

# Genetic Signatures

Investor Presentation – July 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

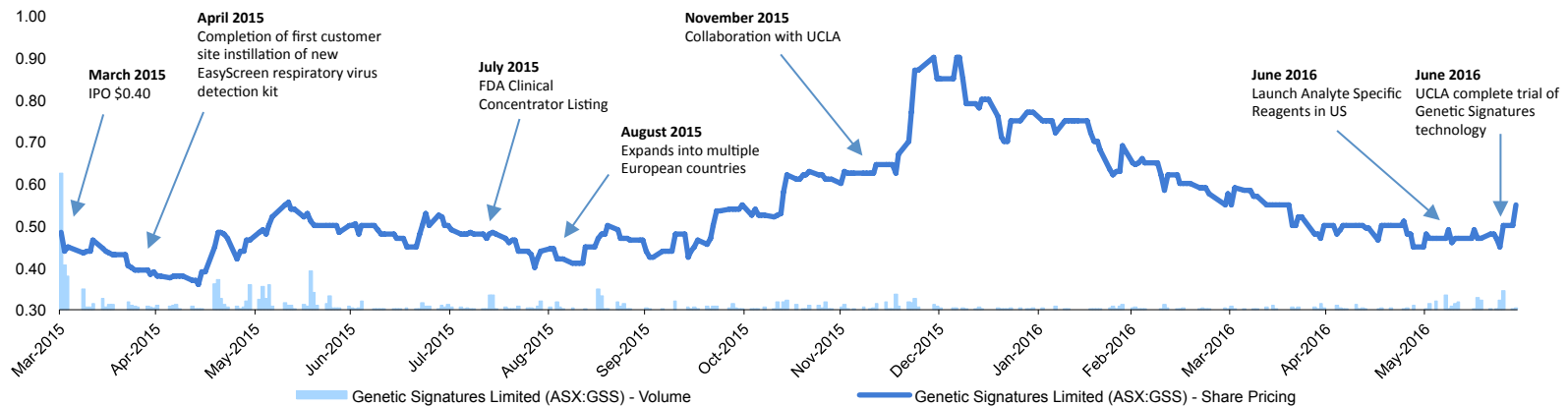
- Genetic Signatures Limited (GSS) designs and manufactures proprietary molecular diagnostic test solutions for **rapid and specific identification of diseases and infections**
- GSS fully owns its proprietary molecular 3Base™ technology with **multiple patents issued, expiring 2031**
- Products led by CE-IVD marked *EasyScreen*™ Gastrointestinal (Enteric) tests are 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*™ tests are currently sold into Australian labs and launching into global markets, with an addressable global market estimated to be **US\$2.1 billion in 2017**
- **Large pipeline** of new commercial 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 (Cellestis Limited acquired by QIAGEN for ~A\$400m in 2011)

# Corporate Summary

Financial Information (A\$)	
ASX Code	GSS
Shares on Issue	72.81m
Market Capitalisation	\$36.4m
Share Price (at market close 20 July, 2016)	\$0.50
Cash at 30 June 2016	\$2.6m

