



2011

Annual Report



The Directors of ANZUP Cancer Trials Group Limited (“ANZUP”) are pleased to submit the Annual Report for 2011.

ANZUP Cancer Trials Group Limited

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ANZUP'S Mission, Objectives and Vision

MISSION

The mission of ANZUP is to conduct and promote cooperative clinical trials and psychosocial research in prostate and other urogenital cancers.

OBJECTIVES

The objectives of the Company are to develop, foster and promote prostate and urogenital cancer research by:

- providing access to clinical trials for all appropriate Australian and New Zealand patients
- increasing involvement of and collaboration with various professional disciplines in clinical and preclinical research
- providing opportunities for clinical research
- building systems to simplify and streamline clinical research of the highest quality
- fostering a culture of research amongst all clinicians involved in the care of patients with urogenital cancers
- providing training opportunities for the next generation of clinical researchers
- providing for translational studies in prostate and other urogenital cancers, including tissue banking from clinical trials for further studies

VISION

The vision of the Company is to minimise the effect of prostate and other urogenital cancer on the community in terms of survival, incidence and quality of life, through research and education and by providing patients and carers with support.

ANZUP'S History

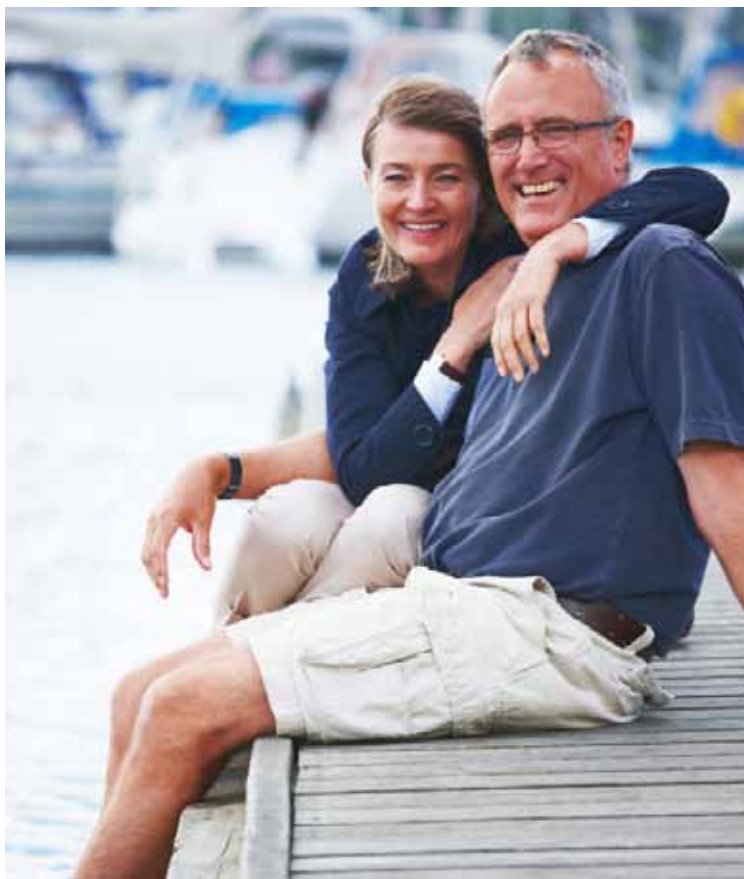
The Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP Cancer Trials Group Ltd, "ANZUP") became a company limited by guarantee on 9 October 2008. The official launch of ANZUP was held on 20th March 2009 in Sydney.

ANZUP is a cooperative and multi-disciplinary organisation with both Australian and international collaborations. ANZUP was formed by the merge of the Australian Prostate and Urogenital cancer Group (APUG) and the Australian and New Zealand Germ Cell Trials Group (ANZGCTG). APUG was formed as a national cooperative clinical trials group encompassing all urologic cancers (prostate, kidney, bladder/urothelial and other related tumours). The aim of APUG was to bring together multiple professional disciplines and interested people to perform high quality clinical trials in urologic cancers, and to promote the systematic collection of data and tissues and facilitate basic and translational research in relation to clinical trials. ANZGCTG was a long established network of over 100 clinicians and researchers and was at the time the only national organisation dedicated to high-quality clinical research for people affected by germ cell cancers including testicular cancer. It was the lead collaborative group for testicular cancer trials in Australia and New Zealand since the 1980's.

Funding for APUG was initially from a grant from the Victorian Cancer Agency while ANZGCTG received funding from the newly created Cancer Australia. Subsequently funding was secured from Cancer Australia to support the merger of APUG and ANZGCTG. ANZUP was awarded ongoing funding from Cancer Australia through its Support for Clinical Trials program from January 2009 until 30 June 2010, and this was renewed from 1 July 2010.

ANZUP was formed to meet a need for greater collaboration within the Australian medical community on research and clinical trials, particularly for urogenital cancers (prostate, testicular, kidney and bladder) and to find better ways to treat cancer in order to improve patient outcomes, particularly life expectancy and quality of life. The network aims to bring together the professionals and organisations that conduct and support clinical and translational cancer research.

ANZUP currently has members from Australia and New Zealand from all relevant professional medical, nursing, allied health, basic science and other disciplines, and consumer/community involvement.

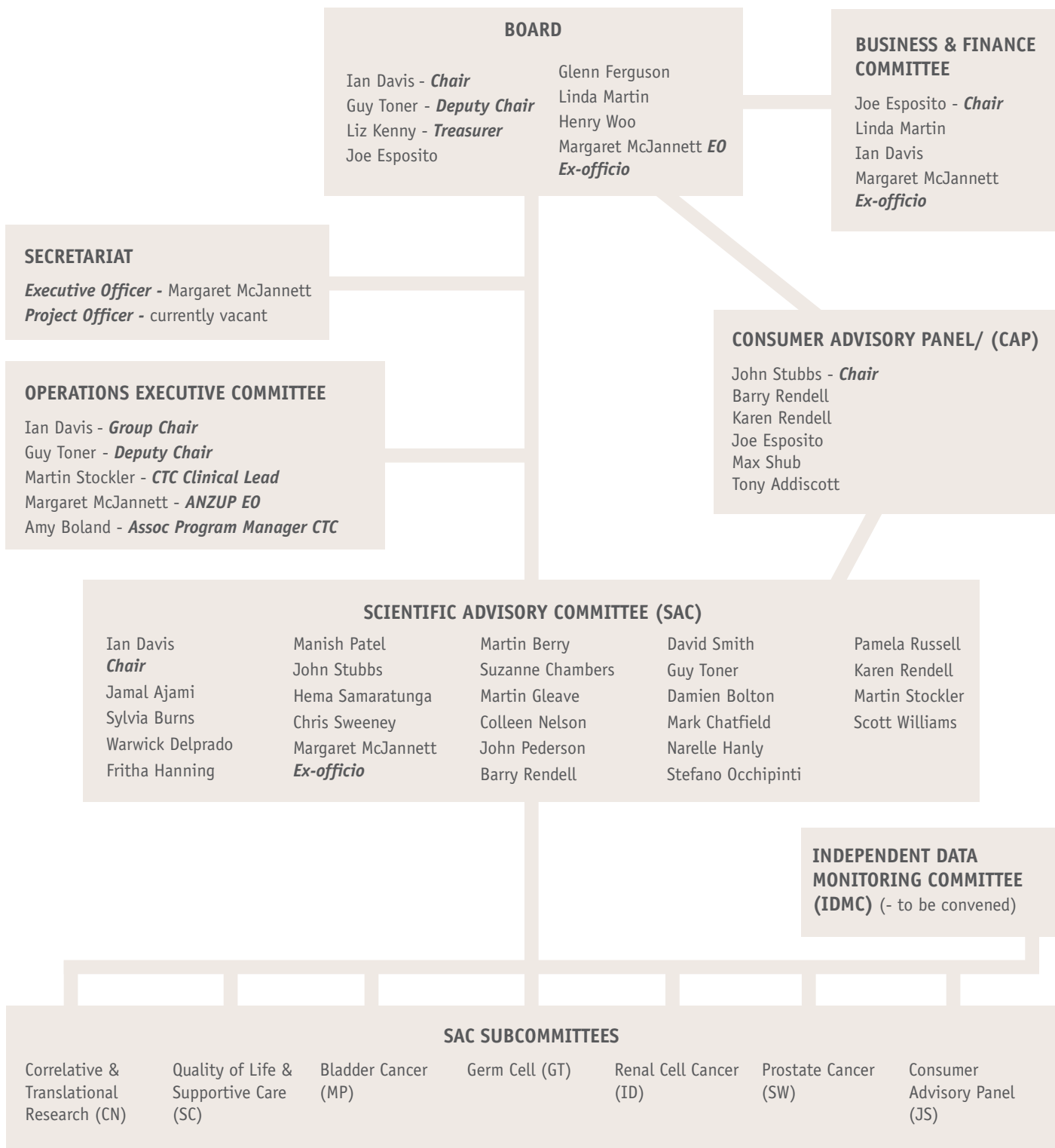


....to improve patient outcomes, particularly life expectancy and quality of life.

Governance Structure

ANZUP ORGANISATIONAL CHART - March 2011

For more details visit <http://www.anzup.org.au/content.aspx?page=ourstructure>



CN - Colleen Nelson, GT - Guy Toner, ID - Ian Davis, JS - John Stubbs, MP - Manish Patel, SC - Suzanne Chambers, SW - Scott Williams

Governance Structure Continued

ANZUP Cancer Trials Group Ltd is a collaborative, national and international, urogenital and prostate cancer, clinical trials and research group. The organisational structure of ANZUP reflects its corporate governance and operational areas of responsibility.

