

## ASX ANNOUNCEMENT

### Non-Deal Roadshow Presentation 25 May 2015

Sydney, 25 May 2015: Genetic Signatures (ASX: GSS) is pleased to release a copy of the presentation that John Melki, PhD., Director & CEO and Robert Birrell, Director & CFO, will be delivering to investors during a non-deal roadshow in Adelaide, Melbourne and Sydney.

The presentation provides an update on the Company's activities.

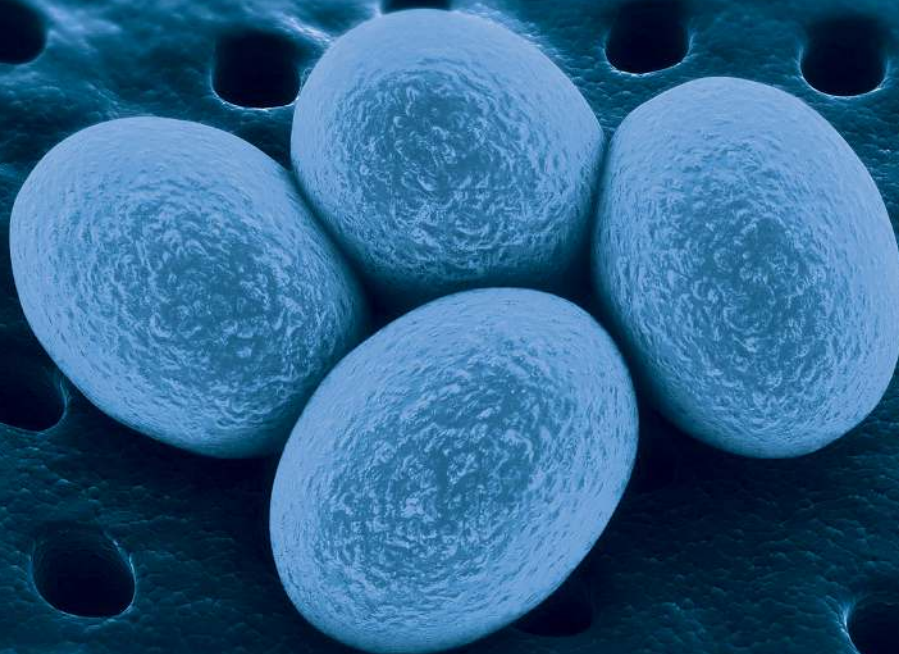
For further information, see our website ([www.geneticsignatures.com](http://www.geneticsignatures.com)) or contact us as below:

Company	Media and Investor Relations
<p><b>John Melki</b>  <b>Chief Executive Officer</b>  john@geneticsignatures.com  T: +61 2 9870 7580</p> <p><b>Robert Birrell</b>  <b>Chief Financial Officer</b>  rob@geneticsignatures.com  T: +61 2 9870 7580</p>	<p><b>Peter Taylor</b>  <b>Investor Relations</b>  <a href="mailto:peter@nwrcommunications.com.au">peter@nwrcommunications.com.au</a>  T: +61 412 036 231</p>

**About Genetic Signatures:** Genetic Signatures is a specialist molecular diagnostics (MDx) company focused on the development and commercialisation of its proprietary platform technology, 3Base™. Founded in 2001 by the late Dr Geoffrey Grigg, the former Chief of Molecular Biology at CSIRO, Genetic Signatures has released a suite of real-time PCR based products for the routine detection of infectious diseases under the EasyScreen™ brand. Molecular diagnostics (MDx) is a modern technique increasingly used by hospitals and pathology laboratories to detect specific sequences of the genome, the DNA or RNA that define an organism.

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. As the spread of infectious diseases around the world continues to grow, the Company plans to launch additional products for the detection of pathogens associated with MRSA, sexual health infections, tuberculosis and meningitis.



