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ANNUAL
REPORT 2013

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IVD OVERVIEW

IVD Australia is the peak body representing sponsors and manufacturers of *in vitro* diagnostics in Australia.

In vitro, literally "in glass" diagnostics (IVDs) comprise the instruments and reagents that are used to perform pathology tests requested by GPs, specialist physicians and other healthcare professionals. These tests are generally performed in accredited public and private pathology laboratories across Australia, but IVDs also include over-the-counter tests such as blood glucose meters for diabetes testing, home pregnancy test kits and other point-of-care tests. Supply of these products is regulated for the Government by the Therapeutic Goods Administration (TGA).

These tests influence over 70% of the medical decisions taken in respect of a patient's health and often comprise over 75% of a patient's health record. However they generally represent less than 15% of a patient's overall healthcare expenditure.

IVD Australia was formed in July 2009 and currently represents multinational companies, local distributors and Australian manufacturers of IVDs. Our members supply products valued at over \$750,000,000 per annum and they employ 2000 people across Australia.

IVD Australia seeks to develop an environment that progresses member companies' prosperity and delivers greater healthcare benefits to the Australian community.

CHAIRMAN'S REPORT



The end of the 2013 fiscal year marks the close of the fourth year of operations of IVD Australia Ltd.

Your industry association has achieved several major milestones within the last year as evidence of our growing profile and maturity.

The highlight of the year from my perspective is the formation of Pathology Awareness Australia Ltd (PAAL). IVD Australia has been the driving force behind bringing together the key stakeholders from our industry to form a united voice to help raise the profile of the pathology sector. Essentially we have agreed to pool some of our financial and human resources to help increase awareness of the value of pathology to the community. Members of PAAL include the Royal College of Pathologists of Australasia (RCPA), the National Coalition of Public Pathology (NCOPP), Pathology Australia (formerly known as the AAPP, which includes Sonic Healthcare and Healthscope Pathology as members along with several others), Primary Healthcare Ltd and IVD Australia. This new entity represents a collaborative effort by the key pathology sector stakeholders to positively influence the future business environment for all of us. This is a major change to the way that things have been done in the past and we feel confident that this is a step in the right direction. It is still early days for PAAL, but rest assured, you will be seeing and hearing a lot more as this team effort gathers momentum.

Another area of achievement during 2013 that is very satisfying is the closer working relationship between IVD Australia and the Australian Government Department of Health and Ageing (DoHA). The most noteworthy

achievement is the successful nomination of our CEO, Dr Peter Harman to the Pathology Services Advisory Committee. This committee makes recommendations to DoHA regarding the funding of items under the Medical Benefits Scheme (MBS). This is the first time that an IVD industry representative has ever been invited to join a DoHA committee involved with the funding side of pathology. Also noteworthy was the successful nomination of our immediate past Chairman, Adrian Tennyenhuis to the Pathology Services Demand Management subcommittee of the Pathology Agreement Advisory Committee (PAAC). Again, this is a major milestone with the IVD industry being represented at the table where reviews of MBS item numbers are undertaken in order to understand the drivers of usage of pathology items.

Your association also continues to work closely with the Therapeutic Goods Administration (TGA) regarding the transition of *in vitro* diagnostics to the new regulatory framework and with the Department of Agriculture, Forestry and Fisheries (DAFF) regarding the quarantine conditions covering the importation of IVDs.

The Board and Secretariat of IVD Australia values the financial commitment of its member companies and the personal commitment of their staff. We are confident that the initiatives described above and the other elements of our strategic plan are working for the benefit of the membership.

Finally, on behalf of the Board I encourage all members to actively promote IVD Australia membership to their non-member peers as we believe that representing all of the manufacturers and suppliers of pathology products in Australia can only enhance the strength of the association.

Bruce Evans
Chairman, IVD Australia

CEO'S REPORT



The 2012/13 financial year has seen further consolidation in the position of IVD Australia within the Australian therapeutic goods sector.

IVD Australia has continued to develop strong relationships with stakeholders within the health sector and the general community as the interest in IVD technology has evolved. Certainly the interest in point-of-care technology and in companion diagnostics has continued to grow and we are experiencing increasing interest from other stakeholders in developing joint approaches to government.

Membership

Whilst your Association continues to consolidate its position as the peak body representing the *in vitro* diagnostics industry, there has been some loss of membership due to mergers and to financial pressure on member companies. At the end of June 2013, IVD Australia had 53 members in total; a decrease of 9 from 2011/12. The total turnover of members exceeds \$750,000,000 and we estimate that members provide well over 85% of all IVDs supplied to professional laboratories and over-the-counter to healthcare consumers. Most companies that supply IVDs are members but we continue to advocate the benefits of IVD Australia membership to those that are not.

Your Association finished the 2012/13 Financial Year with a deficit of \$36,000 leaving us with an accrued surplus to \$256,000. Whilst it was disappointing to not reach the budgeted surplus of \$14,000, this was due to loss of membership of 4 larger companies.

We have continued to provide a range of activities for members, including;

- Three member networking meetings
- Four training sessions on the IVD regulations
- Regular CEO and "Diagnostics digest" newsletters to members

Code of Conduct

The establishment of the Sansom Committee by the Parliamentary Secretary, the Hon Catherine King MP, has continued the focus on the Codes of Conduct across the health sector in general.

IVD Australia has responded to the proposals outlined by the Trimmer Report and the expectation of the community in general. Revision of the IVD Australia Code has occurred during 2013 in order to address some areas where clarification was required and to include areas that were missing such as ghost writing of articles and ownership of IVD companies by health professionals. These changes will be presented to members at the 2013 AGM for ratification.

Value of Pathology Initiative

IVD Australia has had concerns for some time about the low level of understanding regarding the pathology sector currently seen within the Australian community. Various stakeholder groups have made efforts in the past to develop interest in pathology. However these have often been ad hoc and organisation specific.

In February 2013 the stakeholders in the pathology sectors including AAPP, NCOPP, RCPA, and the larger private pathology providers agreed to form Pathology Awareness Australia to commence a campaign to generally promote pathology awareness to the community, other health sector groups and to the government sector. The members appointed London Agency (a PR company) to develop and manage the campaign and we expect it to launch in September 2013.

CEO REPORT continued

IVD Regulation

The IVD regulations have now been in place for 36 months but the uptake of the transition period by both members and non-members has been disappointing. Whilst over 1000 inclusions have been made, the number of transitioned products in Class 3 and 4 is still quite small and IVD Australia is concerned that this reflects several issues:

- Slowness of overseas manufacturers to provide detailed technical files to sponsors;
- Lack of understanding by sponsors of the regulations;
- Decisions taken by sponsors to remove currently supplied products from supply at the end of the Transition Period in June 2014.

