

ANNUAL REPORT 2018

IVD
AUSTRALIA

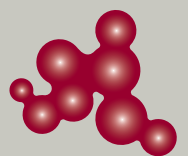


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CHAIR'S REPORT

THE END OF THE 2018 FISCAL YEAR MARKS THE CLOSE OF THE NINTH YEAR OF OPERATIONS OF IVD AUSTRALIA. YOUR INDUSTRY ASSOCIATION HAS ACHIEVED SEVERAL MAJOR MILESTONES WITHIN THE LAST YEAR AS EVIDENCE OF OUR GROWING PROFILE.

Focus on Members Critical Issues

In 2017-18, I was once again proud to be a member of an industry whose members are the drivers of innovative technologies that help deliver a best-in-class healthcare system for all Australians. In vitro diagnostic companies have played a significant role as suppliers and enablers in achieving efficiencies, savings and greater quality through the provision of highly automated pathology solutions coupled with world best practice in after-sales support. It is time to capitalise on the innovative capacity of the IVD Industry.

On behalf of its Members, IVD Australia continues to be at the forefront of efforts to ensure that business conditions for our Members improve. The focus of this last year has been Member's Critical Issues, in particular funding, importation issues and regulatory guidelines – specifically, but not exclusively, the much needed clinical evidence guidelines specific to IVDs.

The Value of being an IVD Australia Member in 2017-2018

The hard work we do for Members has paid off, with two Purchasing Bodies requesting input on their Master Contracts for the IVD Industry. Working on insurance, sole convenience and liquidated damages clauses, amongst many more issues, IVD Australia reviewed and collated the many member submissions we received and submitted to the purchasing bodies.

A Code of Practice is a central guide and reference for industry to support their employee's day-to-day decision making. A code encourages discussions of ethics and compliance, empowering employees to handle ethical dilemmas they encounter in everyday work. It can also serve as a valuable reference, helping employees locate relevant documents, services and other resources related to ethics within industry. IVD Australia has reviewed and renewed the industry Code of Practice to reflect the high standard of our industry's ethics.

A Seat at the Table

We are acutely aware that without a role in discussions of key importance to our industry will result in unintended consequences for our industry. This year we have participated and continued to advocate for all our members in the Pathology Business Group of MSAC (MBS Review); Pathology Awareness Australia (KPKH Campaign); TGA IVD Working Group; TGA RegTech Forum; Department of Health meetings; Department of Agriculture Biological Consultative Group; and Standards Australia.

Vote of Thanks

I also want to recognise the team at IVD Australia; the contribution of my fellow Board Members – Antoinette Violo (Perkin Elmer), John Crothers (Abbott Diagnostics), Paul Cray (Roche Australia), Tony Feneziani (Merck Group), Karen McLeod (MP Biomedicals), Sally Hickman (Werfen Australia), Rayden Rivett (Cepheid), and Vito Trifilo (Tecan Australia). Their dedication to IVD Australia and our Industry has enabled us to drive the strategic agenda at an ever increasing pace.

I would also like to acknowledge the contribution of Jenny Zhou (Tecan Australia) to the Finance, Audit & Risk Management Committee, our Secretariat (Wendy-Jane and Chami) and we continue to have the best people on committees that care deeply about improving our business, and it is this passionate commitment that ensures we can continue our successes.

To our Members, I thank you for your ongoing support and loyalty, and I look forward to growing the value we offer you today and in the future.

Sebastian D'Angelo
Chairman, IVD Australia



CEO'S REPORT

IN 2017-18, WE SAW ONGOING ADVANCES IN TECHNOLOGY AND CONSTANT INNOVATION CONTINUE TO RESHAPE THE PATHOLOGY ENVIRONMENT AND TRANSFORM CUSTOMER EXPERIENCES.

Dear Members

As we prepare to celebrate the tenth year of operation in late 2019, IVD Australia has achieved a number of key strategic, operational and financial targets during the 2018 financial year.

It is gratifying to see our successes play an increasingly critical role in helping members.

In 2017-18, we saw ongoing advances in technology and constant innovation continue to reshape the pathology environment and transform customer experiences. Our focus has been steadfast in ensuring that Australia has the right policies and legislative environment that make it easier to bring innovative diagnostics to Australians who need them; that rewards innovation; and encourages investment. I would like to acknowledge the hard work of the Board, the secretariat and the numerous committees and working groups, populated by experienced professionals from our member companies that have all played an important role in supporting the industry over the past twelve months.

Behind the scenes we are driving significant transformation in the way we work and the systems and tools to enable us to be much more agile and deliver even better value to you, our Members. Establishing our new digital platform and member database and rebranding IVD Australia will take our services to you to a whole new level.

I would like to encourage all member companies to become actively involved in our association. Through your contribution to working groups and your feedback, we can ensure that the association remains in touch with your needs and that we all benefit by pooling our resources for the benefit of the industry. Through our combined efforts, IVD Australia is the spokesperson for our member companies, and our industry is being heard, and is making a difference, in these interesting but challenging times.

Every year, IVD Australia looks to add value by achieving things as an organisation that our Members cannot achieve on their own, and this past year, we have improved the business conditions for IVD businesses, increased the advocacy power of the industry and have commenced projects that will improve market access. We also reviewed our Strategic Plan to ensure IVD Australia is working on the right issues that matter most to you. We need to make sure that all our Members are able to have input into our advocacy and other focussed activities we undertake.

Thank You

To our Members, thank you for your time, and expertise you have given to IVD Australia.

To our Board, Sebastian, John, Paul, Vito, Karen, Rayden and Antoinette, thank you for the leadership, time, and expertise you have given to IVD Australia. You have made a difference through your dedication and continued support, assisting us in improving the business environment for our industry.

TREASURER'S REPORT

I WOULD LIKE TO PRESENT THE IVD AUSTRALIA ACCOUNTS FOR THE FINANCIAL YEAR ENDING JUNE 30, 2018. THE ACCOUNTS, AUDITED BY NEXIA AUSTRALIA, ARE INCLUDED IN THIS ANNUAL REPORT AND ARE AVAILABLE TO THOSE WHO WISH TO HAVE A COPY.

Against a backdrop of a number of years where financial reserves were depleted, I am pleased to report that, through careful control of costs, we have ended the year with a positive balance. This will enable us to continue to ensure the financial stability and security of the organisation; and invest in strategic projects to support our members.

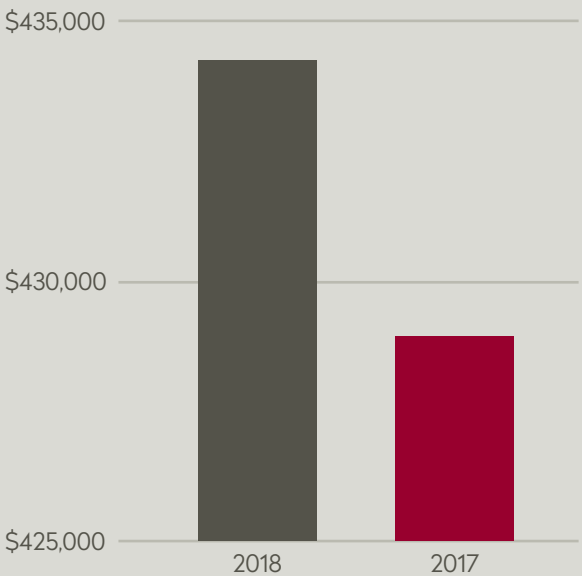
Our income for the year was approximately \$473,807 from a combination of membership, training, events and interest. This income is an increase of approximately \$75,176 on last year's income.

Our expenditure for the year was approximately \$440,000. The majority of this expenditure was for employment costs, administration, events and training. Special Projects accounted for \$92,111, including the Code of Conduct, Pathology Awareness Australia, the Australian GDMS, Re-branding, Purchasing Contracts, and Health Economics. Full details of the income and expenditure (including Auditor adjustments) can be found in the accounts.

