
Genetic Signatures
2015 AGM Presentation

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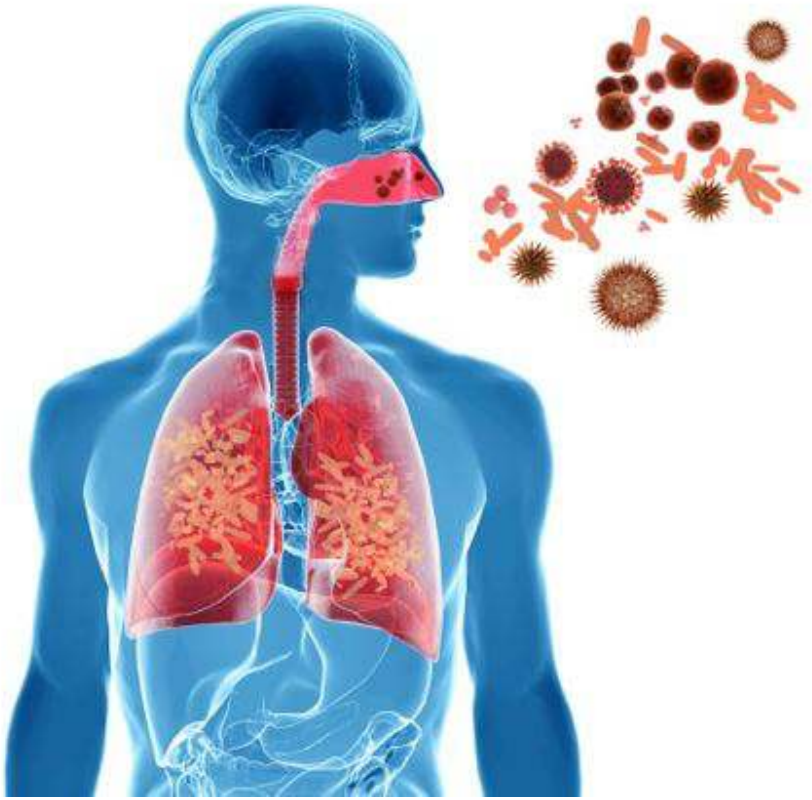
Transforming Molecular Diagnostics

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.

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



Corporate Summary

Capital Structure	
ASX Code	GSS
Shares on Issue	72.9m
Market Capitalisation	$38m
Share Price (at market close 6 November, 2015)	$0.525
Cash at 30 September 2015	$5.47m

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 (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 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

- 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 Cytyc Corporation which developed and sells the ThinPrep Pap
- Founding Chairman of the Australian Proteome Analysis Facility (APAF) in Sydney

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 - **revenue for FY15 up 52% to $1,043,269**
- Diagnostic kit sales revenue increase of 65% on previous year
- **September quarter diagnostic kit sales $442,000 up 44.3% on previous quarter and 138% increase on corresponding 2014 quarter**
- Australian hospitals and laboratories performed GSS *EasyScreen™* tests 55,000 times in FY15
- First molecular diagnostic kits sales to a major national pathology provider
- **First molecular diagnostic kit sales into Europe achieved**
- Government Research Grant received $968,000
- Cash at September 30, $5,472,000

