

AUSTRALIAN CLINICAL TRIALS ALLIANCE LTD.

ABN 60 168 693 972

FINANCIAL REPORT
FOR THE YEAR ENDED 30 JUNE 2020

AUSTRALIAN CLINICAL TRIALS ALLIANCE LTD.
ABN 60 168 693 972

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**AUSTRALIAN CLINICAL TRIALS ALLIANCE LTD.
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DIRECTORS' REPORT

The directors of Australian Clinical Trials Alliance ("ACTA") Limited by Guarantee submit herewith their report on the company for the twelve months ended 30 June 2020.

Board of Directors

The Directors of ACTA during the year ended 30 June 2020 and at the date of this report are as follows. Details of the qualifications, experience, and special responsibilities of each are listed. Directors were in office for this entire period unless otherwise stated.

**Professor John Raymond Zalcborg OAM, MBSS PhD FRACP FRACMA FAHMS FAICD
Chair**

Professor John Zalcborg is Head of the Cancer Research Program in the School of Public Health and Preventive Medicine at Monash University, providing academic leadership to a number of clinical quality registries and holds the inaugural Tony Charlton Chair in Cancer Research at the Alfred Hospital, Melbourne, Australia. Prior to taking up his current position in 2015, he was Director of the Division of Cancer Medicine at the Peter MacCallum Cancer Centre (Peter Mac) in Melbourne for 17 years and Chief Medical Officer at that institution for 5 years.

A co-founder of the Lorne Cancer Conference and the Australasian Gastrointestinal Trials Group (AGITG), he was the prior Chair of the Board of AGITG and a previous board member of Cancer Trials Australia. He was the Co-Chair of the Cancer Drugs Alliance and is the current Chair of the Australian Clinical Trials Alliance. He is also a past board member of the Cancer Institute of New South Wales, Australian Red Cross Blood Service and past-President of the Clinical Oncological Society of Australia (COSA).

He has received several awards including a Medal of the Order of Australia (OAM), the Cancer Achievement Award from the Medical Oncology Group of Australia and the Tom Reeve Award for Outstanding Contributions to Cancer Care from COSA. In 2014, the AGITG created the annual "John Zalcborg OAM Award for Excellence in Cancer Research and in 2018 he was awarded the Red Cross Distinguished Service Medal.

Professor Zalcborg's clinical research interests include gastrointestinal (GI) cancer and quality of care and he has published over 300 articles in peer-reviewed journals. He was the Principal Investigator for the EORTC advanced GIST trial in Australia and continues to be actively involved in trials in this disease, as well as other gastrointestinal cancers, a branch of medical oncology in which he continues an active clinical practice.

**Professor Steven Anthony Rochford Webb, MBBS MPH PhD FCICM FRACP FAHMS
Deputy Chair and Company Secretary**

Professor Steve Webb is a Senior Staff Specialist in Intensive Care Medicine at Royal Perth Hospital and a Professor of Critical Care Research at Monash University. He is a past-Chair of the ANZICS Clinical Trials Group and a member of the Executive of the International Severe Acute Respiratory Illness Consortium. He is a founding Fellow and former member of Council of the Australian Academy of Health and Medical Sciences and a former member of the National Health and Medical Research Council Health Translation Advisory Committee.

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Prof Webb is a trialist with over \$100 million of research funding and has published over 180 manuscripts in peer-reviewed journals including multiple manuscripts in the New England Journal of Medicine, the Journal of the American Medical Association, the British Medical Journal, and The Lancet. In 2009-10, Prof Webb led work that was globally influential in establishing the public health impact of the 2009 H1N1 influenza A pandemic. He has also published definitive clinical trials that directly guide clinical practice and policy related to the care of critically ill patients. He chaired the Human Research Ethics Committee at the University of Western Australia between 2007 and 2017.

Ms Rebecca Lynne James
Independent Director with Expertise in Consumer Presentation
Retired 18 November 2019

Ms Rebecca James is currently a member of the Advisory Board of the Centre for Research in Evidence-Based Practice, Bond University, and an independent member of the MBS Review Taskforce.

She has been a member of public and private boards, including the National Breast and Ovarian Cancer Centre (Deputy Chair), Neopec Pty Ltd (chair) a tissue engineering research consortium based in Melbourne and Health Services Australia Pty Ltd. She has been an independent member of the Medical Services Advisory Committee (MSAC) and between 2012 and 2017 provided consultancy services on policy and government relations to Medicines for Malaria Venture, a not-for-profit based in Switzerland.

Between 2007 and 2012 she was CEO of Research Australia, a not-for-profit membership based policy advocate for health and medical research and innovation. She has been a member of the personal staff of two previous Federal Health Ministers.

Ms Margo June MacGillivray, LLB (HONS) (UQ), LLM (UNI MELB), GAICD
Independent Director with Expertise in Governance and Risk Management

Ms Margo MacGillivray has more than 25 years' experience as a commercial lawyer and corporate executive. Her track record includes Chief Legal Officer positions across a range of industries, a partnership in a leading international law firm and non-executive directorships in the health and medical research sections.

She is currently the Chief Legal Officer for Auscript and For the Record Group and a board member of the Prince Charles Hospital Foundation. She has previously been a board member of Metro South Hospital & Health Service as well as the PA Research Foundation. As a commercially astute lawyer with a strong understanding of business imperatives, Margo has a clear focus on good governance, strategic planning, and enterprise wide risk management.