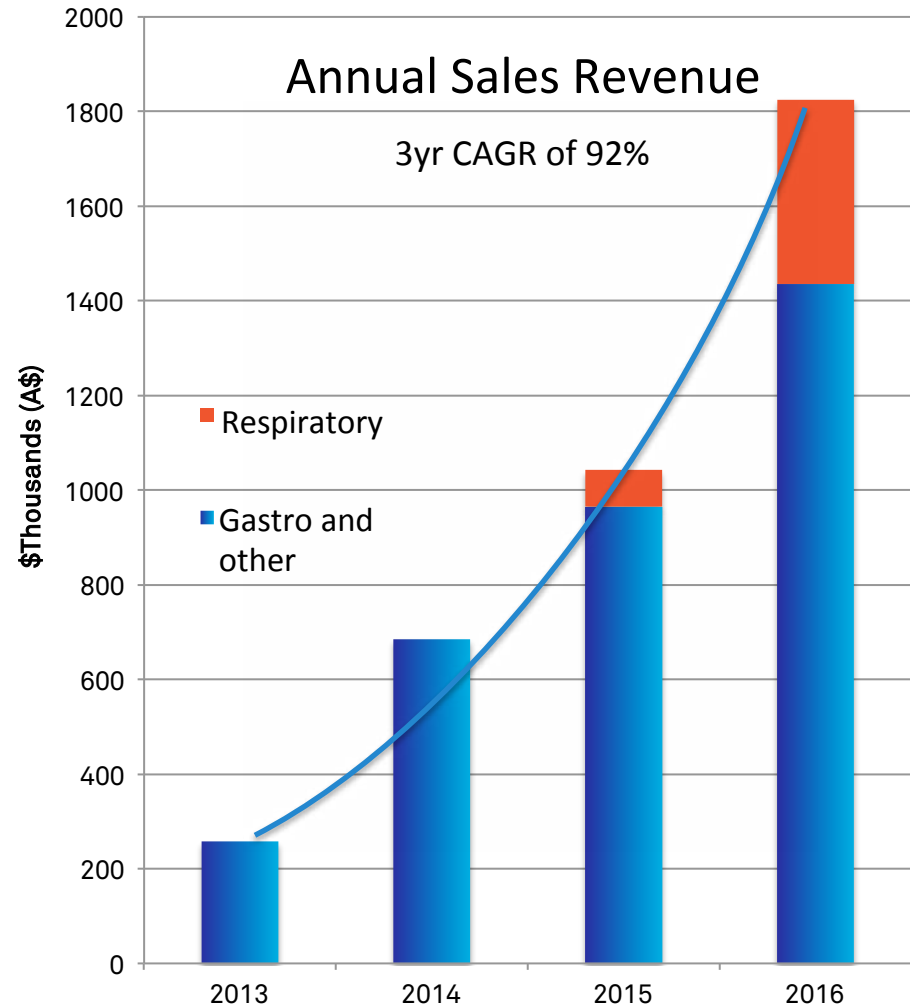
Top Shareholders	%
Asia Union Investment Pty Limited	50.6%
DAK Drafting Services Pty Ltd	2.7%
UBS Nominees Pty Ltd	2.4%
Directors, Management and Advisors	9.0%

## Share Price Performance



# Recent Achievements

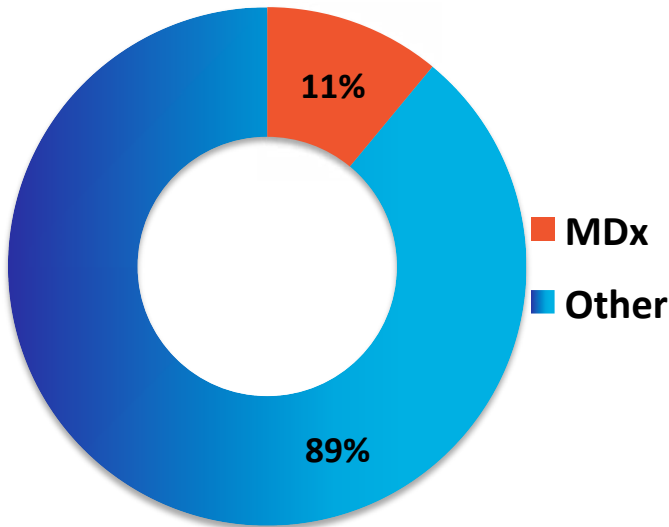
- **Strong sales growth**, with a 3-year CAGR of 92%
- FY16 revenue of A\$1.83M, split ~80% Gastroenteritis, ~20% Respiratory specialist sales
- Advancing R&D development of **5 new diagnostic products**
- **Established direct operations in EU**
- Analyte Specific Reagents (ASRs) **launched in the US** in June 2016
- UCLA **completed product trial and progressing to adopt into routine use**
- GSS now certified for Health Canada, allowing **registration of *in vitro* diagnostics (IVD) products in the Canadian market**



# Large and Growing Global Molecular Diagnostics Market

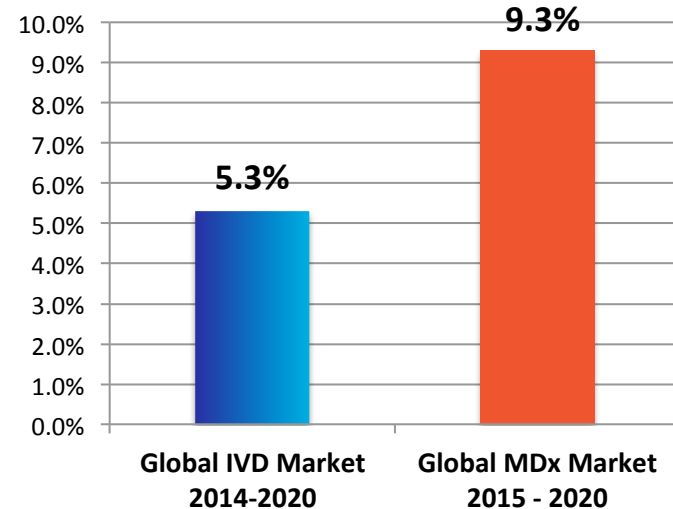
- **Molecular Diagnostics (MDx) Market estimated to be US\$7.6Bn** in 2017 representing 11% of the overall *in vitro* Diagnostics (IVD) market of \$US69.1Bn
- MDx market forecast to grow at an above system CAGR of 9.3% far exceeding the overall IVD market growth, **as MDx techniques replace traditional diagnostics**