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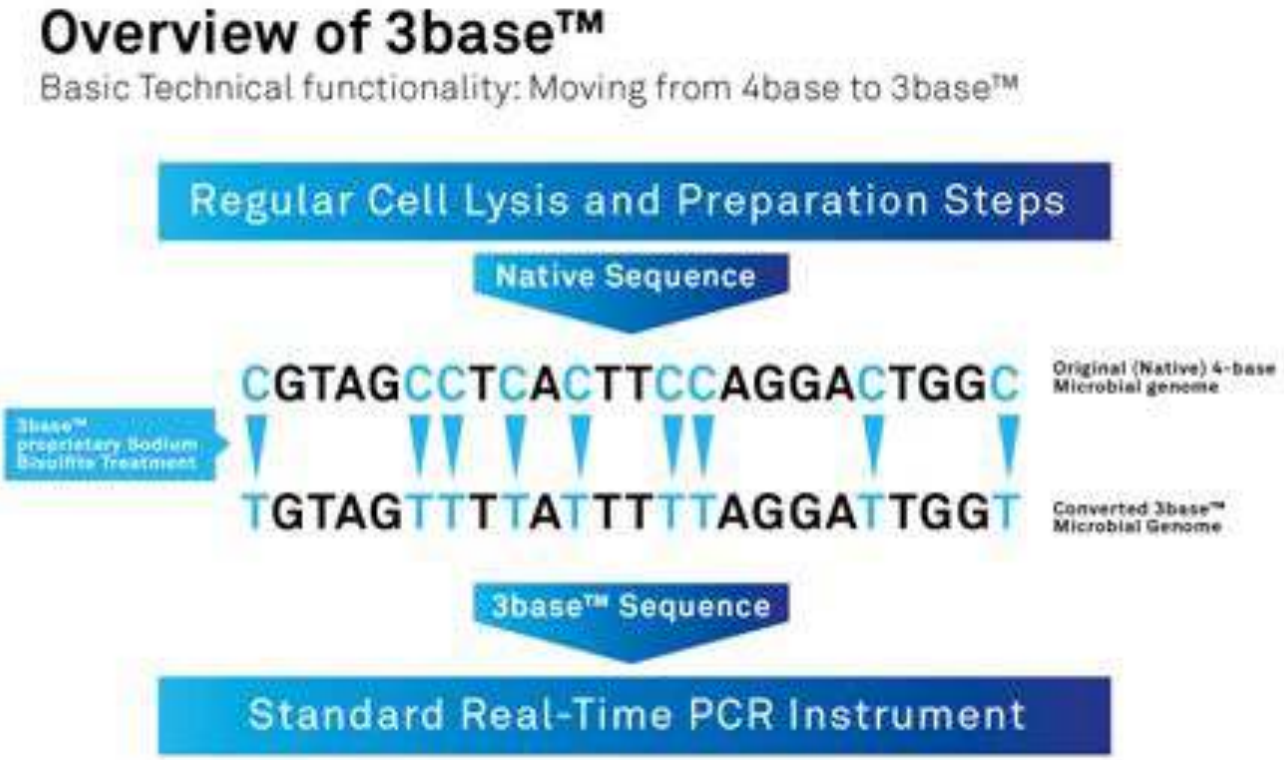
Transforming Global Molecular Diagnostics

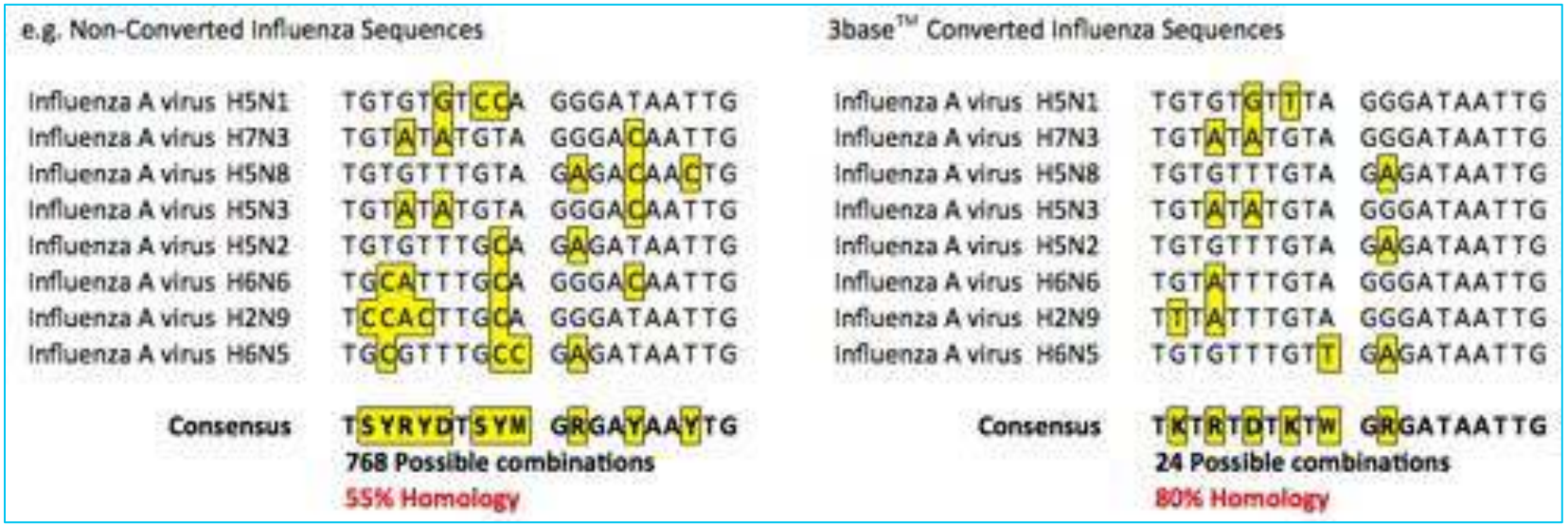
Technology - *3Base*™

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



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**



- 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™* 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. Other tests being evaluated, eg Ebola