- **Board:** The Board comprises the Directors of the Company and is responsible for financial management, corporate governance, reporting and compliance. The Board consists of five elected Directors and up to three Appointed Directors (1 position currently vacant). The Board meets by teleconference approximately once every 2 months and face-to-face several times per year.
- **Finance and Audit Committee:** A subcommittee of the Board. Its main objectives are to assist the Board in the discharge of its responsibility to exercise due care, diligence and skill; and to provide a formal forum for financial management, compliance and control.
- **Secretariat:** The secretariat comprises a part-time Executive Officer and a Project Officer (currently filled on a casual part-time basis). The company's registered office is located in Sydney.
- **Scientific Advisory Committee (SAC):** The SAC consists of a core of members representing the major disciplines relevant to ANZUP, nominated and appointed upon the recommendation of those groups. In addition, chairs of the SAC subcommittees are members of the SAC by virtue of their appointment as Chair. The SAC meets by teleconference quarterly and face-to-face at least once per year.
- **SAC Subcommittees:** The SAC is advised by disease-specific subcommittees (Prostate; Renal; Germ Cell; Bladder) and non-disease-specific subcommittees (Quality of Life & Supportive Care; Correlative and Translational Research; Consumer Advisory Panel). The disease-specific subcommittees are responsible for oversight of trials within their portfolios, as well as development of new trial concepts. These subcommittees meet by teleconference quarterly and face-to-face at least once per year. The non-disease-specific subcommittees are involved as required in trial development and management in order to ensure that maximum value is added to every trial. These subcommittees meet by teleconference as required and face-to-face at least once per year.
- **Consumer Advisory Panel (CAP):** The CAP comprises consumer/community representatives who advise ANZUP at all levels of governance, including the Board and SAC and its subcommittees through to specific trials and research projects. The CAP also provides a conduit for communication from ANZUP back to the community in order to promote research and engage community support. The CAP meets by teleconference as required and face-to-face at least once per year.
- **Operations Executive Committee:** This committee consists of representatives from ANZUP and from the NHMRC Clinical Trials Centre at University of Sydney. The Committee is responsible for oversight of trial and group operations. This Committee meets by teleconference approximately once per month.
- **Independent Data Monitoring Committee (IDMC):** The IDMC is yet to be established but terms of reference have been drafted. It is anticipated that the IDMC will have oversight of multiple clinical trials.
- **Trial Management Committees (TMC):** Each trial has a TMC that meets approximately quarterly by teleconference to ensure oversight of the trial.



The Board Of Directors



Chair: A/Prof Ian Davis

A/Prof Ian Davis is a medical oncologist working at Austin Health and the Ludwig Institute for Cancer Research (LICR) in Melbourne, where he is Head of the Uro-Oncology Laboratory. He held a Victorian Cancer Agency Clinical Researcher Fellowship until the end of 2010 and is an NHMRC Practitioner

Fellow. His primary clinical interests are in urologic cancer and in melanoma, and his primary research interests are in cancer immunology and the biology of urologic cancers. A/Prof Davis is a member of the Cancer Council Victoria Urology and Skin Committees, and the Standing Subcommittee on Research. He is chair of the COSA Urologic Oncology Group and a member of the COSA executive.

Deputy Chair: A/Prof Guy Toner

A/Prof Guy Toner is a graduate of the University of Melbourne. He undertook sub-specialty training in medical oncology at the Alfred Hospital before spending 3 years at Memorial Sloan-Kettering Cancer Centre in New York, where he worked in the GU Service. He developed a special interest in testicular cancer while in New York and his research there formed the basis of his MD thesis. He returned to Melbourne to take up a full-time position at Peter MacCallum Cancer Centre in 1990. His clinical and research interests include all urological cancers and he also has an interest in new drug development. He was Chair of the ANZ Germ Cell Trials Group from 1995 until the group merged to form ANZUP. He is a member of the SAC and Chair of the Germ Cell Sub-Committee.

Treasurer: Dr Lizbeth Kenny

Dr Liz Kenny graduated in Medicine from The University of Queensland in 1980, and completed her specialty training in Radiation Oncology at The Queensland Radium Institute in Brisbane in 1987. Dr Kenny is a Senior Radiation Oncologist at The Royal Brisbane & Women's Hospital. In 2005 she was appointed as Medical Director, Cancer Services Central and is committed to improving Cancer Services in Queensland. Her main areas of specialty interest are Head and Neck Cancer, Breast Cancer and Urological Malignancies.

Dr Kenny currently serves as the Clinical Lead for the Queensland Health Imaging Program. She has served as The Dean of The Faculty of Radiation Oncology, president of the Royal Australian and New Zealand College of Radiologists and President of The Clinical Oncological

Society of Australia. She has been awarded Honorary Memberships of The European Society of Radiology, The Radiological Society of North America and an Honorary Fellowship of The American College of Radiology.

Mr Joe Esposito

Mr Joe Esposito is a Melbourne-based management consultant whose practice has an emphasis on finance and workforce development. Prior to working as a consultant, Mr Esposito had over 20 years experience in corporate banking in Australia and New Zealand and three years as CEO of ASX-listed Jetset Travelworld Limited.

Mr Esposito has a close affinity with the objectives of ANZUP and the needs of consumers. Joe has Bachelor of Commerce and Master of Applied Finance degrees. He is a member of the Australian Institute of Company Directors.

Mr Glenn Ferguson

Mr Glenn Ferguson is a Solicitor of the High Court of Australia and the Supreme Court of Queensland. An experienced commercial and corporate lawyer he has acted in complex transactions and disputes for a range of clients both nationally and internationally.

Until the end of 2010, he was the President of the Law Council of Australia, the peak national body representing the Australian legal profession nationally and internationally. He is also past President of Lawasia, the law association for Asia and the Pacific; and a past president of the Queensland Law Society. He is a Senior Counsellor with the Queensland Law Society and has previously chaired their professional standards committee.

Mr Ferguson is a Founding Fellow of the Australian Academy of Law, a Fellow of the Australian Institute of Company Directors and a Fellow of the Australia and New Zealand College of Notaries. He is Chair of the College of Law Queensland and a member of the Federal Attorney Generals International Legal Services Advisory Council and the Immigration Minister's Advisory Board in relation to the regulation of migration agents. The Queensland Premier selected him in 2004 to Chair Smart Exports Queensland. He has been appointed by both Federal and State Governments to various advisory boards and task forces in the legal, migration and business sectors.

Mr Ferguson has also held or continues to hold a number of board positions in both the public and private sector in the insurance, superannuation, education, sport, charity and information technology areas including chairing a publicly listed company.

The Board Of Directors Continued

Ms Linda Martin

Linda Martin is the Chief Executive Officer of Arthritis Victoria and Osteoporosis Victoria. She was previously Managing Director of consultancy firm, Martin Bonato and Associates Pty Ltd, with a focus primarily in the community and health sectors. Her experience also includes the financial, construction and safety industries. Linda has an extensive knowledge of government processes and has significant experience in seeking funding. Her work in private, public and not for profit organisations includes strategic and business planning, program review, change management, program and project management, performance enhancement, alliance development, leadership and people development and cultural change.

Linda was a senior executive in the Victorian public service, working primarily in the community service sector managing regional operations, programs and major projects. She has also been a lecturer in Social Work at the University of Melbourne.

A/Prof Henry Woo

A/Prof Henry Woo is a urological surgeon with a subspecialty practice in prostate disease. He is an Associate Professor at the Sydney Medical School of the University of Sydney and operates at Westmead Public Hospital and the Sydney Adventist Hospital. In his student days, he was a Board Director of the University of Sydney Union, an elected delegate of the Sydney University Student Representative Council and Producer of a Sydney University Medical Revue. He is currently the Convenor of the 2012 Annual Scientific Meeting of the Urological Society of Australia and New Zealand.

He is the only non-US/European member of the International Greenlight Users Group as well as the International Prostate Research Group. He is regularly invited to teach and perform live surgical demonstrations locally and abroad. He runs a busy clinical trials unit at the Sydney Adventist Hospital with studies in both prostate cancer and benign prostatic hyperplasia.

A/Prof Woo has extensive experience in multicentre clinical trials, amongst which include being Principal Investigator of a study of lower urinary tract symptoms (LUTS) in men with advanced prostate cancer, Principal Investigator of the Urolift treatment for LUTS due to BPH study, co-Chair of the Timing of Androgen Deprivation (TOAD) study and membership of the Trial Management Committee of the RAVES study for prostate cancer. He is also a member of the Scientific Reference Committee of the Prostate Cancer Foundation of Australia.

Meetings of Directors

During the year, eight meetings of directors were held. Attendances by each director was as follows

Director	Director's Meetings	
	Number eligible to attend	Number attended
Ian Davis	9	9
Lizbeth Kenny	9	8
Guy Toner	9	9
John Ramsay (resigned 13 April 2010)	-	-
Henry Woo (appointed 25 June 2010)	5	5
Glenn Ferguson (appointed 30 August 2010)	4	2
Joe Esposito (appointed 13 December 2010)	2	2
Linda Martin (appointed 13 December 2010)	2	1

Strategic and Business Planning:

The Board has developed a Strategic Plan for 2010-2012. This can be found at <http://www.anzup.org.au/content.aspx?page=strategicplan>. Part of the plan involves identification and appointment of Directors with expertise in legal, corporate, accounting and fundraising issues. Other key objective are to continue to build research capacity, extend collaborations and to mentor young investigators.