Breakdown of US\$69.1Bn Global *in vitro* Diagnostics (IVD) Market as at 2017



Source: In Vitro Diagnostics (IVD) Market . Research and Markets, July 2015

CAGR of the Global IVD Market & Global MDx Market



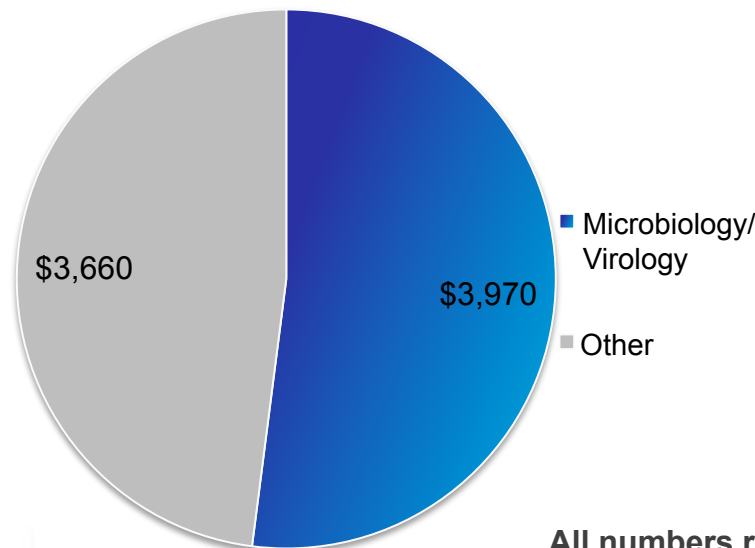
Source: Molecular Diagnostics Market by Application, Forecast to 2020. Markets and Markets, November 2015 and Global In Vitro Diagnostics (IVD) Market Forecast 2013-2020. Allied Market Research, June 2014

*MDx growth expected to drive IVD market demand*

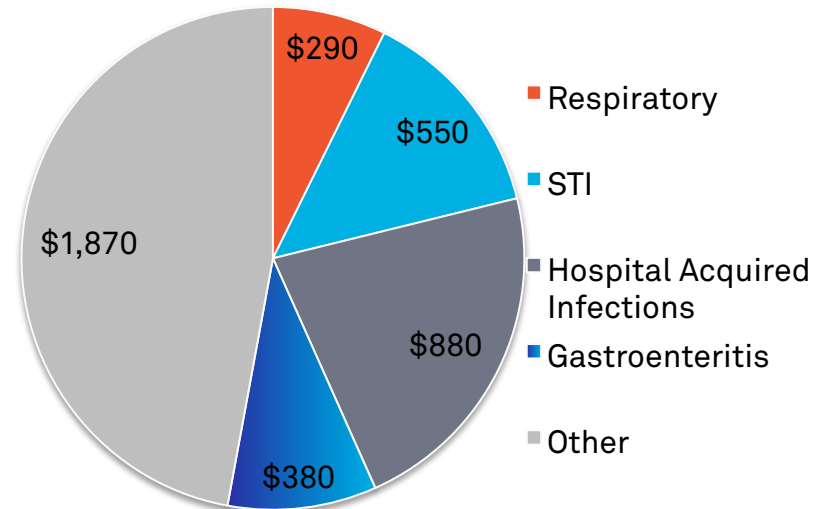
# Large addressable markets

- Genetic Signatures' (GSS) current diagnostics products and pipeline products account for >50% of microbiology/virology diagnostics segment, representing what was a total **addressable market of \$US1.11Bn in 2012**
- This segment is estimated to be worth **US\$2.1Bn by 2017**