# Genetic Signatures

Investor Presentation May 2015



## 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”).

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## INVESTMENT HIGHLIGHTS

Genetic Signatures is a molecular diagnostics (MDx) company operating in the global IVD (*in vitro* diagnostics) industry. **Primary focus on supplying major hospitals and pathology laboratories in testing for infectious diseases.**

- Products already available in Australia with GSS set to launch into large global markets worth **US\$1.11 billion** in 2012 growing to **US\$1.77 billion in 2017**
- Proprietary technology driving product development for large customers in multiple markets
- Experienced management team and board with track record in global molecular diagnostics industry



## CORPORATE SNAPSHOT

Capital Structure	
ASX Code	<b>GSS</b>
Shares on Issue	<b>72.9m</b>
Market Capitalisation	<b>\$30.6m</b>
Share Price (at market close 25 May, 2015)	<b>\$0.42</b>

Directors & Chief Executive	
Nick Samaras	Non-Executive Chairman
John Melki	Director & CEO
Mike Aicher	Executive Director - US
Phillip Isaacs	Non-Executive Director
Pat Noland	Non-Executive Director
Robert Birrell	Director & CFO



## MANAGEMENT & BOARD

### **Nick Samaras**

BSc (Hons), PhD, MBA,  
FAIM, FAICD  
Non-Executive  
Chairman

- More than 20 years' experience in the global life sciences industry, senior executive roles with Applied Biosystems 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**

BSc, PhD  
Managing Director &  
CEO

- Chief Executive Officer since 2011, joined GSS in 2003
- Led the commercialisation of two research products worldwide and five diagnostic products in Australia and Europe as Senior Principal Research Scientist

### **Robert Birrell**

CPA, BEc, M.Comm,  
GAICD  
Executive Director and  
Chief Financial Officer

- More than 30 years' experience in biotech, banking, communication and corporate sectors
- Roles with Macquarie Bank, Industrial Equity Limited, Woolworths Ltd
- Finance Director then Chief Financial Officer of Austar United Communications Ltd, including during IPO in 1999



## MANAGEMENT & BOARD

### **Mike Aicher**

BSc, MBA

**Executive Director –  
U.S Operations)**

- 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 \$1 billion in annual revenue
- Director on boards of Ariosa Diagnostics, Inc. and Omicia, Inc

### **Phillip Isaacs**

MSc JP

Non-Executive Director

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

### **Pat Noland**

BSc, MBA

Non-Executive Director

- More than 20 years of industry experience
- CEO and director of StrataDX, an anatomic pathology laboratory based in Massachusetts, U.S.A
- Previously Senior Vice Present at Laboratory Corporation of America (LabCorp)



## TECHNOLOGY – 3BASE™

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

- GSS' 3Base™ platform is a proprietary molecular technique which changes naturally occurring DNA and RNA sequences to reduce sequence variation between subtypes
- Patent-protected 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



