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Transforming Molecular Diagnostics

Genetic Signatures is a molecular diagnostics (MDx) company operating in the global IVD (*in vitro* diagnostics) industry with new technology in infection control.

Our primary focus is the development and supply of world leading diagnostic solutions to hospitals and pathology laboratories globally for rapid detection and treatment of infectious diseases.



# **Corporate Summary**

Capital Structure	
ASX Code	GSS
Shares on Issue	72.9m
Market Capitalisation	\$34m
Share Price (at market close 22 September, 2015)	\$0.49
Cash at June 30	\$5.46m

1	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
	Tony Radford – appointed 15th September 2015	Non-Executive Director



## 2015 Highlights

### **Financial Growth**

- Completed oversubscribed Initial Public Offering (IPO) to raise \$7.5 million and list on the Australian Securities Exchange (ASX)
- Achieved greater than \$1 million in annual sales revenue for the first time in the history of the Company
- Diagnostic kit sales revenue increase of 65% on prior year
- Australian hospitals and laboratories performed GSS' *EasyScreen*™ tests more than 50,000 times in FY15
- First molecular diagnostic kits sales to a major national commercial pathology provider.
  - First molecular diagnostic kit sales into Europe achieved
  - Includes EU product revenue and continued sales growth of enteric product line in Australia



### 2015 Financial Results

		30 June 2015 \$	30 June 2014 \$	% Increase (decrease)		
	Revenue from continuing operations	1,043,269	684,277	52.5%		
	Net loss from ordinary activities after tax attributable to shareholders	(2,659,120)	(1,728,487)	(53.8)%		
	Net loss for the period attributable to shareholders	(2,659,120)	(1,728,487)	(53.8)%		
	Losses per share (cents per share)	(5.2)	(12.1)	57.0%		
ツ コ 	Net tangible assets (cents per share)	10.8	6.0	80.0%		



### **FY15 Results Overview**

- 52.5% increase in operating revenue to \$1,043,269
- -or personal use only A number of significant non-recurring costs were paid in FY2015 and will not have any further impact on cash flow, including \$515,000 related to the Company's IPO and \$165,000 for capital equipment required to increase product development throughput in the R&D laboratory





# 2015 Operational Highlights

### **Global Market Reach Expansion**

- US subsidiary, Genetic Signatures US Ltd incorporated and its US team expanded
- Established first European sales channel partnerships with distributors for the regions of Italy and Israel

### **Product Range Expansion**

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- Moved into new state of the art premises, allowing for increased product development
- Completed first domestic customer site installation of EasyScreen™
  Respiratory Virus Detection Kit for beta-testing
- First sales of EasyScreen™ Respiratory Virus Detection Kit



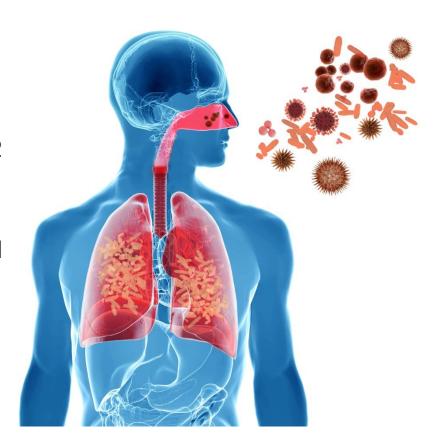
# Genetic Signatures Transforming Global Molecular Diagnostics





### **Company Overview**

- Genetic Signatures provides diagnostic solutions for rapid pathogen detection
- Products already available in Australia and now launching into large global markets, worth **US\$1.11 billion** in 2012 growing to US\$1.77 billion in 2017
- or personal use Proprietary technology driving product development for pathology and hospital customers globally in multiple markets
  - Experienced management team and board with track record in global molecular diagnostics industry





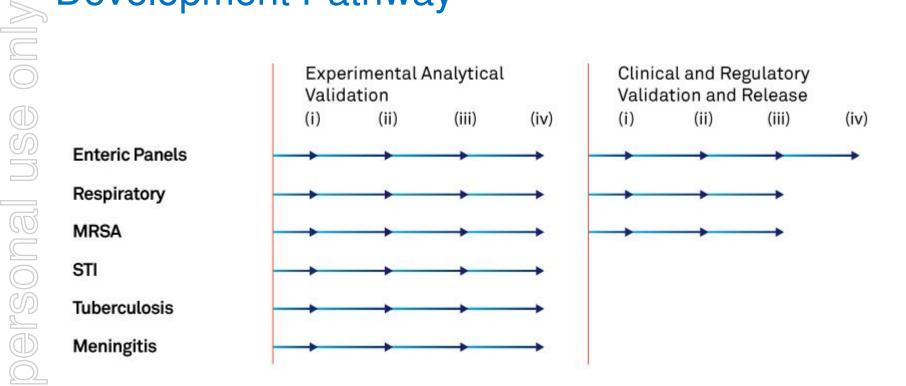
### Technology – 3Base™

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

- or personal use Genetic Signatures 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

# Genetic Signatures

# EasyScreen™ Product Development Pathway



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



Competitive Advantage

 GSS is unique in supplying products that screen over 20 pathogens, including RNA and DNA viruses, in a probe based real-time format

Uses latest technology compatible with existing equipment (open platform)

- Ease of use and automation
- Rapid time to result (<5hrs)</li>

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- High Volume laboratories accommodated
- Separate endogenous extraction and inhibition controls
- Viral, bacterial and protozoan coverage
- Cost effective kits supply
- Ongoing global support





# Global Growth Strategy





### FY16 Activities and Growth

- Expansion of *EasyScreen*™ product range with anticipated commercial release of
  - New Respiratory panel that includes bacterial targets and increases throughput.
  - MRSA assay (otherwise known as 'Golden Staph')
  - Anticipated significant revenue increases from both the addition of new customers from various international markets and expansion of *EasyScreen*™ product menu
- personal use Increasing activity in Europe to support distributors and increase distributor network
  - Anticipating first commercial sales in the USA



## 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
- Dr Tony Radford joins Board of Directors

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### Commercialisation Progress - Europe

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

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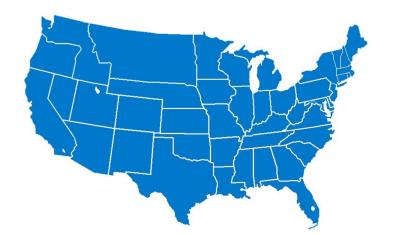
- Increased European sales
   channel partnership network by
   signing distribution agreements
   with partners for the regions of
   Poland and Ireland
- In discussions with distributors in other jurisdictions





## Commercialisation Progress - United States

- Established operations in 2014 with appointment of key personnel
- Anticipate entering market in 2015In FY15 GSS achieved first regulatory step towards full product suite commercialisation in the US with receipt of a United States Food and Drug Administration (FDA) listing for a clinical sample concentrator. The FDA listing means that the Company can legally sell its EasyScreen™ Sample Processing Kit in the US
- Appointment of Pat Noland, to head up Commercial Operations



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### Summary

- rise only 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
  - The 3Base™ platform and products are protected by a **strong patent** portfolio - broad patent protecting the 3Base™ technology platform until 2031
- or personal Products already available in Australia with GSS having launched 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 Europe and the US over the past year
  - **Experienced management team and board** with track record in global molecular diagnostics industry

