

18 October 2016

Markets Announcements Office
ASX Limited Exchange Centre
20 Bridge Street
SYDNEY NSW 2000



Genetic Signatures CEO presentation at the 7th Annual Australian Microcap Investment Conference

- **Genetic Signatures to present its global growth strategy for the development and supply of world leading molecular diagnostic products**
- **The largest conference in Australia focused on microcap investment opportunities**
- **Presentations from the CEOs of 24 of Australia's leading emerging companies**

Sydney, Australia, 18 October 2016: Molecular Diagnostics (MDx) company Genetic Signatures (ASX: GSS) is pleased to release a copy of the presentation that Chief Executive Officer, John Melki, PhD., will deliver today at the 7th Annual Australian Microcap Investment Conference.

Dr Melki will present on Genetic Signatures' commercialisation progress, financial results, and achievements to date. The presentation will also detail the Company's global growth strategy for the sale of world leading solutions for the rapidly growing infectious disease detection market.

Dr Melki said: "2016 was a successful year for Genetic Signatures with record sales revenues and completion of a \$15M capital raising. I am looking forward to updating the microcap conference attendees on our progress over the last 12 months and how we are driving shareholder value by accelerating the Company's growth on a number of fronts."

For further details:

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Chief Executive Officer

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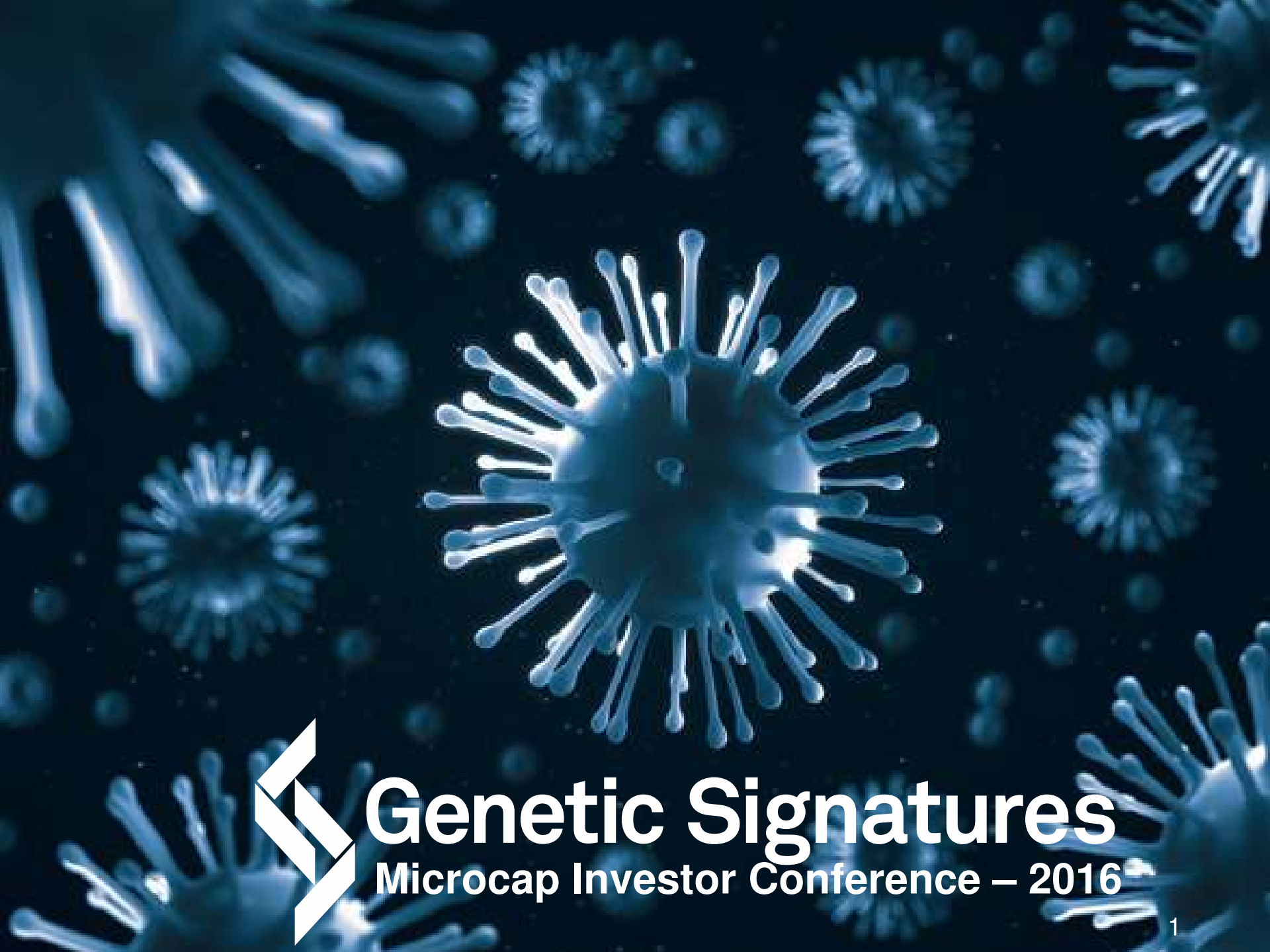
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About the Annual Australian Microcap Investment Conference: The Annual Australian Microcap Investment Conference commenced in 2010 and provides an exciting opportunity for the investment community to hear first hand from over 20 of Australia's leading microcap CEO's about their strategy, their business environment and their growth prospects. The conference has grown to be the largest conference in Australia focussed on emerging companies and regularly attracts over 300 delegates from Australia and internationally.