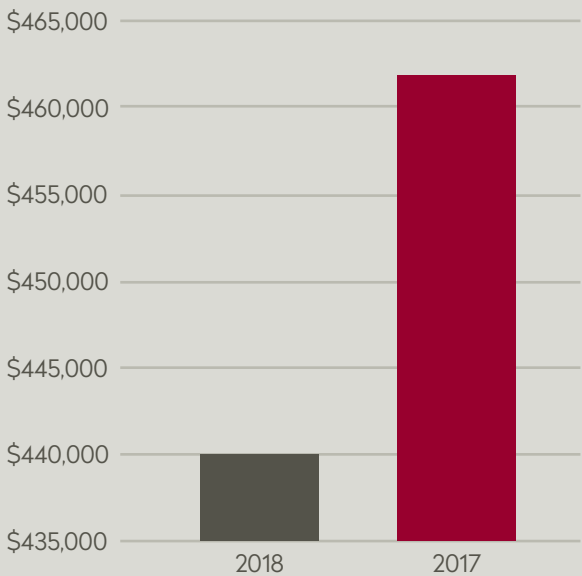
In summary, I am pleased to report a successful year with the financial position of IVD Australia being stable, but with a considerably higher expenditure (37.2%) on Strategic Projects.

Vito Trifilo

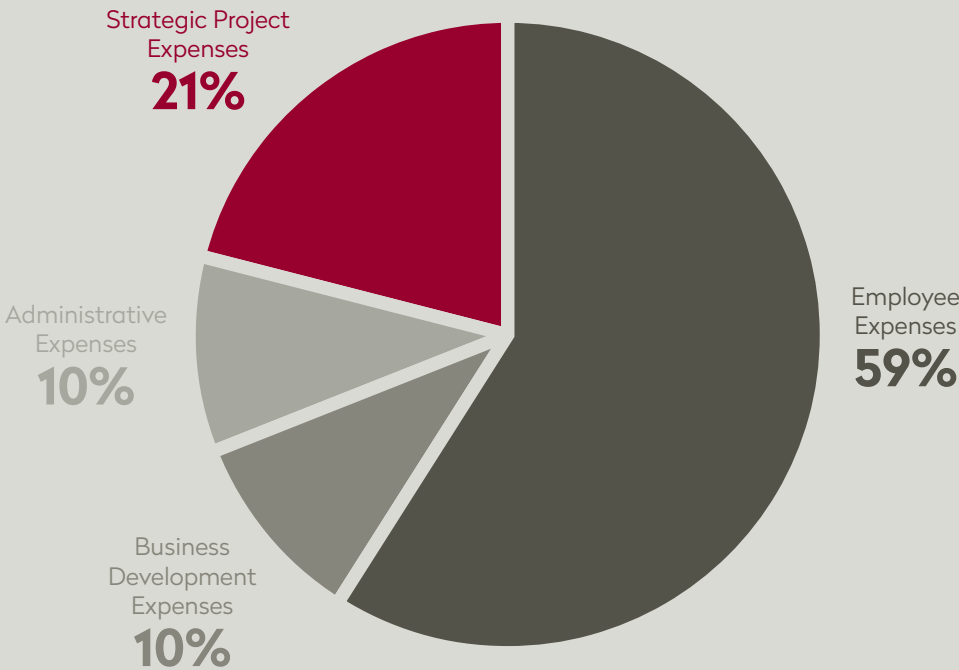
TOTAL INCOME



TOTAL EXPENSES



EXPENSES BREAKDOWN



IVD AUSTRALIA BOARD

Mr Sebastian D'Angelo (Chair)

GENERAL MANAGER,
LABORATORY DIAGNOSTICS DIVISION, SIEMENS
HEALTHCARE – AUSTRALIA & NEW ZEALAND

Sebastian has over 30 years' experience within the Australian IVD industry, having worked as a medical scientist in public pathology laboratories before moving to senior roles at Chiron Diagnostics and Bayer Diagnostics and now at Siemens Healthcare Diagnostics.

Sebastian holds a Bachelor of Applied Science (MLS) degree from RMIT University and a Master of Marketing degree from the Melbourne Business School. He is a Member of the Australian Institute of Company Directors.

Mr Paul Cray (Deputy Chair)

MANAGING DIRECTOR OF ROCHE DIAGNOSTICS
AUSTRALIA PTY. LTD. AND LEADERSHIP TEAM MEMBER
OF ROCHE DIAGNOSTICS ASIA PACIFIC

Paul has over 25 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.

Paul holds a Bachelor of Science degree from University College of Wales, UK, and has undertaken numerous post graduate and executive courses at INSEAD, France, IMD, Switzerland and more recently Mt Eliza Advanced Management Programme, Melbourne Business School. Paul is a Member of the Australian Institute of Company Directors.

Mr David Basseal

DAVID IS THE BUSINESS DIRECTOR, AUSTRALIA & NEW
ZEALAND, BD DIAGNOSTICS

David Basseal has over 20 years industry experience in Life Sciences with 10 years specifically in In-Vitro Diagnostics. David commenced his career as a scientific researcher in the field of proteomics. He entered the commercial arena with Bio-Rad Laboratories Australia/New Zealand and held positions of increasing responsibility over a 7 year period.

Today David is the Business Director for Diagnostics for Australia/New Zealand at Becton Dickinson (BD). This involves the management of two business segments within BD – Pre-Analytical Systems (PAS) and Diagnostics Systems (DS).

Mr John Crothers

REGIONAL DIRECTOR,
ABBOT DIAGNOSTICS PTY LTD

John Crothers is a Regional Director for Australia and New Zealand. Prior to the role of Australia, John was the Commercial Director for Asia Pacific and has also had several years in US Marketing.

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.

With over 25 years experience in the pathology industry in both the laboratory and IVD, the appreciation of the value of the industry in healthcare is a passion that John continues to pursue.

John has a BSc(MLS) from RMIT and a Graduate Diploma Administration from Swinburne University.

Mr Jim Kakaflikas

GENERAL MANAGER, QIAGEN

Jim is Director, Head of Commercial Operations at QIAGEN Pt Ltd and on the QIAGEN Leadership team for Asia Pacific. Prior to joining QIAGEN, Jim was the Enterprise Director at Abbott Diagnostics and was responsible for managing business development for Australia and New Zealand. At Abbott Diagnostics, Jim was also a Director for Global Accounts, working with key customer groups in Europe and the USA. Jim has over 25 years' experience in the In-vitro Diagnostics and healthcare markets, having also worked in a variety of senior marketing, sales and support roles at GlaxoSmithKline and Bayer Diagnostics. Jim started his career as a Medical Scientist in Haematology.

Jim holds a Masters of Business Administration (Australian Graduate School of Management / UNSW) and a Bachelor of Applied Science (MLS) degree from RMIT University.

Mr Ted Maione

GENERAL MANAGER, WERFEN

Ted is the General Manager of Werfen in Australia, moving from the Boston area of United States three years ago.

Ted's career in the IVD industry has spanned the last thirty years, the first twenty of which were with Abbott Diagnostics and the last ten years have been with Werfen/IL. During the twenty years at Abbott he held eight positions of greater responsibility in five different cities throughout the United States. Ten years ago Ted was recruited by Werfen/IL to be the Director of Global Marketing, where his team are responsible for product development and marketing IL's critical care products throughout the world.

