers by subsidising access costs to approved research projects. The Researcher Access subsidy covers 50% of the manufacturing costs for eligible researchers with the remaining 50% to be matched by other funding arranged by the grant recipient.

In 2009-10, RISS Ltd provided funds of \$1.467 million for 23 projects. Since the inception of RISS Ltd in 2007, 36 Researcher Access grants have been awarded representing total funding of \$2.525 million.

Details of recipients of Researcher Access Grants in 2009-10 are provided below.

Research	Researcher / Institution	Funds Allocated \$
cGMP standard operating procedures	Q-GEN	50,000
Gene therapy for HIV	Westmead Hospital	100,000
Novel MRI cell	Cell Therapies	50,000
Dendritic cell immunotherapy	Q-GEN	50,000
Lewis YT cell	Prince Cell Therapies	40,000
Develop a national centre for clinical islet transplantation	Children's Hospital Westmead	50,000
Trial of contact lens-based technique for expansion & transplantation of autologous epithelial progenitors for ocular surface reconstruction	Cell Therapies	100,000
Clinical adoptive immunotherapy for prevention of cytomegalovirus in stem cell transplant patients	Children's Hospital Westmead	50,000
Adoptive immunotherapy for prevention of EBV-related post transplant lymphoproliferative disorder following stem cell transplant	Children's Hospital Westmead	50,000
Multi-centre phase II study to evaluate mesenchymal stromal cells (MSC) for treating refractory Crohn's Disease	Royal Perth Hospital	100,000
Cell-delivered gene therapy for HIV	Children's Hospital Westmead	100,000
Translation of theraphil technology to GMP compliance & Phase I trial ready: ex-vivo expansion of hematopoietic stem cells to produce neutrophils for treatment of neutropenia	Cell Therapies	100,000
Manufacture of cGMP compliant NSC for clinical trials	Queensland Institute of Medical Research/Q-GEN	25,000
Pelvic floor repair using scaffolds and MSCs	Cell Therapies	50,000

GMP production of human islets for transplantation	Cell Therapies	50,000
Establishment of immunotherapy for BK virus in patients undergoing haemopoietic stem cell or renal transplantation	Children's Hospital Westmead	60,000
Use of term amnion derived epithelial stem cells in clinical trials	Cell Therapies	85,000
Gene therapy and chemotherapy for treatment of brain tumours	Children's Hospital Westmead	32,000
Gene therapy for treatment of X-linked Severe Combined Immune Deficiency (SCID-X1)	Children's Hospital Westmead	45,000
Phase I open label study of safety & immune effects of escalating dose of autologous GD2 chimeric antigen receptor-expressing peripheral blood T cells in patients with metastatic BRAF-Mutant & GD2-positive melanoma	Institute of Medical and Veterinary Science/ SA Pathology	100,000

## 4. Smart Surfaces

The Smart Surfaces program involves a seminar series that provides an opportunity for information exchange and networking between researchers, developers and others in the field of cGMP compliant human cell work.

RISS Ltd partnered with the Cooperative Research Centre (CRC) for Polymers to deliver three Smart Surface Seminars in 2009-10 (in Sydney, Melbourne and Perth) with two more (in Brisbane and Adelaide) to be delivered later in 2010.



## GOVERNANCE AND MANAGEMENT

The responsibilities of the RISS Ltd Board are to oversee the strategic direction, financial and operational activities and the risk management processes of the company.

The governance priorities of the Board are to:

- maintain financial sustainability
- comply with all relevant laws and regulations
- report in an open and transparent manner to stakeholders
- engage with stakeholders on our strategic intent
- continually improve performance by establishing appropriate objectives and performance indicators and reviewing performance.

The Board has an Audit Committee chaired by the Company Secretary, and is also assisted in its work by two external committees: an Industry Advisory Committee and Expert Advisory Committee.

In 2009-10, the Board met on 11 occasions.

In addition to the financial statements incorporated as part of this report, RISS Ltd provides a quarterly report to DIISR in respect of its annual grant.

**Terry Slater** BSc, BEc, MPH, FAIM

*Chairman*

Terry Slater is a former senior executive with the Australian Public Service including nine years as chief executive of the Therapeutic Goods Administration (TGA). He also held senior executive level positions within the Health and Housing and Construction departments and the Australian Customs Service, and was CEO of the Australian Food Standards Authority. His most recent corporate role was as CEO of Australians Donate, a government funded company established to oversee transition to new governance arrangements for organ donation and transplantation. Terry is also a Board member of Drinkwise.