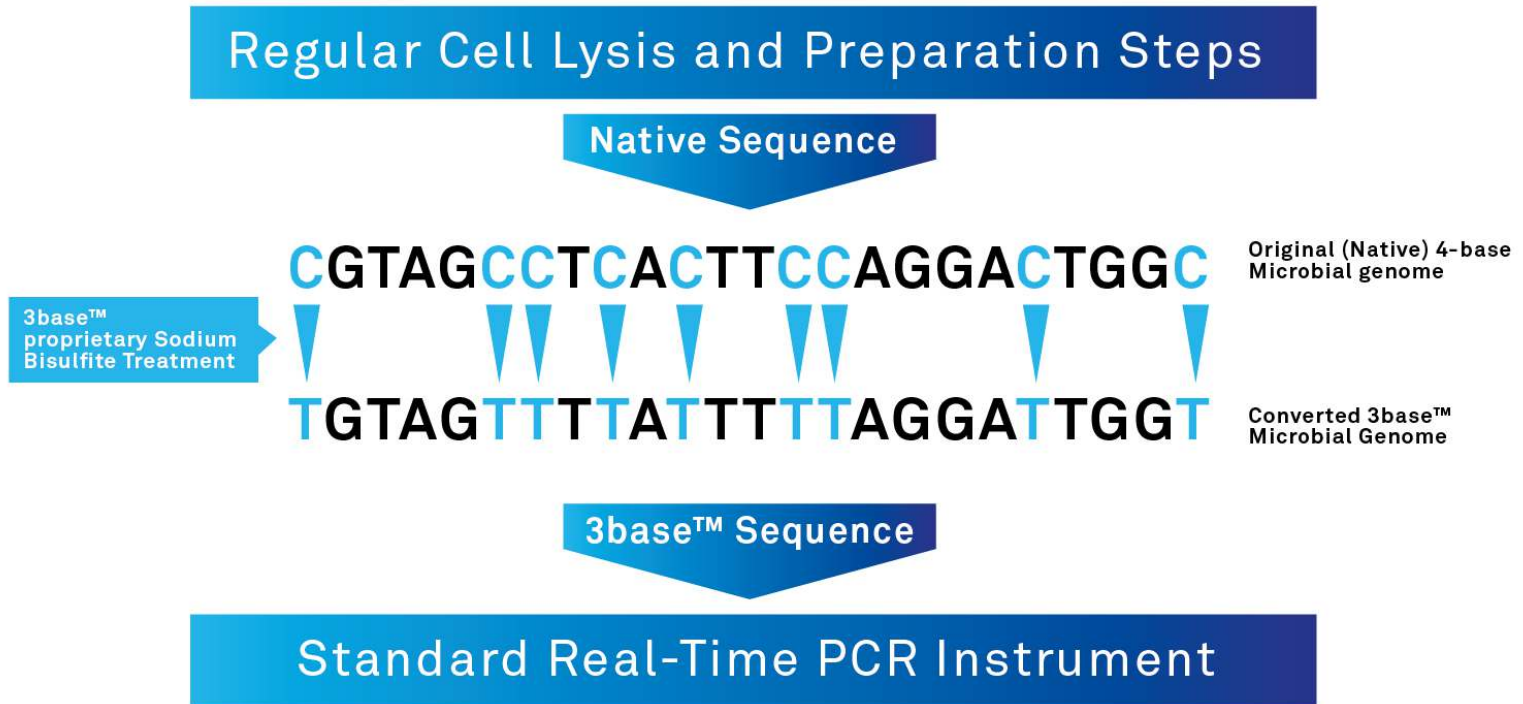


# TECHNOLOGY – 3BASE™

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

## Overview of 3base™

Basic Technical functionality: Moving from 4base to 3base™





## EASYSscreen™ TESTING KITS

- GSS' suite of *EasyScreen*™ products are used by major hospitals in Australia for detection of infectious diseases – more than 37,000 tests performed in FY14, and more than 40,000 in the nine months to end March 2015;
- Products work with existing customer systems 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
- **Enteric Pathogen Detection Kit** detects up to 22 gastroenteritis pathogens, including viral, bacterial and protozoan agents
- **Respiratory Virus Detection Kit** detects up to 15 of the most common respiratory viral infections
- More detection kits in advanced stage of development



# EASYSSCREEN™ PRODUCT DEVELOPMENT PATHWAY

	Experimental & Analytical Validation				Clinical & Regulatory Validation & Release			
	(i)	(ii)	(iii)	(iv)	(i)	(ii)	(iii)	(iv)
Enteric Kits	➔	➔	➔	➔	➔	➔	➔	➔
Respiratory	➔	➔	➔	➔	➔	➔	➔	
MRSA	➔	➔	➔	➔	➔	➔		
STI	➔	➔	➔	➔				
Tuberculosis	➔	➔	➔	➔				
Meningitis	➔	➔	➔	➔				

Each product goes through extensive development and beta testing and adheres to rigorous quality management systems & regulatory approach.