About Genetic Signatures Limited: Genetic Signatures is a specialist molecular diagnostics (MDx) company focused on the development and commercialisation of its proprietary platform technology, 3Base™. Genetic Signatures designs and manufactures a suite of real-time Polymerase Chain Reaction (PCR) based products for the routine detection of infectious diseases under the EasyScreen™ brand. Genetic Signatures' proprietary MDx 3Base™ platform technology provides high-volume hospital and pathology laboratories the ability to screen for a wide array of infectious pathogens, with a high degree of specificity, in a rapid throughput (time-to-result) environment. Genetic Signatures' current target markets are major hospital and pathology laboratories undertaking infectious disease screening.



Genetic Signatures

Microcap Investor Conference – 2016

Disclaimer

This presentation was prepared by Genetic Signatures Limited known as “Genetic Signatures“, (“GSS” or “the Company”), in order to discuss its business with various interested parties. This presentation in its entirety has been released to the market via the Australian Securities Exchange Limited (“ASX”).

This presentation contains statements that involve estimates, risks and uncertainties. Although the Company believes these statements to be reasonable at this time, Genetic Signatures can give no guarantee that the expectations reflected in these statements will prove to be accurate. Actual results could differ materially from those expected for any of a multitude of risks including, but not limited to, those inherent in regulatory or market environments or more generally. In preparing this presentation, the Company has relied upon and assumed, without independent verification, the accuracy and completeness of all information available from public sources, or which was otherwise reviewed by it.

The presentation is proprietary to Genetic Signatures and may not be disclosed to any third party or used for any other purpose without the prior written consent of the Company.

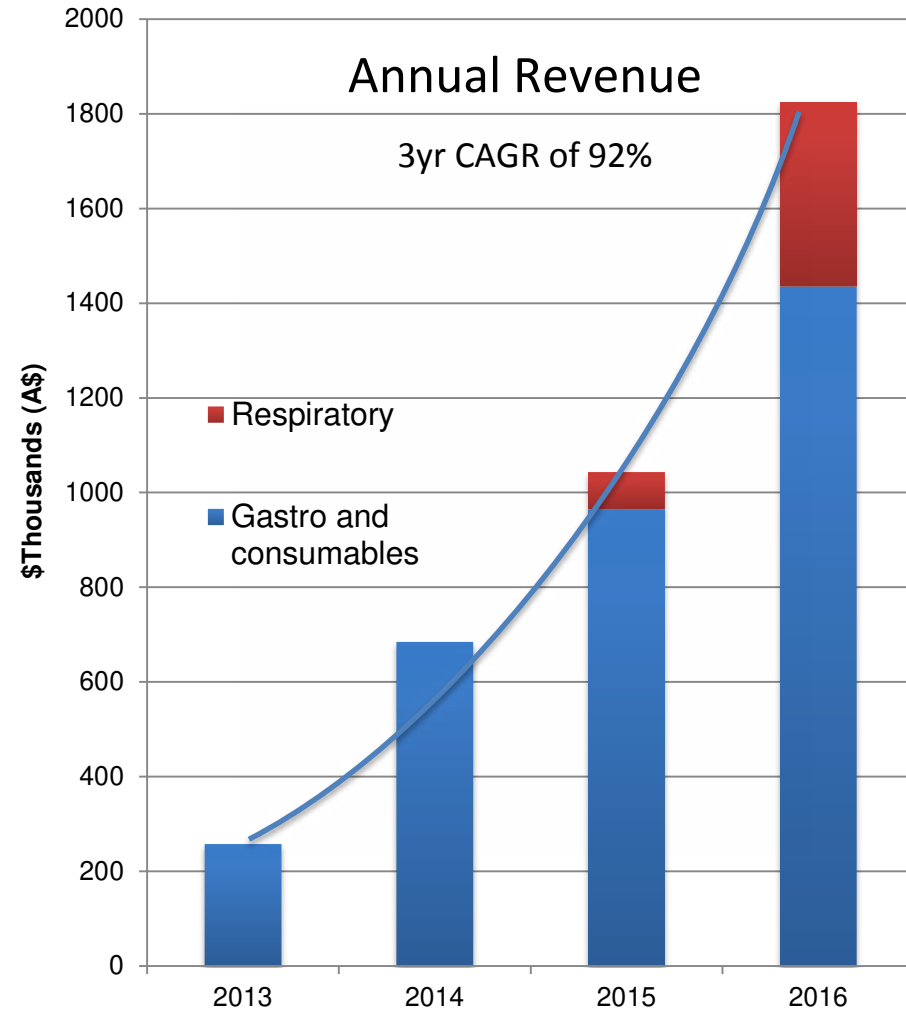
This document does not constitute an offer, solicitation or recommendation in relation to the subscription, purchase or sale of securities in any jurisdiction and does not and will not form part of any securities subscription, purchase or sale contract.

Company Overview

- Genetic Signatures Limited (GSS) designs and manufactures proprietary molecular diagnostic (MDx) test solutions for **rapid and specific identification of diseases and infections**
- GSS fully owns its proprietary molecular 3Base™ technology with **multiple patents issued, expiring in 2031**
- Products led by CE-IVD marked *EasyScreen*™ Gastrointestinal (Enteric) tests currently delivering **rapidly growing revenues in Australia** and from FY17 within Europe and the USA
- **FY16 sales revenue up 75% to A\$1.83M – 92% 3 year CAGR**
- *EasyScreen*™ products have an addressable global market estimated to be **US\$2.1B in 2017**
- **Large pipeline** of new molecular diagnostic tests, to quickly drive further revenues and shareholder value
- Targeting pathology and hospital laboratories in multiple global markets, leading to a **scalable business with high gross margins**
- **Experienced management team and board** with track record in global molecular diagnostics industry and having delivered shareholder returns in the past.