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



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

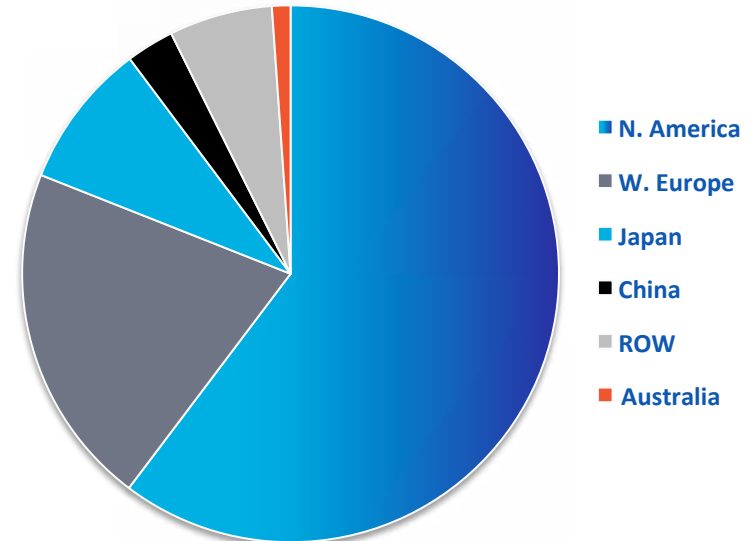


All numbers refer to US\$M

## Regulatory approvals already gained in large portion of US\$7.6Bn 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 slides 5 and 20); 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
- Multiple products and multiple jurisdictions are de-risking the commercialisation process

2017 Estimate MDx Market Size by Region (USD)

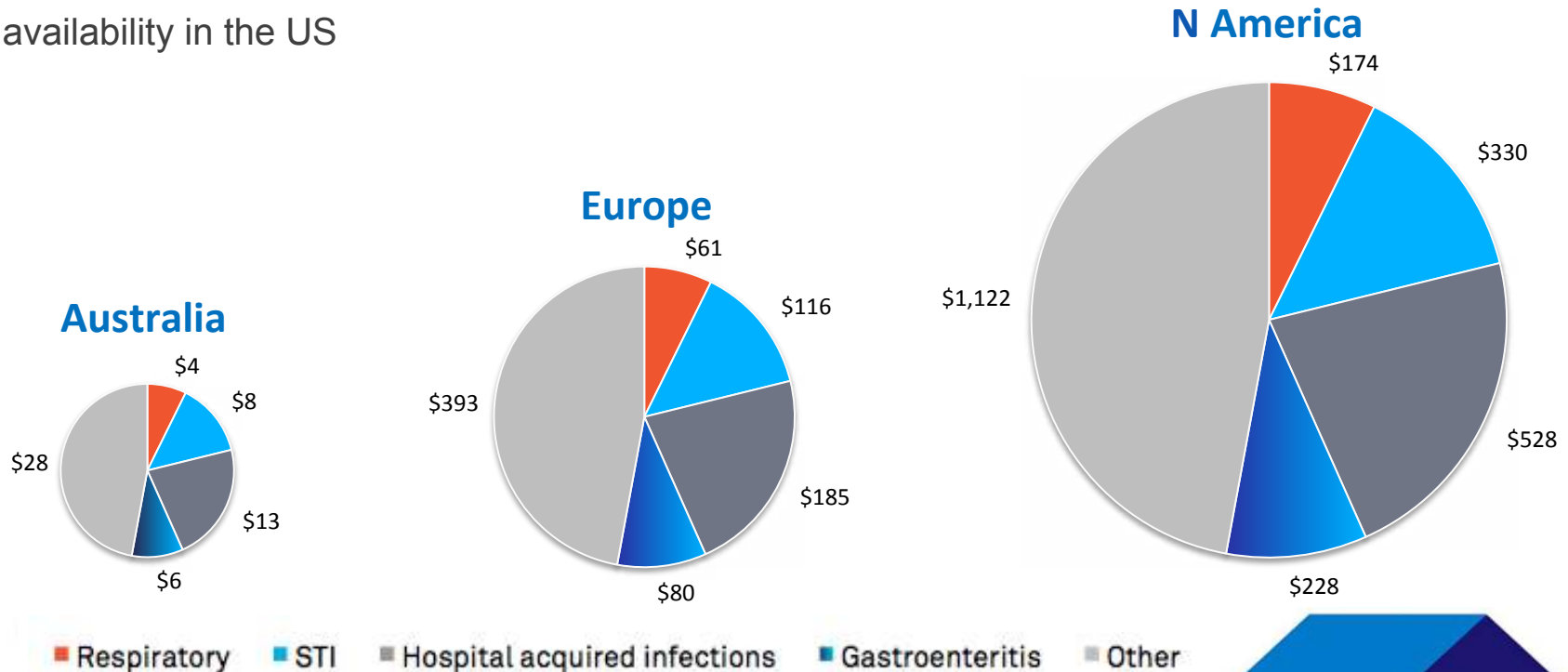


Source: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 94 .