Ms Anne Elizabeth McKenzie, AM
Independent Director with Expertise in the Consumer Sector

Since 2004 Ms Anne McKenzie has worked as a consumer advocate and manager of Consumer and Community Involvement Programs in universities and research organisations. She is currently the Senior Manager of Community Engagement at Telethon Kids Institute in Western Australia.

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Ms Anne McKenzie's key strength of initiating, developing, and implementing sustainable strategies and processes that provide an effective bridge between consumers, the community, researchers, clinicians, and policy makers has underpinned her achievements. She has a strong commitment to support active consumer and community involvement in health service delivery and research.

Ms McKenzie currently serves as a senior consumer representative on key national and state health committees such as the Department of Health, The National Health and Medical Research Council and the National Prescribing Service. She is a former Chair and an Honorary Life Member of the Health Consumers Council WA. In January 2015 she was appointed as a Member of the Order of Australia for significant service to community health through consumer advocacy roles and strategic policy research and development.

Professor Rachael Lisa Morton, MSCMED (CLIN EPI) HONS, PhD
Appointed 18 November 2019

Professor Rachael Morton is Director of Health Economics at the NHMRC Clinical Trials Centre, and Professor and Principal Research Fellow in the Faculty of Medicine and Health at the University of Sydney. Since 1988, the NHMRC Clinical Trials Centre has aimed to improve health practice through better use of clinical trials research, which has involved more than 200 trials and 80,000 patients. At the centre she leads a multidisciplinary team of researchers to improve methods for assessment of the cost-effectiveness of diagnostic and therapeutic interventions across a wide range of clinical areas including cancer, cardiovascular disease, and kidney disease, using within-trial and modelled approaches.

Prof Morton is the President of the Health Services Research Association of Australia and New Zealand, the peak professional body for implementation of trials evidence into practice and policy. Prof Morton received a PhD in health economics and a Master of Science in Medicine Clinical Epidemiology (Hons) at University of Sydney.

She has received competitive grant funding of >\$52M including for large scale clinical trials an NHMRC Sidney Sax Early Career Fellowship to Oxford University, an NHMRC TRIP Fellowship in 2018, and NHMRC Investigator Grant commencing 2021. She is a regular discussant for the Economic Subcommittee of the Pharmaceutical Benefits Advisory Committee (PBAC) and oversees an evaluation team for the Medical Services Advisory Committee (MSAC). Prof Morton has served on national and international clinical trials' research committees including (AKTN, MASC trials [formerly ANZMTG], SHARP (Oxford)) is the inaugural Chair of the Australian and New Zealand Dialysis and Transplant Registry (ANZDATA) PROMs working group; and founding Executive board member of the Melanoma Clinical Outcomes Registry (MeICOR).

Professor Vlado Perkovic, MBSS PhD FASN FRACP FAHMS
Retired 18 November 2019

Professor Vlado Perkovic is Executive Director of The George Institute, Australia, and a Professor of Medicine at The University of NSW. He is a Staff Specialist in Nephrology at the Royal North Shore Hospital. His research focus is in clinical trials and epidemiology, with a focus on the prevention of kidney failure, the cardiovascular risk associated with kidney disease, and the impact of interventions that might mitigate this risk.

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Prof Perkovic has been involved in developing Australian and global guidelines in kidney disease, cardiovascular risk assessment and blood pressure management. He is a member of the National Health and Medical Research Council Principal Committee for Research Translation, is the Chair of International Society of Nephrology Advancing Clinical Trials group and has previously chaired the Scientific Committee of the Australasian Kidney Trials Network.

Prof Perkovic holds a Doctor of Philosophy from the University of Melbourne and completed his undergraduate training at The Royal Melbourne Hospital. He is a Fellow of the Royal Australasian College of Physicians and of the American Society of Nephrology.

**Professor Christopher Michael Reid, BA, DIP ED, MSC, PHD
Appointed 28 November 2018**

Christopher Reid is a cardiovascular epidemiologist with appointments as Research Professor in both the School of Public Health and Preventive Medicine, Monash University, and the School of Public Health at Curtin University. He was appointed as a John Curtin Distinguished Professor in 2018 and is Director of the Monash and Curtin Centre's of Cardiovascular Research and Education (CCRE) and the NHMRC Centre of Research Excellence in Cardiovascular Outcomes Improvement (2016-2020). He holds a National Health and Medical Research Council Principal Research Fellowship (2018-2022) in addition to being the Chief Investigator on an NHMRC Program Grant (2016-2020) focusing on cardiovascular disease prevention. He has been awarded over \$113M as a Chief Investigator and has received continuous NHMRC funding since 2001. His major research interests include clinical outcome registries, randomised controlled trials, and epidemiological cohort studies.

Director experience includes Director, Health Research Innovations Pty Ltd, Executive Board Member of the World Hypertension League, the Australian and New Zealand Alliance for Cardiovascular Trials and the Australian Cardiovascular Alliance and Secretary and Board Member of the Association for Health, Education and Advocacy for the Disadvantaged Inc.

**Mr Kieran Geoffrey Schneemann
Independent Director with Expertise in the Commercial Clinical Trials Sector**

Mr Kieran Schneemann is a highly respected government affairs practitioner with more than 30 years' experience in Canberra. Mr Schneemann has worked for global companies, Australian institutions, and all levels of government, including in federal ministerial offices and the bureaucracy. He has significant experience working with government and, importantly, understands the differences between how Government, business and the Not-for-Profit sectors operate.

At present, Mr Schneemann is Director of Government Affairs with AstraZeneca Australia. He has responsibility for external relations, public affairs, and government relations across the Group. Prior to this, he was Chief Executive of the Pharmacy Guild of Australia and immediately before that, CEO of Medicines Australia. He has worked as Chief of Staff in ministerial offices in the Federal Government, Secretary of various Parliamentary Committees and served in a number of senior positions in the Federal Government bureaucracy for over 15 years.