Recent Achievements

- **Strong sales growth**, with a 3-year CAGR of 92%
- FY16 revenue of A\$1.83M, split ~80% Gastroenteritis, ~20% Respiratory specialist sales
- Recently completed **oversubscribed \$15M capital raising** round
- Advancing R&D development of **5 new diagnostic products**
- **New product for STI infections** in clinical validation
- **Offshore expansion underway in EU and the US**



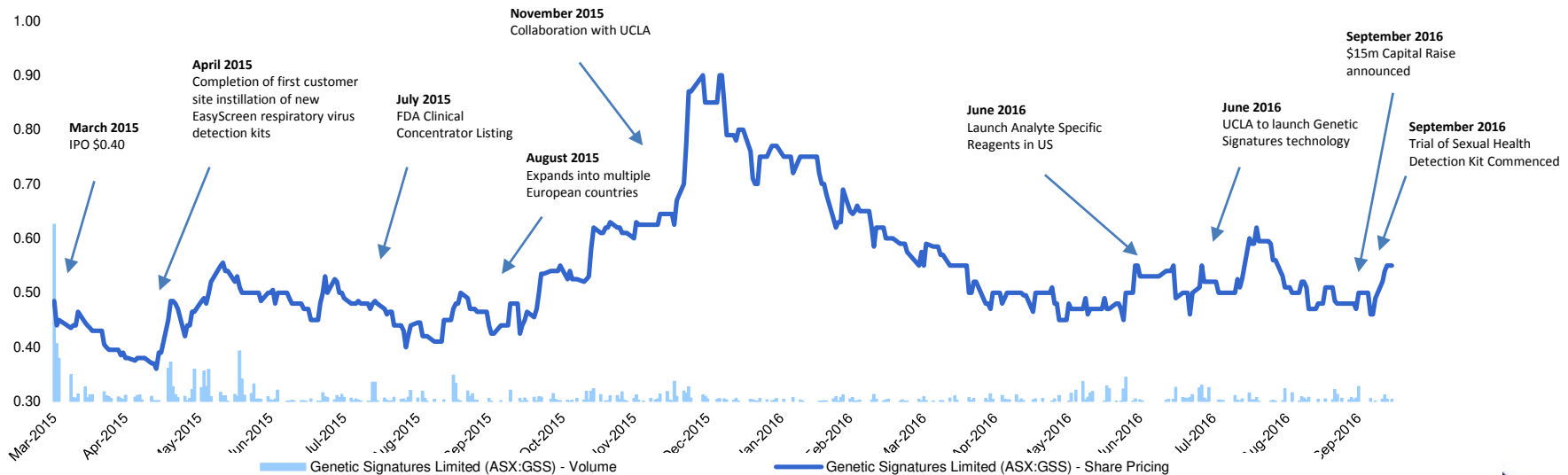
Corporate Summary

Financial Information (A\$)	
ASX Code	GSS
Shares on Issue	85.7m
Market Capitalisation	\$47.1m
Share Price (at market close 14 October, 2016)	\$0.55
Cash at 30 September 2016*	\$7.5m

Top Shareholders	%
Asia Union Investment Pty Limited	43.1%
UBS Nominees Pty Ltd	7.6%
DAK Drafting Services Pty Ltd	2.3%
Directors, Management and Advisors	8.0%

*Tranche 2 of the GSS Capital Raising will add \$8.8M through the issue of 18.8m shares later this week.

Share Price Performance



Experienced Board and Management

Nick Samaras - Non-Executive Chairman

BSc (Hons), PhD, MBA, FAIM, FAICD

- More than 25 years' experience in the global life sciences industry, senior executive roles with Applied Biosystems (now part of Thermo Fisher) and Perkin Elmer
- NHMRC Research Committee member 2006-12, Adjunct Professor La Trobe University, Founder of consulting firm Australis Biosciences and Director of the AGRF and MuriGen Therapeutics

John Melki - Managing Director & CEO

BSc (Hons), PhD

- Chief Executive Officer since 2011, joined GSS in 2003
- Led the commercialisation of two research products worldwide and seven diagnostic products in Australia and Europe

Mike Aicher - Executive Director – US Operations

BSc, MBA

- More than 30 years of industry experience
- Previously CEO and founder of National Genetics Institute (NGI), acquired by Laboratory Corporation of America, Inc (Labcorp) in 2000
- Responsible for LabCorp's Esoteric Businesses in the U.S. which generated more than US\$1 billion in annual revenue
- Director on boards of Kinetic Diagnostics Inc and Omicia, Inc

Experienced Board and Management

Tony Radford, AO - Non-Executive Director

BSc (Hons), PhD

- A member of the CSIRO team that invented the QuantiFERON method for Cellular Immune based diagnostics
- Co-founded the diagnostic company Cellestis Limited which listed on the ASX in 2001
- Former CEO of Cellestis from founding until its acquisition by QIAGEN NV in 2011 for approximately \$400 million
- Established offices and operations in the USA, Europe and Japan, Cellestis developed QuantiFERON –TB Gold, the worldwide benchmark for the diagnosis of tuberculosis infection
- Previous Head of Development (2000) at AMRAD (now part of CSL) in pharmaceutical research

Phillip Isaacs - Non-Executive Director

MSc, JP

- More than 30 years of industry experience
- Previously Managing Director, Asia Pacific, for Beckman Instruments
- Vice President of the Asia Pacific Cytoc Corporation (now part of Hologic) which developed and sells the ThinPrep Pap
- Founding Chairman of the Australian Proteome Analysis Facility (APAF) in Sydney

