



Genetic Signatures

Capital Raising Presentation – September 2016

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Company Overview

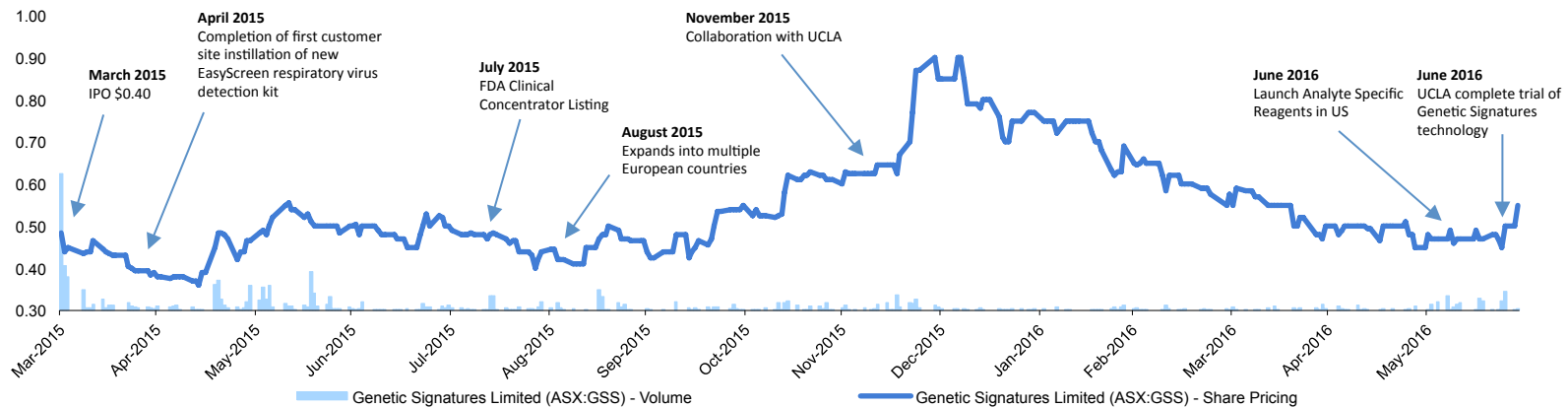
- Genetic Signatures Limited (GSS) designs and manufactures proprietary molecular diagnostic test solutions for **rapid and specific identification of diseases and infections**
- GSS fully owns its proprietary molecular 3Base™ technology with **multiple patents issued, expiring 2031**
- Products led by CE-IVD marked *EasyScreen*™ Gastrointestinal (Enteric) tests are currently delivering rapidly **growing revenues in Australia** and from FY17 within Europe and the USA
- **FY16 sales revenue up 75% to A\$1.83m – 92% 3 year CAGR**
- *EasyScreen*™ tests are currently sold into Australian labs and launching into global markets, with an addressable global market estimated to be **US\$2.1 billion in 2017**
- **Large pipeline** of new commercial molecular diagnostic tests, to quickly drive further revenues and shareholder value
- Targeting pathology and hospital laboratories in multiple global markets, leading to a **scalable business with high gross margins**
- **Experienced management team and board** with track record in global molecular diagnostics industry and having delivered shareholder returns in the past (Cellestis Limited acquired by QIAGEN for ~A\$400m in 2011)

Corporate Summary

Financial Information (A\$)	
ASX Code	GSS
Shares on Issue	72.7m
Market Capitalisation	\$37.0m
Share Price (at market close 30 August 2016)	\$0.51
Cash at 30 June 2016	\$2.6m

Top Shareholders	%
Asia Union Investment Pty Limited	50.6%
DAK Drafting Services Pty Ltd	2.7%
UBS Nominees Pty Ltd	2.4%
Directors, Management and Advisors	9.0%

