



Professional Development in Therapeutics™

ANNUAL REPORT 2012/13

ARCS AUSTRALIA LIMITED
ABN 25 050 334 444
Suite 802, 28 Clarke Street
Crows Nest
NSW 2065

2012/2013 Performance Highlights

2541
Members

94
Number of educational events held

1506
Number of attendees at conferences

1245
Number of attendees at interest area
committees

90%
Average quality rating of educational events

15%
Increase in revenue from educational events

Who We Are

ARCS is a leading independent association that focuses on delivering professional development and member representation within the therapeutics sector.

As a not-for-profit organisation, ARCS is funded by its members and currently represents 2,500 personnel within the sector. ARCS' role is pivotal both in educating newcomers to the industry as well as providing continuous support throughout their careers with ongoing professional development.

What We Do

We provide high-quality training and professional development within the therapeutics sectors.

We encourage and foster the exchange of information via leading-edge conferences, seminars and networking events.

We act as an impartial information portal to provide awareness of relevant government, research and industry activities.



Events and Initiatives in 2012/13

ARCS continued to bring together excellent major conferences during the 2012-13 year including a Regulatory/Health Economics/Quality Conference in Canberra in September 2012, an expanded AGM and education day in North Ryde in November 2012 and an education day prior to canapés and cocktails at the State Library in Melbourne in December 2012. This was followed in 2013 by our largest conference in many years, and our last in Darling Harbour until the site is redeveloped involving clinical research, regulatory affairs, medical affairs, pharmacovigilance, medical information, quality and medical writing. Over 900 attendees from industry, hospitals and other research sites and governments attended, with 125 speakers organised across eight to nine streams covering topics on medicines and medical devices.

ARCS workshops supporting early and intermediate trainees experienced an increase in attendees across the many one, two and three day sessions. Seminars, external contracts and e-learning continued to support supplementary needs of the members.

An initiative in 2012-13 was to start the redevelopment of the interest area committees to include guest speakers and specialised topics. This resulted in increased attendances of 30-50 dial-ins per meeting, with multiple people on some phone lines.

The weekly ARCS news service was extended to cover Asia news.

Representations

ARCS Business Office staff worked on a number of initiatives related to our therapeutics environment. These involved:

- Research governance surveys and education sessions
- Participation in the working party for the clinical trials portal design and specification
- Participation in the working party for the new national clinical trials website, clinicaltrials.gov.au
- Participation in the Research and Development Taskforce with industry and government managers
- Authorship of a response to the McKeon review
- Coordinating industry responses for the ANAO audit of the TGA
- Convening of working groups on pharmacovigilance for consumers, research governance, electronic submissions and risk management plans

Financial Performance

Overall this led to a very successful and profitable year for the ARCS organisation in 2012-13. Due to the phasing of the education events the 2013-14 year is budgeted to have slightly lower income with lower profit levels.

Office and The Team

During the year we welcomed Annick Ah Lan as our first ARCS business team leader and farewellled Belinda King who went on maternity leave. An extensive property search resulted in a decision to maintain the ARCS business office in 802 Clarke St for the next five years, albeit with some office layout changes to improve the trainee and office experience.

The ARCS Business Office also embarked upon a reassessment of the web service, resulting in the identification of necessary changes to the website to improve the user experience.

An ARCS brand manual was completed to ensure consistency of message and imagery.

The team is working on implementing a new ARCS website.

The Future

A new ARCS communication plan is being developed to support a refocus on better member engagement.

Development and implementation of new strategies to grow the organisation.

Constitutional changes are envisaged to help keep the organisation up to date with ongoing environmental trends.

The ACNC now has jurisdiction over most not-for-profit entities (from ASIC) and may require changes to our constitution, business and reporting over the ensuing years; no immediate changes are mandated.

Adrian Bootes
Chief Executive Officer
October 2013

DIRECTORS' REPORT

The Directors of ARCS Australia Limited (ARCS) present this report and the Financial Statements of the Company for the year ended 30 June 2013.

I. DIRECTORS 2012/2013

The details of the Directors who held office during or since the end of the financial year are provided below. Nine meetings in total were held from July 2012 to June 2013.

At the start of this financial year there were four vacant Director positions. Two Directors were appointed on 6 July 2012 and two positions were vacant until the Board election in November 2012. Board elections were held at the AGM on 20 November 2012. Four positions were declared vacant and there were eight nominations for the role of Director. A poll was conducted to determine which nominees would fill the four vacant positions.