**Rob Anderson** FCA, FAICD

*Company Secretary, Chairman of Audit Committee*

Rob Anderson is the Managing Director of Orthogen Australia, which operates in the field of cell therapies for a range of medical products. He is a former Partner (Audit and Advisory) with Deloitte and has had extensive commercial and financial experience in a diverse range of industries and business structures, including consulting to government and industry. Rob is also principal of Anderson Business Consultants.

**Liz Furler** BA (Social Work)

Liz Furler is the CEO of Principals Australia, the peak professional association for principals from all schools sectors. She has previously held senior executive roles with the Commonwealth Department of Health and the Australian National Training Authority, as well as at state government level in both South Australia and Tasmania. She was also CEO of the Royal Australian College of General Practitioners.

**Dr George Morstyn** MB BS, BMedSci, PhD, FRACP, MAICD

*Chairman of Expert Advisory Committee*

George Morstyn has longstanding experience and expertise in translational medicine in the interface between research and commercial practice, with outstanding background in pre-clinical and clinical development and regulatory affairs. He is a former Chief Medical Officer, Senior Vice President and Head of Development at Amgen and is currently on the Board of Proacta, Chemgenex, AMT and Neuprotect. He is Deputy Chairman of the Comprehensive Cancer Centre in Parkville (Melbourne) and a Director and Chairman of the scientific advisory board of Symbio, Japan. Dr Morstyn's substantial clinical experience includes training in medical oncology at the National Cancer Institute in the US and Head of the Clinical Program of the Ludwig Institute for Cancer Research in Melbourne.

## *Industry Advisory Committee*

The role of the Industry Advisory Committee is to provide advice to the Board on developments in both the academic research and commercial aspects of the cell therapy industry. It was established in 2008 and its members comprise:

- Professor John Rasko, Centenary Institute of Cancer Medicine and Cell Biology (Chairman)
- Professor Ian Alexander, Children's Hospital Westmead
- Topaz Conway, Mater Medical Research Institute
- Dr Ian Lewis, Institute of Medical and Veterinary Science/SA Pathology
- Professor Miles Prince, Peter McCallum Cancer Centre
- Dr Marian Sturm, Royal Perth Hospital
- Dr Joanna Youngson, Queensland Institute of Medical Research
- Dr Stewart Hay, CEO, RISS Ltd

## *Expert Advisory Committee*

The role of the Expert Advisory Committee is to provide advice to the Board on applications for funding. None of the members of the Expert Advisory Committee are representatives of facilities eligible for funding. The Committee's members comprise:

- Dr George Morstyn, RISS Ltd Board member (Chairman)
- Dr Patrick Coghlan, Australian Red Cross Blood Service
- Professor Richard Fox AM, St Vincents Hospital Melbourne
- Merryn Hagen, Independent Consultant (formerly with TGA)
- Rita McLachlan, Independent Consultant (formerly with TGA)
- Dr Stewart Hay, CEO, RISS Ltd

## Review of Risk

The Board oversees a comprehensive risk management program which is set out in a Risk Register and reviewed biannually. The Board has established practices to safeguard the organisation and to monitor performance in achieving its goals. This is achieved by:

- a monthly report from the CEO covering performance and risk management
- a biannual review of the Risk Register
- internal quality audit program provided by the ARCBS
- external financial audit

## Management

In 2009-10, RISS Ltd had one full-time staff member, the CEO Dr Stewart Hay, supported by administrative services provided by ARCBS (such as financial administration). The CEO is also an ex-officio member of the Industry Advisory Committee and Expert Advisory Committee.

**Stewart Hay** BSc, PhD, MAICD

CEO

Stewart has extensive and broad-based experience in science having worked in medical research and the pharmaceutical, nutraceutical, biofuel and medical device industries. He joined RISS Ltd in 2008 from AusBiotech where he was responsible for implementing and managing an NCRIS project. Prior to this, he worked in research with CSL, the Walter and Eliza Hall Institute of Medical Research and the Fiona Elsey Cancer Research Laboratory. He has also conducted market feasibility and technical studies as a consultant and has worked with Ventracor and IG Science where he developed new products and a GMP manufacturing facility. Stewart has a PhD in Cancer Cell Biology.

From time-to-time, RISS Ltd also utilises the services of consultants for expert (clinical) and/or corporate support purposes.