EasyScreen™ Testing Kits

- GSS' suite of *EasyScreen*™ 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™* 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

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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 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**

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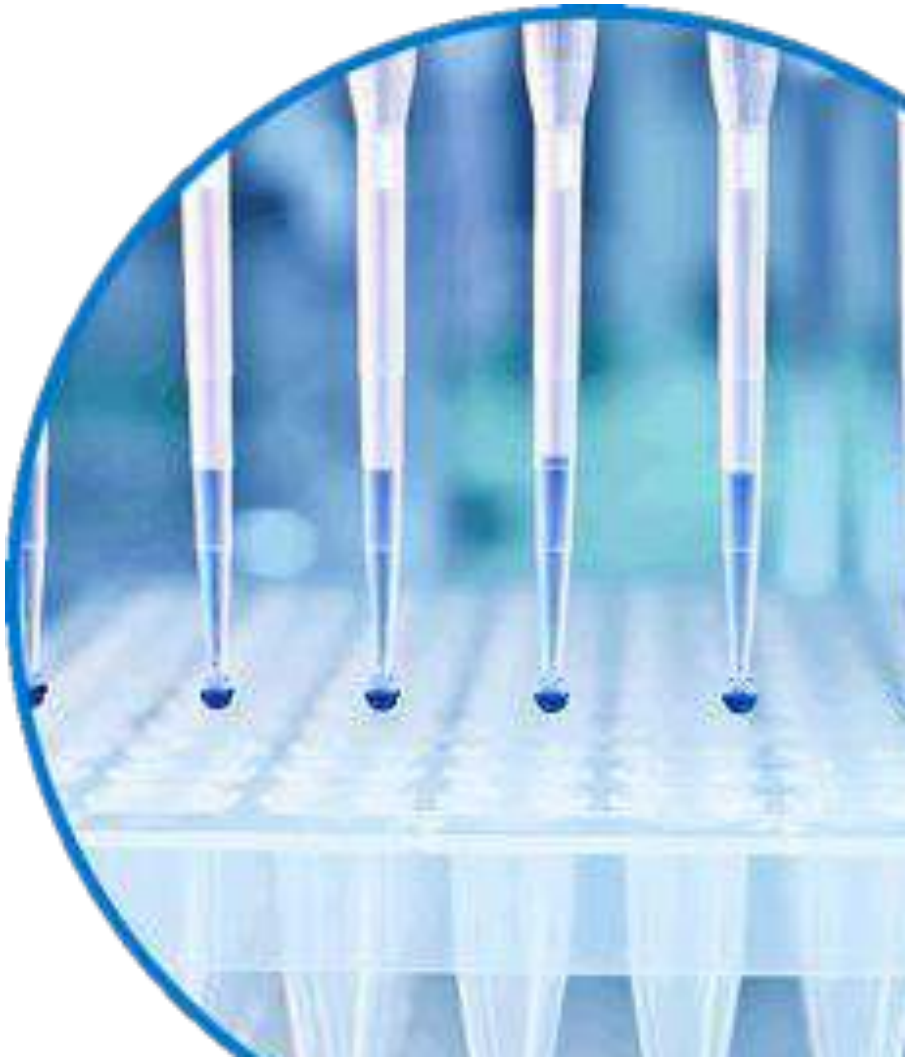
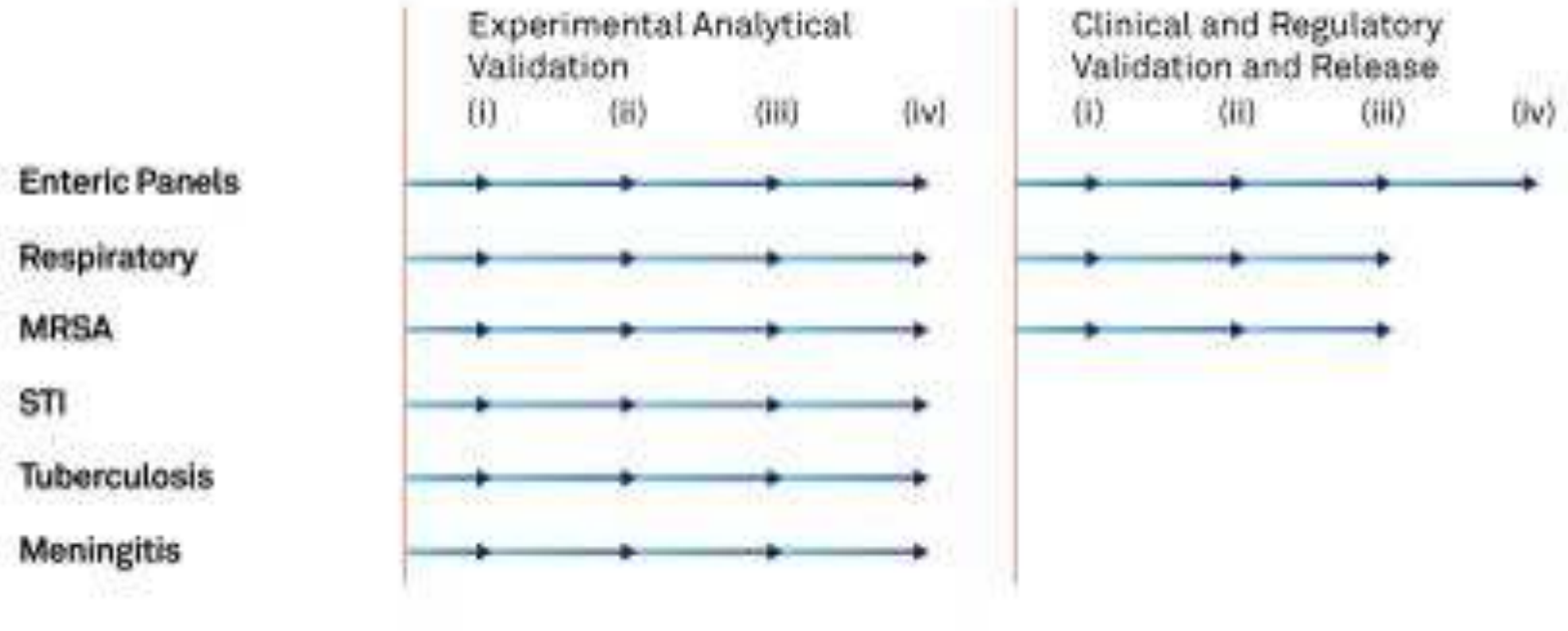
“I find that the fast turnaround time and the number of targets tested in the *EasyScreen*™ assays allow me to more rapidly identify highly infectious agents, potentially stopping the spread to other healthy individuals and thereby saving the health system money.”