	Commencement	Cessation	Board Meetings		Key Activities
			A	B	
Judy Bingham ^{a,b}	1 Jul 2012*		9	9	Company Secretary
Katrina Campion ^c	1 Jul 2012*		7	9	
Miriam Dwyer ^{a,c}	1 Jul 2012*		8	9	Vice President Chair, Membership and Education Committee
Sally Kinrade ^c	6 Jul 2012		7	9	
Tamara Miller ^c	20 Nov 2012		5	6	
Stuart Myers ^b	6 Jul 2012	20 Nov 2012	3	3	
Melanie Seeger ^c	20 Nov 2012		5	6	
Ailsa Surman ^{a,b}	1 Jul 2012*		8	9	President Chair, Corporate Governance Committee; Chair Audit and Risk Management Committee
Lesley White ^{b,c}	20 Nov 2012		5	6	

A – Number of meetings attended B – Number of meetings held during the time the director held office during the year

*Directors were appointed prior to start of financial year

a Corporate Governance Committee

b Audit and Risk Management Committee

c Membership and Education Commerce

Judy Bingham – Director, Company Secretary

Judy is an independent consultant to the biopharmaceutical industry, supporting companies plan and manage development and life cycle programmes, including regulatory strategy and clinical development planning. Until March 2011, Judy held the position of Senior Director Kendle Consulting for Kendle International in the Asia Pacific region. In this role, she was responsible for the leadership of regulatory and medical affairs consulting services.

Prior to joining Kendle, Judy gained extensive experience in clinical research and development, in business development, medical affairs and health economics at CSL and Faulding (now Hospira), and as Director of Pharmacy at Peter MacCallum Cancer Centre.

Judy is a registered pharmacist and has a Bachelor of Pharmacy from Monash University. Her post graduate qualifications include a Masters in Health Science, Fellowship of the Society of Hospital Pharmacists of Australia and Company Directors Course Diploma from the Australian Institute of Company Directors.

Judy has been involved with ARCS for over 15 years and a Board member since 2011. She is a member of the Audit & Risk Management Committee, the Corporate Governance Committee and is currently the ARCS Company Secretary.

Katrina Campion – Director

Katrina has worked in the pharmaceutical industry for 20 years, and has been involved with ARCS in some active capacity for most of this time. Katrina served as a member of the Melbourne Education Subcommittee for many years, and for more than a decade has been a member of the ARCS Board. Katrina has qualifications in nursing, social research and public health, is a graduate of the Australian Institute of Company Directors (GAICD) and Certified ARCS Fellow (ACF).

Katrina was appointed President of ARCS in November 07 and completed a four-year tenure in October 2011. Over the last 12 month period Katrina has been involved with the following board subcommittees: Membership Committee, Corporate Governance and the Audit and Risk Management Committee. During this reporting period Katrina participated in the Membership and Education Committee and Corporate Governance Committee. She was also awarded life membership of ARCS.

Miriam Dwyer – Director, Chair Membership and Education Committee

Miriam is currently the Chief Executive Officer of the Gallipoli Medical Research Foundation, based at Greenslopes Private Hospital in Brisbane. This foundation currently supports four academic research units (Liver Research Unit, led by Prof Darrell Crawford, Centre for Immune & Targeted Therapy lead by Ass Prof Andrew Nicol, the Centre for NTM and Bronchiectasis Research, led by Dr. Rachel Thompson, and PTSD research programme led by Prof Bruce Lawford). Working closely with the Chair of the Board of Directors, Miriam provides direction and leadership to the formulation and achievement of the GMRF's goals and objectives. She leads the senior executive team and assumes overall responsibility for the operation of the GMRF in consultation with the GMRF Executive. She oversees all operational elements of the foundation's Clinical Trials Unit, including feasibility assessments, contract negotiations, resource management and project delivery.

Miriam chairs the Membership and Education Committee, and was appointed Vice President of ARCS in 2012.

Sally Kinrade – Director

Sally was Chief Operating Officer at Phosphagenics Ltd in this period. She has extensive experience in pharmaceutical development, scientific communication and market strategy. Prior to joining Phosphagenics, Sally was an independent consultant specialising in medical affairs and clinical research. Sally's previous experience includes clinical research and brand planning roles with GlaxoSmithKline.

Sally is a pharmacist and has attained a Masters of Public Health.

Sally was appointed a Director of ARCS in July 2012 and was elected to the Board in November 2012. In September 2012 Sally completed a two-day training course for Board members of not-for-profit organisations. Sally is a member of the Membership and Education Committee.

Tamara Miller – Director

Tamara has over 12 years' experience in the clinical research industry, having held project management roles in the UK, USA and Australia. Currently, Tamara is a project manager for the APAC region at ICON Clinical Research. Tamara's project management skills and experience cover all functional areas of clinical research, including clinical, regulatory, medical affairs, pharmacovigilance, compliance, data management and biostatistics. Holding a BSc in biomedical science, Tamara is a member of the Australian Institute of Project Management and a member of the Project Management Institute.

