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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 16 October, 2015)	\$0.465
Cash at June 30	\$5.46m

Directors & Chief Executive	
Nick Samaras	Non-Executive Chairman
John Melki	Director & CEO
Mike Aicher	Executive Director - US
Phillip Isaacs	Non-Executive Director
Tony Radford – appointed 15th September 2015	Non-Executive Director



## **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 and Perkin Elmer
- NHMRC Research Committee member 2006-12, Adjunct Professor La Trobe University, Founder of consulting firm Australia 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 five 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 \$1 billion in annual revenue
- Director on boards of Kinetic Diagnostics Inc and Omicia, Inc



## **Board and Management**

## Tony Radford- Non-Executive Director BSc (Hons), PhD

- Former CEO of Cellestis from founding until its acquisition by QIAGEN NV in 2011 for approximately \$400 million
- Previous Head of Development in 2000 at AMRAD in pharmaceutical research
- 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
- Established offices and operations in the USA, Europe and Japan, Cellestis developed QuantiFERON
   TB Gold, the worldwide benchmark for the diagnosis of tuberculosis infection

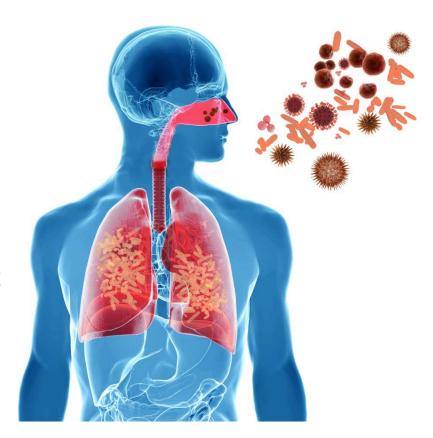
## **Phillip Isaacs - Non-Executive Director** *MSc, JP*

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



## **Company Overview**

- Genetic Signatures provides diagnostic solutions for rapid pathogen detection
- Proprietary technology driving product development for pathology and hospital customers globally in multiple markets, with IP protection to 2031
- 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
- Experienced management team and board with track record in global molecular diagnostics industry



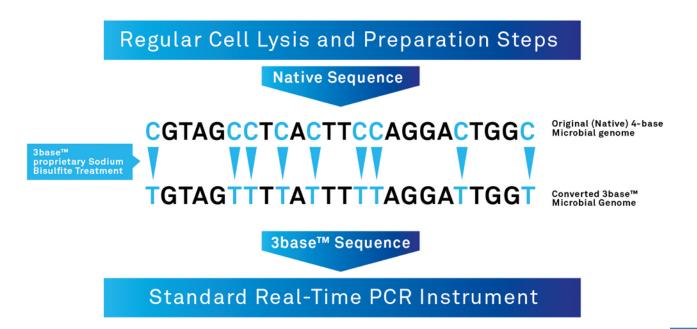


## Technology - 3Base™

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™





## Technology - 3Base™

- 3Base™ improves subtype similarity and reduces variation, allowing easier PCR design
- 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

e.g. Non-Converted Influe	nza Sequences		3base <sup>™</sup> Converted Influer	nza Sequences	
Influenza A virus H5N1	TGTGTGTCCA	GGGATAATTG	Influenza A virus H5N1	TGTGT <mark>G</mark> T <mark>T</mark> TA	GGGATAATTG
Influenza A virus H7N3	TGTATATGTA	GGGA <mark>C</mark> AATTG	Influenza A virus H7N3	TGTATATGTA	GGGATAATTG
Influenza A virus H5N8	TGTGTTTGTA	G <mark>A</mark> GA <mark>C</mark> AA <mark>C</mark> TG	Influenza A virus H5N8	TGTGTTTGTA	GAGATAATTG
Influenza A virus H5N3	TGTATATGTA	GGGA <mark>C</mark> AATTG	Influenza A virus H5N3	TGTATATGTA	GGGATAATTG
Influenza A virus H5N2	TGTGTTTGCA	GAGATAATTG	Influenza A virus H5N2	TGTGTTTGTA	GAGATAATTG
Influenza A virus H6N6	TGCATTTGCA	GGGACAATTG	Influenza A virus H6N6	TGTATTTGTA	GGGATAATTG
Influenza A virus H2N9	TCCACTTGCA	GGGATAATTG	Influenza A virus H2N9	TTTATTTGTA	GGGATAATTG
Influenza A virus H6N5	TGCGTTTGCC	G <mark>A</mark> GATAATTG	Influenza A virus H6N5	TGTGTTTGT <mark>T</mark>	GAGATAATTG
Consensus	TSYRYDTSYM	GRGAYAAYTG	Consensus	TKTRTDTKTW	GRGATAATTG
	768 Possible com	binations		24 Possible comb	inations
	55% Homology			80% Homology	