# Significant Offshore Opportunity

- Strong revenue growth in Australia validates commercial potential of products in offshore markets
- Enteric products have **full 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



All numbers refer to US\$M

# 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

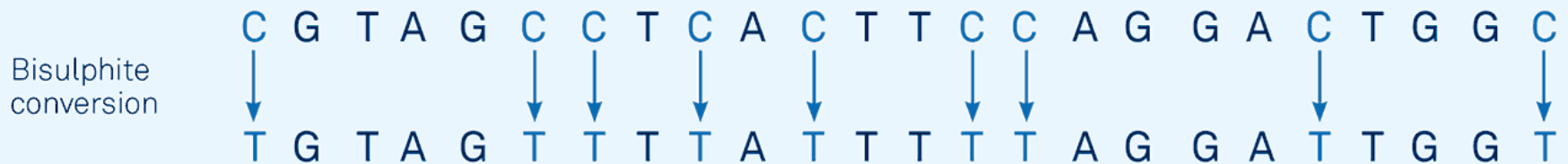
# Genetic Signatures

## Transforming Global Molecular Diagnostics



# 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
Seq 3	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 4	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>I</u>	G A T G G T G A T A T G G T <u>A</u> G A T A T
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
Seq 6	G A T G G <u>C</u> G A <u>C</u> A T G G T <u>I</u> G A <u>I</u> A <u>I</u>	G A T G G T G A T A T G G T <u>I</u> G A T A T
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
<b>Consensus</b>	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
	<b>48</b> possible primer combinations	<b>3</b> 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

# EasyScreen™ Testing Kits

- GSS' suite of *EasyScreen*™ products are being adopted **by major hospitals & pathology laboratories in Australia** for detection of infectious diseases
- Products work to deliver a wider array of highly **specific results in 4-5 hours that would have traditionally taken 4-5 days**
- *EasyScreen*™ technology **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
- **First Products to Market**
  - Enteric Pathogen Detection Kit detects up to **22 gastroenteritis pathogens, including viral, bacterial and protozoan agents**
  - Respiratory Pathogen Detection Kit detects up to **15 of the most common respiratory infections**

# Case Study:

## St Vincent's Hospital Evaluation Study

- *Powerful evidence of efficacy*

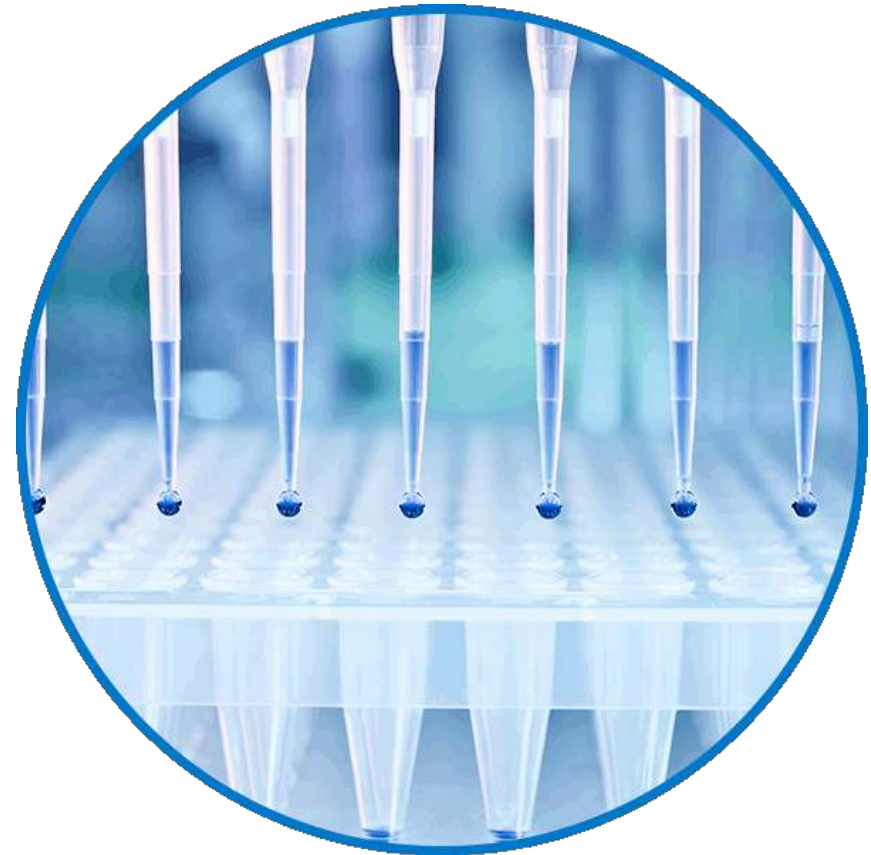
- 221 patient samples compared to traditional culture, microscopy and antibody based tests
- Results in 4 hours**, compared to up to 120 hours for traditional
- Identified 44 infections that existing testing missed**
- Missed infections have substantial downstream consequences, such as closing down of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