Changes in state of affairs:

The Executive Director (John Ramsay) resigned from the Board on 13 April 2010.

A new Executive Officer (Margaret McJannett) was employed as of January 2011.

The Board recommended changes to its composition which came into effect on the passing of the special resolution to amend ANZUP's constitution at the extraordinary general meeting (EGM) held on Friday 25 June 2010 at 12:30pm to 1:15pm.

The first Annual General Meeting was held on Friday 25 June 2010 at 1:15pm to 3:00pm (AEST). The Board was not able to hold the first ANZUP Annual General Meeting in accordance with the usual requirements of the Corporations Act 2001 (Cth) because the company audit was not able to be completed by that deadline. An application was made to ASIC to extend the time by which ANZUP may hold its first AGM to 30 June 2010 pursuant to *s.250P of the Corporations Act 2001*. This application was granted.

In accordance with section 8.13(a) of the ANZUP Constitution, Ian Davis must resign as an elected Director but is eligible to be re-elected and has been nominated for re-election.

Matters affecting ANZUP operations and state of affairs in future financial years:

At the time of preparation of this report, approval of recurrent funding from Cancer Australia under its Support for Clinical Trials scheme had not yet been confirmed after 31 December 2011. This funding will be critical for the future operations of ANZUP. The Board anticipates that Cancer Australia is very likely to approve ongoing funding, at least for a further 18 months.

Additional funding sources will need to be identified in order to support the proposed expansion of activities of ANZUP.

Likely developments in operations and expected results:

ANZUP plans to continue its employment of an Executive Officer and to employ a Project Officer. Further expansion in staff may be necessary depending on the scope of activities. This will only be possible with additional funding. ANZUP plans to continue to develop clinical trials and aims to activate 1-2 new protocols per year.



Chairman's Report

The last 12 months have been a time of both consolidation and opportunity for ANZUP.

At a scientific and clinical level we have continued to build upon our existing trials and brought many of them to successful conclusion, including high level publications and presentations of data at international meetings. Multiple new clinical trials concepts have been considered covering the full range of genitourinary cancer types and stages, with consideration of translational research and supportive care aspects at all levels. Several of these trials are now well advanced in development and will proceed pending successful procurement of project funding.

...we have strengthened our structure and processes...

At the corporate level we have strengthened our structure and processes with a Board that is highly committed and engaged and has the skill sets that we need to continue to move towards achievement of our vision. A major highlight was our successful recruitment of Margaret McJannett as our tireless and energetic Executive Officer. Marg quickly moved to restructure several systems and to set up new strategic alliances including with key stakeholders. As an example, ANZUP is pleased to be a formal partner with COSA at the Annual Scientific Meeting to be held in Perth, 15-17 November 2011. We are also planning a Clinical Professional Day on 14 November, and a joint ANZUP/USANZ meeting to be held in Melbourne on 5 August 2011. All of these initiatives will continue to build our profile and provide new opportunities for collaboration and productive research leading to better outcomes for our patients and their families.

At a national and international level ANZUP is now recognised as the key cooperative trials group in this region for genitourinary cancer. This has led to significant interest in our group from other cooperative trials groups as well as industry, and consequently to additional trial and research opportunities.

Our membership is growing rapidly at about 5% per month. ANZUP is very proud of the eclectic mix of its members, representing the full range of professional disciplines as well as trainees and community representatives. However, given the magnitude of the clinical problems we are addressing, in one sense we are still far too small. We need to continue to engage people in all of the activities of the group, including mentoring the next generation of clinicians and researchers. Please continue to promote ANZUP amongst your friends, colleagues and professional groups. Please also consider how you can best contribute to the group and take advantage of the many opportunities to participate.

Our membership is growing rapidly at about 5% per month

We have been fortunate to secure recurrent funding from Cancer Australia for infrastructure as well as project-specific funding for our various trials. This has facilitated the successes we have had, however the reality is that the support we obtain from these sources is not enough to allow us to undertake all the activities we wish to do. We would be able to provide far more in terms of resources and opportunities with additional funding support, such as more and better face-to-face meetings of the group and its committees, ability to commence trials without the need for waiting for uncertain grant success, better engagement with other groups and with the community, improved communication, additional research opportunities linked to each trial, and many others. We will continue to work towards these goals and have already made significant progress but there is still considerable room to improve. The Board recognises this need and is actively moving to secure additional funding sources. Opportunities to participate in these fundraising and financial activities are available for you if you are interested. Ways in which some of you might be able to help include directing philanthropic interest from your patients/carers or others to ANZUP or consider donating honoraria for industry-supported activities such as advisory boards to ANZUP. Please note that donations to ANZUP above \$2 are tax deductible. ANZUP is able to raise invoices on your behalf if you prefer such payments to be made directly to ANZUP rather than as payment to you then a donation to ANZUP. Similarly, if your patients are looking for opportunities to support genitourinary cancer research, they could consider donations or inclusion of ANZUP in their wills.

On behalf of the Board I would like to thank you for your membership of ANZUP and your interest in and support of its activities. We have come a long way in a short time and the future looks very bright indeed as we aim to achieve our vision.

Ian Davis
Chair, ANZUP

ANZUP Operational Report

Group meetings:

- An Extraordinary General Meeting was held on Friday 25 June 2010 from 12:30pm to 1:15pm AEST, at which the special resolution to amend ANZUP's constitution was passed.
- The first Annual General Meeting was held on Friday 25 June 2010 at 1:15pm to 3:00 pm (AEST).
- The ANZUP Annual Scientific Meeting was held in Melbourne 12 November 2010 and the details of this meeting are available on the ANZUP website www.anzup.org.au.
- An Extraordinary General Meeting of the members of ANZUP Cancer Trials Group Limited was held in the ANZUP office on Thursday 28 April 2011 at 5:30pm. The Business of the Extraordinary General Meeting was to consider and if thought fit, pass the following resolution as a special resolution:

Remove Moore Stephens, as auditor of the company and appoint PKF Chartered Accountants and Business Advisors as auditor with effect from the end of the Extraordinary General Meeting. The resolution was passed unanimously.
- ANZUP Board, Operations Executive, SAC, SAC subcommittees, CAP and Trial Management Committees held regular scheduled teleconferences throughout the year.
- Early in 2011, ANZUP established a Finance and Audit Committee, which plans to meet bi-monthly prior to Board meetings. Its main objectives will be to assist the Board of Directors in discharging its responsibility to exercise due care and diligence; and to provide a formal forum for financial management, compliance and control.

Data and quality:

Cancer Australia-supported trials staff at NHMRC Clinical Trials Centre have continued to contribute to the update and maintenance of ANZUP-specific Standard Operating Procedures (SOPs) to reflect relevant quality standards (GCP ICH) and relevant regulatory guidelines. All trials staff are qualified and are trained in SOPs, consistent with GCP guidelines and the National Statement on Ethical Conduct in Human Research (2007) and have implemented these processes for ANZUP trials.

Databases for the Aprepitant Trial, PAS in SORCE sub-study, and Accelerated BEP Trial have been designed and tested for release by the appointed data systems developer and programmer in the reporting period using the systems 'InForm' and 'ClinTrial'. ANZUP appointed staff at NHMRC Clinical Trials Centre have also contributed to the development of e-CRFs and database systems for future trials, such as the proposed phase III randomised controlled trial of Accelerated BEP, including the review of existing data management SOPs. The systems developed for these processes include interactive real time and batch queries, a complete audit trail, and reporting functions. In addition, clinical trials staff assigned to ANZUP have undertaken training modules to ensure the optimal management of clinical trials data by all staff using these systems.



ANZUP Operational Report Continued

Web Site and communication:

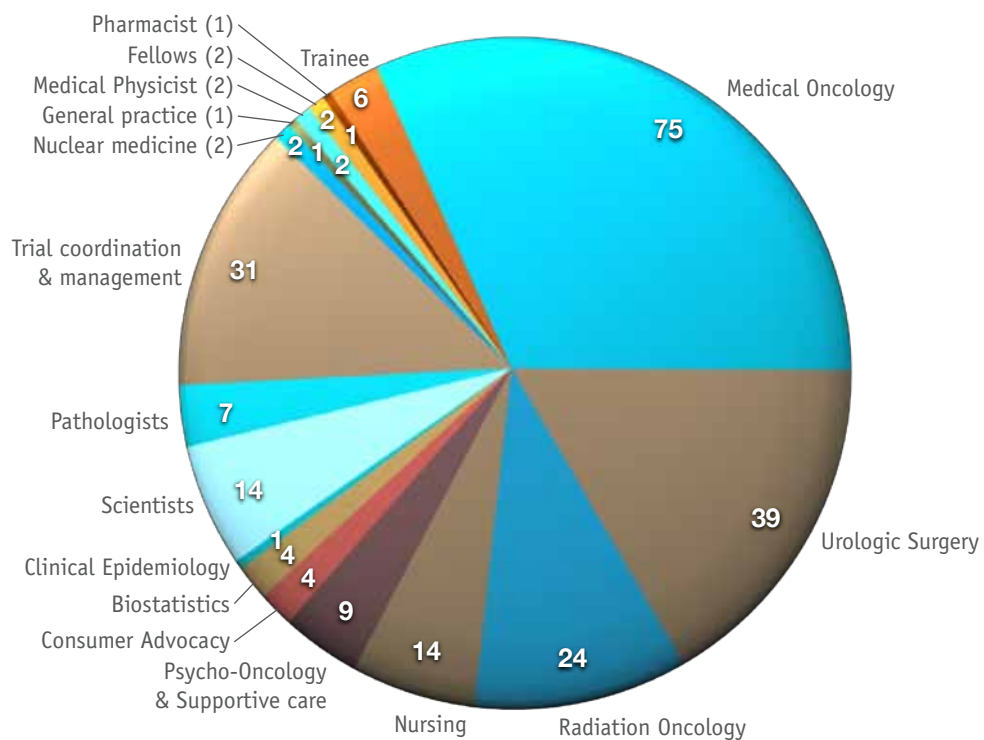
The ANZUP web site www.anzup.org.au continues to be a major part of our communication strategy to engage with our members.