We also remain concerned that TGA is taking over 12 months to undertake Conformity Assessment of those applications that require this step and that this will lead to substantial delays in 2013/14 for sponsors seeking to transition Class 4 IVDs and for Australian manufacturers. These issues have meant that TGA has proposed changes to the Transition period; extending the time period for Class 4 inclusion by 12 months. IVD Australia has strongly recommended however that the whole Transition period be extended by 12 months to 30 June 2015.

Despite numerous discussions with the Department of Agriculture, Forestry and Fisheries, progress on changes to the risk profile and import regulations covering IVDs has been slow. Whilst we have had some improvements in the treatment of lower risk IVDs, importation of human QC material and control organisms and culture media remain problematical.

Government

IVD Australia has credibility in its advocacy relationships with government, regulators and industry stakeholders and has played a significant part in influencing Australia's policy settings and regulatory framework. Through our leadership, representation and initiatives we have been able to influence government policy and regulations.

In addition to our regular meetings with the TGA, IVD Australia has met with the Department of Health and Ageing (DoHA) on a number of occasions, with the Australian Quarantine Inspection Service (AQIS), with the Department of Industry, Innovation and Scientific Research (DIISR) and with the Medical Services Advisory Committee (MSAC) and other Government bodies.

This has resulted in a number of achievements:

- Membership of the Demand Management Advisory Subcommittee.
- Appointment of a representative on the Pathology Services Table Committee.

- Appointment of a representative in the Vitamin D and B12/folate MSAC Reviews.
- Participation in Health Technology Assessment activities undertaken by MSAC.
- Preparation of a submission to MSAC on HbA1c. We are hoping that adoption of the proposed Decision Analytic Protocol results in the establishment of an MBS item for the diagnosis of diabetes using HbA1c by GPs.
- Preparation of a submission to Part 1 of the PBS Review of products for the management of diabetes. This was looking at the use of blood glucose test strips by non-insulin dependent Type 2 diabetics and has the potential to significantly affect the market for these products as it has done in other geographies.

Global Issues

The issues faced by IVD Australia members are not only local but also global ones and are shared by our members' principals overseas. IVD Australia has continued to develop our relationships with sister organisations such as the British In Vitro Diagnostics Association (BIVDA), AdvaMedDx (the IVD arm of the US Medical Device Association) and with the European Diagnostic Manufacturers Association (EDMA). We have been invited to attend the 2013 General Meeting of EDMA at which there will be a collective meeting of IVD Associations from Europe, North America, Japan, China and Africa. We have continued to participate in the Global Medical Technology Alliance (GMTA) which provides a forum in which global industry associations meet to exchange information on worldwide medical technology trends, and jointly develop and advocate policies that encourage innovation to address patients' healthcare needs.

The Challenges Ahead

IVD Australia has continued to build on the progress made over the past three years. We have built on our participation in a number of forums, established our procedures with the Code of Conduct, and now have a permanent office located in an appropriate location accessible to members.

However there are always challenges. We must continue to promote the importance of the pathology sector to the overall healthcare community, in particular the vital role that IVD suppliers play.

IVD Australia will continue to closely monitor the transition period in the IVD Regulations. We have spent considerable time educating members regarding the regulations and the need to transition products in a timely manner. We remain concerned that there will be significant numbers of critical products that are not transitioned, and are cognizant of the impact that this may have on laboratories and healthcare in general.

The results of the past 12 months have not been achieved without a great deal of hard work, and I would like to acknowledge the support provided by our previous Executive Assistant, Ms Glenda Webb and to welcome Ms Chami Gunasinghe to the role. I would also like to acknowledge the support given to me by the Board of Directors, particularly our Chair, Bruce Evans, and I offer my thanks for their assistance and support.

Finally, I would like to thank the Members for their contribution in terms of staff time during the year, and I look forward to IVD Australia continuing to grow during 2013/14.



Peter Harman
Chief Executive Officer



IVD AUSTRALIA BOARD

The Board of IVD Australia is elected by the membership from among the Corporate Representatives of Member Companies.

Board Members are elected for a two year term and appoint a Chair, Vice-Chair and Treasurer from among their number to serve a one year term. Current Board Members are:

CHAIR Mr Bruce Evans

Non-Executive Director, Abacus ALS Pty Ltd

Bruce Evans is a Director and a major shareholder of Abacus ALS Pty Ltd.

Bruce holds a Masters of Business Administration (USQ) and is a Fellow of the Australian Institute of Company Directors. He is a qualified Medical Laboratory Scientist (QUT), who commenced his career in a clinical pathology laboratory and prior to founding his own business Abacus Diagnostics in 1998, worked in sales and marketing for what is now part of Siemens Healthcare Laboratory Diagnostics.

Bruce also holds the position of Director Asthma Foundation Queensland and was previously a Director of the Medical Technology Association of Australia (mtaa.org.au) and its predecessor, the Medical Industry Association of Australia. Through these directorships, Bruce has gained significant experience as a director in the not-for-profit sector.

VICE CHAIR Mr John Crothers

Regional Director, Abbott Diagnostics Pty Ltd

John Crothers is the Regional Director for Abbott Diagnostics in Australia and New Zealand. Prior to his current role, John was the Commercial Director for Asia Pacific and has also had several years experience working in the US organisation.

With over 25 years experience in the pathology industry in both the laboratory and IVD, the recognition of the

value that the pathology industry delivers to healthcare is a passion that John continues to pursue.

John has a Bachelor of Science (Medical Laboratory Science) from RMIT and a Graduate Diploma in Business Administration from Swinburne University.

TREASURER Mr Patrick Cook

Director, Macarthur Cook Group Pty Ltd

Patrick Cook has been in the *in vitro* diagnostics industry for over 30 years.

Patrick holds degrees in Applied Science, Marketing and is a Graduate of the Company Directors Course. He is a Fellow of the Australian Institute of Company Directors and has served on a number of not-for-profit boards.

Patrick worked as a medical scientist for both public and private laboratories and previously held sales & senior marketing positions at Abbott Diagnostics, Roche Diagnostics and Agen Ltd (an Australian publicly listed biotechnology manufacturer and exporter). In 1995 he established and operated his own medical devices import and distribution business. He is currently a business development consultant in biotechnology and in the medical devices area.

Patrick brings a breadth of knowledge to IVD Australia as he has a very good understanding of the industry having worked for major multinationals, in Australian manufacturing and export and as an owner/operator of a distribution company.

DIRECTOR Mr Paul Cray

Managing Director, Roche Diagnostics Australia Pty Ltd

Paul Cray is the Managing Director of Roche Diagnostics Australia Pty. Ltd. and Leadership Team member of Roche Diagnostics Asia Pacific.