IVD AUSTRALIA BOARD (CONTINUE)

Mr Rayden Rivett

GENERAL MANAGER, CEPHEID HOLDINGS PTY LTD

Rayden has been continuously involved in the IVD Industry since 1979 working in sales, marketing and senior management. For 15 years he was Managing Director of bioMérieux in Australia and since 2006 has worked in the USA, Asia-Pacific and more recently in establishing Australian subsidiaries for overseas-based IVD companies. Rayden has represented the IVD sector in the past, being a Board member of MIAA (now MTAA) from 1999 to 2006 and its Vice-Chair (2003-2004), a member of their Diagnostic/IVD Standing Committee 1994-2001, member of the Market Development Committee (1997-2003) and its Chair (2000-2002).

Ms Bernadette Snopek

SENIOR MANAGER, PERKINELMER AUSTRALIA

Bernadette has worked in the healthcare industry for over 20 years. She started her career at the Ludwig Institute for Cancer Research in Parkville as an Assistant Laboratory Manager. Several commercial roles in the Life Sciences industry for a decade and the last ten years have been specific to the Diagnostics industry in South East Asia. She has run her own company manufacturing Australian made goods and self-published a book relating to chronic fatigue syndrome / myalgic encephalomyelitis / fibromyalgia. The book is an aide for sufferers. Her current corporate role specializes in Molecular Diagnostics and Nucleic Acid Products supporting the regional team. Bernadette has been involved with TGA and all regional company product registrations in various South East Asian countries in her role with PerkinElmer.

Mr Vito Trifilo (Treasurer)

GENERAL MANAGER, TECAN AUSTRALIA

I have over 20 years' experience in the Life Science and in vitro diagnostic businesses in the Australian and New Zealand markets. I have had held business development and sales management roles for over 10 years and was an early company representative with AMRAD Pharmacia Biotech during the start-up phase. My current role is General Manager at Tecan Australia (a position that I have held for over 2 years), with ANZ sales, marketing, legal and regulatory responsibilities. Tecan is a leading global provider of laboratory instruments and solutions (strongly automation focussed) in biopharmaceuticals, forensics and clinical diagnostics.

Mr Peter Lowe

NATIONAL SALES MANAGER AND DIRECTOR OF SCIENTIFIC AFFAIRS, MOLECULAR DIAGNOSTICS, ANZ WITH HOLOGIC AUSTRALIA.

Peter has been with Gen-Probe / Hologic since 2011. Prior to Hologic Peter worked for Silliker Australia as the National Operations Director. Peter has been part of the medical industry for 30+ years within various private laboratory groups. The latter years included regulatory and quality responsibilities.

Mr Tony Feneziani

HEAD OF RESEARCH SOLUTIONS ANZ, MERCK GROUP

Tony has over 25 years commercial experience in the in vitro diagnostic and life sciences industries. During this time, Tony has undertaken a range of leadership roles including commercial operations, sales and marketing and business development.

Tony's current role at Merck also includes Country Leadership Team membership of the Merck Life Sciences operation in ANZ

Ms Sally Hickman

GENERAL MANAGER, WERFEN AUSTRALIA & NZ

Sally has over 12 years experience in the Australian IVD industry having undertaken key roles in the areas of strategic marketing and customer account management. In 2012, Sally joined Werfen Australia and assumed key management responsibilities at a time when company took direct operations of key business units in Oceania.

Sally has a passion for diagnostics having trained and worked in public pathology laboratories for more than 5 years in the UK.

Sally holds a Bachelor of Science degree in Biomedical Sciences from The University of Bradford, UK and a Master of Science in Biomedical Sciences degree (specialising in Haematology) from The University of Ulster, UK.

Ms Karen McLeod

DIRECTOR AND COUNTRY MANAGER, MP BIOMEDICALS

Karen's 30-year career in the in-vitro diagnostics and pharmaceuticals industries began as a medical scientist in public pathology and includes varied sales and management roles with Australian based global companies such as BioMérieux, Boehringer Mannheim (now Roche) and GSK. Currently Director and Country Manager at MP Biomedicals, she is responsible for all sales, management, and regulatory functions. Karen has a Bachelor of Applied Science and Graduate Diploma in Marketing from UTS, Sydney and has been a member of the IVD Australia Technical and Regulatory Standing Committee since 2011.

Ms Antionette Violo

REGIONAL SALES DIRECTOR, DIAGNOSTICS, PERKINELMER

My association with the life sciences, human health and diagnostics industries has extended for over 25 years across the commercial and academic sectors. I am currently the Regional Sales Director for PerkinElmer's diagnostic's business in the Applied Genomics division.

My commercial career commenced when I was approached to start the Life Sciences Division of PerkinElmer in Australia. I have been fortunate to progress within the organisation and have managed divisions and many staff across Australia, New Zealand and Asia for over 15 years. A significant achievement I am very proud of has been to partner PerkinElmer in the commercialisation of an Australian developed immunoassay kit (TGR Biosciences).

I was approached to join the Diagnostics Division twelve months ago to develop the Applied Genomics division within the Asia Pacific region. This has been an exciting challenge and a personal interest of mine in observing the impact that translational medicine has on human health outcomes.

THE VALUE OF BEING AN IVD AUSTRALIA MEMBER IN 2017 - 2018

OUR **VISION** IS OF A HEALTHIER AUSTRALIA THAT VALUES OUR MEMBERS AS THE DRIVERS OF INNOVATIVE TECHNOLOGIES THAT HELP DELIVER A BEST-IN-CLASS HEALTHCARE SYSTEM.

OUR **MISSION** IS THAT AS THE INDUSTRY PEAK BODY, WE WILL ADVOCATE AND INFLUENCE KEY STAKEHOLDERS FOR OUR MEMBERS.

Our **VALUES** are:

COMMITMENT – we are passionate about the technological industry we represent and the importance of improving lives of Australian people.

INNOVATION – by driving innovation, our Members provide solutions, through our industry's actions we contribute towards creating a better place for future generations.

COLLABORATION – we seek to build successful partnerships in pursuit of common goals.

STRATEGIC PILLARS

Being the Voice of this innovative industry through strategic collaboration and advocating strongly for policy change with solid health economic data

STRATEGIC PRIORITIES

- Promoting our Regulatory Expertise
- Influencing Political Agendas

STRATEGIC FOCUS

- Provide Expertise on MSAC & Reimbursement Mechanisms
- Provide Expertise on Regulatory Matters
- Add our voice to relevant political agendas

Driving Industry Value through active positioning of our Members' impact on health outcomes as an integral component of Australian Healthcare