- ISO9001 and ISO13485 certified
- Already approved by Australian and European regulators



## TARGETING CRITICAL HEALTH

- Gastroenteritis is a **major widespread clinical problem (16.8 million cases per annum in Australia alone)** resulting in 250,000 visits to hospital emergency departments, 15,000 hospitalisations and 80 deaths)
- GSS' testing offers faster and more reliable diagnosis for better treatment
- Viral Respiratory Infections **kill 3.9 million people per year - one of the top five causes of mortality worldwide**
- GSS' product pipeline includes tests for MRSA (in beta testing), meningitis, TB and STIs



## COMMERCIALISATION IN KEY GLOBAL MARKETS

- Products have completed **extensive customer validation** in Australia over the past four years
- High profile customers including Sydney's Westmead Hospital, St. Vincent's Hospital, Prince of Wales Hospital and Royal North Shore Hospital
- **Established operations in key global markets** of Western Europe and the US over the past year, including appointment of experienced management team led by ex-Laboratory Corporation of America, Inc. (LabCorp) executive Mike Aicher
- Generated **\$520,000** in AU diagnostic sales in FY14, **EU product revenues have commenced in FY15** and anticipate **US revenues around end of CY15**
- Review and analysis of each jurisdiction the company enters includes, but is not limited to, freedom to operate, reimbursement and the dynamic nature of the existing regulatory and market environment



## COMMERCIALISATION PROGRESS

### Australia

- Currently in market with major hospital and pathology group customers
- Testing for 22 causes of gastroenteritis
- Testing for 15 causes of viral respiratory disease
- Next new product in beta testing with customer

### Western Europe

- Established operations in 2013
- Signed Italian distributor and testing with large pathology laboratories, recurrent revenues commencing
- Signed Israeli distributor agreement
- In discussions with distributors in other jurisdictions

### United States

- Established operations in 2014 with appointment of key personnel
- Anticipate entering market in 2015



# COMPETITOR ENVIRONMENT

Table 1 opposite explores the global competitive environment in which GSS operates for infectious disease products, focusing on enteric (otherwise known as or gastroenteritis) screening.

Table 1 incorporates the major criteria utilised by global customers in assessing products for gastroenteritis screening.

GSS is unique in supplying products that

- Screen over 20 pathogens, including RNA and DNA viruses, whilst
- Using the latest technology and being compatible with existing equipment (open platform)
- ease of use and automation

Comparison of attributes of products for enteric screening

Genetic Signatures Products For Enteric Screening	Competing Products for Enteric Screening								
	Genetic Signatures (EasyScreen™)	Biofire FilmArray	Hologic/ Gen-Probe	BD (BD Max)	Tib Molbiol <sup>1</sup>	Fast Track Diagnostics	AusDiagnostics	Luminex	Seegene <sup>2</sup>
Probe based PCR	●	●	●	●	●	●	●	●	●
Combined extraction and PCR set-up platform provided by supplier of IVD kits <sup>3</sup>	●	●	●*	●	●	●	●	●	●
Rapid Time to Result (<5 hours)	●	●	●	●	●	●	●	●**	●
Thorough Coverage of Common Enteric Pathogens (20 or more targets in a run)	●	●	●	●	●	●	●***	●	●
Separate endogenous extraction and inhibition Controls	●	N/A	●	●	●	N/A	●	N/A	●
Open Platform (Extraction and PCR) from multiple suppliers	●	●	●	●	●	●	●****	●	●
Viral, bacterial and Protozoan coverage	●	●	●	●	●	●	●	●	●
Manufactured in Australia	●	●	●	N/A	●	●	●	●	●

● = Yes; ● = No; N/A = Information not available from company website

<sup>1</sup> Distributed in Australia by Roche Diagnostics  
<sup>2</sup> On a single integrated platform  
<sup>3</sup> Seplex End point PCR range  
\* This test is not compatible with Hologic automated instrumentation  
\*\* Does not include pre-treatment time  
\*\*\* Requires the use of multiple assays with redundant targets under current menu  
\*\*\*\* May be compatible with some 3rd party 384-well PCR instrumentation