- 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 trials showed superior performance vs. Digene HC2 assay in reducing false positives
- 3Base<sup>™</sup> delivers greater Sensitivity and Specificity



## 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
- 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



## **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)
- Genetic Signatures' gastroenteritis 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
- Genetic Signatures' product pipeline includes tests for Bacterial Respiratory Infections, MRSA (Golden Staph), meningitis, TB and STI's



# Genetic Signatures Transforming Global Molecular Diagnostics





## *EasyScreen*™ Testing Kits

- GSS' suite of EasyScreen<sup>™</sup> products are used by major hospitals in Australia for detection of infectious diseases – 55,000 tests were sold and used in FY15
- 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<sup>™</sup> 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

## Case Study: St Vincent's Hospital Evaluation Study



- EasyScreen™ vs. Traditional Methods

#### **METHODS:**

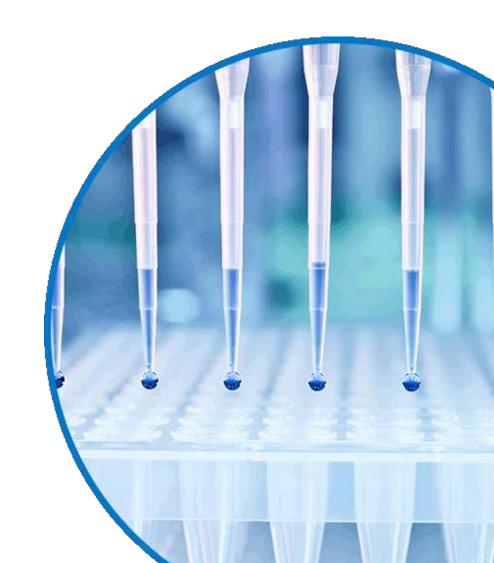
- Primary focus of study was to assess the clinical utility of EasyScreen<sup>™</sup> in detecting infectious agents in 221 patient samples as compared to traditional methods of culture, microscopy and antibody based tests
- Identified 44 infections that existing testing would have missed
- Missed infections 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
Total	53	97



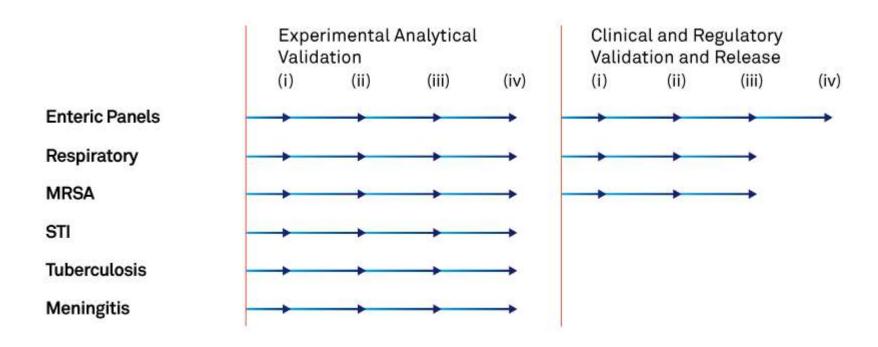
"I find that the fast turnaround time and the number of targets tested in the *EasyScreen*™ assays allow me to more rapidly identify highly infectious agents, potentially stopping the spread to other healthy individuals and thereby saving the health system money."

- Dr Damien Stark



## 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>
- 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





## 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
   55,000 times in FY15
- First molecular diagnostic kits sales to a major national commercial pathology provider.
- First molecular diagnostic kit sales into Europe achieved



## 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%
Net tangible assets (cents per share)	10.8	6.0	80.0%



## **FY15 Results Overview**

 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**

- 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<sup>™</sup> Respiratory Virus Detection Kit



## 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





## Commercialisation Progress - Europe

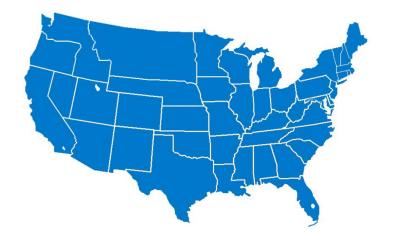
- Established operations in 2013
- Signed Italian distributor and testing with large pathology laboratories, recurrent revenues commencing
- Signed Israeli distributor agreement
- Increased European sales channel partnership network by signing distribution agreements with partners for the regions of Poland and Ireland
- In discussions with distributors in other jurisdictions





## Commercialisation Progress - United States

- Established operations in 2014 with appointment of key personnel
- In 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 in September
- Anticipate entering market in FY15





## 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
- The 3Base<sup>™</sup> platform and products are protected by a strong patent portfolio - broad patent protecting the 3Base<sup>™</sup> technology platform until 2031
- 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