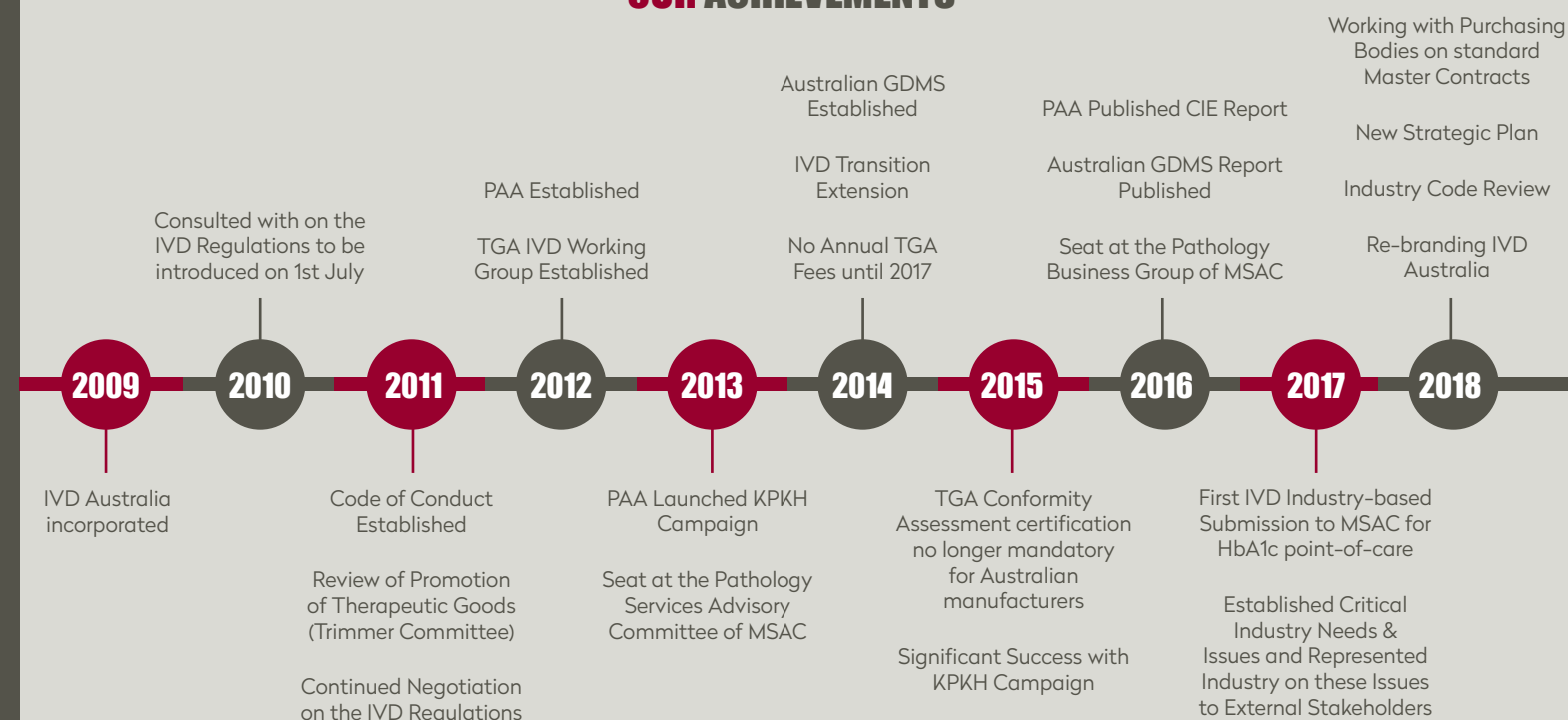
STRATEGIC PRIORITIES

- Generating Health Economic Data & Economic Modelling
- Championing Precision Medicine
- Driving Improved Market Access

STRATEGIC FOCUS

- Focus on Health Priorities
- Promote diagnostics as the driver of precision medicine and improved health outcomes
- Promote Translational Medicine/Translational Pathology
- Focus on health outcomes to improve market access in Australia

OUR ACHIEVEMENTS



RE-BRANDING IVD AUSTRALIA



**PATHOLOGY
TECHNOLOGY
AUSTRALIA**

BRANDING IS EVERYTHING, AND IT STARTS
WITH SOMETHING SIMPLE: A NAME.

Life comes with very few guarantees but one of those is that things will change. Those of our Members who have been around for a while have seen tremendous evolution in our environment. IVD Australia has grown successfully to its present form in response to the changes in the therapeutic goods regulatory environment. It is time to redirect our focus towards the broader regulatory environment and leverage the constant innovative technology our Members provide in pathology. Whether as an individual or as an organisation, we must continue to evolve if we are to survive and thrive.

For an association, its name reflects what the organisation stands for. If it causes uncertainty – as in the case of IVD Australia – it might mean a change is in order?

There is limited recognition for the level of innovation within the IVD industry and IVD Australia's message is often obscured by the reaction to the name and the lack of understanding of what is an 'IVD'. Illustrating this point are quotes from interviews with two Senior Bureaucrats in the Department of Health as a part of our rebranding process ...

"I USE THE TERM IVD BECAUSE THAT'S WHAT TGA USE, BUT TO BE HONEST I'M NOT SURE MOST PEOPLE WOULD REALLY UNDERSTAND WHAT IT MEANS"

"I'D GUESS THAT THERE ARE EVEN SOME PATHOLOGISTS WHO DON'T FULLY UNDERSTAND THE TERM IVD".

With the focus by the Department of Health on pathology, there is no room for 'just' a supplier association and this is how we are currently associated with pathology. Our industry is about so much more than just supply of technology and we need to be readily associated with the innovative providers of solutions that we are.

Our vision is of a healthier Australia that values the power of our technologies, diagnostic tests, and our industry as the driver of innovative healthcare strategies and outcomes.

Thank you for the overwhelming support of our new name.

Sebastian D'Angelo
Chair
IVD Australia Board of Directors

Advantages of the Proposed Change of Name

The Board believes that the proposed change of name will have two key advantages:

- **The proposed name better reflects who we are as an Association and our key strengths as an industry:** IVD Australia is continually evolving, and in doing so, have come to consider our image, identity, "branding," and, consequently, our name. As IVD Australia embarks on its second decade, we need our association's brand to clearly articulate and convey who we are, and who we represent. The role of IVDs in pathology is an important distinction, and the proposed name places the emphasis firmly on technology as our differentiator in this industry.
- **Our VISION is of a healthier Australia that values our members as the driver of innovative technologies that help deliver a best-in-class healthcare system:** The Board considered how our branding could help advance this vision; clearly define the group we represent; and position the association firmly. Pathology Technology Australia is a bold statement that embodies our vision for the future of IVDs in healthcare

What do we hope to achieve by changing the Name?

IVD Australia has an established reputation within the pathology sector which has been built over many years. There are a number of important positives strongly associated with IVD Australia.

IVD Australia is seen as professional, reliable, and possessing strong knowledge and expertise within our membership. It is also often seen as an influential association, particularly in the regulatory sector.

IVD Australia is recognised as providing strong member support, is seen as a connection point for government, and a reliable source of advice on industry issues.

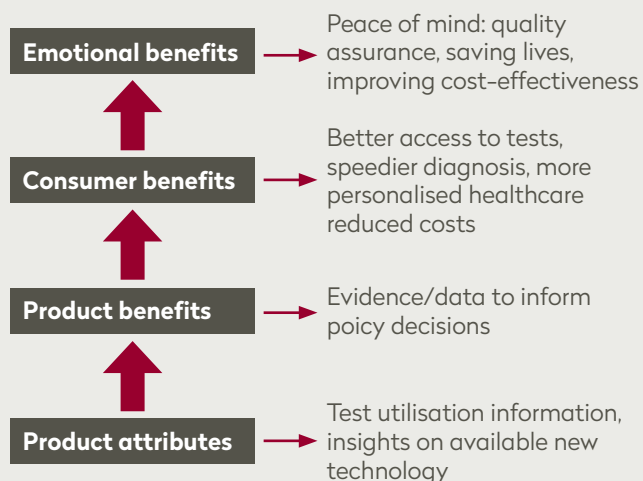
Changing our name and branding will not change these perceptions, but to assist in repositioning IVD Australia, it must be combined with substantive and meaningful changes. Much of this change has already begun with new programs, such as the MSAC Strategic Project, being rolled out for members over the past few years.

Does it align with our Strategic Plan?

Yes. The Strategic Plan clearly reflects the belief by the Board and our Members that our core strength is as the drivers of innovative technologies for the pathology industry. We have no plans to change the scope of our activities as a consequence of this rebranding initiative, as our activities are determined by our Strategic Plan.

INSIGHTS FROM THE BRANDING EXERCISE

Features & benefits of organisation and members



Stakeholder interviews: values

Most important values of industry peak organisations according to interviewees:

- 1. Single voice of an industry**
Most valued attribute across the board
Must be truly representative to the industry
Even when in conflict with their own position
- 2. Industry data/health economic data**
Lots of anecdotal evidence – hard data difficult to come by
May be one of multiple sources – useful to have industry perspective
- 3. Code of practice**
Rely on transparency
Must be credible & authoritative

Brand context

MOTIVATION What does audience want?