Paul has over 28 years experience in the *in vitro* diagnostics industry, undertaking numerous overseas roles with increasing sales, marketing, strategy and general management responsibility in the UK, Canada, USA, Switzerland and Germany. The most recent post was that of Senior Vice President, Global Marketing, Roche Diagnostics, based in Mannheim, Germany.

Paul holds a Bachelor of Science (Joint Honours) degree from University College of Wales, UK, and has undertaken numerous post graduate and executive courses at INSEAD, France, IMD, Switzerland, London Business School and more recently Mt Eliza Advanced Management Programme, Melbourne Business School. Paul is a Member of the Australian Institute of Company Directors and has been Vice Chairperson of IVD Australia since 2009.

DIRECTOR Mr Mark Volling

Regional Managing Director, Alere Pty Ltd

Mark Volling is the Regional Managing Director for Alere in Australia and New Zealand and has over 25 years experience within the Australian IVD industry including senior roles within global companies, local manufacturing and export and distributor-only organisations. Previous to Alere, Mark was the General Manager for Inverness Medical in Australia and New Zealand and led the local acquisition of Panbio Ltd. He possesses an Associate Diploma in Clinical Laboratory Techniques (QIT), Bachelor Business in Finance/Accounting (USQ), Graduate Certificate in Management (USQ) and a Masters of Technology Management (UQ).

DIRECTOR Ms Holly Simmonds

Managing Director, Hologic (Australia) Pty Ltd

Holly Simmonds is the Managing Director of Hologic Australia. Holly holds a Master of Business specialising in Marketing and has worked in many aspects of the medical industry for the past 25 years, predominately in women's health. In addition to 12 years as a Clinical nurse specialist in gynecology oncology at RPAH, Holly has been employed in the medical industry since 1989 by Imed and Valleylab in sales, Autosuture, Tyco in management, N.Stenning & Co as a product manager and Conceptus as a Managing Director.

In addition to sitting on the Board of IVD Australia, Holly is also Director of Simmonds Holdings and Sydney Training and Conference Centre.

PREVIOUS BOARD MEMBERS

Mr Nino Totino

General Manager, Siemens Ltd, Healthcare Sector Diagnostics & Clinical Products Division

Pathology helps
us lead a normal
active life

Mother and children
with Type 1 diabetes



BOARD ATTENDANCE 2012-2013

			2012				2013					
Name	Position	Term	30 Aug	New Positions	18 Oct	13 Dec	20 Feb	18 Apr*	Extraordinary Meeting	19 Jun	Eligible	Attended
Bruce Evans	Chairman	Oct 2012- Oct 2014	✓	Chairman	✓	✓	✓	✓	✓	✓	7	7
Paul Cray	Vice Chair	Dec 2011- Oct 2013	✓	Director	✓	✓	✓	✓	✓	✓	7	7
Patrick Cook	Treasurer	Oct 2012- Oct 2014	✓	Treasurer	✓	✓	✓	Apologies	✓	✓	7	6
Nino Totino	Director	Dec 2011- Oct 2013	✓	Director	✓			Resigned			2	2
Mark Volling	Director	Dec 2011- Oct 2013	✓	Director	✓	✓	✓	Apologies	✓	✓	7	6
John Crothers	Director	Oct 2011- Oct 2013	✓	Vice Chair	✓	✓	✓	✓	✓	✓	7	7
Holly Simmonds	Director	Oct 2012- Oct 2014		Director	✓	✓	✓	Apologies	✓	✓	6	5

* Not an official board meeting as attendance did not meet quorum standards

CODE OF CONDUCT ADMINISTRATION COMMITTEE

In last year's report, I foreshadowed a busy year ahead as we embarked on the first review of our Code.

I was not mistaken. Over the past year, the Code has been subject to review not only by members of the Code Administration Committee (CAC) but by member companies, external stakeholder groups and finally by an independent expert engaged by the Association for this purpose. The result is a draft revision that will be submitted to the Members for adoption at the Annual General Meeting. By the time you read this Report, the Members' decision will be known. In anticipation of a favourable outcome, I will outline the thinking that has guided the CAC in its review of the Code and development of the 2nd edition.

Firstly, this Code revision has provided us with the opportunity to "dot the i's and cross the t's". It has allowed us to correct some minor anomalies, to address recent marketing phenomena such as social media and to engage in lively debate on questions of grammatical correctness.

Secondly, the revised Code reflects our past three years' experience of Code administration. Our industry sector is unique, and this is evidenced by the way in which members have adopted the Code. Unlike our sister organisations in the therapeutic goods industry, our members have not engaged in formal complaint about each other's marketing practices but have proactively sought advice from the CEO in interpretation and application of the Code to their own activities. This is regarded as a healthy and positive sign, and we have created a new section in the Code to recognise the CEO's and the CAC's role in interpreting the Code through the provision of advice and development of guidance documents. We have also developed a formal mechanism for the provision of mediation between companies in dispute, in what we believe to be a "first" for this industry.

Finally, the revised Code is closely aligned to the recommendations of the Trimmer Group to which IVD Australia was a signatory. The Samson Committee is currently reviewing those recommendations and determining ways to implement them across the therapeutic goods sector. In aligning our Code to the Trimmer Group recommendations, we demonstrate our ongoing commitment to industry best practice.

The CAC's next task will be to develop guidance documents for the assistance of our members. As always, the input of members and external stakeholders is encouraged.

Pam Davis
Chairman, Code Administration Committee

Committee Membership Code of Conduct Administration Committee

Pam Davis - Chair
North Shore Heart
Research Foundation

Ross Brown
Institute of Haematology RPAH
Representing AIMS

Graham Bullman
Siemens Ltd. Australia and
New Zealand Healthcare Sector
Representing IVD Australia

Peter Graham
Representing AACB

George Koumantakis
Roche Diagnostics
Representing IVD Australia

Helen Mikolaj
Consumer representative

Bev Rowbotham
Representing RCPA

Melita Lambiris
Elitech Group P/L
Representing
IVD Australia

Sepehr Tabrizi
Dept Microbiology
& Infectious Diseases
Royal Melbourne
Hospital
Representing NCOPP

TECHNICAL & REGULATORY STANDING COMMITTEE

July 2013 saw the IVD industry enter the final year of the transition period for compliance with the new TGA IVD Regulations... or does it?

2013 will be remembered as the year of the consultation; the most significant of these for IVD sponsors being the TGA consultation on "Proposed Amendments to the new regulatory framework for *in vitro* Diagnostic Medical Devices (IVDs)".