## LOOKING AHEAD

### *Our vision for the future is ambitious.*

Having 'put in the hard yards' of establishing and building the brand of RISS Ltd within the relevant stakeholder community over three years, we now look to build on the momentum that has been created as well as leverage our added value.

The substantial increases in applications to RISS Ltd, the solid utilisation of facilities, the first regulatory approvals for cell therapy products and several infrastructure developments all reflect a growing interest in the field. As described in this report, the Researcher Access program has shown a significant increase in interest and the uptake of gap analyses in 2009-10 indicates that our Quality Consulting program has been effectively utilised.

Our key tasks over the final twelve months of NCRIS funding will be to:

- assist in finalising the development of new facilities to offset the demand at current centres
- attract more researchers to sites that are under-utilised
- continue to prosecute the case for increased investment in the people providing the expertise and delivering the outcomes
- develop a proposal for a role in the implementation of translational research infrastructure through the Super Science Fund and the Education Investment Fund.

*In the longer term, we also believe that RISS Ltd is well placed to take a leading and independent role in facilitating and promoting investment in research infrastructure that specifically builds Australia's capability in translational research to ensure the most efficient and effective outcome nationally.*

Finally, while we have realised significant gains for the research community in our funding partnerships with State governments and public sector research organisations, RISS Ltd believes there is scope to expand the base of funding sources. This includes government; but also importantly, an assessment of the potential opportunity to work with our facilities and other stakeholders to attract non-government sources of funding, including utilising the charitable status of RISS Ltd through, for example, specific purpose campaigns and/or broader philanthropic or industry support.

## FINANCIAL STATEMENTS

# DIRECTORS' REPORT

The directors of Research Infrastructure Support Services Limited ("RISS") submit herewith the annual financial report of the company for the financial year ended 30 June 2010. In order to comply with the provisions of the Corporations Act 2001, the directors report as follows:

The names and particulars of the directors of the company during or since the end of the financial year are:

<b>Name</b>	<b>Title</b>	<b>Date of Appointment</b>	<b>Qualification</b>
Ms. Elizabeth Furler	Chair of RISS Industry Consultative Committee and Board Member	11/12/2007	B.A (Social Work)
Dr. George Morstyn	Chair RISS Expert Advisory Committee and Board Member	11/12/2007	MB BS, B. Med. Sci, PhD, FRACP, MAICD
Mr. Terry Slater	Chairman	16/08/2007	BSc, BEc, MPH, FAIM
Mr. Rob Anderson	Co. Secretary and Chairman - Audit Committee	16/08/2007	FCA, FAICD

The above named directors held office during and since the end of the financial year unless otherwise stated.

### *Company secretary*

Mr Rob Anderson (FCA, FAICD) - appointed as at 16 August 2007

### *Principal activities*

RISS is an Australian not-for-profit company formed to promote investment in research infrastructure in the field of human cell and cellular based products for transplantation.

No significant change in the nature of these activities occurred during the year.

### *Review of operations*

The deficit of the company for the financial year amounted to \$82,107 (2009: \$46,374 surplus).

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### *Changes in state of affairs*

No significant changes in the company's state of affairs occurred during the financial year.

### *Subsequent events*

There has not been any matter or circumstance occurring subsequent to the end of the financial year that has significantly affected, or may significantly affect, the operations of the company, the results of those operations, or the state of affairs of the company in future financial years.

### *Future developments*

Disclosures of information regarding likely developments in the operations of the company in future financial years and the expected results of those operations is likely to result in unreasonable prejudice to the company. Accordingly, this information has not been disclosed in this report.

### *Environmental regulations*

The company's operations are not regulated by any significant environmental regulation under a law of the Commonwealth or of any State or Territory.

### *Dividends*

Under the company's constitution there are no dividends payable.

### *Indemnification of officers and auditors*

No indemnities have been given or insurance premiums paid, during or since the end of the financial year, for any person who is or has been an officer or auditor of the company, except that a premium has been paid to obtain insurance for directors and officers of the company. The amount of the premium paid can not be disclosed as a condition of the insurance contract.