Source: Company



# Case Study: Major Hospital, Sydney, Australia: Pilot Study 2013 – *EasyScreen*<sup>TM</sup> vs Traditional

## METHODS:

- Primary focus of this study was to assess the clinical utility of *EasyScreen*<sup>TM</sup> in detecting infectious agents in 279 patient samples as compared to their existing methods
- **Results generated in approximately 4 hours, which compares to up to 4 days** when using traditional microbiology techniques
- **Additional 79 pathogens detected** (last column) that would not have been detected using traditional microbiology testing methods

Pathogen detected	<i>EasyScreen</i> <sup>TM</sup>	Sensitivity %	Specificity %	Additional pathogens
Viruses (Noro, Rota, Adeno, Astro)	69	100	97.1%	25
<i>C. difficile</i>	58	84.8	99.4	9
<i>Campylobacter</i> spp.	48	100	100	0
<i>Salmonella</i> spp.	42	97.7	100	1
<i>Shigella</i> spp.	11	100	99.5	0
<i>L. monocytogenes</i>	1	NA	NA	1
<i>Y. enterocolitica</i>	3	100	100	2
<i>D. fragilis</i>	10	100	100	10
<i>B. hominis</i>	17	100	100	16
<i>G. intestinalis</i>	12	92.3	100	7
<i>Cryptosporidium</i> spp.	3	100	100	3
<i>Entamoeba</i> complex	5	NA	NA	5
Totals	279			79

Table 2: Major Hospital Pilot Study 2013 – *EasyScreen*<sup>TM</sup> versus Traditional Methods





# Case Study: St Vincent’s Hospital (SydPath), Sydney Australia: Evaluation Study 2014 – EasyScreen™ vs Traditional Methods

## METHODS:

- Primary focus of study was to assess the clinical utility of EasyScreen™ in detecting infectious agents in 221 patient samples as compared to traditional methods
  - **Identified 44 infections that existing testing would have missed.**
  - Missed infections within the hospital environment can have substantial downstream consequences such as the 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>

Table 3: St Vincents Hospital (SydPath) Evaluation Study 2014 - EasyScreen versus Traditional Methods



## INTELLECTUAL PROPERTY

- The 3Base™ platform and products are protected by a strong patent portfolio, securing rights in the markets in which it chooses to operate.
- Patent portfolio has been built over 13 years and patents granted in the major jurisdictions in which it operates or expects to operate.
- Broad patent protecting the 3Base™ technology platform until 2024, and a more specific patent protecting the use of 3Base™ in each of the Company's products until 2031. Protection applies to all existing products and products in development.
- GSS' patent portfolio together with its experience and knowledge provides protection from competitors copying its techniques and competitive advantages.



## SUMMARY

- **EasyScreen™ Respiratory & Enteric Pathogen Detection Kits** provide **faster & more accurate screening** for viral, bacterial and protozoan pathogens – **tests are processed in hours instead of days, with fewer false positives and negatives**
- Products already available in Australia with GSS set to launch into global markets worth US\$1.11 billion in 2012 growing to **US\$1.77 billion in 2017**
- **Established operations in key global markets** of Western Europe and the US over the past year, including appointment of experienced management team
- **Experienced management team and board** with track record in global molecular diagnostics industry
- The 3Base™ platform and products are protected by a **strong patent portfolio** - broad patent protecting the 3Base™ technology platform until 2024, and a more specific patent protecting the use of 3Base™ in each of the Company's products until 2031



## MILESTONES - SNAPSHOT

### Achieved – CY 2015

- IPO
- Continued sales growth of enteric product line
- Initial Revenues generated from second product line – Respiratory

### To lookout for – balance of CY 2015

- Continued sales growth
- Additional EU distributorships
- Release of third product line – MRSA (“Golden Staph”)
- Initial US Revenues targeted around end CY2015



**CONTACT:**

**John Melki**

**Chief Executive Officer**

**john@geneticsignatures.com**

**T: +61 2 9870 7580**

**www.geneticsignatures.com.au**