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Mr Schneemann is a past board member of Research Australia and currently a Director on the Board of CanTeen Australia.

**Professor (Robert) John Simes AO, BSC (MED) MBBS SM FRACP MD FAHMS
Retired 18 November 2019**

Professor John Simes is the founding Director of the NHMRC Clinical Trials Centre, University of Sydney. Since 1988, the Centre has aimed to improve health practice through better use of clinical trials research which has involved more than 200 trials and 80,000 patients. He was the founding Director of Sydney Catalyst, which helps facilitate translational cancer research amongst more than 500 individual members from 30 institutions in Sydney and regional NSW.

Prof Simes is a practising medical oncologist in neuro-oncology at Royal Prince Alfred Hospital and Chris O'Brien Lifecare. He is Professor of Clinical Epidemiology at the Sydney Medical School. He is also a senior principal research fellow of NHMRC. Prof Simes received a Doctor of Medicine at University of Sydney in cancer clinical trials and a Master of Science in Biostatistics at Harvard University.

He has served on many national and international clinical trials' research committees including cancer co-operative groups (AGITG, ANZ-BCTG, COGNO), cardiovascular studies and neonatal trials. He was an inaugural member of the Medical Services Advisory Committee (1998-2004), a member of the Cancer Institute NSW Board (2003-2010) and the chair of the NHMRC Large Scale Clinical Trials Committee (2003-2007).

Prof Sime's research interests include clinical trials methodology, quality of life assessment, integrating trial evidence to improve clinical practice and health outcomes. He has published over 350 peer-reviewed publications. He has received the NSW Premier's Award for Outstanding Cancer Researcher of the year (2016), the Medical Oncology Group of Australia Cancer Achievement Award (2010) and the Harvard Alum Award in Biostatistics (2009).

**Professor Judith Trotman, MBCHB, FRACP, FRCPA
Appointed 21 November 2017**

Professor Judith Trotman, Head of Department, Haematology and founding Director of Clinical Research Unit, Concord Hospital, Sydney is a member of the Australasian Leukaemia Group (ALLG) with a specialist interest in lymphoma research. Prof Trotman is currently a member of the ALLG's Scientific Advisory Committee and has previously held appointment to the ALLG's Finance and Audit Committee. As PI on several clinical trials she has insight to the challenges and opportunities faced by trial networks in delivering investigator-initiated research.

Recognising the central role of study coordinators in clinical research she partnered with them in developing ClinTrial Refer, an App that has facilitated coordinator / haematologist collaboration with an eight-fold increase in cross-referrals, and increased access to clinical trials for patients. Prof Trotman is committed to ongoing recognition and promotion of investigator-initiated research across the health and academic sector.

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Ms Leonie Wilcox, BSC RN
Appointed 18 November 2019

Leonie Wilcox worked as a registered nurse in midwifery and operating theatres, before earning a degree in Statistics from Macquarie University. She has since worked in clinical trials and research positions in hospitals and universities and has taught in undergraduate statistics programs at Macquarie University and University of NSW. Since 2006, Leonie has been the manager of the Australasian Bone Marrow Transplant Recipient Registry.

Leonie has been a member of the Board of Directors of the Arrow Bone Marrow Transplant Foundation since 2007.

Meetings of Directors

During the financial year, five board meetings were held. Attendance by each Director was as follows:

| Director | Meetings held whilst a Director | Meetings attended whilst a Director |
|-------------------|---------------------------------|-------------------------------------|
| R L James | 2 | 2 |
| M.M. MacGillivray | 5 | 4 |
| A. McKenzie | 3 | 1 |
| R. Morton | 3 | 2 |
| V. Perkovic | 2 | 0 |
| C.M. Reid | 5 | 5 |
| K.G. Schneemann | 5 | 4 |
| R.J. Simes | 2 | 1 |
| J. Trotman | 5 | 3 |
| S.A.R. Webb | 5 | 3 |
| L. Wilcox | 3 | 3 |
| J.R. Zalcborg OAM | 5 | 5 |

Principal Activity

The Australian Clinical Trials Alliance (ACTA) was incorporated as a not-for-profit company limited by guarantee on 21 March 2014 to provide a national mechanism for supporting high-quality investigator-led clinical trials within the Australian healthcare system.

ACTA's mission is to promote effective and cost-effective health care in Australia through investigator-initiated clinical trials and clinical quality registries that generate evidence to support decision-making by health practitioners, policymakers, and consumers.

On 30 June 2020, ACTA's Member profile consisted of 66 Full and Associate Member Clinical Trial Networks (CTNs), trial Coordinating Centres (CCs) and Clinical Quality Registries (CQRs), together with 16 Affiliate Member organisations and 168 individual Affiliate Members. In the event of winding up, Members are liable for up to \$10. The total amount that Members of the company are liable to contribute if the company is wound up is \$2,500.

DIRECTORS' REPORT

Company Objectives and Strategies

ACTA's vision is for *better health through best evidence*.

To improve health outcomes in Australia, ACTA's 2018-2021 Strategic Plan aims to:

1. Grow Australia's capacity to conduct high-quality clinical trials to improve evidence by:
 - a) Supporting the coordinated development of new CTNs, CQRs and CCs to fill identified gaps.
 - b) Increasing clinical research capacity through greater education and training opportunities for researchers and consumers.
 - c) Developing frameworks for improved research prioritisation and impact.
 - d) Developing and promoting transformational models of a learning health system.