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



**“I find that the fast turnaround time and the number of targets tested in the *EasyScreen*<sup>™</sup> 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



# 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 existing 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



# Global Growth Strategy

- Focus on regions with regulatory approvals
  - Australia, Europe and US, together account **for >80% of world MDx 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

- Currently 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
      - FY16 Sales revenue up 75% to AU\$1.83M
      - 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
    - Australia forms base for EU and US approvals and release
    - Product expansion will drive revenue and market share growth
    - Product development pipeline includes tests for 2<sup>nd</sup> generation respiratory virus, atypical pneumonia, STIs, antibiotic resistance panel, meningitis and flavivirus (including Zika, Dengue, yellow fever, etc)
- 

## Commercialisation Progress - Australia (Cont)

- Dedicated R&D labs and network of clinical partners driving **new product development**
- 4 *EasyScreen*<sup>™</sup> products for Gastroenteritis have TGA approval
  - *C. difficile* detection and reflex kits; Enteric Protozoan & Bacterial Kits
- 2 more *EasyScreen*<sup>™</sup> kits are being validated for TGA approval
  - Respiratory and Enteric Viral infections
- 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*<sup>™</sup> kits have CE-IVD approval
  - *C. difficile* detection and reflex kits; Enteric Protozoan and Bacteria infections



# Commercialisation Progress - Europe

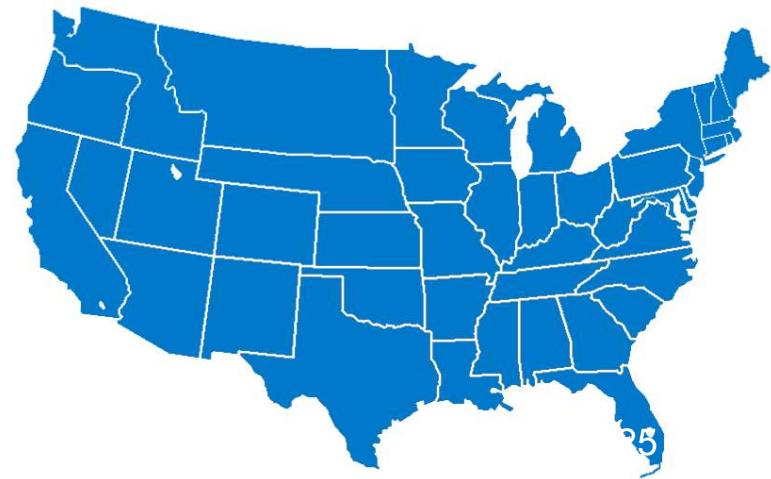
- 2 more *EasyScreen*<sup>™</sup> kits are being validated for CE-IVD approval
  - For Respiratory and Enteric Viral infections
- European Director, Sales and Support, appointed, based in the Netherlands
- Establishing direct Sales and Support in Europe
  - Mix of Direct sales and distributors, similar to Cellestis model
- Also providing local support for the existing European distribution network
- Strong client engagement established for upcoming products





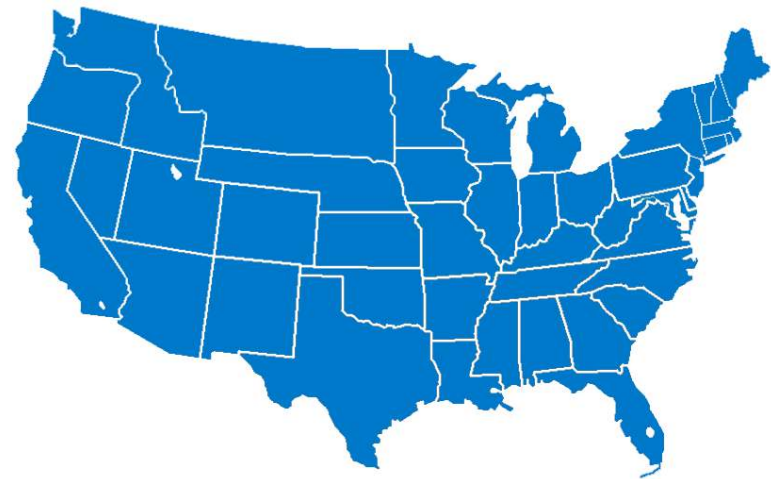
# Commercialisation Progress – North America