Genetic Signatures

Transforming Global Molecular Diagnostics



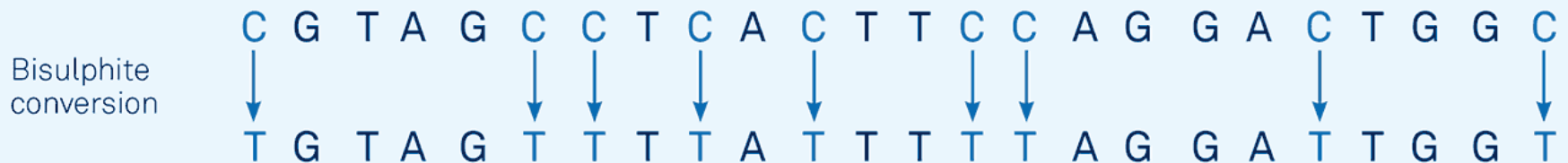
Genetic Signatures - 3Base™ Technology

A transformational MDx technology enabling customers to identify a wider array of patient infections

- Genetic Signatures' 3Base™ platform is a proprietary molecular technique which changes naturally occurring DNA and RNA sequences to reduce sequence variation between subtypes
- Patented chemical transformation of DNA and RNA sequences to reduce genetic code complexity
- Process can enhance detection of multiplexed assays where multiple targets are detected in the one tube
- Achieved by allowing a simpler design of molecular assays for the simultaneous detection of multiple targets

Unique 3Base™ Technology

3base™ Mechanism



- GSS' unique platform technology converts original 4-base microbial genome to 3-base, thereby reducing complexity in molecular testing
- Applicable in testing for infectious diseases and chronic diseases including cancers
- The conversion occurs during standard procedures and there are no additional steps for the end user.

Technology - 3Base™

- **Massive reduction in complexity**
- e.g a 10 digit number comprised of the numbers 1,2,3 and 4 has **1,048,576 combinations**
- a 10 digit number comprised of the numbers 1,2 and 3 has **59,049 combinations**
- **Reduces complexity by 97% yet maintains or increases accuracy**

	Before	After
Seq 1	G A T G G <u>C</u> G A <u>I</u> A T G G T <u>I</u> G A <u>C</u> A <u>C</u>	G A T G G T G A T A T G G T <u>I</u> G A T A T
Seq 2	G A T G G <u>I</u> G A <u>C</u> A T G G T <u>A</u> G A <u>I</u> A <u>C</u>	G A T G G T G A T A T G G T <u>A</u> G A T A T
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Seq 5	G A T G G <u>I</u> G A <u>I</u> A T G G T <u>G</u> G A <u>C</u> A <u>C</u>	G A T G G T G A T A T G G T <u>G</u> G A T A T
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Seq 7	G A T G G <u>I</u> G A <u>I</u> A T G G T <u>G</u> G A <u>C</u> A <u>C</u>	G A T G G T G A T A T G G T <u>G</u> G A T A T
Seq 8	G A T G G <u>I</u> G A <u>C</u> A T G G T <u>A</u> G A <u>I</u> A <u>C</u>	G A T G G T G A T A T G G T <u>A</u> G A T A T
Seq 9	G A T G G <u>I</u> G A <u>I</u> A T G G T <u>A</u> G A <u>I</u> A <u>C</u>	G A T G G T G A T A T G G T <u>A</u> G A T A T
Seq 10	G A T G G <u>I</u> G A <u>I</u> A T G G T <u>G</u> G A <u>I</u> A <u>C</u>	G A T G G T G A T A T G G T <u>G</u> G A T A T
Consensus	G A T G G <u>Y</u> G A <u>Y</u> A T G G T <u>D</u> G A <u>Y</u> A <u>Y</u>	G A T G G T G A T A T G G T <u>D</u> G A T A T
	75% homology over 20 bases	95% homology over 20 bases
	48 possible primer combinations	3 possible primer combinations

- Sufficient information is retained for genotyping equivalent to native (4Base) genomic assays
- No loss of clinical specificity is observed by this base conversion
- e.g. HPV clinical trial showed superior performance vs. Digene assay in reducing false positives (J. Clin. Virol. 42:22-6. 2008)
- 3Base™ delivers greater Sensitivity and Specificity, in a rapid assay

3base™ Simplifying Pathology Testing

- Pathology providers strive to **Minimise work, Maximise results**
 - Desire to get **more results per patient specimen**
 - Thus put more and more primers and probes for more and more diseases in a single tube and sample, to get more answers with less work - multiplexing

However ---

- Each primer probe combination has a set of conditions and temperatures that work best. **Non-optimum conditions lead to a loss of specificity, sensitivity, or both.**
- The more primers and probes in a tube, the more they can interfere with each other

EasyScreen[™] Testing Kits

- **First Products to Market**
 - **22 gastroenteritis pathogens, including viral, bacterial & protozoan**
 - **15 of the most common respiratory infections**
- Being adopted **by major hospitals & pathology laboratories** for detection of infectious diseases
- Deliver a wider array of highly **specific results in 4-5 hours that would have traditionally taken 4-5 days**
- **Works on equipment found in any diagnostic laboratory**
- 1mL product volume is sufficient for 50 individual tests, driving an attractive and operationally leveraged business model
 - **Scalable manufacturing, not limiting growth**

Case Study:

St Vincent's Hospital Evaluation Study

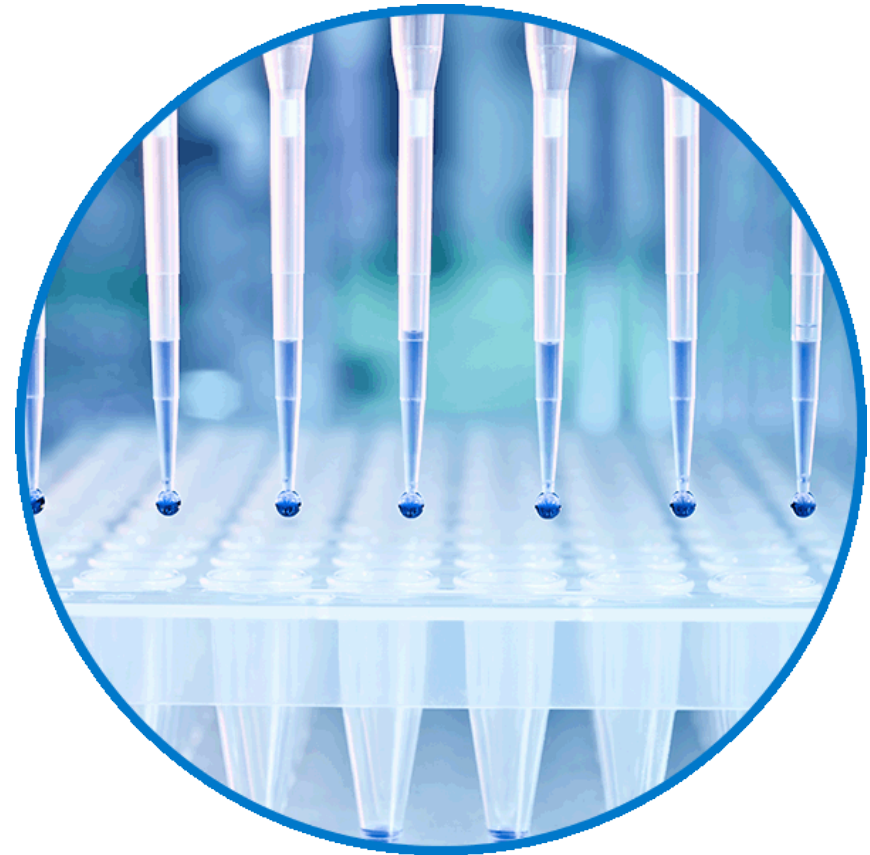
- *Powerful evidence of efficacy*

- 221 patient samples compared to traditional culture, microscopy and antibody based tests
- Results in 4 hours**, compared to up to 120 hours for traditional
- Identified 44 infections that existing testing missed**
- Missed infections have substantial downstream consequences, such as closing down of wards (**e.g Norovirus group II**)

Pathogen	Conventional Methods*	EasyScreen™
<i>Campylobacter</i>	7	9
<i>Salmonella</i>	8	9
<i>Shigella</i>	5	6
<i>C. difficile</i>	3	7
<i>Yersinia</i>	-	1
<i>Cryptosporidium</i>	-	1
<i>Giardia</i>	9	12
<i>Dientamoeba fragalis</i>	4	20
<i>Blastocystis hominis</i>	16	21
<i>Entamoeba histolytica</i>	1	1
Norovirus group 2	-	7
Adenovirus	-	1
Adenovirus 40/41	-	1
Sapovirus	-	1
Total	53	97

“I find that the fast turnaround time and the number of targets tested in the *EasyScreen*[™] assays allow me to more rapidly identify highly infectious agents, potentially stopping the spread to other healthy individuals and thereby saving the health system money.”

- Dr Damien Stark,
KOL and Senior Microbiologist, St. Vincent's
Hospital Sydney



EasyScreen[™] Products in Development

- Product expansion will drive revenue and market share growth
 - Product development pipeline includes tests for
 - 2nd generation respiratory virus,
 - atypical pneumonia,
 - STIs, with clinical evaluation trial announced in September
 - Antibiotic resistance panel,
 - Meningitis
 - Flavivirus (including Zika, Dengue, West Nile, Yellow Fever, etc)
- **Two new products to be released** in next 6-12 months
- **Preliminary STI results to be presented at Molecular Conference today**

Advantages of 3base™ Technology

Significant benefits to the health system

Patient

- Patients receive more accurate test results
- Faster turn around time; 4-5 hours vs 4-5 days under traditional methods
- Improved efficacy and breadth of infection detection leading to improved patient experience

Pathology Groups / Hospitals

- Cost savings due to decreased time spent evaluating samples
- Delivers greater sensitivity and specificity
- More results per patient specimen
- Reduces complexity in molecular testing
- Common workflow between tests
- Compatible with existing equipment i.e. no CAPEX requirement
- Point of differentiation

Government

- Reduce hospital stays through more effective infection detection
- Fast turnaround time allows rapid detection and reduces spread of infectious diseases
- Reduced sick leave for nursing staff
- Reduces repeat doctor visits

Minimise work, Maximise results, Drive value

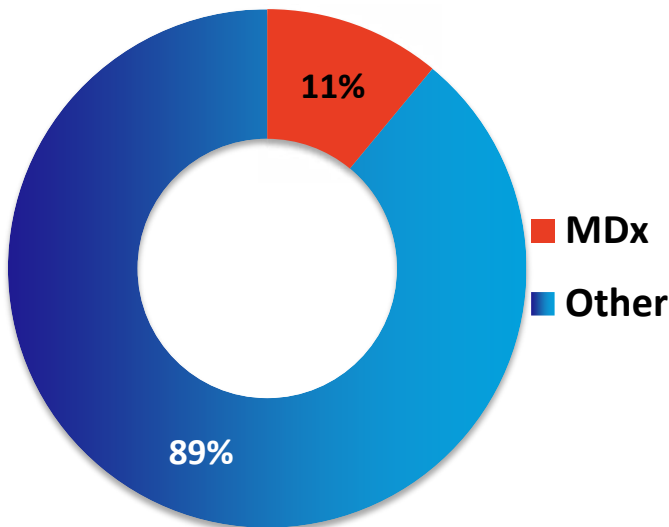
Global Growth Strategy and Commercial Progress