2. Improve the effectiveness and efficiency of clinical trial practice by:
 - a) Creating communities of practice to maximise the impact of ACTA reference groups.
 - b) Identifying and promoting best-practice guidelines to achieve optimal CTN operational standards.
 - c) Exploring innovative, value-adding shared services, tools and technologies for CTNs and CQRs.
 - d) Enhancing links between ACTA members to enable efficient cross-sector learning.
 - e) Engaging with consumers and other stakeholders to further improve best practice models.

3. Promote, advocate and collaborate to strengthen the sector by:
 - a) Developing and implementing marketing and communications to deliver key messages.
 - b) Focusing advocacy for best practice and evidence-based healthcare.
 - c) Maintaining relationships with all stakeholders based on trust and respect.
 - d) Providing advice as the authoritative point of contact for members and policymakers.
 - e) Collaborating with Industry to advance the sector.

4. Build a sustainable and well-run organisation by:
 - a) Building the membership base and connect with members to ensure optimal engagement.
 - b) Identifying new ways of engaging with external stakeholders.
 - c) Developing governance systems to ensure responsive and responsible leadership.
 - d) Furthering internal processes and policy to ensure effective and efficient management.
 - e) Diversifying and expanding funding sources.

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Review of Operations and Major Achievements

ACTA gratefully acknowledges the invaluable support and contributions from its Members and operational funding from the Australian Government's Medical Research Future Fund (MRFF).

During the 2019/20 financial year, ACTA continued to deliver on the program of work agreed under the MRFF *Lifting Clinical Trials and Registries Capacity – Clinical Trials Networks Program*.

ACTA continued to advance health and medical research priorities in Australia and their implementation in evidence-based healthcare, by facilitating knowledge sharing and promoting the growth of the investigator-initiated clinical trials sector, which is vital to the continued improvement of health outcomes for all Australians.

The key areas of activity and focus for the year were:

- CTN efficiency and effectiveness
- Network management
- CTN sector expansion
- Impact and implementation of CTN trials
- Embedding clinical trials in healthcare
- Strengthening consumer engagement in trials
- Research prioritisation
- Innovative trials design and conduct
- Innovative outcome data
- CQRs and registry randomised trials
- Statistics in trial

Across eight Reference Groups and three Special Interest Groups, including experts in their fields, the ACTA Community identified barriers and implemented best-practice guidance to support specific aspects of the conduct of clinical trials, CTNs and CQRs. This included the continued development of tools to support optimal CTN operations, and assist the establishment of emerging networks in areas of high priority, identified through a sector-wide gap analysis.

To facilitate knowledge sharing and professional development, ACTA provided a range of educational events throughout the year, including an annual scientific meeting (ACTA International Clinical Trials Conference 2019), workshops, and webinars.

ACTA continued to develop its governance, communication and stakeholder engagement structures. In addition to the Board, the Advisory Council, Executive Committee, Finance, Audit and Risk Committee, Membership Committee and Nominations Committee provided guidance and strategic direction. ACTA participated in public, and targeted consultations and representatives participated in national committees to provide a voice for the investigator-initiated trial sector. Primary communication channels included the ACTA website, a monthly electronic newsletter, Twitter and LinkedIn.

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Highlights

In October 2019, the ACTA International Clinical Trials Conference brought together the ACTA Community, together with policymakers, industry and consumers. The Conference was opened by the Hon. Greg Hunt MP, Minister for Health, and the supported by the Australian Department of Health as Principal Partners. The Conference and accompanying workshops highlighted the importance of clinical trials in delivering quality care and treatment, innovation and economic value to the health care system throughout Australia and was attended by over 400 delegates.

ACTA's redeveloped website was launched in November 2019 to highlight the activities and resources of ACTA and the broader sector. With the growing content being developed and shared by the ACTA Community, the website was designed to make it easier to search and find programs, topics, resources and key stakeholders.

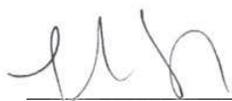
In addition, ACTA launched an online and interactive Consumer Involvement and Engagement in Clinical Trials Toolkit, in collaboration with Clinical Trials: Impact & Quality (CT:IQ). The Toolkit is based on international best practice and locally developed resources and provides tools and guidance on consumer involvement and engagement in clinical trials in Australia.

COVID-19

In 2020, the COVID-19 pandemic caused significant disruption to healthcare providers and the clinical trials sector. In recognition of this impact, the Board of ACTA opted to delay the annual invoicing of Members for six months. ACTA produced a dedicated newsletter and area on the website to make key resources available to the sector. An online forum was also rapidly established, in collaboration with PRAXIS, CT:IQ and ARCS Australia, to allow cross-sector communications and problem-solving. On request by the Government, ACTA established an Advisory Committee to provide recommendations to the Department of Health on the National Medical Stockpile for the provision of drugs for trials conducted in Australia on COVID-19.

ACTA operations were impacted by COVID-19, both in the availability of ACTA Board and Reference Group member and key opinion leaders, and the ability to continue planned activities. All anticipated travel was cancelled over the 3rd and 4th quarters of the financial year. In some cases, activities needed to be cancelled or postponed and where possible were moved to a virtual environment. This led to considerable underspend on the MRFF grant over 2020. A variation of contract was granted in July to extend the grant by six months.