This consultation was the culmination of numerous meetings TGA undertook with industry and laboratories to ascertain potential impediments to registration and possible tests at risk of not being available past the end of the transition period. Many a discussion was had to try to determine what a 'critical' and/or 'endangered' assay might be.

One of the proposed amendments, if implemented, will see an extension of the transition period to 30 June 2015, at the very least for manufacturers requiring Conformity Assessment Certificates to be issued for Class 4 products. However, the amendments are unlikely to be adopted until early 2014 given the upcoming Federal election. It is therefore important at this time for members to continue to progress their submissions based on the 30 June 2014 deadline.

TARSC continues to represent the IVD industry at the TGA Technical and Regulatory Forum and the IVD Working Group. Topics include, for example, TGA IVD Transition Plan, outstanding Guidance document on software, TGA/NATA Memorandum Of Understanding, the broader Medical Device reforms, the rollout of the Adverse Events (DAEN) and Recalls (SARA) databases, issues with the Uniform Recall (URTG) procedure and streamlining of TGA business processes.

Of particular note is the TGA IVD Activity Report. While no major concerns have been raised to date regarding Class 1-3 submission timeframes, TARSC has expressed its concern with the pace at which conformity assessment applications (Class 4) are being processed and the ever increasing number of in-process submissions. TGA has assured industry this is 'as expected' but IVD Australia will still push for timely processing.

IVD Australia again ran successful training days covering both the Basics of the TGA Regulations and the more advanced Conformity Assessment Certification course. Attendees at the latter course were lucky enough to benefit from attendance by not one, but two, TGA assessors.

In late 2012, the Department of Agriculture Fisheries and Forestry (DAFF) revamped AQIS permits covering IVDs culminating in the majority of diagnostic products being covered by only three possible blanket permit lines. This was in part due to the tireless efforts of Peter Harman and other TARSC members in educating AQIS and DAFF on the minimal risks posed by IVDs. Ongoing consultations in 2013 have resolved issues arising due to oversight of certain IVD products.

TARSC continues to monitor global regulatory activities including the ANZTPA, European IVD reforms and the activities of the International Medical Device Regulators Forum (IMDRF) for their impact to Australian sponsors.

Sally Jennings

Abbott Diagnostics
RA QA & IBP Manager

Committee Membership

The Technical and Regulatory Standing Committee

Sally Jennings - Chair
Abbott Australasia P/L

George Koumantakis
Roche Diagnostics
Australia P/L

Walter Shepherd
Immuno P/L

Karen McLeod
MP Biomedicals

Lilies Chen
BioRad Laboratories P/L

Hiram Chipperfield
Alere Australia P/L

Hoon Koh
Siemens Healthcare

Peter Lowe
GenProbe/Hologic Inc

Peter Traynor
ThermoFisher Scientific
ANZ P/L

Susan Alder
Minerva Medica P/L

POINT OF CARE TESTING

The Working Group was established in 2012 ahead of the ACRRM Congress in Fremantle, WA to promote point of care testing (PoCT) IVDs to GPs and Clinicians in rural & remote areas of Australia.

Our lectures and hands-on workshop at the Congress were a great success with 7 member companies demonstrating their test platforms and over 40 attendees.

IVD Australia has been invited back to the ACRRM congress this year in Cairns in November, following the success of the Workshop in Fremantle. Representatives from IVD Australia member companies will again have the opportunity to demonstrate a variety of PoCT products covering INR, Infectious Diseases, Biochemistry

and Haematology. Guest speakers will present to the audience of GPs on "PoC HIV Testing in Qld" and "The Basics of PoCT".

The POC Working Group has been an integral part of the efforts of IVD Australia to raise the profile of PoCT with the Department of Health and Ageing, State Pathology services and the general community. In this area, the Working Group produced an IVD Australia Position Paper on Point-of-Care Testing to customers, politicians, and other stakeholders.

The Working Group through its Diabetes subgroup made several major submissions to Government reviews including the PBS Review of Products for the Management of Diabetes and the MSAC Review of HbA1c testing. The Working Group also commented on the NPAAC revision of the Laboratory Supervision Standard as this applies to Category M Laboratories.

The release of the first point-of care test for HIV early in 2013 has greatly increased the spotlight on point-of-care testing and its benefits to the community and helped establish PoCT as a main stay of effective healthcare delivery in Australia. The goal now is to extend the availability of PoCT and its reimbursement to other tests such as INR and to establish a quality assurance and training framework for PoCT in conjunction with other stakeholders.

My thanks go to all WP members for their efforts in supporting the Working Group and the IVD Secretariat in this important area for IVD Australia members.

Martin Roccliffe M I Biol

Chair, Point-of-Care Working Group
AMSL POC Division Manager

Committee Membership The PoCT Committee

Martin Roccliffe - Chair
AMSL LTD

Adrienne Ripley
Roche Diagnostics P/L

Helen Persano
bioMerieux Australia P/L

Judy Ward
Alere Australia P/L

Barry Wilson
Abbott Australasia P/L

VALUE OF PATHOLOGY

Our industry, like many in Australia and across the world, is experiencing pressures that continue to test all of us but are a guarantee of further change. Talk of further reimbursement cuts in pathology is loud and clear and will have implications for all members of IVD Australia.

One common issue that continues to affect all of us is the lack of awareness of the VALUE that pathology delivers to the health system. This leads to a lack of appreciation of the VALUE that IVD suppliers contribute in delivering the high quality innovative products that are key to our customers providing world class pathology services to the Australian community.

As many of you have already heard from Peter and I, IVD Australia has been embarking on a collaborative approach to change the lack of awareness. The good news is that significant progress has been made.

A company has been established under the name of Pathology Awareness Australia Limited (PAAL). Members representing the key stakeholders in the Pathology Industry are on the PAAL board and include:

Royal College of Pathology Australasia
Dr Debra Graves, CEO (Vice-Chair)

Pathology Australia
Prof. Katherine McGrath, CEO

Primary Healthcare
Mr Neville Moller, CEO - Dorevitch Pathology

Sonic Healthcare
Mr Colin Jackson, Director

National Coalition of Public Pathology
Mr Scott Jansson, Past President (Treasurer)

IVD Australia
Mr John Crothers, Director (Chair of PAAL) and
Dr Peter Harman, CEO (Secretary)

With the incorporation of PAAL, funding has now been committed and an awareness campaign is being launched under the brand....



This brand will be central to our messaging to the general public, consumer health organisations, government and other health care professionals about the relevance of pathology in delivering healthcare in Australia.

We will shortly be launching a website highlighting the VALUE we deliver and the supporter base of key organisations advocating the "Value of Pathology".

There is a call to action. We want people to respond by signing up on the website, developing a supporter base that can be called upon if and when required to ensure our voice is heard.