Large and Growing Global Molecular Diagnostics Market

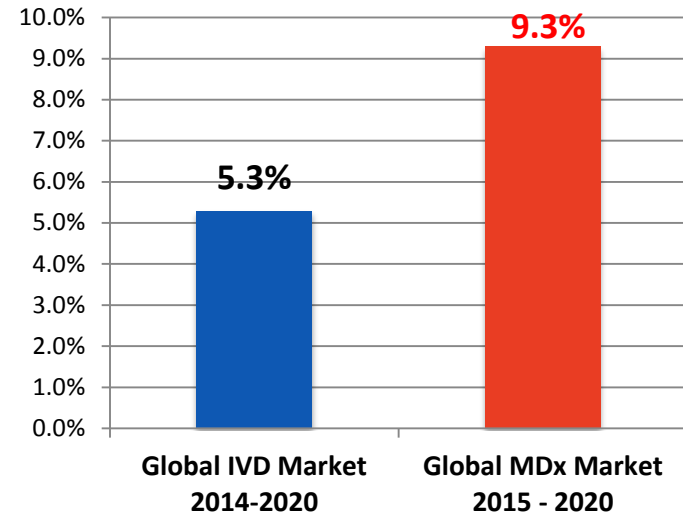
- **Molecular Diagnostics (MDx) Market estimated to be US\$7.6B** in 2017 representing 11% of the overall *in vitro* Diagnostics (IVD) market of \$US69B
- MDx market forecast to grow at an above system CAGR of 9.3% far exceeding the overall IVD market growth, **as MDx techniques replace traditional diagnostics**

Breakdown of US\$69B Global *in vitro* Diagnostics (IVD) Market as at 2017



Source: www.mddionline.com/article/global-vitro-diagnostics-market-grow-691-billion-2017

CAGR of the Global IVD Market & Global MDx Market

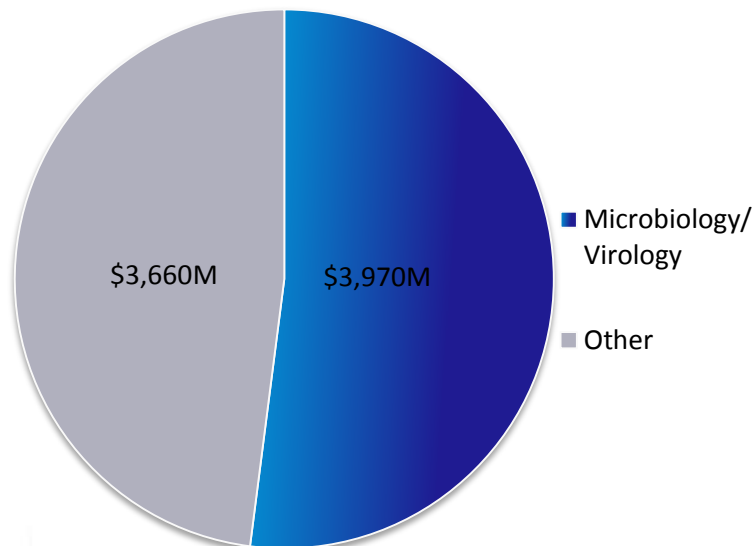


Source: www.marketsandmarkets.com/PressReleases/molecular-diagnostic.asp and www.researchbeam.com/in-vitro-diagnostic-ivd-market

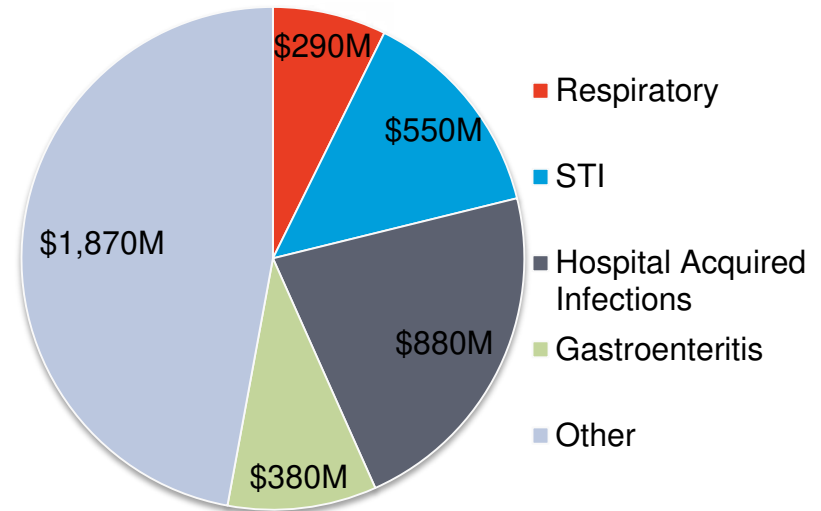
Large addressable markets

- Genetic Signatures' current diagnostics products and pipeline products account for >50% of microbiology/virology diagnostics segment, representing what was a total **addressable market of \$US1.1B in 2012** and estimated to be worth **US\$2.1B by 2017**