## FINANCIAL STATEMENTS

### *Directors' meetings*

The number of meetings of the company's directors whilst the director was in office held during the financial year ended 30 June 2010 and the number of meetings attended by each director were:

<b>Director</b>	<b>Available for:</b>	<b>Attended:</b>
Dr George Morstyn	11	10
Liz Furler	11	11
Terry Slater	11	11
Rob Anderson	11	11

### *Proceedings on behalf of the company*

No person has applied for leave of Court to bring proceedings on behalf of the company or intervene in any proceedings to which the company is a party for the purpose of taking responsibility on behalf of the company for all or any part of those proceedings.

The company was not a party to any such proceedings during the year.

### *Auditor's independence declaration*

The auditor's independence declaration is included on page 4 of the annual report.

Signed in accordance with a resolution of directors made pursuant to s.298(2) of the Corporations Act 2001.

On behalf of the Directors

**Director**

Melbourne, 27 September 2010

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The Board of Directors  
Research Infrastructure Support Services Limited  
Level 6, 464 St. Kilda Road  
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27 September 2010

Dear Board Members,

**Research Infrastructure Support Services Limited**

In accordance with section 307C of the Corporations Act 2001, I am pleased to provide the following declaration of independence to the directors of Research Infrastructure Support Services Limited.

As lead audit partner for the audit of the financial statements of Research Infrastructure Support Services Limited for the financial year ended 30 June 2010, I declare to the best of my knowledge and belief, there have been no contraventions of:

- (i) the auditor independence requirements of the Corporations Act 2001 in relation to the audit; and
- (ii) any applicable code of professional conduct in relation to the audit.

Yours sincerely

DELOITTE TOUCHE TOHMATSU  
Robert D D Collie  
Partner  
Chartered Accountants

## FINANCIAL STATEMENTS

# INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF RISS LTD

We have audited the accompanying financial report, being a special purpose financial report, of Research Infrastructure Support Services Limited, which comprises the statement of financial position as at 30 June 2010, and the statement of comprehensive income, the statement of cash flows and the statement of changes in equity for the year ended on that date, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration of the company as set out on pages 7 to 17.

### *Directors' Responsibility for the Financial Report*

The directors of the company are responsible for the preparation and fair presentation of the financial report and have determined that the accounting policies described in Note 3 to the financial statements, which form part of the financial report, are appropriate to meet the financial reporting requirements of the Corporations Act 2001 and are appropriate to meet the needs of the members. The directors' responsibility also includes establishing and maintaining internal control relevant to the preparation and fair presentation of the financial report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

### *Auditor's Responsibility*

Our responsibility is to express an opinion on the financial report based on our audit. No opinion is expressed as to whether the accounting policies used, as described in Note 3, are appropriate to meet the needs of the members. We conducted our audit in accordance with Australian Auditing Standards. These Auditing Standards require that we comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance whether the financial report is free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial report, whether due to fraud or error. In making those risk assessments, the auditor

## FINANCIAL STATEMENTS

considers internal control relevant to the entity's preparation and fair presentation of the financial report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the financial report.

The financial report has been prepared for distribution to the members for the purpose of fulfilling the directors' financial reporting requirements under the Corporations Act 2001. We disclaim any assumption of responsibility for any reliance on this report or on the financial report to which it relates to any person other than the members, or for any purpose other than that for which it was prepared.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

### *Auditor's Independence Declaration*

In conducting our audit, we have complied with the independence requirements of the Corporations Act 2001.

### *Auditor's Opinion*

In our opinion, the financial report of Research Infrastructure Support Services Limited is in accordance with the Corporations Act 2001, including:

- (a) giving a true and fair view of the company's financial position as at 30 June 2010 and of its performance for the year ended on that date in accordance with the accounting policies described in Note 3; and
- (b) complying with Australian Accounting Standards to the extent described in Note 3 and the Corporations Regulations 2001.

DELOITTE TOUCHE TOHMATSU

Robert D D Collie  
Partner  
Chartered Accountants

Melbourne, 27 September 2010

## FINANCIAL STATEMENTS

# DIRECTORS' DECLARATION

As detailed in Note 3 to the financial statements, the company is not a reporting entity because in the opinion of the directors there are unlikely to exist users of the financial statements who are unable to command the preparation of reports tailored so as to satisfy specifically all of their information needs. Accordingly, these special purpose financial statements have been prepared to satisfy the directors' reporting requirements under the Corporations Act 2001.

The directors declare that:

- (a) in the directors' opinion, there are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable; and
- (b) in the directors' opinion, the attached financial statements and notes thereto are in accordance with the Corporations Act 2001, including compliance with accounting standards and giving a true and fair view of the financial position and performance of the company.