Share Price Performance



Capital Raising Details

- Genetic Signatures has raised \$14m via a Two Tranche Placement to institutional and sophisticated investors with a Share Purchase Plan to raise a further \$1m to follow
- The Placement was oversubscribed with strong support from offshore specialist healthcare investors and domestic institutional investors
- Offer price \$0.47 represents a discount of 7.8% to last close and a discount of 9.6% to 30 day VWAP

Post-transaction capital structure	Amount of shares
Existing capital	72,674,407
Tranche I Placement shares	10,901,161
Tranche II Placement shares	18,886,074
Share Purchase Plan shares*	2,127,660
Total	104,589,302

*Assumes SPP fully subscribed

Use of funds	(\$A'000's)
Australian commercial expansion	\$824
EU commercial expansion	\$1,373
US commercial expansion	\$2,075
Regulatory approvals, USA, FDA	\$4,066
Product development pipeline (R&D)	\$2,150
Future working capital	\$3,667
Costs of the offer	\$845
Total	\$15,000

Capital Raising Timetable

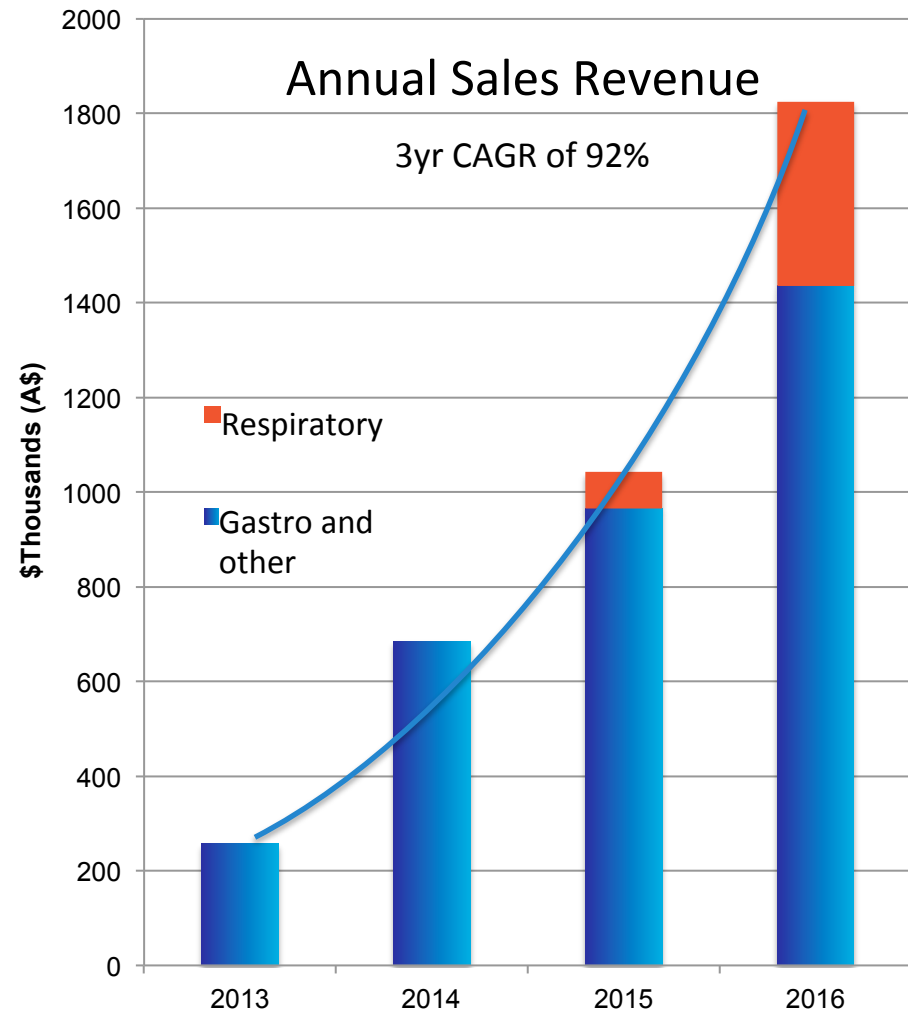
Trading halt	Wednesday, 31 August 2016
Transaction announced & Company resumes trading	Friday, 2 September 2016
Placement Tranche 1 Settlement of new shares	Wednesday, 7 September 2016
Placement Tranche 1 Allotment of new shares	Thursday, 8 September 2016
SPP opens	Friday 9 September 2016
SPP closes	Friday, 23 September 2016
Special meeting of shareholders to consider resolution to approve the issue of Placement Tranche 2 new shares	On or around Monday 10 October 2016
Placement Tranche 2 Settlement of new shares*	On or around Thursday 13 October 2016
Placement tranche 2 Allotment of new shares*	On or around Friday 14 October 2016