Tamara was elected to the Board in November 2012 and has served on the Membership and Education committee.

Stuart Myers – Director

As a graduate scientist, Stuart undertook medical research in transplant immunology along with academic teaching, in the UK for 12 years and maintains a keen interest in the development of immunology as a science and clinical discipline. Stuart entered the pharmaceutical industry, following emigration to Australia in 1982 and over a ten year period, was appointed to several senior management positions in quality assurance, regulatory affairs, and marketing. Subsequently, Stuart held top management positions in Australia for multinational biopharmaceutical companies together with regional responsibilities in Europe and Asia. Stuart holds positions on the boards of several of biopharmaceutical companies. In 1998, Stuart co-founded a clinical research and development consultancy operating out of Sydney, and remains a director today.

Stuart undertakes advocacy activities about the need to maintain robust biopharmaceutical and medical device industries in Australia. He is passionate about the importance of good continuing professional education being available and utilised in Australia to support quality research and development. Stuart believes that in order to support these industries into the future, it is essential to maintain the quality of the scientific base in Australia required for their wellbeing.

Stuart nominated and was invited to be an ARCS board member in July 2012 and became a member of the Audit and Risk Management Committee overseeing financial performance and the determination, assessment and mitigation of all risk to the association.

Melanie Seeger – Director

In her role as Medical Affairs Manager at Celgene Pty Ltd Melanie oversees the medical information and medical affairs functions. Her experience in the pharmaceutical industry includes various positions within medical departments as well as early roles in sales. In addition, Melanie has experience in planning and delivery of primary care health programmes. Melanie holds a Bachelor of Science, a Master of Public Health and has completed the Certificate IV in Assessment and Workplace Training.

A member of ARCS for many years, Melanie has been active in various interest area groups. Melanie was elected to the ARCS Board in November 2012 and is a member of the Membership and Education Committee.

Ailsa Surman – President, Chair Corporate Governance Committee, Chair Audit and Risk Management Committee

Ailsa has worked in the pharmaceutical industry in Australia, New Zealand and the UK for over 15 years, in a variety of areas including medical information, pharmacovigilance and regulatory affairs. She has degrees in biochemistry and pharmacology and currently is a regulatory affairs consultant at Eli Lilly Australia Pty Limited.

Ailsa works on both local and global regulatory affairs projects. Ailsa has been a member of ARCS since arriving in Australia in 2005, and was co-convenor of the Regulatory Education Sub-Committee for three years. Ailsa joined the ARCS Board in 2009 and was appointed President in October 2011.

Lesley White – Director

Lesley has 19 years' experience working in the pharmaceutical industry both in Australia and the UK. Lesley is currently the Hospira Regional Director of Regulatory Affairs for ANZ, Japan and Asia. She leads all regulatory activities across the region in support of the company's generic, proprietary, biosimilar and medical device portfolios and oversees 75 staff across 10 countries. In her role Lesley is responsible for all agency interactions, strategy development, product compliance and lifecycle management, budgeting and resource management. Lesley is also a graduate of the Australian Institute of Company Directors (GAICD). Lesley has been a member of ARCS since 2004 and became a Director of ARCS in 2012. Lesley serves on the Membership Committee and Audit and Risk Management Committee.

2. COMPANY SECRETARY

The appointed Company Secretary is Judy Bingham, effective 20 December 2012.

3. SHORT- AND LONG-TERM OBJECTIVES AND STRATEGY

The company's purpose is to provide support in the form of networking opportunities, representation of member interests, education and information services for the benefit of its members, and for interested non-members. Members include those contributing scientific services and expertise to the therapeutics development process and/or utilisation of pharmaceuticals and medical technologies. Members of ARCS may work in areas including, but not limited to, regulatory affairs, clinical research, health economics, pharmacovigilance, medical affairs, medical writing and the provision of medical information.

The objective of ARCS is to advance our members' professional interests and provide a forum for education and exchange of information.

The company's strategy for achieving this objective is to ensure that:

- ARCS is identified as the leading professional development organisation for individuals working in the therapeutics industry
- ARCS identifies and delivers educational programmes of value to all its members
- ARCS facilitates a wide range of opportunities for information exchange and networking for all its members
- ARCS is seen as a key stakeholder in regulatory decision-making
- ARCS seeks involvement in initiatives that impact its members
- ARCS represents all members, from entry-level graduates to members with industry-wide roles and senior executives
- Programmes and forums offer a clear value proposition for members
- Programmes and forums are on specific subjects and targeted at specific audiences.
- Programmes and forums are consistently rated by participants as high quality, relevant and current
- Clear professional development pathways are in place
- The company operates in compliance with applicable regulations
- The company is financially viable