Signed in accordance with a resolution of the directors made pursuant to s.295(5) of the Corporations Act 2001.

On behalf of the Directors

**Director**

Melbourne, 27 September 2010

FINANCIAL STATEMENTS

## STATEMENT OF COMPREHENSIVE INCOME

*for the year ended 30 June 2010*

	Note	2010 \$	2009 \$
Continuing operations			
Revenue	4	<b>1,936,842</b>	2,025,973
Other income	4	-	5,526
Distribution of funds		<b>(1,522,000)</b>	(1,520,000)
Consultancy fees	5	<b>(202,179)</b>	(210,508)
Directors fees	5	<b>(50,500)</b>	(60,900)
Hosting fees - ARCBS		<b>(72,000)</b>	(82,000)
Audit fees	5	<b>(10,090)</b>	(12,525)
Other administration expenses		<b>(162,180)</b>	(99,192)
(Deficit)/surplus before tax	5	<b>(82,107)</b>	46,374
Income tax expense	3(a)	-	-
<b>(Deficit)/surplus for the year</b>		<b>(82,107)</b>	46,374
Other comprehensive income			
		-	-
<b>Total comprehensive (loss)/income for the year</b>		<b>(82,107)</b>	46,374

FINANCIAL STATEMENTS

## STATEMENT OF FINANCIAL POSITION

at 30 June 2010

	Note	2010 \$	2009 \$
<b>Current assets</b>			
Cash and cash equivalents	8(a)	1,032,018	1,078,517
Trade and other receivables	6	10,614	16,770
<b>Total current assets</b>		<b>1,042,632</b>	1,095,287
<b>Total assets</b>		<b>1,042,632</b>	1,095,287
<b>Current liabilities</b>			
Trade and other payables	7	1,032,879	1,003,427
<b>Total current liabilities</b>		<b>1,032,879</b>	1,003,427
<b>Total liabilities</b>		<b>1,032,879</b>	1,003,427
<b>Net assets</b>		<b>9,753</b>	91,860
<b>Equity</b>			
Retained earnings		9,753	91,860
<b>Total equity</b>		<b>9,753</b>	91,860

## STATEMENT OF CHANGES IN EQUITY

*for the year ended 30 June 2010*

	Retained Earnings \$	Total \$
Balance at 1 July 2008	45,486	45,486
Surplus for the year	46,374	46,374
<b>Total comprehensive income for the year</b>	46,374	46,374
<b>Balance at 30 June 2009</b>	91,860	91,860
Deficit for the year	(82,107)	(82,107)
<b>Total comprehensive loss for the year</b>	(82,107)	(82,107)
<b>Balance at 30 June 2010</b>	9,753	9,753

FINANCIAL STATEMENTS

## STATEMENT OF CASH FLOWS

*for the year ended 30 June 2010*

	Note	2010 \$	2009 \$
<b>Cash flows from operating activities</b>			
Receipts from Commonwealth Government		<b>2,072,400</b>	2,033,900
Payments to suppliers, fees and grants paid		<b>(2,166,741)</b>	(2,012,858)
Interest received		<b>47,842</b>	50,973
Net cash (used in) / generated by operating activities	8(b)	<b>(46,499)</b>	72,015
<b>Net (decrease) / increase in cash and cash equivalents</b>		<b>(46,499)</b>	72,015
<b>Cash and cash equivalents at the beginning of the year</b>		<b>1,078,517</b>	1,006,502
<b>Cash and cash equivalents at the end of the year</b>	8(a)	<b>1,032,018</b>	1,078,517

## NOTES TO THE FINANCIAL STATEMENTS

### *1. General information*

Research Infrastructure Support Services Limited is a public company limited by guarantee, incorporated and domiciled in Australia.

The address of its registered office and principal place of business are as follows:

<b>Registered office</b>	<b>Principal place of business</b>
Level 6, 464 St. Kilda Road MELBOURNE VIC 3004	c/o ACRBS, National Transplant Services Level 6, 464 St. Kilda Road MELBOURNE VIC 3004

### *2. Adoption of new and revised Accounting Standards*

#### **2.1 Standards and Interpretations affecting amounts reported in the current period (and/or prior periods)**

The following new and revised Standards and Interpretations have been adopted in the current period and have affected the amounts reported in these financial statements.