In the coming months we will also commence putting materials in collection centres, on member websites and using other avenues to ensure that our BRAND is noticed and action is taken.

As a member of IVD Australia your voice is critical and your actions fundamental to the success of this program. Campaign such as this only achieves success if there is a wide uptake of the public relations exercise that we are embarking on.

WHAT YOU CAN DO:

1: Communicate to your organisation:

- The initiative that is being undertaken and have everyone in your organisation visit the website and register their support.
- That there is a presentation template that can be obtained from the IVD Australia website, detailing the background, activities and call to action.

2: Carry the brand.

- Update your website to include the brand logo and also link to www.knowpathology.com.au
- Obtain images from the website that can then be printed and displayed in your workplace.
- Add the brand to your business cards - even on the back if you are restricted. Consider the branding guidelines on the website.
- Tell your friends through social media. Make your network aware of the initiative and consider how they may be able to help.



3: Get actively involved.

- There will be ongoing activities to develop awareness. If you are interested in taking an active role, please advise Peter Harman.

The clear aim of improving awareness is to ensure we are VALUED for what we do. This awareness will then lead to appreciation of the VALUE and in turn the necessary investment to ensure we continue to deliver the highest quality pathology to Australians. This should also have people consider pathology as a professional career.

We do know that this campaign will not "move the needle" overnight. The Board of PAAL are committed to drive awareness by investing over the coming years while ensuring key metrics for success are in place that maintain a common focus and drive outcomes that the 26,000 people who work in the pathology sector can see real change for the better.

Thank you for your continued support through IVD Australia and I look forward to your participation in driving awareness of the VALUE of PATHOLOGY.

John Crothers
Vice Chariman





FINANCIAL STATEMENTS

FOR THE PERIOD
ENDED 30 JUNE 2013

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The financial statements cover IVD Australia Limited as an individual entity. The financial statements are presented in the Australian currency.

The financial statements were authorised for issue by the directors on 15 August 2013. The company has the power to amend and reissue the financial statements.

DIRECTORS' REPORT

30 June 2013

The directors present their report together with the financial statements of IVD Australia Limited ('Company') for the financial year ended 30 June 2013 and the auditor's report thereon.

1. General information

(a) Directors

The names of the directors in office at any time during the period, or since 30 June 2013 are:

Names	Appointed/Resigned
Bruce William Evans	8 July 2009 to present
Patrick Ian Cook	22 October 2011 to present
Paul Simon Cray	8 July 2009 to present
John Crothers	14 October 2011 to present
Nino Totino	8 July 2009 to 16 November 2012
Mark Stephen Volling	10 December 2009 to present
Holly Simmonds	18 October 2012 to present

(b) Company Particulars

IVD Australia Limited was incorporated on the 8 July 2009. The company is domiciled in Australia and is a public company limited by guarantee. The addresses of the registered office and principal place of business are listed below:

Registered Office
Lower Ground Suite 2
55 Phillip Street
PARRAMATTA NSW 2150

Principal Place of Business
Lower Ground Suite 2
55 Phillip Street
PARRAMATTA NSW 2150

(c) Company Secretary

Peter Harman has held the position of company secretary since the company was incorporated on 8 July 2009.

(d) Principal Activity

The principal activity of IVD Australia Limited during the financial year involved facilitating the growth and development of the in - vitro diagnostics industry in Australia.

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

(e) Objectives and Strategy

The company's short term objectives are:

- To retain members and have 55 members by June 2014
- To maintain a Reserve Fund of \$250,000.
- To present TGA Regulatory Training to members as required in 2013/14
- To implement the 2nd edition of the Code of Conduct by November 2013
- To ensure regular ongoing meetings with Members to determine their sector issues
- To work with Pathology Awareness Australia and other stakeholders to launch a Value of Pathology program by December 2013

The company's long term objectives are:

- To grow the Association to a sustainable future and maintain a financially viable Association
- To provide up to date industry and regulatory information
- To increase public and government knowledge and understanding of the value of the IVD industry
- To maintain recognition as the peak body representing the IVD industry
- To provide leadership in the commercial technical and regulatory environment in which members operate
- To implement and operate a Code of Conduct that is representative of the IVD and wider community
- To provide an equitable and transparent complaints process
- To demonstrate strong corporate governance of the sector
- To influence direct regulatory policy to the benefit of members

To achieve these objectives, the entity has adopted the following strategies:

- Grow current membership base by creating clearly identifiable benefits of IVD Australia membership
- Set and manage budgets that include a contingency fund
- Actively encourage and support participation by all members
- Provide easily accessible relevant and current industry information to members
- Provision of quality training and networking opportunities for members
- Engage with RCPA, NCOP and AAPP to build active co operation and consultation on reimbursement issues
- Engage with all levels of government to ensure IVD Australia is recognised as a key stakeholder in the pathology industry
- Develop relevant publications on topics that can demonstrate IVD Australia's benefits to the community such as POCT, the role of diagnostics in prevention and treatment of chronic disease and the IVD Australia code of conduct
- Work with regulatory agencies and participate in government committees, taskforces and working groups
- Monitor legislation and policies for their effect on IVDs
- Ensure that timely and transparent ballots are held for the Board and all Committees
- Create a clear and transparent Code of Conduct process
- Ensure fair and equitable representation of all members
- Create opportunities for members to proactively engage in Association activities
- Ensure that IVD Australia is recognised by the TGA as the peak body regarding supply of *in vitro* diagnostics in Australia and ensure regular, robust and continuing dialogue with TGA via forums, committees and one on one meetings
- Develop an understanding of IVD benefits within the Consumer Health Forum and other consumer groups
- Develop links with and enhance knowledge of the benefits of IVDs within the Health and Insurance sectors
- Develop and promote a range of policies that support the IVD Sector including POCT, Chronic Disease, Pharmacogenomics and Reimbursement

2. Business review

(a) Operating results

The Company continued to engage in its principal activity, the results of which are disclosed in the attached financial statements.

The net deficit of the Company for the financial year ended 30 June 2013 amounted to \$ 32,609 (2012 net surplus \$96,755)

(b) Dividends

The Constitution of the company does not permit the payment of dividends.

3. Other items

(a) Significant Changes in State of Affairs

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

(b) Events Subsequent to Reporting Date

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

(c) Likely Developments

The company will continue to pursue its principal activities at a surplus. It is not expected that the results in future years will be adversely affected by the continuation of those operations.

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

(d) Environmental Regulations

The company's operations are not regulated by any significant environmental regulation under Australian Law.