2017 Estimate of Microbiology/Virology segment of global \$US7.6B MDx market



2017 Estimate of GSS Microbiology/Virology Addressable Market of US\$2.1B

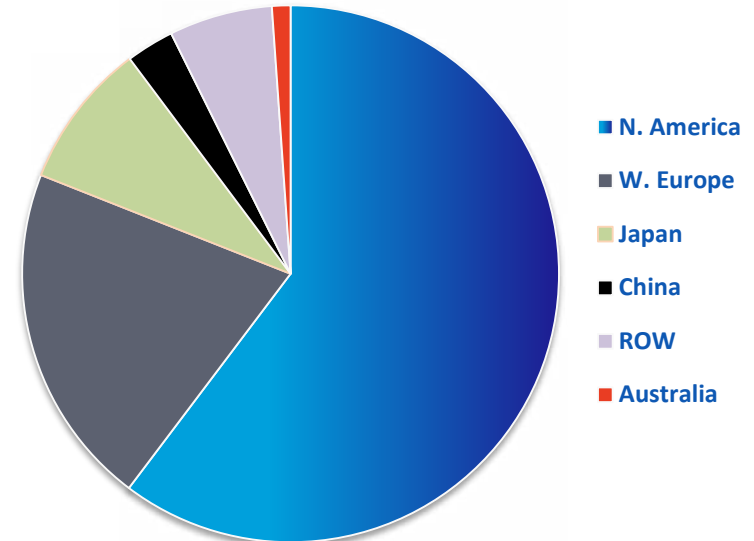


Source: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 168 and www.transparencymarketresearch.com/pressrelease/global-enteric-disease-testing-market.htm

Regulatory approvals already gained in large portion of global market - driving revenue

- **Full regulatory approval for ~22% of the global market** in Gastroenteritis testing, with partial approval (Clinical Concentrators, Analyte Specific Reagents) in the USA
- Validation of company strategy with revenues ramping quickly following approvals (see Australia); European & North American revenues expected to contribute in FY17
- Further molecular diagnostic approvals sought for new products in key global markets, driving further revenue in other product categories - driving shareholder value

2017 Estimate MDx Market Size by Region (USD)

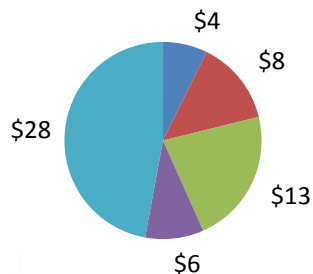


Source: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 94 .

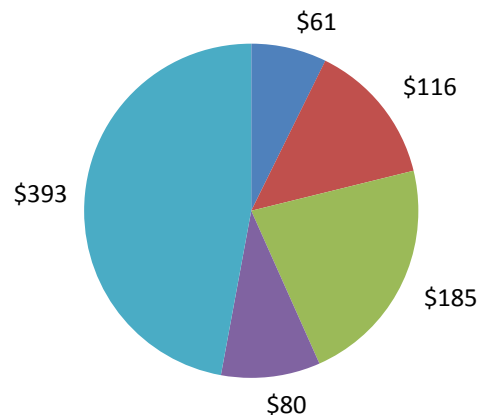
Significant Offshore Opportunity

- Strong revenue growth in Australia validates commercial potential of products in offshore markets
- Enteric products have **CE-IVD approval in Europe** which is 10-20x Australian market
- Specialist clinical sales of Enteric ASR tests into N. America commencing in FY17
- Specialist respiratory sales commenced in Australia (~20% of FY16 revenue) with imminent availability in the US
- Multiple products and multiple jurisdictions are de-risking the commercialisation process

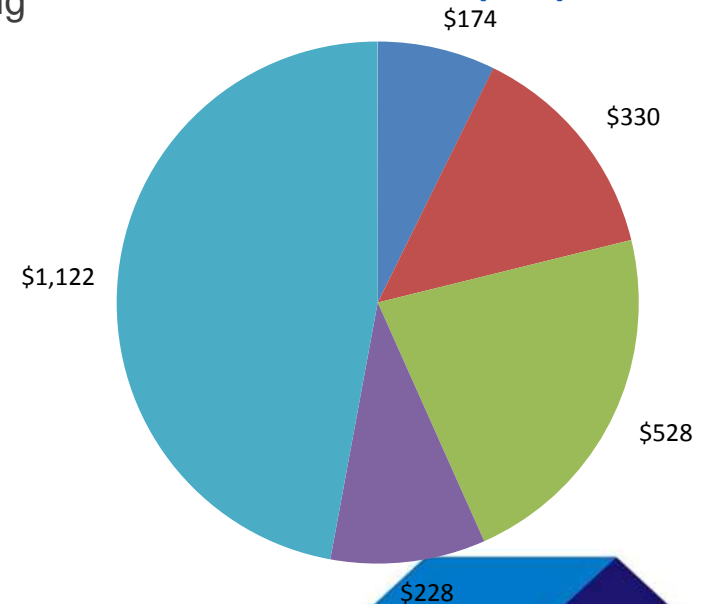
Australia (\$M)



Europe (\$M)



N America (\$M)



■ Respiratory
 ■ STI's
 ■ Hospital acquired infections
 ■ Gastroenteritis
 ■ Other

Commercialisation



Global Growth Strategy

- Focus on regions with regulatory approvals
 - Australia, Europe and US, together **>80% of world market**
- **Extend footprint in both Europe and US**
 - Europe has unique testing and reimbursement strategies – local knowledge is critical
 - Full distributor model in select countries, with local support
 - US growth via direct sales and support
- **Realise early revenue** from specialist products (e.g ASRs in the US)
 - Larger revenues to follow with additional approvals
- Expand product range and complete regulatory approvals for new products
- Prepare first products for FDA approval to achieve full regulatory approvals

Commercialisation Progress - Australia

- In market with major hospital and pathology group customers, including St. Vincent's Sydney and Australian Clinical Labs
- Driving strong revenue growth for Australian sales, 92% 3yr CAGR
 - Revenue split ~ 80% gastroenteritis, 20% respiratory
 - Revenue accounts for 2% of total Australian molecular market (AU\$58M)
 - 6% of Australian addressable molecular market (AU\$31M)
- **Two new products to be released** in next 6-12 months
 - STI testing kit in clinical validation trial, preliminary results to be **presented at a molecular conference today**
 - Australia forms base for EU and US approvals and release
 - Product expansion will drive revenue and market share growth