Director



John Raymond Zalcborg OAM
Chair

Dated: 17 September, 2020

AUDITOR'S INDEPENDENCE DECLARATION TO THE DIRECTORS OF AUSTRALIAN CLINICAL TRIALS ALLIANCE LTD

In relation to our audit of the financial report of Australian Clinical Trials Alliance Ltd for the financial year ended 30 June 2020 to the best of my knowledge and belief, there have been no contraventions of the auditor independence requirements of the *Corporations Act 2001* or any applicable code of professional conduct.



PKF

Melbourne, 17 September 2020



Steven Bradby

Partner

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STATEMENT OF SURPLUS OR DEFICIT & OTHER COMPREHENSIVE INCOME
FOR THE YEAR ENDED 30 JUNE 2020

| | Note | 2020 \$ | 2019 \$ |
|---|----------|-----------------------------|------------------------------|
| Revenue | 3 | | |
| Event sponsorship & registrations | | 372,494 | 69,972 |
| Membership fees | | 86,188 | 75,088 |
| Project revenue | | 70,000 | 30,000 |
| Revenue from grants | | 1,663,361 | 1,562,391 |
| Other income | | 146,319 | 83,696 |
| Total revenue & other income | | 2,338,361 | 1,821,147 |
| Expenditure | 4 | | |
| Audit & legal | | (11,339) | (10,841) |
| Consultancy expenses | | (422,657) | (203,346) |
| Depreciation & amortisation expense | | (7,587) | (18,512) |
| Employee benefit expenses | | (1,167,564) | (1,092,333) |
| Event & meeting expenses | | (509,719) | (44,801) |
| Operating expenses | | (150,105) | (183,021) |
| Total expenditure | | <u>(2,268,971)</u> | <u>(1,552,854)</u> |
| Net surplus/(deficit) before income tax | | 69,391 | 268,293 |
| Income tax expense | | <u>-</u> | <u>-</u> |
| Net surplus/(deficit) for the year | | 69,391 | 268,293 |
| Other comprehensive income for the year | | <u>-</u> | <u>-</u> |
| Total comprehensive surplus/(deficit) for the year | | <u><u>69,391</u></u> | <u><u>268,293</u></u> |

The accompanying notes form part of these financial statements.

AUSTRALIAN CLINICAL TRIALS ALLIANCE LTD.
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STATEMENT OF FINANCIAL POSITION

AS AT 30 JUNE 2020

| | Note | 2020 \$ | 2019 \$ |
|----------------------------------|------|-------------------------|-------------------------|
| ASSETS | | | |
| CURRENT ASSETS | | | |
| Cash & cash equivalents | 5 | 1,859,984 | 2,400,529 |
| Accounts & other receivables | 6 | 16,753 | 63,462 |
| Other assets | 7 | <u>10,078</u> | <u>130,195</u> |
| TOTAL CURRENT ASSETS | | <u>1,886,815</u> | <u>2,594,186</u> |
| NON-CURRENT ASSETS | | | |
| Property, plant & equipment | 8 | <u>15,809</u> | <u>19,560</u> |
| TOTAL NON-CURRENT ASSETS | | <u>15,809</u> | <u>19,560</u> |
| TOTAL ASSETS | | <u><u>1,902,624</u></u> | <u><u>2,613,746</u></u> |
| LIABILITIES | | | |
| CURRENT LIABILITIES | | | |
| Accounts & other payables | 9 | 185,080 | 236,385 |
| Provisions | 10 | 35,663 | 23,874 |
| Deferred revenue | 11 | <u>1,147,195</u> | <u>1,888,192</u> |
| TOTAL CURRENT LIABILITIES | | <u>1,367,938</u> | <u>2,148,451</u> |
| TOTAL LIABILITIES | | <u>1,367,938</u> | <u>2,148,451</u> |
| NET ASSETS | | <u><u>534,685</u></u> | <u><u>465,295</u></u> |
| EQUITY | | | |
| Retained funds | | <u>534,685</u> | <u>465,295</u> |
| TOTAL EQUITY | | <u><u>534,685</u></u> | <u><u>465,295</u></u> |

The accompanying notes form part of these financial statements.

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STATEMENT OF CHANGES IN EQUITY
FOR THE YEAR ENDED 30 JUNE 2020

| | Accumulated Funds \$ | Total \$ |
|--|----------------------------|----------------|
| Balance at 1 July 2018 | 197,002 | 197,002 |
| Comprehensive income | | |
| Net surplus/(deficit) for the year | 268,293 | 268,293 |
| Total comprehensive income for the year attributable to the member of the company | - | - |
| | 465,295 | 465,295 |
| Balance at 30 June 2019 | | |
| Balance at 1 July 2019 | 465,295 | 465,295 |
| Comprehensive income | | |
| Net surplus/(deficit) for the year | 69,391 | 69,391 |
| Total comprehensive income for the year attributable to the member of the company | - | - |
| | 534,685 | 534,685 |
| Balance at 30 June 2020 | | |

The accompanying notes form part of these financial statements

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STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 30 JUNE 2020

| | Note | 2020 \$ | 2019 \$ |
|---|-----------|-------------------------|-------------------------|
| Cash flows from operating activities | | | |
| Receipts from Australian Taxation Office | | 50,000 | - |
| Receipts from grants & other income | | 1,295,651 | 1,649,649 |
| Payments to Australian Taxation Office | | (389,254) | (331,801) |
| Payments to suppliers & employees | | <u>(1,525,343)</u> | <u>(1,123,982)</u> |
| Net cash provided by operating activities | 13 | <u>(568,945)</u> | <u>193,866</u> |
| Cash flows from investing activities | | | |
| Interest income | | 30,802 | 11,923 |
| Payment for property, plant & equipment | | (4,175) | (21,594) |
| Withholding tax received | | <u>1,774</u> | <u>-</u> |
| Net cash provided by investing activities | | <u>28,401</u> | <u>(9,671)</u> |
| Net increase in cash held | | (540,545) | 184,195 |
| Cash and cash equivalents at beginning of financial year | | <u>2,400,529</u> | <u>2,216,334</u> |
| Cash and cash equivalents at end of financial year | 13 | <u><u>1,859,984</u></u> | <u><u>2,400,529</u></u> |

The accompanying notes form part of these financial statements

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NOTES TO THE FINANCIAL STATEMENTS
FOR THE YEAR ENDED 30 JUNE 2020

The financial statements cover Australian Clinical Trials Alliance Ltd. as an individual entity. Australian Clinical Trials Alliance Ltd. is a company limited by guarantee, incorporated and domiciled in Australia.