(e) Indemnification and Insurance of Officers and Auditors

Insurance Premiums

During the financial year, the company has paid premiums in respect of directors' and officers' liability insurance contracts for the year ended 30 June 2013 and since the end of that financial year, the Company has paid or agreed to pay premiums in respect of such insurance contracts for the year ended 30 June 2014. Such insurance contracts insure against certain liability (subject to specific exclusions) persons who are or have been directors or executive officers of the Company.

The Directors have not included details of the nature of the liabilities covered or the amount of the premium paid in respect of the directors' and officers' liability insurance contracts, as such disclosure is prohibited under the terms of the contracts.

Indemnification

Since the end of the previous financial year, the Company has not indemnified or made a relevant agreement for indemnifying against a liability any person who is or has been an officer or auditor of the Company.

(f) Members' Guarantee

Each member of the Company undertakes to contribute to the assets of the Company in the event of it being wound up, while he/ she is a member, or within one year after he/ she ceases to be a member, for the payment of debts and liabilities of the Company, charges and expenses of a winding up, and for the adjustment of the rights of the contributions among themselves, such amounts as may be required not exceeding twenty five dollars (\$25.00).

(g) Lead Auditor's Independence Declaration

The lead auditor's independence declaration is set out on page 8 and forms part of the Directors' Report for the financial year ended 30 June 2013.

4. Director Information

(a) Information on Directors

Patrick Ian Cook (Treasurer)	<ul style="list-style-type: none">- Bachelor of Applied Science (Biomed)- Graduate Diploma in Marketing- FAICD- Certificate IV in Training and Assessment- Managing Director- Experience in IVD Sector: 34 years
Bruce William Evans (Chairperson)	<ul style="list-style-type: none">- Bachelor of Applied Science (Medical Laboratory Science)- Master of Business Administration (MBA)- Fellow of Australian Institute of Company Directors (FAICD)- Managing Director- Experience in the IVD Industry: 2 years clinical pathology laboratory experiences, 10 years sales and marketing IVD experience, 15 years general management and company director to IVD industry experience
Paul Simon Cray (Deputy Chair)	<ul style="list-style-type: none">- BSc Hons, University College of Wales- Post Graduate Certificate of Marketing, University of NSW- Post Graduate residential courses at IMD, Switzerland- Managing Director- Experience in the IVD industry: 30 Years in 6 Countries
Nino Totino	<ul style="list-style-type: none">- BSc (Hons)- General Manager- Experience in the IVD industry: 15 Years
Mark Stephen Volling	<ul style="list-style-type: none">- Masters in Technology Management (Biotech)- Grad Cert Management (International Bus)- B Bus (Accounting/Finance)- Associate Dip Clinical Lab Tech- Regional Managing Director- Experience in IVD industry: 31 Years (Commercial - 20 years)
John Crothers	<ul style="list-style-type: none">- B.AppSc (MLS), Grad Dip Bus Admin- Regional Director, Australia- Experience in the IVD industry - 18 years across ANZ, USA and Asia
Holly Simmonds	<ul style="list-style-type: none">- Gynae-oncology clinical nurse specialist (Equivalent to Bachelor of Nursing)- Current Company Directorships include: Hologic (Australia) Pty Ltd, Simmonds Holdings, Sydney Training and Conference Centre, IVD Australia- Registered nurse for 12 years- Sales and Marketing - 25 years in medical device industry overall- 6 years MD of IVD company and 5 years MD of Conceptus (Australia) Pty Ltd - Medical Device Company

(b) Meetings of Directors

During the financial year, 6 meetings of directors (including committees of directors) were held. Attendances by each director during the year were as follows:

	Directors' Meetings	
	Number eligible to attend	Number attended
Bruce William Evans	6	6
Patrick Ian Cook	6	6
Paul Simon Cray	6	5
John Crothers	6	6
Nino Totino	2	2
Mark Stephen Volling	6	5
Holly Simmonds	5	5
John Crothers	6	5

Signed in accordance with a resolution of the Board of Directors



Bruce William Evans
Director



Patrick Ian Cook
Director

Dated 15 August 2013

In the opinion of the directors of IVD Australia Limited:

1. The financial statements and notes, as set out on pages 24 to 34, are in accordance with the *Corporations Act 2001* and:
 - (a) comply with Accounting Standards (including the Australian Accounting Interpretations) and the Corporations Regulations 2001; and
 - (b) give a true and fair view of the financial position as at 30 June 2013 and of the performance for the year ended on that date of the Company.
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 the Board of Directors.



Bruce William Evans
Chairman and Director



Patrick Ian Cook
Treasurer and Director

Dated 15 August 2013

The Board of Directors
IVD Australia Limited
PO Box 298
Parramatta CBD BC NSW 2124

Dear Board Members

Auditors Independence Declaration under Section 307C of the Corporations Act 2001

In accordance with section 307C of the *Corporations Act 2001*, I am pleased to provide the following declaration of independence to the directors of IVD Australia Limited.

As lead audit partner for the audit of the financial statements of IVD Australia Limited for the financial year ended 30 June 2013, I declare that, to the best of my knowledge and belief, there have been no contraventions of:

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

Yours sincerely



Nexia Court & Co
Chartered Accountants



Ian Stone
Partner

Sydney
Dated: 15 August 2013

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Independent member of Nexia International



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Independent Audit Report to the members of IVD Australia Limited

Report on the Financial Report

We have audited the accompanying financial report, being a special purpose financial report, of IVD Australia Limited, which comprises the statement of financial position as at 30 June 2013, and the income statement, statement of comprehensive income, statement of changes in equity and cash flow statement for the year ended on that date, a summary of significant accounting policies, other explanatory notes and the directors' declaration.

Directors' Responsibility for the Financial Report

The directors of the company are responsible for the preparation and fair presentation of the financial report and have determined that the accounting policies described in note 1 to the financial statements, which form part of the financial report, are appropriate to meet the requirements of the Corporations Act 2001 and are appropriate to meet the needs of the members. The directors' responsibility also includes establishing and maintaining internal controls relevant to the preparation and fair presentation of the financial report that is free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

Auditor's Responsibility

Our responsibility is to express an opinion on the financial report based on our audit. No opinion is expressed as to whether the accounting policies used, as described in note 1, are appropriate to meet the needs of the members. We conducted our audit in accordance with Australian Auditing Standards. These Auditing Standards require that we comply with relevant ethical requirements relating to audit engagements and plan and perform the audit to obtain reasonable assurance whether the financial report is free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial report. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial report, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the directors, as well as evaluating the overall presentation of the financial report.

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

Our procedures include reading the other information in the Annual Report to determine whether it contains any material inconsistencies with the financial report.

Our audit did not involve an analysis of the prudence of business decisions made by directors or management.