We have circulated two editions of the newsletter "UPDate" to our members and are looking to develop a more frequent ANZUP e-news in the coming months. Other regular communication continues via the website in relation to subcommittee meetings, teleconferences and emails.

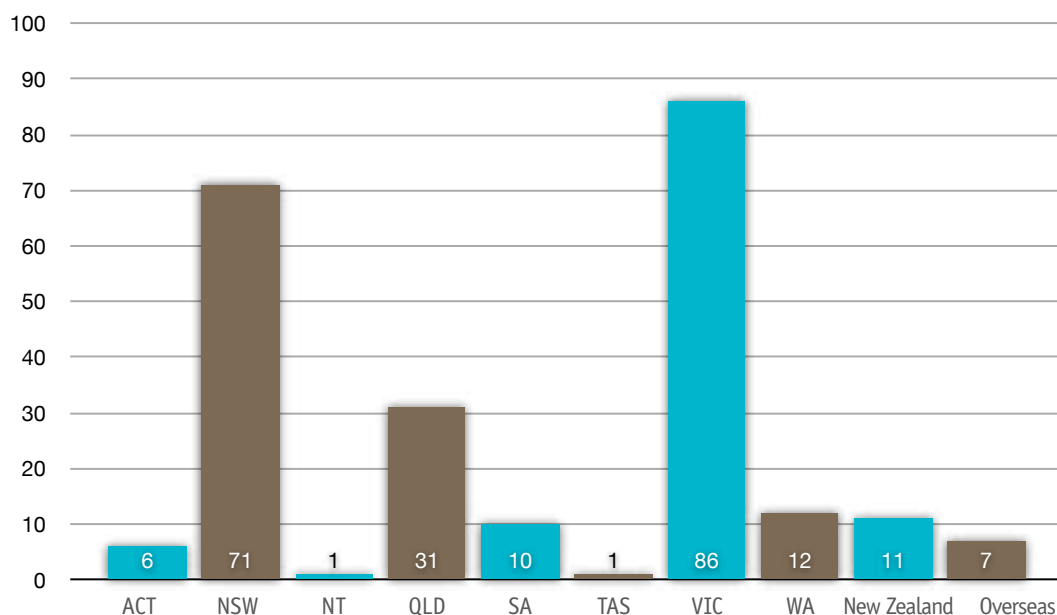
Group Membership:

As at 31 March 2011, ANZUP had 236 members covering a wide range of professional disciplines. The breakdown of membership was as follows:

By Discipline:



By Geography



ANZUP Advisory Committee & Subcommittee Chairs and Deputy Chairs

ANZUP BOARD ADVISORY COMMITTEES:

Business & Finance Committee	<i>Chair</i>	Joe Esposito
Scientific Advisory Committee (SAC)	<i>Chair</i>	Ian Davis
	<i>Deputy Chair</i>	Martin Stockler

ANZUP SAC SUBCOMMITTEE CHAIRS:

Correlative and Translational Research	Colleen Nelson
Germ Cell	Guy Toner
Renal Cell Cancer	Ian Davis
Consumer Advisory Panel	John Stubbs
Bladder Cancer Subcommittee	Manish Patel
Quality of Life & Supportive Care	Suzanne Chambers
Prostate Cancer Subcommittee	Scott Williams



ANZUP & NHMRC CLINICAL TRIALS CENTRE COLLABORATION:

Operations Executive Committee	<i>Chair</i>	Ian Davis
	<i>Deputy Chair</i>	Guy Toner

Scientific Advisory Committee & Subcommittee Research Highlights

Scientific Advisory Committee

The SAC continued to meet quarterly and held a face-to-face meeting in November 2010. The SAC appointed a Deputy Chair earlier this year (A/Prof Martin Stockler).

The various SAC subcommittees comprise ANZUP's "engine room" in terms of identification of opportunities, engagement of various disciplines, mentorship and training, and of course protocol development and oversight. The SAC has oversight of the various clinical trials and related research programs and advises the Board on research priorities. The SAC is set up to ensure that all disciplines are represented and that community input through the Consumer Advisory Panel is heard and acted upon. As protocols are proposed by the subcommittees, each protocol is also considered and further developed with a view to incorporating input and opportunities from our non-disease-specific committees, including the Correlative and Translational Research and the Quality of Life & Supportive Care committees. The activities of these committees are indispensable as we plan the best possible trials we can do.

Germ Cell:

The Germ Cell Sub-Committee's membership originally comprised the executive of the ANZ Germ Cell Trials Group, one of ANZUP's predecessors. In early 2011 Dr Peter Grimison was appointed as the Deputy Chair. The sub-committee continues to encourage new members, particularly young investigators, to contribute to our work. A number of projects were completed this year.

1. The phase II study of accelerated BEP completed its recruitment target of 45 patients from 14 participating sites. Preliminary results were presented at this year's ASCO meeting by Peter Grimison.
2. The aprepitant antiemetic study completed its planned accrual of 50 patients from nine participating sites. The final results are to be presented at the MASCC meeting this year. Preliminary reports indicate that the regimen was very effective in controlling nausea and vomiting with a five day cisplatin regimen.
3. ANZUP collaborated with PoCoG (psycho-oncology group) to perform a questionnaire and qualitative analysis of survivorship issues in testicular cancer patients who had completed treatment within the last five years. Ben Smith is the Principal Investigator for PoCoG and is in the process of analysing these results.
4. The randomised comparison of two regimens of BEP was reported in the Lancet in 2001 with relatively brief follow up. Recently, Peter Grimison has led our effort to update these results and published the long-term follow up in JNCI. The results confirm our earlier conclusion that the more dose intensive regimen was associated with improved survival outcomes.

The main study currently accruing at the moment is the 'Chemotherapy and Cognition study' which is prospectively monitoring cognitive function in patients managed with and without chemotherapy for testicular cancer. Prof Ian Olver is the Principal Investigator and the study has achieved accrual of 131 of the planned 154 participants. The study is open at 15 sites in Australia and New Zealand and accrual should be completed by the end of 2011.

The Germ Cell Sub-Committee has submitted two project grants to NHMRC for consideration of funding by Cancer Australia. The first is for funding to start the proposed international phase III study of Accelerated BEP. The second is to support Australian and New Zealand participation in an MRC study of imaging as part of a surveillance program for stage I seminoma (TRISST). TRISST is designed to assess CT vs MRI and three vs seven follow up scans as the preferred modality/schedule for surveillance. The aim of the study is to identify whether reduced diagnostic radiation exposure is possible for this group of patients who have an expected cure rate of 99% and an average life expectancy of 45+ years (and are therefore at risk of second malignancies from diagnostic radiation exposure). Finally, the sub-committee is keen to participate in the international TIGER study. This is a randomised comparison of conventional vs high dose chemotherapy as first line salvage therapy for relapsed testicular cancer. Participation is dependent on identifying funding to support the study.

Scientific Advisory Committee & Subcommittee Research Highlights continued

Prostate Cancer:

1. RAVES (“Randomised Adjuvant versus Early Salvage” radiotherapy post-prostatectomy) is a phase III multi-centre randomised trial comparing adjuvant radiotherapy (RT) given within 4 months of surgery with early salvage RT in patients with positive margins or pathological T3 disease and a post-operative PSA ≤ 0.1 ng/mL following radical prostatectomy. It is an initiative of TROG (TROG 08.03) in collaboration with the Urological Society of Australia and New Zealand (USANZ) and ANZUP. The trial co-chairs are Radiation Oncologists, A/Prof Andrew Kneebone (Royal North Shore Hospital, Sydney) and Dr Maria Pearse (Auckland City Hospital). Once randomised, those in the adjuvant arm have radiotherapy (64 Gy) within 4 months of surgery, while those in the salvage arm have a PSA each 3 months and treatment within 4 months of a PSA ≥ 0.2 ng/mL being detected. The primary endpoint will be the biochemical failure rate, while more advanced clinical measures will also be assessed secondarily, along with QoL (EORTC QLQ-C30 and PR25, anxiety/depression) and toxicity. The study has a non-inferiority design, assessing whether salvage radiotherapy is not more than 10% worse in biochemical outcome than adjuvant therapy. This translates into an accrual aim of 470 patients over 5 years. The study has gathered funding from multiple agencies (including NHMRC and state cancer councils) of over \$2 million which has enabled QA systems development and widespread rollout. Several substudies are available for RAVES, including tissue banking with a view to translational studies, as well as contribution to a genetic epidemiology register and testing of a decision analysis method (in development). The study is actively accruing with 141 patients randomised to date.
2. ProCare is a phase I/II randomised controlled trial of follow up of men with prostate cancer in primary care. It is led by Professor Jon Emery (University of WA) and the PC4 (Primary Care Collaborative Cancer Clinical Trials) group. ANZUP is a co-sponsor of the trial and provided assistance in the protocol development. The study seeks to develop and test a model of shared care that aims to reduce unmet needs and psychological distress, for men who have completed curative treatment for prostate cancer. Participants treated for prostate cancer will be randomized to receive either usual care (in accordance with local hospital practice) or trial shared-care (between hospital and primary care) for routine follow-up. A phase I pilot study will be used to finalise an intervention for testing in a randomized phase II trial. The study defines the frequency of post treatment follow-up visits for the first 12 months of follow-up, including PSA testing and physical examination, in both arms. The intervention will be based on a shared care model where two of the routine hospital visits are replaced by GP visits. Eligible men who have provided written informed consent to participate in the study will be randomised 1:1 to either the usual care (CONTROL) or trial share care (INTERVENTION) arm. Randomisation will be performed centrally and will be stratified by treatment type (surgery or radiotherapy) and site. The target population is men who have recently completed curative treatment for prostate cancer and who meet the eligibility criteria defined in the study protocol. A total of 188 men will be recruited to participate in the study from a number of tertiary treatment centres in Victoria and Western Australia. The study has been awarded a substantial NHMRC project grant (congratulations to the team) and is looking to open at selected centres soon.

