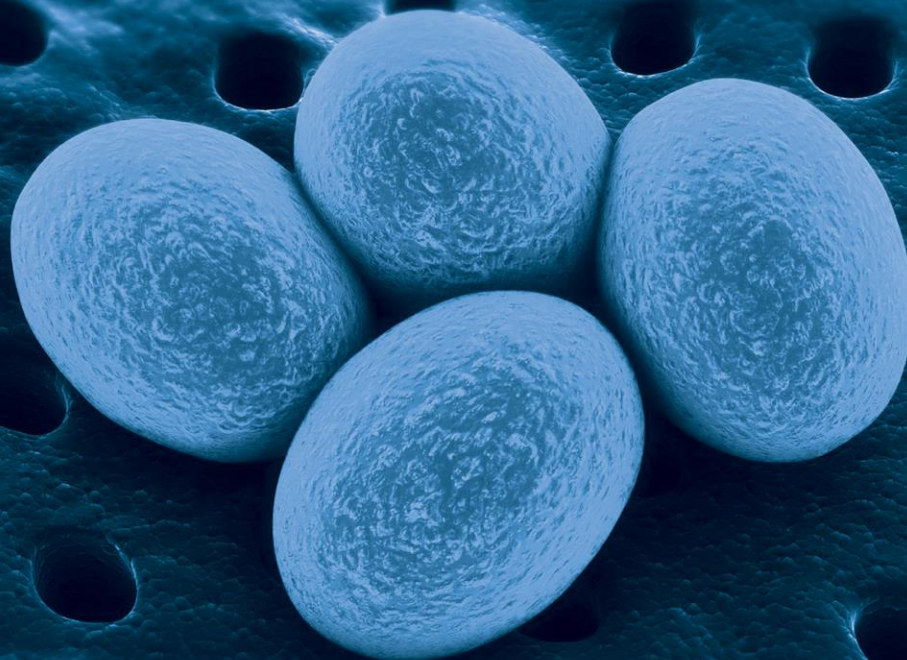


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# Genetic Signatures

Bioshares Presentation July 2015



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## THE GSS IPO EXPERIENCE:

- Why IPO?
- Who to Use?
- Once in...
- Take 2



## 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>\$32.8m</b>
Share Price (at market close 17 July, 2015)	<b>\$0.45</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

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## 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

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

### METHODS:

Primary focus of this study was to assess the clinical utility of *EasyScreen*™ 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> ™	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*™ versus Traditional Methods

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## 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



## 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>2</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> Seeplex 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 96-well PCR instrumentation

Source: Company



# EASYSSCREEN™ PRODUCT DEVELOPMENT PATHWAY

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## 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



## 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

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## 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

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## 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

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