Saving time
Saving money
Saving lives

BEHAVIOUR What is our audience doing?

Interested in data, new insights, clearer perspective for informing policy decisions

INSIGHT Cause - effect

CONVENTIONS How is the category behaving?

Personalised healthcare and testing
Fast-paced innovation

CULTURE What is happening in local and global culture?

Disruptive technology
Rise of the informed patient
Better consumer access and choice

Stakeholder interviews: areas of interest

- Speedier detection
- Earlier diagnosis
- Personalised health data
- Reduced costs to perform tests
- Reduced barriers to accessing tests
- Insights on personal risks
- Data on test utilisation

Perceptions of the sector

Limited recognition for the level of innovation within the IVD industry



THE CONCEPT & THE DESIGN



VALUE OF PATHOLOGY



Key achievements:

- Leading Google ranking for many pathology related search terms.
- 21,000 user database.
- \$150,000 of free Google Adwords per year.
- Newsletter CTR> 40% – well above industry average.
- 170,000 social media reach per week.
- Requests slips in General Practice from 8 pathology companies.
- LTO HCP survey found 24% of HCPs surveyed (n448) had heard of KPKH and were interested in new research, tests and technologies.
- Public & private collection centre promotion to consumers.
- 40 Health Consumer Organisations support initiative.
- Over 90 parliamentary laboratory tours.
- 5 Australian Parliament House events.
- \$2,700,000 free air time for 3 TV Community Service Announcements.



TECHNICAL & REGULATORY STANDING COMMITTEE

THE TECHNICAL AND REGULATORY STANDING COMMITTEE IS FOCUSED ON THE REGULATORY ISSUES THAT AFFECT THE IVD INDUSTRY.

Over the past year the TARSC committee has

- Drafted an IVD clinical evidence guideline which has been provided to the TGA. This guideline has been requested by the TGA and will provide guidance industry on clinical evidence requirements. TARSC's proactive approach will help ensure that Australian requirements are fit for purpose and consistent with requirements globally.
- Developed a joint Unique Device Identification (UDI) policy with MTAA, AusBiotech and ADIA.
- Advocated for practical regulation by providing comments on number of consultations such as import permit requirements and oral fluid drug testing standard.
- Delivered a strong IVD industry regulatory training program through the TGA Sponsor information day held in Canberra, 11 October 2017

TARSC Committee

Susan Alder	Alex Leung
Suellen Blackaby	Peter Lowe
Fouzia Calder	Karen MacLeod
Lilies Chen	Libby McDermott
Hiram Chipperfield	David McLean
Merrilyn Colussi	Aileen O'Connor
Michael Gunter	Rayden Rivett
Kasey Kime	Melissa Robins
Hoon Koh	Walter Shepherd
Melita Lambiris	Peter Traynor
Lopeti Lavulo	

POLICY COMMITTEE

THE POLICY COMMITTEE IS AN ADVISORY COMMITTEE TO THE IVD AUSTRALIA BOARD.

The role of this Committee is to coordinate the advocacy, policy development, and campaigning/educational activities among our members. It identifies critical areas for IVD Australia's strategic advocacy engagement. It pursues engagement with government at a number of levels, as well as collaboration with the academic sector and greater education of the community on development issues.

Over the past year, the Policy Committee has :

- Worked with Purchasing Bodies on standard Master Contracts
- Had oversight of the development of the Australian Standard for Vendor Credentialing
- Had oversight of the development of the next Health Economics Report

Policy Committee

Paul Cray
Sebastian D'Angelo
Bernadette Snopek
Mark Volling

MARKETING DEVELOPMENT COMMITTEE

THE ROLE OF THIS COMMITTEE IS TO ASSIST IN THE ONGOING DEVELOPMENT OF THE MARKET FOR IN VITRO DIAGNOSTIC PRODUCTS IN AUSTRALIA.

To this end the Committee will participate in the development of policies that assist in the growth of the overall market for human pathology testing.

Over the past year, the Market Development Committee has :

- Developed the prioritisation criteria for industry MSAC applications
- Developed a strategy of raising the awareness of the clinical and cost utility of diagnostics in the provision of effective healthcare

Market Development Committee

Tom Berkovits
Jenny Carson
John Crothers
John Emmerson
Jim Kakaflikas
Brooke Troth
Mark Volling

CODE ADMINISTRATION COMMITTEE

THE RESPONSIBILITY OF THE CODE ADMINISTRATION COMMITTEE IS TO ENSURE EFFECTIVE OPERATION AND ADMINISTRATION OF THE IVD AUSTRALIA CODE OF CONDUCT.

Over the past year, the Code Committee has :

- Drafted & reviewed the proposed revisions to the Code
- Reviewed Codes from Asia Pacific Medical Technology Association and other international Codes of Practice
- Maintained a "watching brief" on the Code Certification Program.

Code of Conduct Administration Committee

Pam Davis
Chami Gunasinghe
Melita Lambiris
Helen Mikolaj
George Koumantakis
Wendy-Jane Morrow
Kevin Carpenter

MARKETING & COMMUNICATIONS COMMITTEE

THE ROLE OF THIS COMMITTEE IS TO OVERSEE THE DEVELOPMENT AND IMPLEMENTATION OF STRATEGIC COMMUNICATIONS RELEVANT TO IDENTIFIED IVD INDUSTRY STAKEHOLDERS.

It provides strategic advice on the delivery of promotional campaigns and events designed to increase awareness of IVD Australia and our brand and positioning, including the retention and attraction of IVD Australia members. It also supports the management of media issues. Over the past 12 months this committee has

- Organised a number of different networking functions for IVD members and guests
- Developed a social media strategy to be implemented in 2018/19 financial year
- Rebranding of our association with a new name, look and feel to ensure we are relevant to our members and stakeholders.

Marketing & Communication Committee

Cassandra Anderson
John Emmerson
Jim Kakaflikas
Antionette Violo
Bernadette Snopek
Vito Trifilo

FINANCE, AUDIT & RISK MANAGEMENT COMMITTEE

The committee assists the Board to discharge its obligations in overseeing the operation and appropriateness of financial and non-financial controls in the company, financial reporting (both internal and external) and risks associated with non-compliance with statutory and regulatory requirements within the risk management framework.

2017-18 Major Projects: Financial management of the organisation and oversee the annual audit; and Risk Management: updating governance and financial policies; membership review

Finance, Audit & Risk Management Committee

Sebastian D'Angelo

Chami Gunasinghe

Wendy-Jane Morrow

Rayden Rivett

Vito Trifilo

Jenny Zhao

IVD AUSTRALIA EVENTS

IVD AUSTRALIA NETWORKING & EVENTS ORGANISING COSTS, NO INCOME

- AGM – September with AACB
- Update – February with RCPA's Path Update

SUPPORTED ORGANISING COSTS, NO INCOME

- PAA
- Parliamentary attendance
- Lab tours – Ambassadors
- AACB Conference – Sponsorship, IVD Event





FINANCIAL STATEMENTS

FOR THE YEAR ENDED
30 JUNE 2018

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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 23 August 2018.
The company has the power to amend and reissue the financial statements.

DIRECTOR'S REPORT

THE DIRECTORS PRESENT THEIR REPORT ON THE COMPANY FOR THE FINANCIAL YEAR ENDED 30 JUNE 2018.