The financial statements were authorised for issue on 17 September 2020 by the directors of the company.

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Preparation

These general purpose financial statements have been prepared in accordance with the requirements of the Corporations Act 2001, Australian Accounting Standards Reduced Disclosure Requirements, Accounting Interpretations and other authoritative pronouncements of the Australian Accounting Standards Board.

The company is a not-for-profit entity for financial reporting purposes under Australian Accounting Standards. Material accounting policies adopted in the preparation of these financial statements are presented below and have been consistently applied unless stated otherwise.

The financial statements, except for cash flow information, have been prepared on an accruals basis and are based on historical costs, modified, where applicable, by the measurement at fair value of selected non-current assets, financial assets and financial liabilities. The amounts presented in the financial statements have been rounded to the nearest dollar.

In the current year, the company has adopted all of the new and revised standards and interpretations issued by the Australian Accounting Standards Board (the AASB) that are relevant to its operations and effective for the current annual reporting period. The adoption of these new and revised Standards and Interpretations has not resulted in any significant changes to any of the company's accounting policies.

(a) Revenue

The company currently adopted AASB 15 *Revenue from Contracts with Customers* and AASB 1058 *Income of Not-for-Profit Entities* with a date of initial application of 1 July 2019. The modified retrospective method has been applied, which means the comparative information has not been restated and continues to be reported under AASB 118 *Revenue*, AASB 1004 *Contributions* and related interpretations. The key changes did not have a material impact on RACS' financial report for the financial year.

Grants

Government and other funding is received or receivable on the condition that sufficiently specific performance obligations are met. Such grants are recognised as deferred income and revenue is recognised as services are performed or conditions fulfilled, being the expenditure incurred relating to the specified grant.

Membership & Similar Services Revenue

Membership and similar revenues are recognised on an accrual basis as the related services are delivered.

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NOTES TO THE FINANCIAL STATEMENTS
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Sponsorship Revenue

Sponsorship revenue is recognised on a straight line basis over the sponsorship contract period, unless the sponsorship is payable on achieving specified milestones, in which case revenue is recognised on the completion of the contracted milestone.

Contributions

A contribution occurs when the company receives an asset without directly giving approximately equal value to the other party to the transfer. Contributions include donations and certain government grants. Income from contributions is recognised when the company obtains control, economic benefits are probable, and the amount can be measured reliably.

Income arising from contributions is measured at the fair value of the contributions received or receivable.

Events Revenue

Revenue from organising and hosting events is recognised in the period in which the events are held.

Interest Income

Interest revenue is recognised when it becomes receivable on a proportional basis taking in to account the interest rates applicable to the financial assets.

(b) Property, Plant & Equipment

Each class of property, plant and equipment is carried at cost or fair value as indicated, less, where applicable, accumulated depreciation and any impairment losses.

Plant & Equipment

Plant and equipment are measured on the costs basis and are therefore carried at cost less accumulated depreciation and any accumulated impairment losses. In the event the carrying amount of plant and equipment is greater than the estimated recoverable amount, the carrying amount is written down immediately to the estimated recoverable amount and impairment losses are recognised either in profit or loss or as a revaluation decrease if the impairment losses relate to a revalued asset. A formal assessment of recoverable amount is made when impairment indicators are present.

Plant and equipment that have been contributed at no cost, or for nominal cost, are valued and recognised at the fair value of the asset at the date it is acquired.

(c) Depreciation

The depreciable amount of all fixed assets is depreciated on a diminishing value basis over the assets useful life to the entity commencing from the time the asset is held ready for use. The depreciation rates used for each class of depreciable assets are:

| Class of Fixed Asset | Depreciation Rate |
|-----------------------------|--------------------------|
| Plant & Equipment | 40% - 100% |

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NOTES TO THE FINANCIAL STATEMENTS
FOR THE YEAR ENDED 30 JUNE 2020

The assets residual values and useful lives are reviewed, and adjusted if appropriate, at the end of each reporting period.

Gains and losses on disposals are determined by comparing proceeds with the carrying amount. These gains or losses are recognised in profit or loss in the period in which they arise. When revalued assets are sold, amounts included in the revaluation surplus relating to that asset are transferred to retained earnings.

(d) Employee Benefits

Short-Term Employee Benefits

Provision is made for the Company's obligation for short-term employee benefits. Short-term employee benefits are benefits (other than termination benefits) that are expected to be settled wholly within 12 months after the end of the annual reporting period in which the employees render the related service, including wages, salaries, superannuation and sick leave. Short-term employee benefits are measured at the (undiscounted) amounts expected to be paid when the obligation is settled.

The Company's obligations for short-term employee benefits such as wages, salaries and superannuation are recognised as part of accounts and other payables whilst annual leave is recognised as part of provisions in the statement of financial position.