- Dr Damien Stark



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)
- 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 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™* Respiratory Virus Detection Kit

Commercialisation Progress - Australia

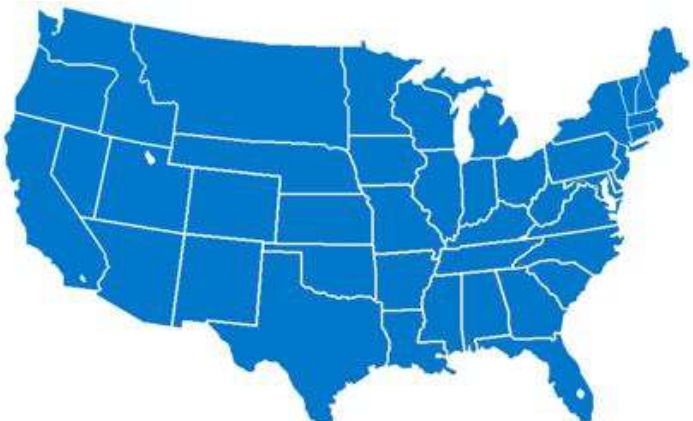
- Currently in market with major hospital and pathology group customers
- Australian hospitals and laboratories performed GSS EasyScreen™ tests ~55,000 times in FY15
- Testing for 22 causes of gastroenteritis
- Testing for 15 causes of viral respiratory disease
- Next new product in beta testing with customer
- Dr Tony Radford joined 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
- **University of California Los Angeles to collaborate with Genetic Signatures on transformative molecular platform technology**



Immense US Market Potential

- US has 5,686 registered hospitals
  - Over 900,000 staffed beds
  - Over 35 million admissions

- *3Base™* 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"

- 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 research Genetic Signatures' technology
  - Patient outcome studies – define superior patient care through implementation of broad pathogen screening protocols
  - Head-to-Head comparison between *3Base™* assays and traditional methods and available molecular alternatives
  - Overall cost of care economic benefit of *3Base™* technology implementation

- Engaged with leading US commercial laboratories and hospital systems to introduce *3Base™* technology
  - Evaluate *3Base™* versus traditional 4 base molecular performance
  - Evaluate widespread adoption of molecular methods versus traditional methods

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™ platform and products are protected by a patent portfolio - **protecting the 3Base™ 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

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