1. GENERAL INFORMATION

(a) Directors

The names of the directors in office at any time during, or since 30 June 2017 are:

Names	Appointed/Resigned
Mr Sebastian D'Angelo (Chair)	20 February 2014 to present
Mr Paul Cray (Deputy Chair)	11 September to present
Mr Vito Trifilo (Treasurer)	17 September 2015 to present
Mr John Crothers	14 October 2011 to present
Bernadette Snopek	17 September 2015 to 30 August 2017
Jim Kakaflikas	17 September 2015 to 30 August 2017
Rayden Rivett	17 September 2015 to present
David Basseal	17 September 2016 to 27 September 2018
Mark Volling	11 September 2018 to 25 October 2018
Peter Lowe	11 September 2017 to 14 February 2018
Ted Maione	11 September 2017 to 28 March 2018
Sally Hickman	21 February 2018 to present
Antionette Violo	28 February 2018 to present
Karen McLeod	28 February 2018 to present
Tony Feneziani	28 February 2018 to present

(b) Company secretary

Wendy-Jane Morrow was appointed as company secretary on 1 July 2014 and held the position of company secretary for the entire year.

(c) Principal activities

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

No significant changes in the nature of the Company's activity occurred during the financial year.

(d) Short term objectives

The Company's short term objectives are to:

- To retain and grow the diversity of members by June 2018
- To maintain a Reserve Fund of \$240,000
- To present TGA Regulatory Training to members as required in 2017-18
- To ensure regular ongoing meetings with Members to determine the industry's key issues
- To work with Pathology Awareness Australia and other stakeholders to maintain the 'Know Pathology Know Healthcare' program.

(e) Long term objectives

The Company's long term objectives are to:

- To cultivate 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 operate a Code of Conduct that is representative of the IVD and wider community with an equitable and transparent complaints process.
- To demonstrate strong corporate governance of the sector
- To influence direct regulatory policy to the benefit of members.

(f) Strategy for achieving the objectives

To achieve these objectives, the Company 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, NCOPP and PA 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
- As the peak body for the IVD Industry, work with regulatory agencies and participate in government committees, taskforces and working groups, forums, committees and one-on-one meetings
- 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
- Develop an understanding of IVD benefits within the Consumer Health Community
- 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.

(g) Business Review**(i) Operating results**

The Company continued to engage in its principal activity, the results of which are disclosed in the attached financial statements. The net surplus of the Company for the financial year ended 30 June 2018 amounted to \$15,377 (2017:\$35,787).

(ii) Dividends

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

(h) Significant changes in state of affairs

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

(i) 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.

(j) 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.

(k) Environmental regulations

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

(l) Indemnification and insurance of officers and auditors

Insurance Premiums

During the financial year, the company has paid or agreed to pay premiums in respect of such insurance contracts for the year ended 30 June 2018. 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.

(m) 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).

(n) Information on directors

The names of each person who is a director at the date of this report are:

Mr Sebastian D'Angelo (Chair)

General Manager, Laboratory Diagnostics Division, Siemens Healthcare – Australia & New Zealand.

Sebastian has over 30 years' experience within the Australian IVD industry, having worked as a medical scientist in public pathology laboratories before moving to senior roles at Chiron Diagnostics and Bayer Diagnostics and now at Siemens Healthcare Diagnostics.

Sebastian holds a Bachelor of Applied Science (MLS) degree from RMIT University and a Master of Marketing degree from the Melbourne Business School. He is a Member of the Australian Institute of Company Directors.

Mr Paul Cray (Deputy Chair)

Managing Director of Roche Diagnostics Australia Pty. Ltd. and Leadership Team member of Roche Diagnostics Asia Pacific.

Paul has over 25 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.

Paul holds a Bachelor of Science degree from University College of Wales, UK, and has undertaken numerous post graduate and executive courses at INSEAD, France, IMD, Switzerland and more recently Mt Eliza Advanced Management Programme, Melbourne Business School. Paul is a Member of the Australian Institute of Company Directors.

Mr Vito Trifilo (Treasurer)

General Manager, Tecan Australia.

Vito has over 20 years' experience in the Life Science and in vitro diagnostic businesses in the Australian and New Zealand markets. He has held business development and sales management roles for over 10 years and was an early company representative with AMRAD Pharmacia Biotech during the start-up phase. His current role is General Manager at Tecan Australia (a position that he has held for over 2 years), with ANZ sales, marketing, legal and regulatory responsibilities. Tecan is a leading global provider of laboratory instruments and solutions (strongly automation focused) in biopharmaceuticals, forensics and clinical diagnostics.

Mr John Crothers

Regional Director, Abbott Diagnostics Pty Ltd.

John Crothers is the Regional Director for Australia and New Zealand. Prior to the role in Australia, John was the Commercial Director for Asia Pacific and has also had several years in US Marketing. With over 25 years' experience in the pathology industry in both the laboratory and IVD, the appreciation of the value of the industry in healthcare is a passion that John continues to pursue.

John has a BSc(MLS) from RMIT and a Graduate Diploma in Business Administration from Swinburne University.

Mr Tony Feneziani

Head of Research Solutions ANZ, Merck Group

Tony has over 25 years commercial experience in the in vitro diagnostic and life sciences industries. During this time, Tony has undertaken a range of leadership roles including commercial operations, sales and marketing and business development.

Tony's current role at Merck also includes Country Leadership Team membership of the Merck Life Sciences operation in ANZ.

Ms Sally Hickman

General Manager, Werfen Australia & NZ

Sally has over 12 years experience in the Australian IVD industry having undertaken key roles in the areas of strategic marketing and customer account management. In 2012, Sally joined Werfen Australia and assumed key management responsibilities at a time when company took direct operations of key business units in Oceania.

Sally has a passion for diagnostics having trained and worked in public pathology laboratories for more than 5 years in the UK. Sally holds a Bachelor of Science degree in Biomedical Sciences from The University of Bradford, UK and a Master of Science in Biomedical Sciences degree (specialising in Haematology) from The University of Ulster, UK.

Ms Karen Macleod

Director and Country Manager, MP Biomedicals

Karen's 30-year career in in the in-vitro diagnostics and pharmaceuticals industries began as a medical scientist in public pathology and includes varied sales and management roles with Australian based global companies such as BioMerieux, Boehringer Mannheim (now Roche) and GSK. Currently Director and Country Manager at MP Biomedicals, she is responsible for all sales, management, and regulatory functions. Karen has a Bachelor of Applied Science and Graduate Diploma in Marketing from UTS, Sydney and has been a member of the IVD Australia Technical and Regulatory Standing Committee since 2011.

Mr Rayden Rivett

General Manager, Cepheid Holdings Pty Ltd

Rayden has been continuously involved in the IVD Industry since 1979 working in sales, marketing and senior management. For 15 years he was Managing Director of bioMérieux in Australia and since 2006 has worked in the USA, Asia-Pacific and more recently in establishing Australian subsidiaries for overseas-based IVD companies. Rayden has represented the IVD sector in the past, being a Board member of MIAA (now MTAA) from 1999 to 2006 and its Vice-Chair (2003-2004), a member of their Diagnostic/IVD Standing Committee 1994-2001, member of the Market Development Committee (1997-2003) and its Chair (2000-2002).

Ms Antoniette Violo

Regional Sales Director, Diagnostics, PerkinElmer

Her association with the life sciences, human health and diagnostics industries has extended for over 25 years across the commercial and academic sectors. She is currently the Regional Sales Director for PerkinElmer's diagnostic's business in the Applied Genomics division. Her commercial career commenced when she was approached to start the Life Sciences Division of PerkinElmer in Australia. She has been fortunate to progress within the organisation and have managed divisions and many staff across Australia, New Zealand and Asia for over 15 years. A significant achievement she is very proud of has been to partner PerkinElmer in the commercialisation of an Australian developed immunoassay kit (TGR Biosciences).