Commercialisation Progress - Australia (Cont)

- Dedicated R&D labs and network of clinical partners driving **new product development**
- 4 *EasyScreen*[™] products for Gastroenteritis have TGA approval
- 2 more *EasyScreen*[™] kits are being validated for TGA approval
- TGA approved manufacturer
 - dual ISO 9001 and 13485 certifications
 - Approval allows products to come to market quicker
- Dedicated validation team, performing validation experiments for TGA, CE-IVD and FDA
- Anticipate new products and increased market share will drive strong revenue growth

Commercialisation Progress - Europe

- Western European market ~20% of the global molecular diagnostics market
 - Addressable market of ~US\$435M
- Targeting first significant recurring revenues in FY17
- Full distributors appointed in Italy, Israel, Poland and Ireland
 - Currently setting up trials and applying for hospital tenders
- 4 *EasyScreen*[™] kits have CE-IVD approval
- 2 more *EasyScreen*[™] kits are being validated for CE-IVD approval



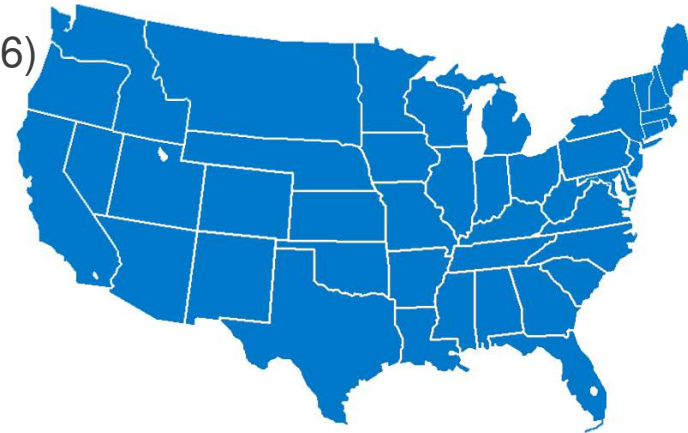
Commercialisation Progress - Europe

- European Director, Sales and Support, appointed, based in the Netherlands
- Establishing direct Sales and Support in Europe
 - Mix of Direct sales and distributors, similar to Cellectis model
- Also providing local supporting for the existing European distribution network
- Strong client engagement established for upcoming products



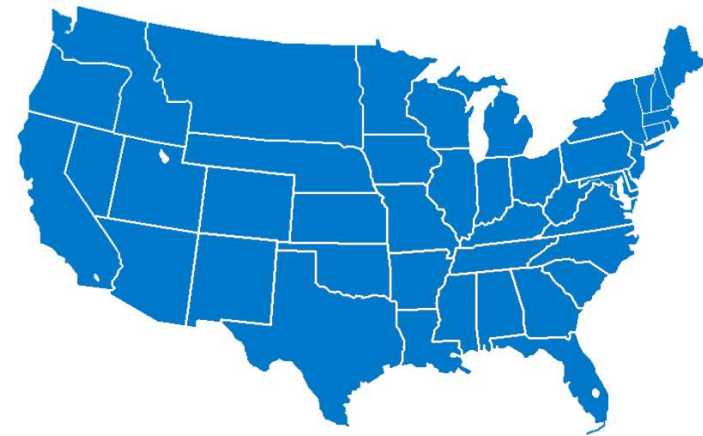
Commercialisation Progress – North America

- US market 50-60% of the global molecular diagnostics market
 - **Up to ~US\$1,265M addressable market**
- Anticipate first sales in FY17
- Direct sales and support model with established and experienced US team
- Early revenue underpinned by US FDA listing for Clinical Sample Concentrator achieved in FY16. *EasyScreen*™ Sample Processing Kits can now be legally sold to laboratories in the US to yield 3base nucleic acids from patient specimens
- **Analyte Specific Reagents (specialist sales) launched in the US at the largest US microbiology conference** (June 2016)
 - further step towards full product suite commercialisation
 - Allows 3base™ products to be sold to **thousands of CLIA certified laboratories**



Commercialisation Progress – North America

- UCLA evaluation concluded with successful product trial, upcoming publication and progressing to adopt into routine use
- First products are being prepared for full FDA approval, allowing unrestricted sales in the US
 - FDA approval opens pathway to a broader group of clinical laboratories, where sales are not restricted to specialist laboratories
 - FDA pre-submission meeting is being planned
 - First product is the Enteric Protozoan kit
- Genetic Signatures now certified by Health Canada, clearing the way for *registering in vitro* diagnostics (IVD) sales into the Canadian market



Outlook

Significant progress made during FY16 & further strong growth expected in FY17

- FY16 sales revenues of AU\$1.83M , representing a 3 year CAGR of 92%
- Launch of specialist products for sale into Australia and prepared for US
- Alliances made with leading KOL and health laboratories in the US (UCLA) and globally

Progressing significant offshore opportunities

- Expect to capture a similar % of sales in Europe, similar to Australian growth trajectory
 - **Addressable market of ~US\$435M**
- Commence sales of ASRs into the US market
 - **Addressable market up to ~US\$1265M**
- Launch FDA approval process for two products including Enteric Protozoan Kit
- Target commencing FDA work for 3 products

Driving Shareholder value

- Accelerate revenues through distribution and direct sales activities globally
- Accelerate R&D and approval activates globally, unlocking further revenues and strategic value within molecular test portfolio
- Targeting cash flow breakeven in FY18

A microscopic view of a dense population of bacteria, likely E. coli, showing individual rod-shaped cells and their flagella. The image is rendered in a blue color scheme.

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