(*) Assumes stockholder approval (>50%) is granted at the EGM

The above timetable is indicative only and may be varied subject to the ASX Listing Rules

Recent Achievements

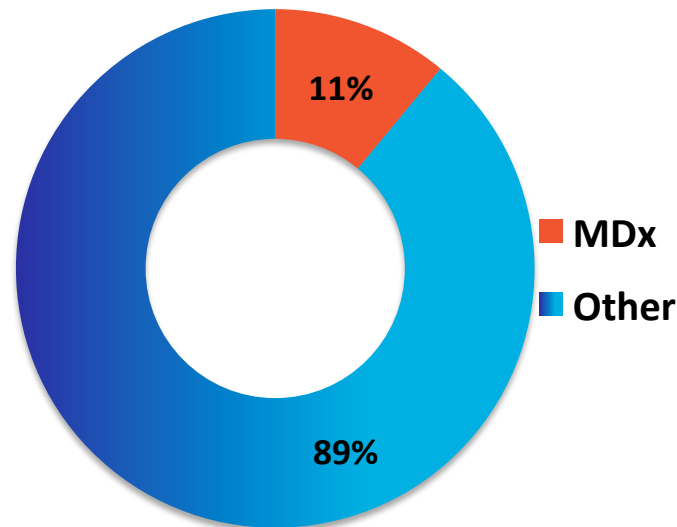
- **Strong sales growth**, with a 3-year CAGR of 92%
- FY16 revenue of A\$1.83M, split ~80% Gastroenteritis, ~20% Respiratory specialist sales
- Advancing R&D development of **5 new diagnostic products**
- **Established direct operations in EU**
- Analyte Specific Reagents (ASRs) **launched in the US** in June 2016
- UCLA **completed product trial and progressing to adopt into routine use**
- GSS now certified for Health Canada, allowing **registration of *in vitro* diagnostics (IVD) products in the Canadian market**



Large and Growing Global Molecular Diagnostics Market

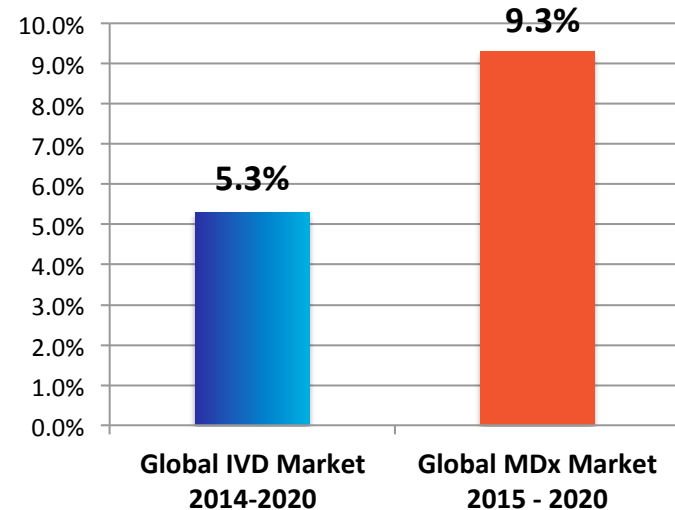
- **Molecular Diagnostics (MDx) Market estimated to be US\$7.6Bn** in 2017 representing 11% of the overall *in vitro* Diagnostics (IVD) market of \$US69.1Bn
- MDx market forecast to grow at an above system CAGR of 9.3% far exceeding the overall IVD market growth, **as MDx techniques replace traditional diagnostics**