2. MEETINGS OF DIRECTORS

During the financial year, 11 meetings of directors (excluding committees of directors) were held. Attendances by each director during the year were as follows:

DIRECTORS' MEETING		
	NUMBER ELIGIBLE TO ATTEND	NUMBER ATTENDED
Mr Sebastian D'Angelo (Chair)	11	10
Mr Paul Cray (Deputy Chair)	9	9
Mr Vito Trifilo (Treasurer)	11	10
Mr John Crothers	11	10
Ms Sally Hickman	3	2
Ms Antoniette Violo	6	4
Mr Rayden Rivett	11	8
Ms Karen Macleod	6	5
Mr Tony Feneziani	4	4
Mr Jim Kakaflikas	2	1
Bernadette Snopek	2	2
Ted Maione	9	6
David Basseal	3	2
Peter Lowe	5	4
Mark Volling	1	1

3. AUDITOR'S INDEPENDENCE DECLARATION

The lead auditor's independence declaration in accordance with section 307C of the Corporations Act 2001, for the year ended 30 June 2018 has been received and can be found on page 8 of the financial report.

Signed in accordance with a resolution of the Board of Directors:

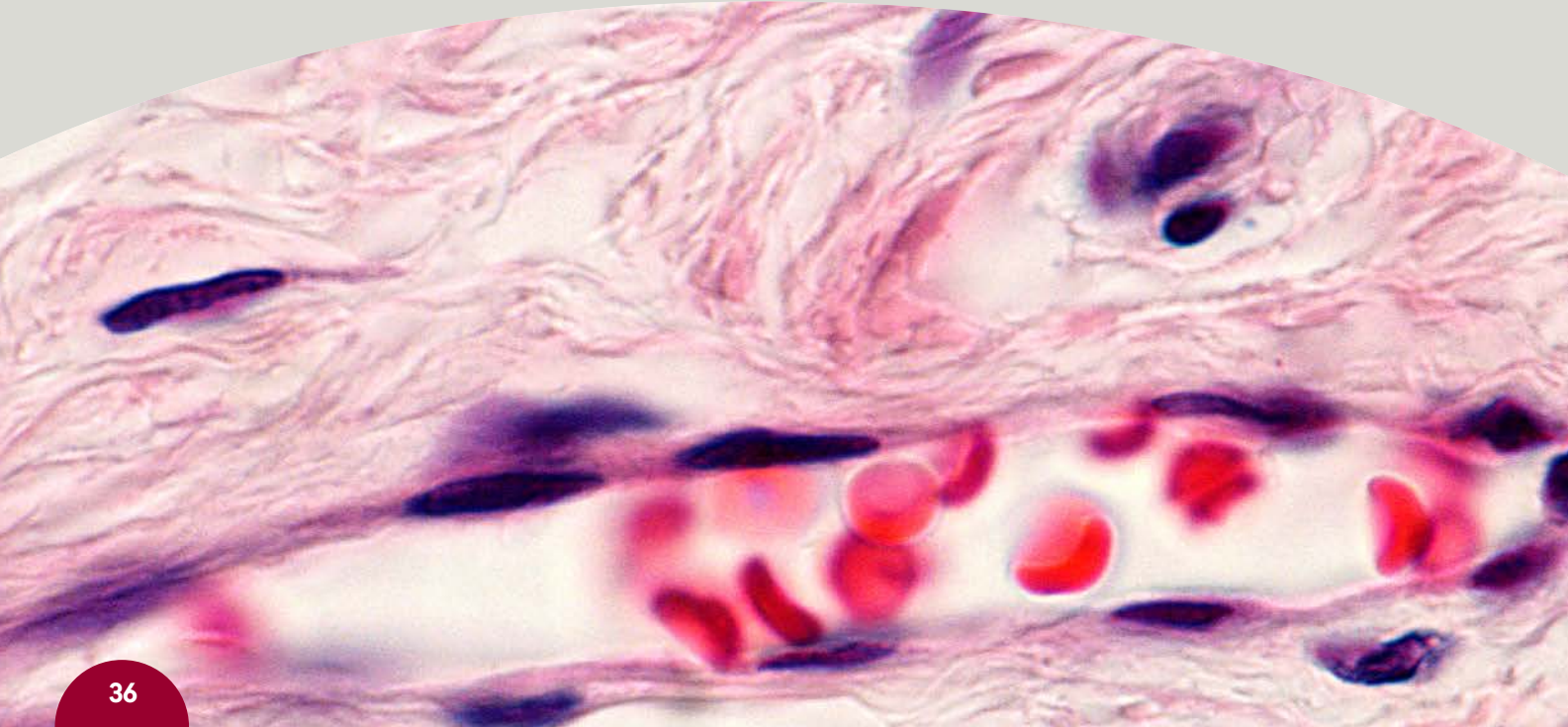


Director
Mr Sebastian D'Angelo (Chair)

Dated: 23 August 2018



Director
Mr Vito Trifilo (Treasurer)





Auditor's Independence Declaration under section 307C of the Corporations Act 2001

As audit partner for the audit of the financial statements of IVD Australia Limited for the financial year ended 30 June 2018, I declare that to the best of my knowledge and belief, there have been no contraventions of:

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

Nexia
Nexia Sydney Partnership

Mark Boyle
Mark Boyle

Partner
Sydney

Dated:

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INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF IVD AUSTRALIA LIMITED

Report on the Audit of the Financial Report

Opinion

We have audited the financial report of IVD Australia Limited (the Company), which comprises the statement of financial position as at 30 June 2018, the statement of profit or loss and other comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, and the directors' declaration.

In our opinion, the accompanying financial report of the Company 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 2018 and of its financial performance for the year then ended; and
- ii) complying with Australian Accounting Standards – Reduced Disclosure Requirements and the Corporations Regulations 2001.

Basis for opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the 'auditor's responsibilities for the audit of the financial report' section of our report. We are independent of the Company in accordance with the Corporations Act 2001 and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 Code of Ethics for Professional Accountants (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

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

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

Other information

The directors are responsible for the other information. The other information comprises the information in IVD Australia Limited's annual report for the year ended 30 June 2018, but does not include the financial report and the auditor's report thereon.

Our opinion on the financial report does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of the other information we are required to report that fact. We have nothing to report in this regard.



INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF IVD AUSTRALIA LIMITED (CONTINUED)

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 gives a true and fair view and is free from material misstatement, whether due to fraud or error.

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

Auditor's responsibility for the audit of the financial report

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

A further description of our responsibilities for the audit of the financial report is located at The Australian Auditing and Assurance Standards Board website at: www.auasb.gov.au/auditors_files/ar4.pdf. This description forms part of our auditor's report.

Nexia
Sydney Audit Partnership

Mark Boyle
Partner

Dated:
Sydney

DIRECTORS' DECLARATION

In the opinion of the directors of the Company declare that:

1. The financial statements and notes, as set out on pages 12 to 20, are in accordance with the Corporations Act 2001, including:
 - a. Complying with Australian Accounting Standards - Reduced Disclosure Requirements (including the Australian Accounting Interpretations) and the Corporations Regulations 2001; and
 - b. Giving a true and fair view of its financial position as at 30 June 2018 and of its performance for the year ended on that date; and.
2. There are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

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

Director
Mr Sebastian D'Angelo (Chair)

Dated: 23 August 2018

Director
Mr Vito Trifilo (Treasurer)

STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED 30 JUNE 2018

		2018	2017
	NOTE	\$	\$
Revenue	2	433,881	466,365
Interest income		7,120	7,442
TOTAL INCOME		441,001	473,807
Employee benefits expense	3(a)	(254,332)	(268,993)
Depreciation expense	3(b)	(400)	(1,150)
Administrative expenses		(170,892)	(167,877)
TOTAL EXPENSES		(425,624)	(438,020)
SURPLUS/(DEFICIT) FOR THE YEAR		15,377	35,787
Other comprehensive income		-	-
Other comprehensive income		-	-
TOTAL COMPREHENSIVE INCOME FOR THE YEAR		15,377	35,787