(e) Provisions

Provisions are recognised when the entity has a legal or constructive obligation, as a result of past events, for which it is probable that an outflow of economic benefits will result and that outflow can be reliably measured. Provisions recognised represent the best estimate of the amounts required to settle the obligation at the end of the reporting period.

(f) Income Tax

The company is a not-for-profit organisation established to support and facilitate clinical scientific research conducted by investigator initiated clinical trials within the Australian healthcare system. The company is a fund with sufficient links with public universities or public hospitals. The company itself does not conduct the scientific research. The research is conducted by the university or hospital, or by other bodies in conjunction with the university or hospital. The company enables the research by various means, including providing representation and support for research, education and training.

For the purposes of Australian taxation legislation, the company is exempt from income tax. The company meets the criteria and has self-assessed as a tax exempt not-for-profit scientific research fund. The company is required to re-assess tax exempt status on an annual basis.

(g) Accounts & Other Receivables

Accounts & other receivables include amounts due from customers for goods sold and services performed in the ordinary course of business. Receivables expected to be collected within 12 months of the end of the reporting period are classified as current assets. All other receivables are classified as non-current assets.

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NOTES TO THE FINANCIAL STATEMENTS
FOR THE YEAR ENDED 30 JUNE 2020

(h) Cash & Cash Equivalents

Cash & cash equivalents include cash on hand, deposits held at call with banks, other short-term highly liquid investments with original maturities of three months or less, and bank overdrafts. Bank overdrafts are shown within borrowings in current liabilities on the statement of financial position.

(i) Trade & Other Payables

Trade & other payables represent the liabilities for goods and services received by the company that remain unpaid at the end of the reporting period. The balance is recognised as a current liability with the amounts normally paid within 30 days of recognition of the liability.

(j) Goods & Services Tax (GST)

Revenues, expenses and assets are recognised net of the amount of GST, except where the amount of GST incurred is not recoverable from the Australian Taxation Office (ATO).

Receivables & payables are stated inclusive of the amount of GST receivable or payable. The net amount of GST recoverable from, or payable to, the ATO is included with other receivables or payables in the statement of financial position.

2. ECONOMIC DEPENDENCY

The company is reliant upon grants for the support of its principal activities. Under an agreement dated 16 June 2017 with the Commonwealth of Australia as represented by and acting through the Department of Health, the company agreed to deliver the Program 'Strengthening the Capacity, Efficiency and Effectiveness of Clinical Trials Networks through the Australian Clinical Trials Alliance', over the period ending 30 August 2020. The company is reliant on receipt of the agreed level of grant funding in order to complete the project.

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NOTES TO THE FINANCIAL STATEMENTS
FOR THE YEAR ENDED 30 JUNE 2020

| | 2020 | 2019 |
|---|------------------|------------------|
| | \$ | \$ |
| 3. REVENUE & OTHER INCOME | | |
| ACTA Annual Summit registrations | - | 35,622 |
| International Conference | 423,152 | - |
| Ticketed Workshops | - | 57,624 |
| Government funding - Grants recognised for services performed | 1,663,361 | 1,562,391 |
| Interest received | 32,480 | 11,922 |
| Membership fees | 86,188 | 75,088 |
| Project funding | 70,000 | 30,000 |
| Sponsorship income | - | 29,114 |
| ATO Cash Flow Boost | 50,000 | - |
| Other revenue | 13,181 | 19,386 |
| | 2,338,361 | 1,821,147 |
| 4. EXPENDITURE | | |
| Audit & legal | 11,339 | 10,841 |
| Consultancy expenses (relating to MRFF deliverables) | 422,657 | 203,346 |
| Depreciation & amortisation expense | 7,587 | 18,512 |
| Employee benefit expenses | 1,167,564 | 1,092,333 |
| Event & meeting expenses | 509,719 | 44,801 |
| Rent expense | 63,112 | 49,844 |
| Travel expenses | 21,996 | 30,649 |
| Other operational expenses | 64,998 | 102,528 |
| | 2,268,971 | 1,552,854 |
| 5. CASH & CASH EQUIVALENTS | | |
| Cash at bank | 404,911 | 361,194 |
| Short-term deposits | 1,455,073 | 2,039,335 |
| | 1,859,984 | 2,400,529 |
| 6. ACCOUNTS & OTHER RECEIVABLES | | |
| CURRENT | | |
| Accounts receivable | 636 | 47,867 |
| Deposits | 16,117 | 15,498 |
| Withholding tax paid | - | 96 |
| | 16,753 | 63,462 |

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NOTES TO THE FINANCIAL STATEMENTS
FOR THE YEAR ENDED 30 JUNE 2020

| | 2020 | 2019 |
|--|------------------|------------------|
| | \$ | \$ |
| 7. OTHER ASSETS | | |
| INTERNATIONAL CONFERENCE | | |
| Funds held for Conference as at 30 June 2019 | - | 115,932 |
| Made up of; | | |
| Cash | - | 78,461 |
| Receivables | - | 37,471 |
| Prepayments | 10,078 | 14,263 |
| | <u>10,078</u> | <u>130,195</u> |
| 8. PROPERTY, PLANT & EQUIPMENT | | |
| Plant & equipment | 46,675 | 42,839 |
| Less accumulated depreciation | <u>(30,866)</u> | <u>(23,279)</u> |
| | <u>15,809</u> | <u>19,560</u> |
| 9. ACCOUNTS & OTHER PAYABLES | | |
| CURRENT | | |
| Accounts payable | 131,067 | 24,515 |
| Accrued expenses | - | 53,199 |
| Good & services tax | 46,009 | 123,711 |
| Payroll expenses payable | 702 | (39) |
| Superannuation payable | 7,302 | 13,566 |
| Withholding taxes payable | - | 21,433 |
| | <u>185,080</u> | <u>236,385</u> |
| 10. PROVISIONS | | |
| CURRENT | | |
| Provision for annual leave | <u>35,663</u> | <u>23,874</u> |
| | <u>35,663</u> | <u>23,874</u> |
| 11. DEFERRED REVENUE | | |
| CURRENT | | |
| Income in advance | - | 77,575 |
| Deferred Grant Income | <u>1,147,195</u> | <u>1,810,557</u> |
| | <u>1,147,195</u> | <u>1,888,132</u> |