The START trial (“Surveillance Therapy Against Radical Treatment”) was a randomised trial comparing the long-term outcomes for men with “low-risk” prostate cancer managed either with conventional curative therapy, or by entry into a rigorous program of active surveillance. The study was led by the National Cancer Institute of Canada Clinical Trials Group (NCIC CTG PR.11; RTOG 0873). ANZUP was to be the local lead with direction from A/Prof Jeremy Millar (William Buckland Radiotherapy Centre, The Alfred Hospital, and Melbourne). There was considerable enthusiasm for this trial amongst the Prostate subcommittee membership, the SAC, and most significantly the Consumer Advisory Panel. A grant application through Cancer Australia and the Prostate Cancer Foundation of Australia was successful in securing seed funding and

Scientific Advisory Committee & Subcommittee Research Highlights continued

a significant amount of activity was undertaken to commence the trial, including feasibility assessments and study site selection. Unfortunately the START trial was closed in North America due to difficulties in accrual and was therefore unable to commence in Australia and New Zealand. Unspent funds from the grant have been returned. This is a very unfortunate outcome as ANZUP believes this is an important clinical question and one that, perhaps uniquely, could have been addressed in Australia and New Zealand. ANZUP will continue to look for opportunities to study related questions.

A number of other concepts have been discussed recently. Lively discussions have been had around concepts such as psychosocial Interventions for men with advanced prostate cancer, or the use of novel agents in the castrate-resistant pre-chemotherapy setting. A grant application has been submitted for a mindfulness intervention (see Quality of Life and Supportive Care Committee report below). Many other opportunities exist and we are open to any suggestions.

Renal Cell Cancer:

The RCC subcommittee continues to meet regularly and it is gratifying to see its membership continue to increase. Our current trials include:

1. **SORCE.** This trial, led by the Medical Research Council UK, is now open to recruitment at all 22 planned Australian sites and has accrued over 20% of its planned ANZ accrual target. The study aims to determine whether adjuvant sorafenib is effective in intermediate and high risk resected RCC and, if so, whether treatment needs to be for one or three years. Australia is accruing very well but we need to continue to identify patients in a timely fashion as patients must enter the study within 91 days of surgery. Experience within Australia has paralleled that of overseas sites: the study can only succeed when there is close, regular and meaningful communication between urologists and medical oncologists. This close multidisciplinary engagement is one of the tenets under which ANZUP operates and the SORCE trial is an excellent example of how a cooperative trials group can work very effectively and answer questions that otherwise would not be answered.

Substudies of SORCE include TRANSORCE, which involves collection of blood and tissue for future analysis. ANZUP has elected to participate in TRANSORCE to provide opportunities for local basic science researchers to access these samples and to contribute to this international endeavour. Another SORCE substudy is "PAS in SORCE," developed by ANZUP researchers and aiming to determine patient preferences and expectations in relation to the treatment and its toxicity. This is a very important study and has now been rolled out at 31 UK sites also. This is an example of ANZUP taking a leading role on the international stage. Both TRANSORCE and PAS will be the subject of future grant applications.

2. **EVERSUN.** EVERSUN is the flagship ANZUP first-line study for advanced RCC and aims to assess the safety and feasibility of alternating sunitinib and everolimus, with the hypotheses that this approach is safe and might delay or prevent the development of resistance. EVERSUN has opened to recruitment at 13 Australian centres and at the time of writing has accrued about 20% of its target. Referrals for this study have not been as high as expected, probably because patients are being treated in the community with sunitinib through the PBS. All patients should be offered the opportunity to participate in research. ANZUP encourages all who treat these patients to refer them where appropriate to their local EVERSUN site before commencing systemic therapy. We also encourage our consumer and non-medical members to promote this and other trials so that there is an expectation for all of our patients that the option of a clinical trial will be discussed with them where appropriate.

A translational study (EVERSUN-T) is in planning and is the subject of a grant application led by Sonia Yip. This study has had considerable input from the Correlative and Translational Research subcommittee. Several other concepts are under consideration by the committee.

Scientific Advisory Committee & Subcommittee Research Highlights continued

Bladder Cancer:

The bladder cancer subcommittee is currently developing two new clinical trials:

1. Sequential BCG and mitomycin C versus BCG alone in the treatment of non-muscle invasive bladder cancer (NMIBC). This is a randomised trial which compares sequential treatment to the gold standard of BCG alone for NMIBC. We are currently applying for funding for the trial's pilot phase. Ten centres around Australia have been identified to participate. If the pilot phase recruits well, a second, larger phase with many more centres will be implemented. This study is a first for ANZUP in that it involves early-stage disease and will be driven primarily by surgeons. Input from the Correlative and Translational research subcommittee and the Quality of Life and Supportive Care subcommittee has been invaluable.
2. Cabazitaxel chemotherapy as second line therapy for advanced urothelial cancer. This phase 2 study is also under development pending the securing of funding.

Correlative and Translational Research:

The Correlative and Translational Research Committee meets as required to consider new concepts and protocols in the process of development as ANZUP trials. The broad representation of the committee members and the corresponding access to a wide range of platform technologies means that ANZUP is able to ensure that strong science underpins each of its studies. Recent examples of input from the committee include the development of EVERSUN-T, the translational component of the ANZUP EVERSUN renal cell carcinoma trial, in which blood will be collected for assay of factors known to be relevant to RCC biology. An experimental aim of EVERSUN-T will be to assess circulating tumour cells, for which there are very limited data in RCC. The committee has also provided advice in the development of the trial of non muscle invasive bladder cancer involving sequential BCG and mitomycin C versus BCG alone. This means that key basic science questions can be answered in this study as well as the clinical objectives. Both of these translational protocols are the subject of current grant applications. The committee will continue this activity, with research and future grant applications proposed for studies collected for TRANSORCE. We continue to welcome the interest and participation of any ANZUP member with links to correlative and translational research.

Quality of life and supportive care:

The Quality of Life and Supportive Care Committee continues to provide advice across the Group about these aspects of trial design. Several committee members are also involved as Chief and Associate Investigators in a current and just submitted project grant submission to the NHMRC and Cancer Australia to trial tele-based mindfulness-based cognitive group therapy for men with advanced prostate cancer. The project is co-badged with ANZUP, Griffith University and Cancer Council QLD and builds on a pilot study funded by BeyondBlue and Cancer Council QLD. This ambitious project, if successful in obtaining funds, will involve men in QLD, NSW, Vic and WA and will be the first randomised control trial in psychosocial support for men with advanced prostate cancer.



Consumer Advisory Panel

Consumer News

John Stubbs – the Consumer Advisory Panel Chair has just been appointed to the Advisory Committee of the Australian New Zealand Clinical Trials Registry (ANZCTR). The Committee will provide strategic advice to the ANZCTR Operational Executive in relation to the operation and development of the ANZCTR. Other members include: CMO, TGA, University of Sydney, Industry reps, AHEC Member, clinical research community and HRC from New Zealand. The appointment is for three years.

Engagement with Indigenous groups

This matter continues to provide the CAP with a challenge. Through links to the Human Rights and Equal Opportunity Commission (HREOC) and Mick Gooda, the Indigenous Commissioner, some headway is being developed. The CVSA 'Cancer Conversations Project' has developed a novel way of engagement with the Indigenous community and we are awaiting the results. A National Indigenous Cancer Research group has formed and administrated through the Loewja Institute. CAP is in contact with both organisations

Consumer Network

For a number of years now the Executive Officers from the CCTG's have operated as a national network to meet and exchange ideas regarding the operation of the Groups. This has now been extended to the consumer members of the CCTGs and their first meeting was held in February 2011. Leonie Young from the ANZBCTG - the longest formed CCTG was elected chair at the first meeting held in February 2011. John Stubbs was elected Deputy Chair. The consumer network will provide valuable support to all consumers and address issues regarding training, collaboration, mentoring and succession planning. This development was the direct result of ANZUP's new EO, Margaret McJannett, when she was EO of COSA and a welcome addition to the cancer consumer scene!

Clinical Trials

The Government has finally released its CTAG report and the onus will be on consumers to really ensure that clinical trials are a recognised element of good patient outcomes.

Australian Cancer Trials online (ACTonline)

Formally launched at COSA in November 2010, this website was designed to enable all cancer clinical trials to be 'posted' on the one portal and provide patients, consumers with a one stop shop. The website has not lived up to its potential and needs revision and engagement of the CCTGs to ensure its potential is not lost. Further engagement with the CCTGs to ensure full utilisation will be undertaken by the CAP in collaboration with other CCTGs.