STATEMENT OF FINANCIAL POSITION

AS AT 30 JUNE 2018

		2018	2017
	NOTE	\$	\$
ASSETS			
CURRENT ASSETS			
Cash and cash equivalents	4	291,679	373,284
Trade and other receivables	5	2,247	6,800
TOTAL CURRENT ASSETS		293,926	380,084
NON-CURRENT ASSETS			
Plant and equipment	6	2,214	261
TOTAL NON-CURRENT ASSETS		2,214	261
TOTAL ASSETS		296,140	380,345
LIABILITIES			
CURRENT LIABILITIES			
Trade and other payables	7	41,052	46,526
Employee benefits	8	9,475	14,017
Income received in advance	9	14,533	104,099
TOTAL CURRENT LIABILITIES		65,060	164,642
Employee benefits		12,018	12,018
TOTAL NON-CURRENT LIABILITIES		12,018	12,018
TOTAL LIABILITIES		77,078	176,660
NET ASSETS		219,062	203,685
EQUITY			
Retained earnings		219,062	203,685
TOTAL EQUITY		219,062	203,685

STATEMENT OF CHANGES IN EQUITY

FOR THE YEAR ENDED 30 JUNE 2018

2018	RETAINED EARNINGS \$	TOTAL \$
Balance at 1 July 2017	203,685	203,685
Surplus for the year	15,377	15,377
Balance at 30 June 2018	219,062	219,062

2017	RETAINED EARNINGS \$	TOTAL \$
Balance at 1 July 2016	167,898	167,898
Deficit for the year	35,787	35,787
Balance at 30 June 2017	203,685	203,685

STATEMENT OF CASH FLOW

FOR THE YEAR ENDED 30 JUNE 2018

	2018	2017
NOTE	\$	\$
CASH FLOWS (USED IN)/FROM OPERATING ACTIVITIES		
Receipts from customers	381,772	554,263
Payments to suppliers and employees	(468,226)	(462,835)
Interest received	7,202	7,241
	(79,252)	98,669
CASH FLOWS USED IN INVESTING ACTIVITIES		
Acquisition of plant and equipment	(2,353)	-
	(2,353)	-
Net (decrease)/increase in cash and cash equivalents	(81,605)	98,669
Cash and cash equivalents at beginning of year	373,284	274,615
CASH AND CASH EQUIVALENTS AT END OF FINANCIAL YEAR	4	291,679
		373,284

NOTES TO THE FINANCIAL STATEMENTS

FOR THE YEAR ENDED 30 JUNE 2018

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 company is primarily involved in facilitating the growth and development of the in-vitro diagnostics industry in Australia.

(b) Basis of Preparation

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

(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 and is presented net of returns, discounts and rebates.

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 on its membership income under the tax law principle of mutuality. Due to its limited non-member income and deductible expenditure the company has no income tax payable.

(f) Goods and Services Tax (GST)

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

Receivables and payable are stated inclusive of GST.

The net amount of GST recoverable from, or payable to, the ATO is included as part of receivables or payables in the statement of financial position.

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

(g) Cash and cash equivalents

Cash and cash equivalents include cash on hand, deposits held at call with banks and other short-term highly liquid investments.

(h) Plant and Equipment

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 Profit or Loss and Other 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
• Computer Equipment	3 years

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

The AASB has issued new and amended Accounting Standards and Interpretations that have mandatory application dates for future reporting periods. The directors have decided against early adoption of these Standards, but does not expect the adoption of these standards to have any impact on the reported position or performance of the Company.

(l) Critical Accounting Estimates and Judgements

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

	2018	2017
	\$	\$
Member subscriptions	427,024	450,368
Other revenue	-	5,860
Conference revenue	6,857	10,137
	433,881	466,365

3. EXPENSES

(a) Employee benefits expense		
Wages and salaries	236,802	246,753
Superannuation	21,226	22,240
	258,028	268,993
(b) Depreciation expense		
Depreciation – computer equipment	321	730
Depreciation – furniture and fixtures	79	420
	400	1,150

4. CASH AND CASH EQUIVALENTS

Cash at bank	51,679	133,284
Term deposits	240,000	240,000
	291,679	373,284

5. TRADE AND OTHER RECEIVABLES

Trade receivables	-	2,750
GST paid	-	1,721
Accrued Interest	2,247	2,329
	2,247	6,800

6. PLANT AND EQUIPMENT

	2018	2017
	\$	\$
Furniture, fixtures and fittings – at cost	2,589	2,589
Accumulated depreciation	(2,589)	(2,510)
	-	79
Computer equipment – at cost	11,607	9,254
Accumulated depreciation	(9,393)	(9,072)
	2,214	182
Total plant and equipment	2,214	261

(a) Movements in carrying amounts of plant and equipment

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

	FURNITURE, FIXTURES AND FITTINGS	COMPUTER EQUIPMENT	TOTAL
	\$	\$	\$
YEAR ENDED 30 JUNE 2018			
Balance at the beginning of year	79	182	261
Additions	-	2,353	2,353
Depreciation expense	(79)	(321)	(400)
Balance at the end of the year	-	2,214	2,214

7. TRADE AND OTHER PAYABLES

Other payables	12,575	25,876
Accrued expenses	22,613	20,650
GST collected	5,864	-
	41,052	46,526

All above liabilities are short-term. The carrying values are considered to be a reasonable approximation of fair value.

8. EMPLOYEE BENEFITS

Annual leave	9,475	14,017
	9,475	14,017
Long service leave	12,018	12,018
	12,018	12,018

9. OTHER LIABILITIES

	2018	2017
	\$	\$
Income in advance	14,533	104,099

10. AUDITORS REMUNERATION

Payable to the auditors of the company - Nexia Sydney Partnership		
Audit services	10,800	10,400
Non-audit services	5,064	3,410
	15,864	13,810

11. SUPERANNUATION COMMITMENTS

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

12. RELATED PARTY TRANSACTIONS

(a) Transactions with key management personnel

Key management personnel include the directors and the Chief Executive Officer. 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: \$201,775 (2017: \$227,943). No other benefits were received or provided.

(b) Transactions with related entities

Unless otherwise stated, none of the transactions incorporate special terms and conditions and no guarantees were given or received.

The only transactions with related parties of IVD Australia Limited were membership subscription fees received from organisations in which the Directors are employed.

13. CONTINGENT LIABILITIES

There are no contingent liabilities that have been incurred by the Company in relation to 2018 or 2017.

14. EVENTS OCCURRING AFTER THE 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.

IVD AUSTRALIA MEMBERS

Member Companies

- Abbott Australasia Pty Ltd
- Agena Biosciences (Asia Pacific)
- Alere
- Astral Scientific Pty Ltd
- Atomo Diagnostics
- Australasian Medical and Scientific Ltd
- BD Diagnostics ANZ
- bioMérieux Australia Pty Ltd
- Bio-Rad Laboratories Pty Ltd
- Blackaby Diagnostics Pty Ltd
- Cepheid Holdings Pty Ltd
- Dako Australia Pty Ltd
- ESL Biosciences Australia (2012) P/L
- Grifols Australia Pty Ltd
- Hologic (Australia) Pty Ltd
- Illumina Australia Pty Ltd
- Immuno Pty Ltd
- Integrated Sciences Pty Ltd
- Macarthur Cook Group Pty Ltd

- Merck Millipore Australia Pty Ltd
- MP Biomedicals Australasia
- Paragon Therapeutic Technologies Pty Ltd
- PerkinElmer Pty Ltd
- Pro-Health Asia Pacific Pty Ltd
- QIAGEN Pty Ltd
- Randox (Australia) Pty Ltd
- Roche Diagnostics Australia Pty Ltd
- Siemens Healthineers
- SJ Alder Pty Ltd
- SpeeDx Pty Ltd
- Sysmex Australia Pty Ltd
- Tecan Australia
- ThermoFisher Scientific
- Werfen Australia Pty Ltd

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