#### **Standards affecting presentation and disclosure**

AASB 101 Presentation of Financial Statements (as revised in September 2007), AASB 2007-8 Amendments to Australian Accounting Standards arising from AASB 101 and AASB 2007-10 Further Amendments to Australian Accounting Standards arising from AASB 101

AASB 101 (September 2007) has introduced terminology changes (including revised titles for the financial statements) and changes in the format and content of the financial statements.

## FINANCIAL STATEMENTS

### **2.2 Standards and Interpretations in issue not yet adopted**

At the date of authorisation of the financial statements, the following applicable Standards and Interpretations listed below were in issue but not yet effective.

Standard/Interpretation	Effective for annual reporting periods beginning on or after	Expected to be initially applied in the financial year ending
AASB 2009-5 Further Amendments to Australian Accounting Standards arising from the Annual Improvements Project	1 January 2010	30 June 2011
AASB 124 Related Party Disclosures (revised December 2009), AASB 2009-12 Amendments to Australian Accounting Standards	1 January 2011	30 June 2012

### **3. Significant accounting policies**

#### **Financial reporting framework**

The company is not a reporting entity because in the opinion of the directors there are unlikely to exist users of the financial statements who are unable to command the preparation of reports tailored so as to satisfy specifically all of their information needs. Accordingly, these special purpose financial statements have been prepared to satisfy the directors' reporting requirements under the Corporations Act 2001.

#### **Statement of compliance**

The financial statements have been prepared in accordance with the Corporations Act 2001, the recognition and measurement requirements specified by all Australian Accounting Standards and Interpretations, and the disclosure requirements of Accounting Standards AASB 101 'Presentation of Financial Statements', AASB 107 'Cash Flow Statements' and AASB 108 'Accounting Policies, Changes in Accounting Estimates and Errors'.

#### **Basis of preparation**

The financial statements have been prepared on the basis of historical cost, except for the revaluation of certain non-current assets and financial instruments. Cost is based on the fair values of the consideration given in exchange for assets. All amounts are presented in Australian dollars, unless otherwise noted.

### ***Going concern***

The company currently operates under a five year funding agreement with the Department of Innovation, Industry, Science & Research (DIISR). On the completion of the agreement in September 2011 there is currently no option in place to renew the funding.

Notwithstanding this factor, the financial report has been prepared on the basis that the company is a going concern basis, which assumes the continuity of normal business activities and the realisation of assets and the settlement of liabilities in the ordinary course of business. The directors of the company are of the view that this is appropriate on the basis of the following assumptions:

- There is an expectation that the company will be successful in an application to administer a further grant scheme on behalf of an authority for the coming 3 years.
- Furthermore, management are exploring other options to restructure the company and apply for alternative sources of funding.

The financial report does not include adjustments relating to the recoverability and classification of recorded asset amounts nor to the amounts and classification of liabilities that might be necessary should the company not continue as a going concern.

### ***Critical accounting judgements and key sources of estimation uncertainty***

In the application of the company's accounting policies, which are described below, the directors are required to make judgements, estimates and assumptions about carrying values of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

The following significant accounting policies have been adopted in the preparation and presentation of the financial statements:

#### ***(a) Income tax***

The company is exempt from income tax under subdivision 50-B of the Income Tax Assessment Act 1997.

## FINANCIAL STATEMENTS

### **(b) Cash and cash equivalents**

Cash comprises cash on hand and demand deposits. Cash equivalents are short-term, highly liquid investments that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value.

Bank overdrafts are shown within borrowings in current liabilities in the statement of financial position.

### **(c) Comparative amounts**

Where necessary, comparatives have been reclassified and repositioned for consistency with the current year disclosures.

### **(d) Financial assets**

Financial assets comprise of trade and other receivables.

#### Trade and other receivables

Trade and other receivables that have fixed or determinable payments that are not quoted in an active market are classified as 'receivables'. Receivables are measured at amortised cost using the effective interest method less impairment.

Interest income is recognised by applying the effective interest rate.

#### Impairment of financial assets

Financial assets, other than those at fair value through profit or loss, are assessed for indicators of impairment at each reporting date. Financial assets are impaired where there is objective evidence that as a result of one or more events that occurred after the initial recognition of the financial asset the estimated future cash flows of the investment have been impacted.