- 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 **~11,000 CLIA certified laboratories**



# Commercialisation Progress – North America

- **UCLA evaluation concluded with successful product trial, publication to follow 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 activities globally, unlocking further revenues and strategic value within molecular test portfolio
- Targeting cash flow breakeven in FY18

# Appendix



# Comparable companies demanding large valuations

- Comparable companies within the molecular diagnostics field trade on an average revenue multiple of 8.6x
- This multiple exists under the spectre of the 3 year CAGR of the three closest comparable companies being an average of 9.1%
- GSS' 3 year CAGR has been 92%. With strong growth to continue driven by expanded product range and new geographies

	Stock code	Market Capitalisation (\$US m)	2016 Consensus Revenue (\$US m)	Market Capitalisation/ Revenue	3 Year Revenue CAGR
Seegene	KOSDAQ: 096530	\$840.9	\$64.1	13.1x	1.6%
Genmark	NASDAQ: GNMK	\$419.3	\$47.7	8.8x	15.9%
Cepheid	NASDAQ: CPHD	\$2,405.0	\$621.7	3.9x	9.8%
			Average	8.6x	9.1%
			Median	8.8x	9.8%

# Technology - 3Base™

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

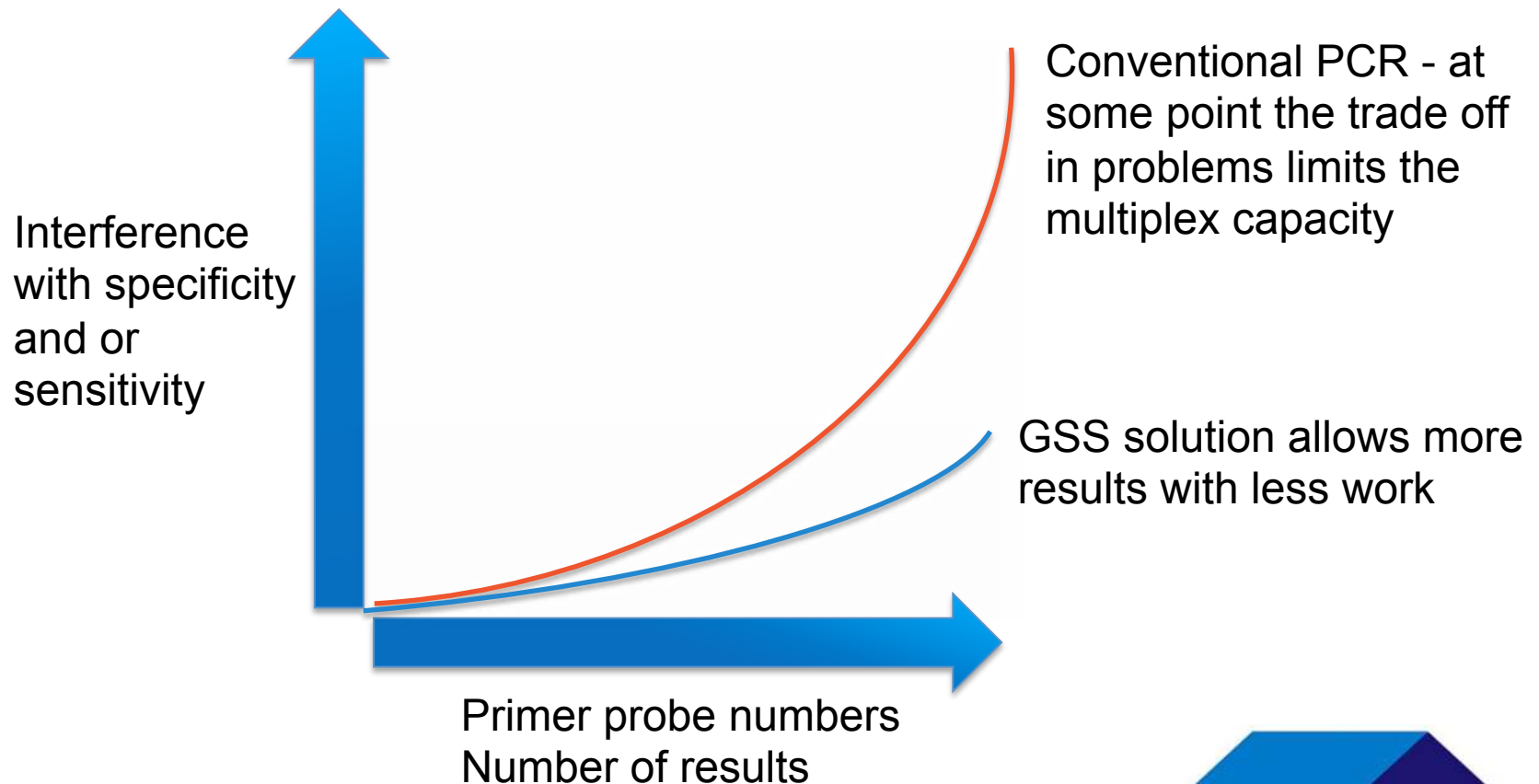
- Genetic Signatures' 3Base™ platform is a proprietary molecular technique which changes naturally occurring DNA and RNA sequences to reduce sequence variation between subtypes
- Patented chemical transformation of DNA and RNA sequences to reduce genetic code complexity
- Process can enhance detection 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