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

Auditor's Opinion

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

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



Nexia Court & Co
Chartered Accountants



Ian Stone
Partner

Sydney
Dated: 15 August 2013

STATEMENT OF COMPREHENSIVE INCOME

For the Year Ended 30 June 2013

	Note	2013 \$	2012 \$
Revenue	2	384,480	477,480
Total income		384,480	477,480
Depreciation expense	3(b)	(3,709)	(3,034)
Administration expense		(139,401)	(112,788)
Employee benefits expense	3(a)	(232,537)	(237,734)
Travel expenses		(41,442)	(27,169)
Total expenses		(417,089)	(380,725)
Surplus for the year		(32,609)	96,755
Other comprehensive income		-	-
Total comprehensive income for the year		(32,609)	96,755

STATEMENT OF FINANCIAL POSITION

30 June 2013

	Note	2013 \$	2012 \$
ASSETS			
CURRENT ASSETS			
Cash and cash equivalents	4	298,122	289,358
Trade and other receivables	6	20,857	8,617
Other assets	5	19,897	17,539
Current tax receivable		837	-
TOTAL CURRENT ASSETS		339,713	315,514
NON-CURRENT ASSETS			
Property, plant and equipment	7	5,347	5,671
TOTAL NON-CURRENT ASSETS		5,347	5,671
TOTAL ASSETS		345,060	321,185
LIABILITIES			
CURRENT LIABILITIES			
Trade and other payables	8	32,739	13,593
Employee benefits	9	10,171	13,964
Other liabilities	10	45,012	3,881
TOTAL CURRENT LIABILITIES		87,922	31,438
NET ASSETS		257,138	289,747
EQUITY			
Retained earnings		257,138	289,747
TOTAL EQUITY		257,138	289,747

STATEMENT OF CHANGES IN EQUITY

For the Year Ended 30 June 2013

2013	Retained Earnings \$	Total \$
Balance at 1 July 2012	289,747	289,747
Surplus for the year	(32,609)	(32,609)
Balance at 30 June 2013	257,138	257,138

2012	Retained Earnings \$	Total \$
Balance at 1 July 2011	192,992	192,992
Surplus for the year	96,755	96,755
Balance at 30 June 2012	289,747	289,747

STATEMENT OF CASH FLOWS

For the Year Ended 30 June 2013

	2013 \$	2012 \$
Cash from operating activities:		
Receipts from customers	450,134	502,829
Payments to suppliers and employees	(454,895)	(434,251)
Interest received	16,910	18,028
	12,149	86,606
Cash flows from investing activities:		
Purchase of property, plant and equipment	(3,385)	(1,807)
	(3,385)	(1,807)
Net cash increase (decreases) in cash and cash equivalents	8,764	84,799
Cash and cash equivalents at beginning of year	289,358	204,559
Cash and cash equivalents at end of year	298,122	289,358

NOTES TO THE FINANCIAL STATEMENTS

For the Year Ended 30 June 2013

1 Summary of Significant Accounting Policies

(a) General Information

The financial report covers IVD Australia Limited as an individual entity. IVD Australia Limited ('the Company') is a Company limited by guarantee, incorporated and domiciled in Australia. The address of the Company's registered office is Lower Ground Suite 2, 55 Phillip Street, Parramatta NSW 2150. The company is primarily involved in facilitating the growth and development of the *in vitro* diagnostics industry in Australia.

(b) Basis of Preparation

The financial report is a general purpose financial report that has been prepared in accordance with Australian Accounting Standards, Australian Accounting Interpretations, other authoritative pronouncements of the Australian Accounting Standards Board and the *Corporations Act 2001*.

The financial statements of IVD Australia Limited comply with Australian Accounting Standards as issued by the AASB.

Early Adoption of Standards:

The company has elected to apply the following pronouncements to the annual reporting period beginning 1 July 2012:

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

This includes applying the revised pronouncement to the comparatives in accordance with AASB 108 *Accounting Policies, Changes in Accounting Estimates and Errors*. The adoption of AASB 1053 and AASB 2010 2 allowed the entity to remove a number of disclosures. There was no other impact on the current or prior year financial statements.

(c) Function and Presentation

These financial statements are presented in Australian dollars, which is the company's functional currency.

(d) Revenue and Other Income

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

Revenue from the sale of goods is recognised at the point of delivery as this corresponds to the transfer of significant risks and rewards of ownership of the goods and the cessation of all involvement in those goods.

Interest revenue is recognised using the effective interest rate method.

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

(e) Income Tax

The company is exempt from income tax under the provisions of the *Income Tax Assessment Act*.

(f) Goods and 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 Tax Office. In these circumstances the GST is recognised as part of the cost of acquisition of the asset or as part of an item of the expense. Receivables and payables in the statement of financial position are shown inclusive of GST.

Cash flows are presented in the statement of cash flows on a gross basis, except for the GST component of investing and financing activities, which are disclosed as operating cash flows.

(g) Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and term deposits with banks.

(h) Property, Plant and Equipment

Property, plant and equipment is stated at historical cost less depreciation. Historical cost includes expenditure that is directly attributable to the acquisition of the items.

Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the company and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the Statement of Comprehensive Income during the financial period in which they are incurred.

Depreciation of assets is calculated using the straight line method to allocate their cost, net of residual values, over their useful lives, as follows:

- Office Fixtures 3-5 years

The assets' residual values and useful lives are reviewed, and adjusted if appropriate, at each Statement of Financial Position date.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

(i) Trade and other payables

Trade creditors and other payables, are recognised at the nominal transaction value without taking into account the time value of money.

(j) Employee Benefits

Provision is made for the Company's liability for employee benefits arising from services rendered by employees to balance date. Employee benefits that are expected to be settled within one year have been measured at the amounts expected to be paid when the liability is settled.

(k) New Accounting Standards for Application in Future Periods

The AASB has issued new, revised and amended standards and interpretations that have mandatory application dates for future reporting periods and which the Company has not adopted early.

(l) Critical Accounting Estimates and Judgments

The Directors evaluate estimates and judgments incorporated into the financial report based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and based on current trends and economic data, obtained both externally and within the Company.