#### Derecognition of financial assets

The company derecognises a financial asset only when the contractual rights to the cash flows from the asset expire, or it transfers the financial asset and substantially all the risks and rewards of ownership of the asset to another entity. If the company neither transfers nor retains substantially all the risks and rewards of ownership and continues to control the transferred asset, the company recognises its retained interest in the asset and an associated liability for amounts it may have to pay. If the company retains substantially all the risks and rewards of ownership of a transferred financial asset, the company continues to recognise the financial asset and also recognises a collateralised borrowing for the proceeds received.

**(e) Financial instruments issued by the company**

Other financial liabilities

Other financial liabilities, including borrowings, are initially measured at fair value, net of transaction costs.

Other financial liabilities are subsequently measured at amortised cost using the effective interest method, with interest expense recognised on an effective yield basis.

The effective interest method is a method of calculating the amortised cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments through the expected life of the financial liability, or, where appropriate, a shorter period.

**(f) Revenue**

RISS is a not-for-profit company and receives a principal part of its income from government grants as cash. Amounts granted can be recognised only as revenue when the company gains control, the economic benefits are probable and the amount of the contribution can be reliably measured.

Revenue is measured at the fair value of the consideration received or receivable.

Interest revenue is accrued on a time basis, by reference to the principal outstanding and at the effective interest rate applicable, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to that asset's net carrying amount.

**(g) Goods and Services Tax (GST)**

Revenues, expenses and assets are recognised net of the amount of goods and services tax (GST), except:

- i. where the amount of GST incurred is not recoverable from the taxation authority, it is recognised as part of the cost of acquisition of an asset or as part of an item of expense;
- or
- ii. for receivables and payables which are recognised inclusive of GST.

The net amount of GST recoverable from, or payable to, the taxation authority is included as part of receivables or payables.

Cash flows are included in the statement of cash flows on a gross basis. The GST component of cash flows arising from investing and financing activities which is recoverable from, or payable to, the taxation authority is classified as operating cash flows.

## FINANCIAL STATEMENTS

2010	2009
\$	\$

### 4. Revenue

An analysis of the company's revenue for the year, from continuing operations is as follows:

<b>Continuing operations</b>		
Grant revenue	<b>1,884,000</b>	1,520,000
Other operating revenue	<b>5,000</b>	455,000
Interest revenue	<b>47,842</b>	50,973
	<b>1,936,842</b>	2,025,973
Other income - reimbursement of legal expenses	-	5,526
	-	5,526

### 5. (Deficit)/surplus for the year

(Deficit)/surplus for the year has been arrived at after charging the following items of expense:

Consultancy fees	<b>(202,179)</b>	(210,508)
Directors fees	<b>(50,500)</b>	(60,900)
Audit of the financial report (i)	<b>(10,090)</b>	(12,525)

(i) The auditor of the financial report is Deloitte Touche Tohmatsu

### 6. Trade and other receivables

Trade receivables	<b>5,500</b>	-
Prepaid expenses	<b>5,114</b>	16,648
Goods and services tax recoverable	-	122
	<b>10,614</b>	16,770

### 7. Trade and other payables

Trade payables	<b>55,000</b>	-
Accrued expenses	<b>62,123</b>	104,300
GST payable	<b>26,356</b>	-
Grant funding payable	<b>889,400</b>	683,900
Other payables	-	215,227
	<b>1,032,879</b>	1,003,427

2010	2009
\$	\$

## 8. Cash and cash equivalents

### (a) Reconciliation of cash and cash equivalents

For the purposes of the statement of cash flows, cash and cash equivalents includes cash on hand and in banks and investments in money market instruments, net of outstanding bank overdrafts. Cash and cash equivalents at the end of the year as shown in the statement of cash flows can be reconciled to the related items in the statement of financial position as follows:

Cash and cash equivalents	<b>1,032,018</b>	1,078,517
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### (b) Reconciliation of (deficit)/surplus for the year to net cash flows from operating activities

(Deficit)/surplus for the year	(82,107)	46,374
<b>Movement in working capital:</b>		
(Increase)/decrease in assets:		
Trade and other receivables	6,156	(12,872)
Increase in liabilities:		
Trade and other payables	29,452	38,513
Net cash (used in) / from operating activities	(46,499)	72,015