# 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

# 3base™ Simplifying Pathology Testing

More Primers, more Probes, more Problems





# 3base™ Advantages

GSS is winning market share due to the following:

- Unique 3base™ products that screen over 20 pathogens, including RNA and DNA viruses, in a probe based real-time format
  - **No post amplification analysis required**
- Uses latest technology compatible with existing equipment (open platform)
  - **No capex required**
- High-Throughput workflow, from sample to result
  - **Scalable, able to manage high volumes, labs performing 200+ specimens/day**
- Separate endogenous extraction and inhibition controls
- Viral, bacterial and protozoan coverage
- Ease of use and automation
- Cost effective



# Immense US Market Potential

- US has 5,686 registered hospitals
  - Over 900,000 staffed beds
  - Over 35 million admissions
  - **11,000 CLIA certified laboratories**
- *3Base*<sup>™</sup> Technology offers unique advantages for the US Market
  - High numbers of pathogens detected delivers desirable patient outcomes
  - Assays available for *C. difficile*, which the CDC cites as an “urgent threat”
  - ASRs reduce regulatory barriers
- Independent and commercial labs represent approximately 50% of the US laboratory testing market

# US Market Trends

- Centers for Disease Control and Prevention (CDC) estimates that annually, at **least two million illnesses and 23,000 deaths are caused by antibiotic-resistant bacteria in the United States alone**
- The Infectious Disease Society of America produced a policy paper “Better Tests, Better Care: Improved Diagnostics” in which the society advocates for molecular testing development and adoption to improve patient care and distinguish between bacterial and viral pathogens
- Laboratories are **bracing for implementation of the Preserve Access to Medicare Act which will likely lower reimbursement** beginning in 2017
  - Laboratories will consider new methods for diagnosis
    - Adopt molecular technology to speed broad diagnosis
  - Laboratories will seek to lower their operating expense
    - **Favour high throughput to improve efficiency**
    - **Favour open platform systems to lower capital expense requirement**

# US Market Expansion Approach

- Discussions underway with Key Opinion Leaders to trial Genetic Signatures' technology
  - Patient outcome studies – define superior patient care through implementation of broad pathogen screening protocols
  - Head-to-Head comparison between *3Base*<sup>™</sup> assays and traditional methods and available molecular alternatives
  - Overall cost of care economic benefit of *3Base*<sup>™</sup> technology implementation
- Engaged with leading US commercial laboratories and hospital systems to introduce *3Base*<sup>™</sup> technology
  - Evaluate *3Base*<sup>™</sup> versus traditional 4 base molecular performance
  - Evaluate widespread adoption of molecular methods versus traditional methods
- **ASRs allow access to CLIA certified laboratories**
- Full FDA approval to allow direct marketing of 3 Base benefits is the final goal

A microscopic view of a dense population of bacteria, likely E. coli, showing individual rod-shaped cells and a complex network of fine, hair-like structures (pili) connecting them. The image is rendered in shades of blue and white.

**Contact:**

**John Melki**  
**Chief Executive Officer**  
[john@geneticsignatures.com](mailto:john@geneticsignatures.com)

[www.geneticsignatures.com](http://www.geneticsignatures.com)