John Stubbs
Chair ANZUP CAP

Papers & Presentations

Papers:

Comparing two BEP regimens for good-prognosis germ-cell tumours: long-term analysis of a randomised trial.

Grimison P, Stockler M, Thomson D, Olver I, Harvey V, GebSKI V, Lewis C, Levi J, Boyer M, Gurney H, Craft P, Boland A, Simes RJ, Toner G. *Journal of the National Cancer Institute* 2010; 102(16): 1253–1262. Published online 14 July 2010.

Management of Advanced Germ Cell Tumors: IGCCC Intermediate- and Poor-Risk Patients.

Grimison PS, Toner GC. In: Scardino, Linehan, Zelefsky, Vogelzang, et al. *Comprehensive Textbook of Genitourinary Oncology*, 4e; 2011:594-602.

Presentations:

Bleomycin dosing for germ cell tumours – are we too cautious?

Houghton B, Grimison PS, Toner GC, Chatfield M, Thomson DB, Friedlander M, GebSKI V, Boland A, Rosenthal M, Gurney H, Stockler M. Annual Scientific Meeting of the Medical Oncology Group of Australia, Sydney 2010.

The effect of pulmonary function testing on bleomycin dosing in germ-cell tumors.

Houghton B, Grimison PS, Toner GC, Chatfield M, Thomson DB, Friedlander M, GebSKI V, Boland A, Rosenthal M, Gurney H, Stockler M. ASCO Genitourinary Cancers Symposium; 17–19 Feb 2011; Orlando.

Merit Award winner.

Understanding the psychosocial sequelae of surviving testicular cancer.

Smith A, King M, Butow P, Olver I, Lockett T, Grimison P, Toner G, Stubbs J, Stockler M, Hovey E. Oral Presentation at the OZPOS and PoCoG Psycho-Oncology Professional Day Melbourne, November 2010.

Accelerated BEP for advanced germ cell tumours: an ongoing multi-centre phase I/II trial.

Grimison PS, Stockler M, Thomson DB, Friedlander M, GebSKI V, Boland AL, Chatfield M, Rosenthal M, Gurney H, Wong SS, Toner GC, Australian and New Zealand Urogenital and Prostate Cancer Trials Group. Asian Oncology Summit; 9–11 Apr 2010; Nusa Dua, Bali.

Understanding the psychosocial sequelae of surviving testicular cancer.

Smith AB, King M, Butow P, Olver I, Lockett T, Grimison P, Toner G, Stockler M, Hovey E, Stubbs J. Clinical Oncological Society of Australia (COSA) Annual Scientific Meeting; 9–11 Nov 2010; Melbourne. *Asia-Pacific Journal of Clinical Oncology* 2010; 6(suppl 3): 201. Abstract 344.

Accelerated BEP for advanced germ cell tumours: An Australian multicenter phase I/II trial.

Grimison PS, Thomson DB, Stockler MR, Chatfield MD, Friedlander M, GebSKI V, Boland AL, Houghton BB, Gurney H, Rosenthal M, Singhal N, Kichenadasse G, Wong SS, Lewis CR, Vasey PA, Toner GC; Australian and New Zealand Urogenital and Prostate Cancer Trials Group. American Society of Clinical Oncology Annual Meeting; 4–8 Jun 2011; Chicago

Patterns of Care for Stage 1 Testicular Cancer in Australia in 2010.

Houghton B, Stockler M, Chatfield M, Toner G, Davis I, Grimison P. Medical Oncology Group of Australia Annual Scientific Meeting, 2011.

Losing your marbles: Understanding the psychosocial issues faced by testicular cancer survivors.

Smith AB, King M, Butow P, Olver I, Lockett T, Grimison P, Toner G, Stockler MR, Hovey E, Stubbs J. Abstract submitted to the 13th World Congress of Psycho-Oncology, Turkey, October 2011

Patterns of Care for Stage 1 Testicular Cancer in Australia in 2010.

Houghton B, Stockler M, Chatfield MD, Toner G, Davis ID, Grimison PS. Poster Presentation at the European Multidisciplinary Cancer Congress, Stockholm, Sept 2011.

Phase 2 Trial of Aprepitant on Days 1 to 7 for Patients with Germ Cell Tumours having Cisplatin on Days 1 to 5

Thomson DB, Grimison PS, Chatfield M, Stockler MR, Toner GC, GebSKI V, Harrup RA, Underhill C, Kichenadasse G, Singhal N, Davis ID, Boland AL, McDonald A, Olver IN, Australian and New Zealand Urogenital and Prostate Cancer Trials Group. American Society of Clinical Oncology Annual Meeting, June 2011. *Journal of Clinical Oncology*, 2011; 29 (15S): Abstract e19577.

Phase 2 Trial of Aprepitant on Days 1-7 for Patients with Germ Cell Tumours having Cisplatin on Days 1-5.

Olver I, Grimison P, Chatfield M, Stockler MR, Toner G, GebSKI V, Harrup VA, Underhill C, Kichenadasse G, Singhal N, Boland AL, McDonald A, ThomsonDB, Australian and New Zealand Urogenital and Prostate Cancer Trials Group. Poster Presentation at the MASCC/ISOO International Symposium on Supportive Care. Athens, Greece. June 23-25, 2011

Stage I seminoma treatment options

Toner G (Invited Presentation) 4th Triennial Best Practice Workshop in Urologic Oncology, Sydney, June 2010.

Financial Report

ANZUP Cancer Trials Group Limited

ABN: 32 133 634 956

Annual financial report - 31 March 2011

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The directors of ANZUP Cancer Trials Group Limited (the company) submit their annual financial report for the year ended 31 March 2011.

Directors

The following persons were directors of the company during the whole of the year and up to the date of this report:

Ian Davis
Lizbeth Kenny
Guy Toner

The following persons were appointed as directors during the year and continue in office at the date of this report:

Henry Woo	25 June 2010
Glenn Ferguson	30 August 2010
Joe Esposito	13 December 2010
Linda Martin	13 December 2010

John Ramsay was a director from the beginning of the year until his resignation on 13 April 2010.

Information on directors

Ian Davis MB, BS, PhD, FRACP, FACHPM. *Chairman.*

Associate Professor Ian Davis MB BS PhD FRACP FACHPM is a medical oncologist working at Austin Health and the Ludwig Institute for Cancer Research (LICR) in Melbourne, where he is Head of the Oncology Laboratory. He held a Victorian Cancer Agency Clinical Researcher Fellowship until the end of 2010 and is an NHMRC Practitioner Fellow. His primary clinical interests are in cancer immunology and the biology of urological cancers. A/Prof Davis is a member of COSA Council and chair of the COSA Urologic Oncology group.

Lizbeth Kenny MD, BS, FRANZCR, FACR. *Treasurer.*

Dr Liz Kenny MD BS FRANZCR FACR graduated in Medicine from The University of Queensland in 1980, and completed her specialty training in Radiation Oncology at The Queensland Radium Institute in Brisbane in 1987. Liz is a Senior Radiation Oncologist at The Royal Brisbane & Women's Hospital. In 2005 she was appointed as Medical Director, Cancer Services, Central and is committed to improving Cancer Services in Queensland. Her main areas of specialty are Head and Neck Cancer, Breast Cancer and Urological Malignancies.

Guy Toner MBBS, MD, FRACP.

Associate Professor Guy Toner MBBS MD FRACP is a graduate of the University of Melbourne. He undertook sub-specialty training in medical oncology at the Alfred Hospital before spending three years at Memorial Sloan-Kettering Cancer Center in New York, where he worked in the GU Service. He developed a special interest in testicular cancer while in New York and his research there formed the basis of his MD thesis. He returned to Melbourne to take up a full-time position at Peter MacCallum Cancer Centre in 1990. His clinical and research interests include all urological cancers and he also has an interest in new drug development. He was Chair of ANZGCTG since 1995.

ANZUP Cancer Trials Group Limited
Directors' report
31 March 2011 (continued)

Henry Woo

Henry Woo is a urological surgeon with a subspecialty practice in prostate disease. He is a Clinical Associate Professor at the Sydney Medical School of the University of Sydney and operates at Westmead Public Hospital and the Sydney Adventist Hospital. In his student days, he was a Board Director of University of Sydney Union and an elected delegate of the Sydney University Student Representative Council and a Producer of a Sydney University Medical Revue. He is currently the Convenor of the 2012 Annual Scientific Meeting of Urological Society of Australia and New Zealand. He is the only non-US/European member of the International Greenlight Users Group as well as the International Prostate Research Group. He is regularly invited to teach and perform live surgical demonstrations locally and abroad. He runs a busy clinical trials unit at the Sydney Adventist Hospital with studies in both prostate cancer and benign prostatic hyperplasia. He has extensive experience in multicentre clinical trials, amongst which include being Principle Investigator of a study of lower urinary tract symptoms (LUTS) in men with advanced prostate cancer, Principal Investigator of Urolift treatment for LUTS due to BPH study, co-Chair of the Timing of Androgen Deprivation (TOAD) study and being on the Trial Management Committee of the RAVES study for prostate cancer. He is also a member of the Scientific Research Committee of the Prostate Cancer Foundation of Australia.