## 9. Commitments for expenditure

### Operating lease commitments

Not longer than 1 year	9,254	8,674
	9,524	8,674

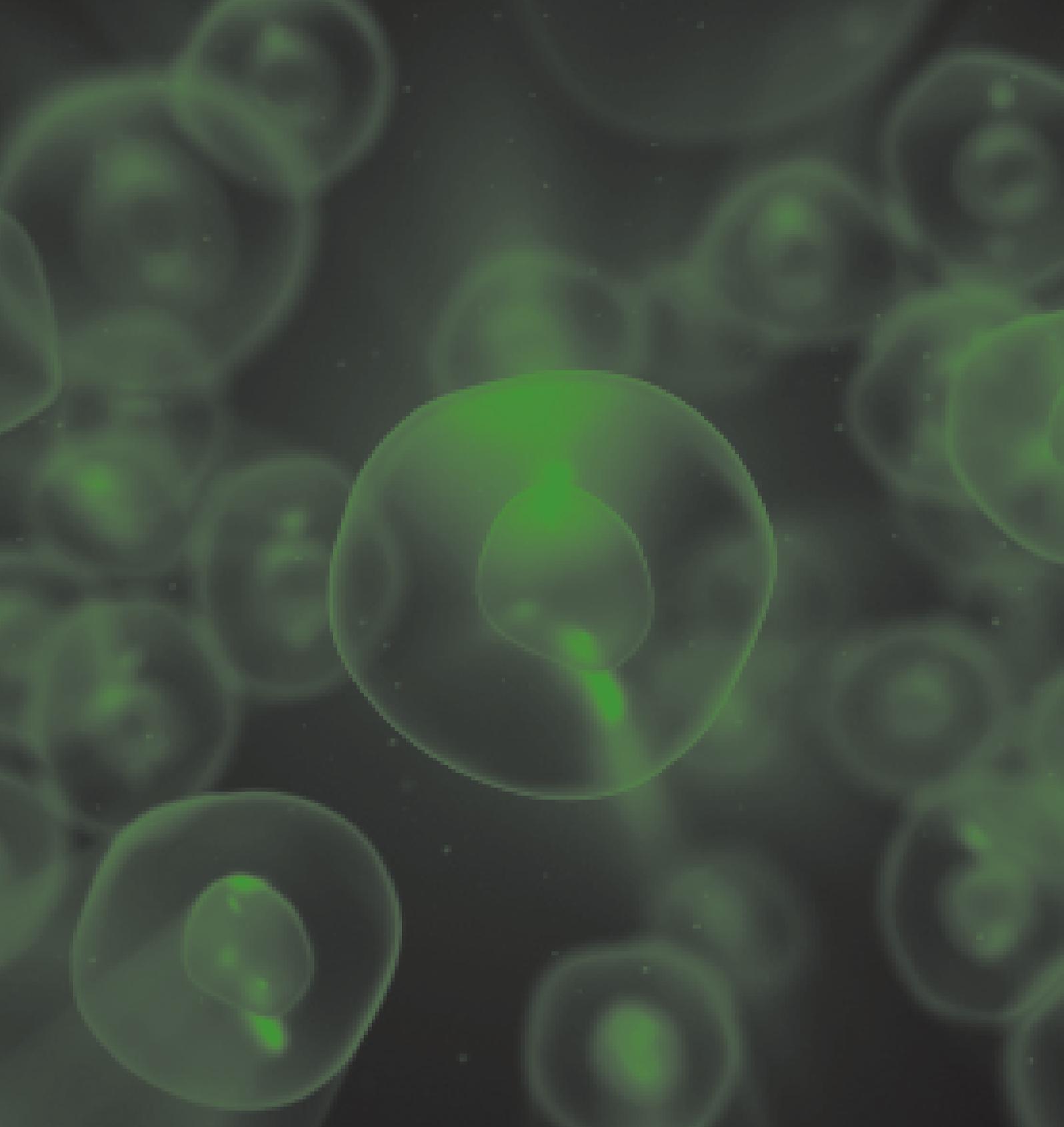
## FINANCIAL STATEMENTS

### *10. Subsequent events*

During the financial year, a researcher made a successful application for grant assistance. RISS provided assistance by subsidising \$100,000 of the cost to access a clean room facility. In March 2010 the applicant was given a six month extension to complete the project but the decision to cancel this extension was made in July 2010. The grant was returned to the company in August 2010.

Except as noted above, there has not been any other matter or circumstances occurring subsequent to the end of the financial year that has significantly affected, or may significantly affect, the operations of the company, the results of those operations, or the state of affairs of the company in future financial years.





RISS



RESEARCH  
INFRASTRUCTURE  
SUPPORT SERVICES



National Collaborative Research  
Infrastructure Strategy