2 Revenue

Continuing operations	2013 \$	2012 \$
Member subscriptions	354,572	435,713
Training income	13,510	19,523
Interest revenue	16,398	22,244
	384,480	477,480

3 Expenses

(a) Employee benefits expense

Wages and salaries	191,478	192,000
Other associated personnel expenses	22,714	26,834
Superannuation	18,345	18,900
	232,537	237,734

(b) Depreciation expense

Depreciation - computer equipment	3,098	2,937
Depreciation - furniture and fixtures	611	97
	3,709	3,034

4 Cash and Cash Equivalents

Cash at bank	98,122	89,358
Term deposits	200,000	200,000
	298,122	289,358

5 Other Assets

Prepayments	1,897	16,009
Security deposit	-	1,530
Lease guarantee	18,000	-
	19,897	17,539

NOTES TO THE FINANCIAL STATEMENTS continued

6 Trade and other receivables

	2013 \$	2012 \$
CURRENT		
Trade receivables	3,704	4,216
GST paid	17,153	4,401
	<u>20,857</u>	<u>8,617</u>

7 Property, Plant and Equipment

NON CURRENT		
Furniture, fixture and fittings		
At cost	3,589	1,327
Accumulated depreciation	(708)	(97)
Total furniture, fixture and fittings	2,881	1,230
Computer equipment		
At cost	10,047	8,924
Accumulated depreciation	(7,581)	(4,483)
	<u>2,466</u>	<u>4,441</u>
Total property, plant and equipment	<u>5,347</u>	<u>5,671</u>

(a) Movements in Carrying Amounts

Movement in the carrying amounts for each class of property, plant and equipment between the beginning and the end of the current financial year:

	Furniture, Fixtures and Fittings \$	Computer Equipment \$	Total \$
Balance at 30 June 2013			
Balance at the beginning of year	1,230	4,441	5,671
Additions	2,262	1,123	3,385
Depreciation expense	(611)	(3,098)	(3,709)
Balance at 30 June 2013	<u>2,881</u>	<u>2,466</u>	<u>5,347</u>

8 Trade and other payables

CURRENT		
GST Collected	12,954	323
PAYG Payable	4,073	3,969
Accrued expenses	15,712	9,301
	<u>32,739</u>	<u>13,593</u>

9 Provisions

CURRENT		
Provision for annual leave	10,171	13,964
	<u>10,171</u>	<u>13,964</u>

10 Other liabilities

CURRENT		
Income in advance	45,012	3,881
	<u>45,012</u>	<u>3,881</u>

11 Auditors' Remuneration

	2013 \$	2012 \$
Payable to the auditors of the company - Nexia Court & Co		
- Audit services	8,250	7,875
- Non-audit services	3,073	2,800
	<u>11,323</u>	<u>10,675</u>

12 Cash Flow Information

(a) Reconciliation of cash

	2013 \$
Cash at the end of the financial year as shown in the statement of cash flows is reconciled to items in the statement of financial position as follows:	
Cash and cash equivalents	<u>298,122</u>
	<u>298,122</u>

(b) Reconciliation of Cash Flow from Operations with Profit after Income Tax

Net surplus for the year	(32,609)
Cash flows excluded from profit attributable to operating activities	
Adjustments for	
Depreciation and amortisation	3,709
Changes in assets and liabilities	
Change in trade and other receivables	(12,240)
Change in trade and other payables	19,146
Change in tax receivable	(837)
Change in other assets	(2,358)
Change in employee benefits	(3,793)
Change in other liabilities	41,131
Net cash flows from operating activities	<u>12,149</u>

13 Key Management Personnel Compensation

(a) Key Management Personnel Remuneration

Key management personnel include the directors and the Chief Executive Officer, Peter Harman. All directors are honorary and as such no payments are made to the directors. Short term benefits received by key management personnel during the year were: \$188,370 (2012: \$183,120). No other benefits were received or provided.

(b) Transactions with Related Entities

The only transactions with related parties of IVD Australia Limited were membership subscription fees received.

14 Future Commitments

IVD Australia has committed to contribute \$35,000 to the start up of Pathology Awareness Australia Limited ('PAAL'). It is expected that PAAL will invoice IVD Australia the full amount in the first week of its incorporation in the 2013/2014 financial year.

NOTES TO THE FINANCIAL STATEMENTS continued

15 Contingent Liabilities

Operating lease commitments subsequent to year end

	2013 \$	2012 \$
Payable - minimum lease payments		
- no later than 12 months	39,600	36,300
- between 12 months and 5 years	6,600	42,900
	46,200	79,200

16 Superannuation Commitments

The company has a legal obligation to contribute superannuation for all employees. The company contributes to complying accumulation superannuation plans.

17 Events After Balance Date

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

18 Company Details

Registered office

The registered office of the company is:
IVD Australia Limited
Lower Ground Suite 2
55 Phillip Street
PARRAMATTA NSW 2150

Principal place of business

The principal place of business is:
Lower Ground Suite 2
55 Phillip Street
PARRAMATTA NSW 2150

IVD AUSTRALIA
MEMBERS

at June 30 2013

Abacus ALS Pty Ltd	Enterix (Australia) Pty Ltd	Novartis Vaccines and Diagnostics Pty Ltd
Abbott Australasia Pty Ltd	ESL Biosciences (Australia) Pty Ltd	Paragon Therapeutic Technologies
Acrapack Pty Ltd	Genera Biosystems Limited	PerkinElmer Pty Ltd
Alere Australia Pty Ltd	Glenn Street Entreprises Pty Ltd	Prohealth Asia Pacific Pty Ltd
Archer Emery & Associates	Grifols Australia Pty Ltd	Qiagen Pty Ltd
Astral Scientific Pty Ltd	Healthworld Ltd	Randox Laboratories Pty Ltd
AusDiagnostics Pty Ltd	Helena Laboratories (Australia) Pty Ltd	r-biopharm Pty Ltd
Australasian Medical & Scientific Pty Ltd	HemoCue Australia Pty Ltd	Roche Diagnostics Australia Pty Ltd
bioMerieux Australia Pty Ltd	Hologic (Australia) Pty Ltd	Sequenom Inc
Bio-Rad Laboratories Pty Ltd	Human Genetic Signatures Pty Ltd	Siemens Ltd. Australia and New Zealand Healthcare Sector
Blackaby Diagnostics Pty Ltd	Illumina Australia Pty Ltd	Southern Cross Diagnostics Pty Ltd
Brandwood Biomedical Pty Ltd	Immuno Pty Ltd	Sysmex Asia Pacific Pty Ltd
Clinical Genomics Pty Ltd	Integrated Sciences Pty Ltd	Thermo Fisher Scientific ANZ Pty Ltd
CSL Limited Biotherapies Division	Leica Microsystems Pty Ltd	Universal Biosensors Pty Ltd
Diagnostic Solutions Pty Ltd	Life Bioscience Pty Ltd	Vela Diagnostics Pty Ltd
Diagnostic Technology Pty Ltd	Macarthur Cook Group Pty Ltd	
Dagnostica Stago Pty Ltd	Merck Pty Ltd	
Dutec Diagnostics Pty Ltd	Minerva Medica Pty Ltd	
Elitech Group Pty Ltd	MP Biomedicals (Australia) Pty Ltd	

Pathology
saved my life

John - Kidney Transplant Recipient