Glenn Ferguson

Glenn Ferguson is a Solicitor of the High Court of Australia and the Supreme Court of Queensland. An experienced commercial and corporate lawyer he has acted in complex transactions and disputes for a range of clients both nationally and internationally. He is currently the President of the Law Council of Australia (the peak national body which represents the legal profession nationally and internationally), Past President of Lawasia (the law association for Asia and the Pacific) and a Past President of the Queensland Law Society. He is also a Senior Counsellor with the Queensland Law Society and has previously chaired their Professional Standards Committee. He is a Founding Fellow of the Australian Academy of Law, a Fellow of the Australian Institute of Company Directors and a Fellow of the Australia and New Zealand College of Notaries. He is Chair of the College of Law Queensland, a member of the Federal Attorney Generals International Legal Services Advisory Council and the Immigration Ministers Advisory Board in relation to the regulation of migration agents. The Queensland Premier selected him in 2004 to chair Smart Exports Queensland. He has been appointed by both Federal and State Governments to various advisory boards and task forces in the legal, migration and business sectors.

Joe Esposito

Joe Esposito is a Melbourne based management consultant whose practice has an emphasis on finance and workforce development. Prior to consultancy, Joe had over 20 years in corporate banking in Australia and New Zealand and three years as CEO of ASX-listed Jetset Travelworld Limited. Joe has a close affinity with the objectives of ANZUP and the needs of consumers. Joe has Bachelor of Commerce and Master of Applied Finance degrees. He is a member of the Australian Institute of Company Directors.

Linda Martin

Linda Martin is the Chief Executive Officer of Arthritis Victoria and Osteoporosis Victoria. She was previously Managing Director of consultancy firm, Martin Bonato and Associates Pty. Ltd., with a focus primarily in the community and health sectors. Her experience also included the financial and safety industries. Prior to working as a consultant, Linda was a senior executive in the Victorian public service, working primarily in the community service sector managing regional operations, programs and major projects. She has also been a lecturer in Social Work at the University of Melbourne. Linda has an extensive knowledge of government processes and has significant experience in fund raising. Her work in private, public and not for profit organisations includes strategic and business planning, program review, change management, program and project management, performance enhancement, alliance development, leadership and people development.

Company Secretary

Guy Toner held the position of Company Secretary from 1 April 2011 until his resignation on 9 February 2011. Margaret McJannett was appointed Company Secretary on 9 February 2011 and continues in office at the date of this report. Ms McJannett also serves as the company's Executive Officer.

Meetings of Directors

During the year, nine meetings of directors were held. Attendances by each director was as follows:

	Directors' meetings	
	Number eligible to attend	Number attended
Ian Davis	9	9
Lizbeth Kenny	9	8
Guy Toner	9	9
John Ramsay (resigned 13 April 2010)	-	-
Henry Woo (appointed 25 June 2010)	5	5
Glenn Ferguson (appointed 30 August 2010)	4	2
Joe Esposito (appointed 13 December 2010)	2	2
Linda Martin (appointed 13 December 2010)	2	1

Principal activity

The principal activity of the company is to develop and conduct cancer research in urogenital and prostate cancers.

Objectives of the company

The short and long term objectives of the company are to develop, foster and promote prostate and urogenital cancer research by:

- providing access to clinical trials for all appropriate Australian and New Zealand patients;
- increasing involvement of and collaboration with various professional disciplines in clinical and preclinical research;
- providing opportunities for clinical research;
- building systems to simplify and streamline clinical research of the highest quality;
- fostering a culture of research amongst all clinicians involved in the care of patients with urogenital cancers;
- providing training opportunities for the next generation of clinical researchers; and
- providing for translational studies in prostate and other urogenital cancers, including tissue banking from clinical trials for further studies.

The company intends to meet these objectives through performing industry sponsored and other clinical trials, ensuring these trials are widely accessible to patients, creating strong links with Cancer Australia and other peak bodies, engaging professional disciplines at all levels of protocol development and implementation, and securing funding to support clinical research training positions.

Review of operations

The company's net income for the year was \$42,935 (2010: \$10,728 net loss for the 18 month period since incorporation).

At 31 March 2011, the company had net assets of \$32,207 (2010: \$10,728 net asset deficiency).

Changes in state of affairs

There were no significant changes in the state of affairs of the company during the year ended 31 March 2011.

Subsequent events

No matters or circumstance have arisen since the end of the year that have significantly affected, or may significantly affect, the operations of the company, the results of these operations, or the state of affairs of the company in future years.

Future developments

Likely developments in the operations of the company and the expected results of those operations in future years have not been included in this report as the inclusion of such information is likely to result in unreasonable prejudice to the company.

Court proceedings

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.

Environmental issues

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

Indemnification of officers and auditors

The company has paid premiums to insure each director against liabilities for costs and expenses incurred by them in defending any legal proceedings arising out of their conduct involving a wilful breach of duty in relation to the company. The amount of the premium paid during the period was \$1,210 (2010: \$2,000 for the 18 month period since incorporation).

Auditors' independence declaration

A copy of the auditors' independence declaration as required under section 307C of the Corporations Act 2001 is set out on page 6.

Signed in accordance with a resolution of Directors.



Ian Davis
Chairman

Sydney
13 July 2011



Chartered Accountants
& Business Advisers

AUDITOR'S INDEPENDENCE DECLARATION

As lead auditor for the audit of ANZUP Cancer Trials Group Limited for the year ended 31 March 2011, I declare that to the best of my knowledge and belief there have been:

- (a) no contraventions of the auditor independence requirements of the Corporations Act 2001 in relation to the audit; and
- (b) no contraventions of any applicable code of professional conduct in relation to the audit.

PKF

Paul Buhl
Partner

Sydney
13 July 2011

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Liability limited by a scheme approved under Professional Standards Legislation.

ANZUP Cancer Trials Group Limited
Statement of Comprehensive Income
For the year ended 31 March 2011

	Notes	12 months ended 31 March 2011	18 months ended 31 March 2010
		\$	\$
Revenue	2	264,275	652,325
Employee benefits expenses		(33,653)	(135,817)
Administration expenses	3	<u>(187,687)</u>	<u>(527,236)</u>
Net income/(loss) for the year		<u><u>42,935</u></u>	<u><u>(10,728)</u></u>
Other comprehensive income		<u>-</u>	<u>-</u>
Total comprehensive income/(loss)		<u><u>42,935</u></u>	<u><u>(10,728)</u></u>

The above statement of comprehensive income should be read in conjunction with the accompanying notes.

ANZUP Cancer Trials Group Limited
Statement of Financial Position
For the year ended 31 March 2011

	Notes	2011 \$	2010 \$
Current assets			
Cash and cash equivalents	4	105,195	18,493
Trade and other receivables	5	<u>1,541</u>	<u>173,624</u>
Total current assets		106,736	192,117
Non-current assets			
Office equipment		<u>367</u>	-
Total non-current assets		367	-
Total assets		<u>107,103</u>	<u>192,117</u>
Current liabilities			
Trade and other payables	6	73,122	151,117
Employee benefits		<u>1,774</u>	<u>1,728</u>
Total current liabilities		72,896	152,845
Non-current liabilities			
Other payables	7	<u>-</u>	<u>50,000</u>
Total non-current liabilities		-	50,000
Total liabilities		<u>74,896</u>	<u>202,845</u>
Net surplus/(deficiency)		<u><u>32,207</u></u>	<u><u>(10,728)</u></u>
Equity			
Retained earnings/(deficit)		<u>32,207</u>	<u>(10,728)</u>
Total equity		<u><u>32,207</u></u>	<u><u>(10,728)</u></u>

The above statement of financial position should be read in conjunction with the accompanying notes.

ANZUP Cancer Trials Group Limited
Statement of Changes in Equity
For the year ended 31 March 2011

	Retained earnings/ (deficit) \$	Total equity \$
Balance as at 9 October 2008	-	-
Total comprehensive loss for the year	<u>(10,728)</u>	<u>(10,728)</u>
Balance at 31 March 2010	<u>(10,728)</u>	<u>(10,728)</u>
Total comprehensive income for the year	<u>42,935</u>	<u>42,935</u>
Balance as at 31 March 2011	<u><u>32,207</u></u>	<u><u>32,207</u></u>

The above statement of changes in equity should be read in conjunction with the accompanying notes.

ANZUP Cancer Trials Group Limited
Statement of Cash Flows
For the year ended 31 March 2011

	Notes	12 months ended 31 March 2011	18 months ended 31 March 2010
		\$	\$
Cash flows from operating activities			
Receipts from grants		411,648	537,693
Receipts from sundry income		21,263	11,368
Receipts from donations		20	29,640
Payments to suppliers and employees		<u>(344,529)</u>	<u>(560,208)</u>
Net cash inflow from operating activities	9	<u>88,402</u>	<u>18,493</u>
Cash flows from investing activities			
Payments for office equipment		<u>(1,700)</u>	<u>-</u>
Net cash outflow from investing activities		<u>(1,700)</u>	<u>-</u>
Net increase in cash and cash equivalents			
Cash and cash equivalents at the beginning of the year		<u>18,493</u>	<u>-</u>
Cash and cash equivalents at the end of the year	4	<u>105,195</u>	<u>18,493</u>

The above statement of cash flows should be read in conjunction with the accompanying notes.

Note 1. Summary of significant accounting policies

Reporting basis and conventions

This financial report is a general purpose financial report which has been prepared in accordance with Australian Accounting Standards - Reduced Disclosure Requirements, including the Australian Accounting Interpretations and other authoritative pronouncements of the Australian Accounting Standards Board and the *Corporations Act 2001*.

This financial report covers ANZUP Cancer Trials Group Limited (the company) as an individual entity for the year ended 31 March 2011. The company is limited by guarantee and is incorporated and domiciled in Australia.