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NOTES TO THE FINANCIAL STATEMENTS
FOR THE YEAR ENDED 30 JUNE 2020

| | 2020 \$ | 2019 \$ |
|--|------------------|------------------|
| 12. COMPANY DETAILS | | |
| The registered office and principal place of business is: Level 2 Suite 1 24 Albert Road SOUTH MELBOURNE VIC 3205 | | |
| 13. CASH FLOW INFORMATION | | |
| (a) Reconciliation of Cash | | |
| Cash at bank | 404,911 | 361,194 |
| Short-term deposits | 1,455,073 | 2,039,335 |
| | <u>1,859,984</u> | <u>2,400,529</u> |
| Reconciliation of cash flow from operations | | |
| (b) with profit after income tax | | |
| Net surplus/(deficit) for the year | 69,391 | 268,293 |
| Depreciation | 7,587 | 18,512 |
| Interest presented as investing cash flow | (30,802) | (11,923) |
| (Increase)/decrease in Assets | | |
| Accounts & other receivables | 46,709 | (56,828) |
| Other assets | 120,117 | (126,589) |
| Increase/(decrease) in Liabilities | | |
| Accounts & other payables | (51,305) | 89,217 |
| Other liabilities | (730,641) | 13,184 |
| Net cash provided by operating activities | <u>(568,945)</u> | <u>193,866</u> |

Receipts from Australian Taxation Office, totalling \$50,000, are in relation to a Federal Government COVID-19 Stimulus Announcement (ATO Cash Flow Boost)

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NOTES TO THE FINANCIAL STATEMENTS
FOR THE YEAR ENDED 30 JUNE 2020

| | 2020 | 2019 |
|---|-------------|-------------|
| | \$ | \$ |
| 14. LEASE COMMITMENTS | | |
| Commitment for minimum lease payments in relation to non-cancellable operating leases are payable as follows: | | |
| Within one year | - | 9,388 |
| Later than one year but not later than five years | - | - |
| | - | 9,388 |

Commitments relate to lease of premises for Level 2, Suite 1, 24 Albert Road South Melbourne, 3205.

15. SUBSEQUENT EVENTS

To allow for the future sustainability of ACTA, on 27 July 2020, ACTA received correspondence from the Medical Research Future Fund (MRFF) confirming their successful application for the 2020 Enhancing Clinical Trials Networks Capabilities Grant.

As part of the project, labelled 'Embedding clinical trials for "Better health through best evidence"', ACTA will receive up to the maximum grant funding amount of \$5,000,000 over a 4 year period spanning until the 2023/2024 financial year. The terms of ACTA's recently approved funding grant has not been signed at the time of preparation of these financial statements.

16. OPERATING FUNDS

Please note that the total amount of operating funds which ACTA will carry forward into the 2021 financial year is \$534,595. These funds are operational in the context that they are not aligned to grant deliverables.

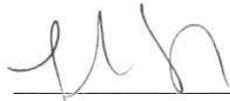
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DIRECTORS' DECLARATION

In accordance with a resolution of the directors of Australian Clinical Trials Alliance Ltd., the directors of the company declare that:

1. 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; and
2. There are reasonable grounds to believe that the company will be able to pay its debts as and when they become due and payable.

Director



John Raymond Zalcborg OAM

Dated: 17 September, 2020

INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF AUSTRALIAN CLINICAL TRIALS ALLIANCE LTD

Report on the Financial Report

Auditor's Opinion

We have audited the accompanying financial report of Australian Clinical Trials Alliance Ltd (the company), which comprises the statement of financial position as at 30 June 2020, the statements of surplus or deficit and other comprehensive income, changes in equity, and cash flows for the year ended on that date, a summary of significant accounting policies, other explanatory notes and the directors' declaration.

In our opinion, the financial report is prepared in accordance with the *Corporations Act 2001*, including:

- (a) giving a true and fair view of the financial position of the company as at 30 June 2020 and of its financial performance for the year ended on that date; and
- (b) complying with Australian Accounting Standards – Reduced Disclosure Requirements and the *Corporations Regulations 2001*.

Basis for opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Report* section of this report.

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

We are independent of the company in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

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.

In preparing the financial report, the directors are responsible for assessing the company's ability to continue as a going concern, disclosing, as applicable, matters relating to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the company or to cease operations, or have no realistic alternative but to do so.

Auditor's Responsibilities for the Audit of the Financial Report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the financial report.

As part of an audit in accordance with the Australian Auditing Standards, we exercise professional judgement and maintain professional scepticism throughout the audit. We communicate with the directors regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

A further description of our responsibilities for the audit of the financial report is located at the Auditing and Assurance Standards Board website at: <http://www.auasb.gov.au/Home.aspx>. This description forms part of our auditor's report.

PKF
Melbourne, 17 September 2020

Steven Bradby
Partner