Longer term objectives include:

- Increased engagement with clinical researchers, research and governance personnel in hospitals and private sites
- Providing education services to like-minded organisations where appropriate
- Providing membership options and education services to New Zealand and South-East Asia
- Providing or facilitating training to personnel in related sectors (medical devices and diagnostics) where appropriate

4. PRINCIPAL ACTIVITIES

The company's principal activities during the year were:

- Developing updated and/or new education events and workshops, including new technical and soft skill courses
- Engaging with leading regulatory and reimbursement authority personnel to ensure that our education and networking event schedule provides opportunities to hear of and anticipate change in key government areas relevant to our members
- Facilitating discussions between member groups in the form of Interest Area Committee meetings
- Facilitating growth of communication and engagement between site and sponsor clinical research personnel
- Facilitating regional networking events
- Implementation of a more effective and compliant email communication system for members and non-members
- Development and distribution of a weekly email news service of topics relevant to members
- Expansion of a LinkedIn group with networking and information for ARCS members and potential members
- Submissions on issues of interest to ARCS members
- Participation in the Pharmaceuticals Industry Council's Research and Development Taskforce, to effect meaningful improvements in the clinical research sector
- Updating the association's branding and imagery
- Identification of potential website revisions

These activities have assisted the company in achieving its objectives by:

- Providing high quality, relevant and current education programmes that are targeted to specific member groups
- Providing opportunities for members to exchange information
- Providing information relevant to members
- Representing member interests in significant areas
- Enhancing the value proposition of ARCS membership

5. PERFORMANCE MEASURES

The company measures performance as follows:

- Number of members
- Delivery of education events to each participant group
- Attendance at education and networking events
- Quality rating of education events
- Cost effectiveness of education events
- Education income
- Opening rates and click-through for ARCS electronic communications
- Effectiveness of financial control measures
- Ongoing financial viability of the company

6. MEMBERS' GUARANTEE

In accordance with the company's constitution, each member is liable to contribute an amount not exceeding \$10.00 in the event that the company is wound up. On the basis of membership numbers at 30 June 2013, the total amount members would contribute is \$25,410.

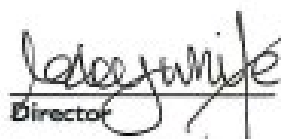
7. AUDITORS' INDEPENDENCE DECLARATION

The lead auditors' independence declaration for the year ended 30 June 2013 has been received and is attached.

This Directors' Report is made and signed in accordance with a resolution of the Board of Directors made pursuant to section 298(2) of the Corporations Act.



Director



Director
Dated this 31st day of October 2013

E Psaltis & Co

Chartered Accountants and Business Advisers

INDEPENDENT AUDITOR'S REPORT To the members of ARCS Australia Limited

Report on the Financial Report

We have audited the accompanying financial report of ARCS Australia Limited, which comprises the statement of financial position as at 30 June 2013, the statement of comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, notes comprising a summary of significant accounting policies and other explanatory information, and the directors' declaration.

Directors' Responsibility for the Financial Report

The directors of the company are responsible for the preparation of the financial report that gives a true and fair view in accordance with Australian Accounting Standards - Reduced Disclosure Requirements and the *Corporations Act 2001* and for such internal control as the directors determine is necessary to enable the preparation of the financial report that is free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on the financial report based on our audit. We conducted our audit in accordance with Australian Auditing Standards. Those standards require that we comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance about 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 considers internal control relevant to the entity's preparation of the financial report that gives a true and fair view 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.

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

Independence

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

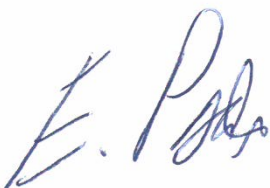
We confirm that the independence declaration required by the *Corporations Act 2001*, which has been given to the directors of ARCS Australia Limited, would be in the same terms if given to the directors as at the time of this auditor's report.

Opinion

In our opinion the financial report of ARCS Australia Limited is in accordance with the *Corporations Act 2001*, including:

- (i) giving a true and fair view of the company's financial position as at 30 June 2013 and of its performance for the year ended on that date; and
- (ii) complying with Australian Accounting Standards - Reduced Disclosure Requirements and the *Corporations Regulations 2001*;

E Psaltis & Co



Edward Psaltis
Principal

Sydney, 31 OCT 2013

E Psaltis & Co

Chartered Accountants and Business Advisers

AUDITOR'S DECLARATION OF INDEPENDENCE

To the directors of ARCS Australia Limited :

I declare that, to the best of my knowledge and belief, for the year ended 30 June 2013, 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.

E Psaltis & Co



Edward Psaltis
Principal

Sydney, 31 OCT 2013





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