Early adoption of standards

The company has elected to apply the following pronouncements to the annual reporting period beginning 1 April 2010:

AASB 1053: Application of Tiers of Australian Accounting Standards and AASB 2010-2 Amendments to Australian Accounting Standards arising from Reduced Disclosure Requirements.

Historical cost convention

The financial report has been prepared on an accrual basis and is based on historical costs. Cost is based on the fair values of the consideration given in exchange for assets.

Accounting policies

(a) Going concern

The financial report has been prepared on a going concern basis. Refer to Note 14 for considerations regarding economic dependence.

(b) Income tax

The company is exempt from the payment of income tax under section 50-35 of the Income Tax Assessment Act 1997. The company is a deductible gift recipient.

(c) Revenue recognition

Grant funding is recognised in the Statement of Comprehensive Income when it is controlled. When there are conditions attached to grant funding relating to the use of those funds for specific purposes, it is recognised as deferred revenue until such conditions are met or services provided.

Other income is recognised in the period to which it relates.

All revenue is stated net of the amount of goods and services tax (GST).

(d) Cash and cash equivalents

Cash and cash equivalents includes cash on hand, deposits held at call with financial institutions and other short-term, highly liquid investments with original maturities of three months or less that are readily convertible to known amounts of cash which are subject to an insignificant risk of changes in value.

(e) Employee benefits

Provisions are measured at the present value of management's best estimate required to settle the present obligation at the reporting date. **The discount rate used to determine the present value reflects current market assessments of the time value of money and the risks specific to the liability. The increase in the provision due to the passage of time is recognised as interest expense.**

ANZUP Cancer Trials Group Limited
Notes to the financial statements
For the year ended 31 March 2011
(continued)

Note 1. Summary of significant accounting policies (continued)

(f) Goods and Services Tax (GST)

Revenues, expenses and assets are recognised net of the amount of associated GST, unless the GST incurred is not recoverable from the taxation authority. In this case it is recognised as part of the cost of acquisition of the asset or as part of the expense.

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

Cash flows are presented on a gross basis. The GST components of cash flows arising from investing or financing activities which are recoverable from, or payable to the taxation authority, are presented as operating cash flow.

(g) Comparative figures

Comparative figures in this report are for the first period of operation of the company, covering the 18 month period from incorporation on 9 October 2008 to 31 March 2010. When required by Accounting Standards, comparative figures have been adjusted to confirm to changes in presentation for the current year.

(h) New accounting standards issued but not yet effective

The following standards, amendments to standards and interpretations have been identified as those which may impact the company in the period of initial application. They are available for early adoption at 31 March 2011, but have not been applied in preparing these financial statements.

- (i) AASB 2009-5: Further Amendments to Australian Accounting Standards arising from the Annual Improvements Project [AASB 5, 8, 101, 107, 117, 118, 136 & 139] (effective for reporting periods beginning 1 July 2010).
- (ii) AASB 2009-12: Amendments to Australian Accounting Standards [AASBs 5, 8, 108, 110, 112, 119, 133, 137, 139, 1023 & 1031 and Interpretations 2, 4, 16, 1039 & 1052] (effective for reporting periods beginning 1 July 2011).
- (iii) AASB 2010-4: Further Amendments to Australian Accounting Standards arising from the Annual Improvements Project [AASB 1, AASB 7, AASB 101 & AASB 134 and Interpretation 13] (effective for reporting periods beginning 1 July 2011).

The company intends to apply the new standards and interpretations from the effective dates. The company is yet to assess any potential impact on the financial statements.

Note 2. Revenue

	12 months ended 31 March 2011 \$	18 months ended 31 March 2010 \$
Grants income	241,451	611,317
Donations	20	11,368
Sundry income	<u>22,804</u>	<u>29,640</u>
	<u><u>264,275</u></u>	<u><u>652,325</u></u>

ANZUP Cancer Trials Group Limited
Notes to the financial statements
For the year ended 31 March 2011
(continued)

Note 3. Administration expenses

	12 months ended 31 March 2011	18 months ended 31 March 2010
	\$	\$
Grant funding	52,088	49,000
Consulting fees	48,000	161,396
Legal fees	20,534	109,718
Information technology	15,069	46,344
Insurance	11,564	11,295
Travel and accommodation	4,367	46,442
Telephone and teleconferencing charges	1,613	11,073
Staff training	-	17,309
Depreciation	1,333	-
Sundry expenses	33,119	74,659
	<u>187,687</u>	<u>527,236</u>

Note 4. Current assets - cash and cash equivalents

	2011	2010
	\$	\$
Cash at bank	<u>105,195</u>	<u>18,493</u>

Note 5. Current assets - trade and other receivables

	2011	2010
	\$	\$
Other receivables	1,541	8,397
Accrued revenue from Cancer Australia	-	165,227
	<u>1,541</u>	<u>173,624</u>

Note 6. Current liabilities - trade and other payables

	2011	2010
	\$	\$
Trade payables	-	19,800
Accruals	23,122	81,317
Deferred revenue	50,000	50,000
	<u>73,122</u>	<u>151,117</u>

Further explanation of deferred revenue is included in Note 7.

Note 7. Non-current liabilities - other payables

	2011	2010
	\$	\$
Deferred revenue	<u>-</u>	<u>50,000</u>

Deferred revenue pertains to revenue received from Bayer Australia Limited during the 18 month period ended 31 March 2010. This revenue was designated for use in clinical trials during the years ended 31 March 2011 and 31 March 2012.

ANZUP Cancer Trials Group Limited
Notes to the financial statements
For the year ended 31 March 2011
(continued)

Note 8. Remuneration of auditors

The following fees were paid or payable for services provided by the auditor:

	12 months ended 31 March 2011 \$	18 months ended 31 March 2010 \$
Audit of the financial report	3,500	7,500
Other services - assistance with preparation of the financial report	2,000	-
	<u>5,500</u>	<u>7,500</u>

PKF were appointed auditors for the year ended 31 March 2011. The previous auditors were Moore Stephens.

Note 9 Key management personnel disclosures

	12 months ended 31 March 2011 \$	18 months ended 31 March 2010 \$
Key management personnel compensation	<u>-</u>	<u>92,887</u>

For the 12 months ended 31 March 2011, amounts paid to key management personnel comprising directors totalled Nil (18 months ended 31 March 2010: \$92,887 in consulting fees were paid to John Ramsay, a director and the previous Executive Officer who also acted as a consultant. John Ramsay resigned as a director on 13 April 2010).

Note 10. Reconciliation of cash flows from operations with net income/(loss) for the year

	12 months ended 31 March 2011 \$	18 months ended 31 March 2010 \$
Net income/(loss) for the year	42,935	(10,728)
Depreciation	1,333	-
Change in operating assets and liabilities		
(Increase)/decrease in trade and other receivables	172,083	(173,624)
Increase/(decrease) in trade and other payables	(127,995)	201,117
Increase/(decrease) in employee benefits	46	1,728
Net cash provided by operating activities	<u>88,402</u>	<u>18,493</u>

Note 11. After balance date events

No other matters or circumstances have arisen since the end of the financial year which may significantly affect the operations of the company, the results of those operations, or the state of affairs of the company in subsequent years.

ANZUP Cancer Trials Group Limited
Notes to the financial statements
For the year ended 31 March 2011
(continued)

Note 12. Contingent liabilities and capital commitments

The company has no contingent liabilities or capital commitments as at year end (2010: nil).

Deferred revenue pertains to revenue received from Bayer Australia Limited during the 18 month period ended 31 March 2010. This revenue was designated for use in clinical trials during the years ended 31 March 2011 and 31 March 2012.

Note 13. Members' guarantee

The company is limited by guarantee. If the company is wound up, each member of the company undertakes to contribute to the assets of the company an amount not exceeding \$50 for payment of the debts and liabilities of the company including the costs of the winding up. This undertaking continues for one year after a member ceases to be a member of the company.

At 31 March 2011, the number of members was 236 (2010: 124).

Note 14. Economic dependence

The company is dependent on funding from Cancer Australia for the majority of its revenue used to operate the business. At the date of this report, the Directors have no reason to believe that Cancer Australia will not continue to provide funding.

Note 15. Company details

The registered office and principal place of business of the company is:

Level 4, Medical Foundation Building
92-94 Parramatta Road
Camperdown NSW 2050

ANZUP Cancer Trials Group Limited Directors declaration

The directors of the company declare that:

1. The financial statements and notes set out on pages 27 to 35 are in accordance with the *Corporations Act 2001* and that they:
 - a. comply with Australian Accounting Standards - Reduced Disclosure Requirements and the *Corporations Regulations 2001*; and
 - b. give a true and fair view of the company's financial position as at 31 March 2011 and of its performance for the year ended on that date.
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.

This declaration is made in accordance with a resolution of Directors.



Ian Davis
Chairman

Sydney
13 July 2011



Chartered Accountants
& Business Advisers

INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF ANZUP CANCER TRIALS GROUP LIMITED

Report on the Financial Report

We have audited the accompanying financial report of ANZUP Cancer Trials Group Limited (the company), which comprises the statement of financial position as at 31 March 2011, 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*.

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Chartered Accountants
& Business Advisers

Opinion

In our opinion the financial report of ANZUP Cancer Trials Group 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 31 March 2011 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*.

A handwritten signature in black ink that reads 'PKF'.

PKF

A handwritten signature in black ink that reads 'Paul Bull'.

Paul Bull
Partner

Sydney
13 July 2011



ANZUP Cancer Trials Group Limited

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