Breakdown of US\$69.1Bn Global *in vitro* Diagnostics (IVD) Market as at 2017



Source: In Vitro Diagnostics (IVD) Market . Research and Markets, July 2015

CAGR of the Global IVD Market & Global MDx Market



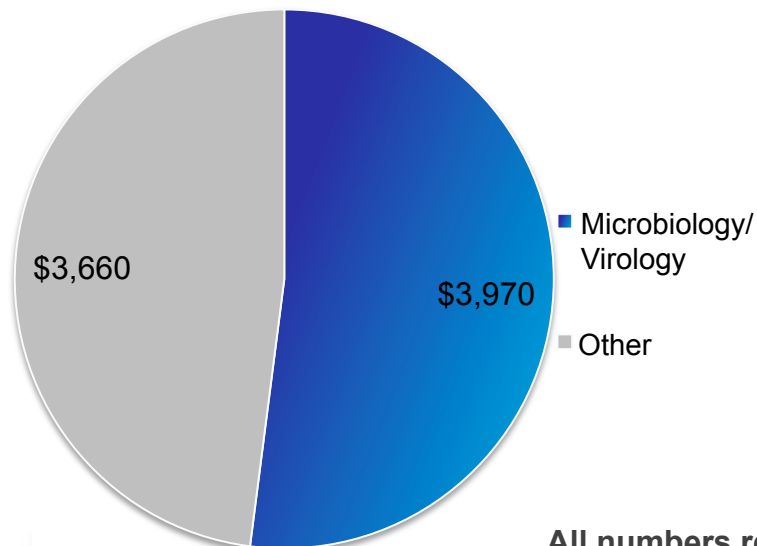
Source: Molecular Diagnostics Market by Application, Forecast to 2020. Markets and Markets, November 2015 and Global In Vitro Diagnostics (IVD) Market Forecast 2013-2020. Allied Market Research, June 2014

MDx growth expected to drive IVD market demand

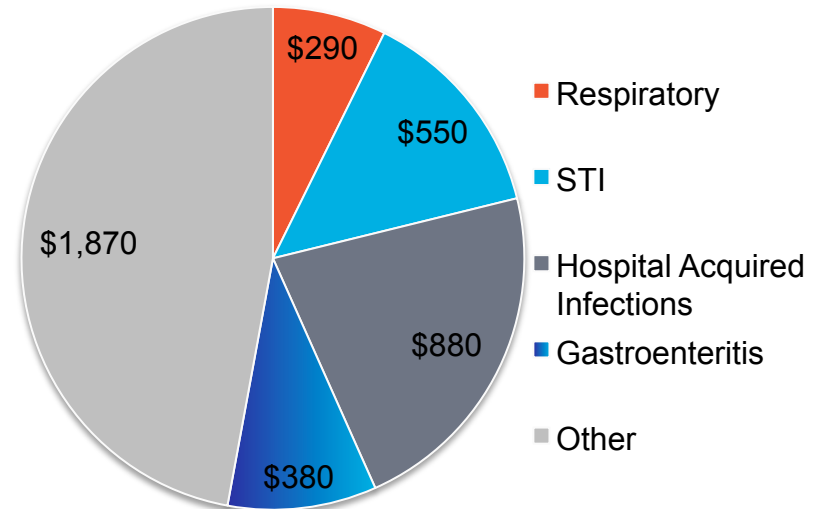
Large addressable markets

- Genetic Signatures' (GSS) current diagnostics products and pipeline products account for >50% of microbiology/virology diagnostics segment, representing what was a total **addressable market of \$US1.11Bn in 2012**
- This segment is estimated to be worth **US\$2.1Bn by 2017**

2017 Estimate of Microbiology/Virology segment of global \$US7.6Bn MDx market



2017 Estimate of GSS Microbiology/Virology Addressable Market of US\$2.1Bn

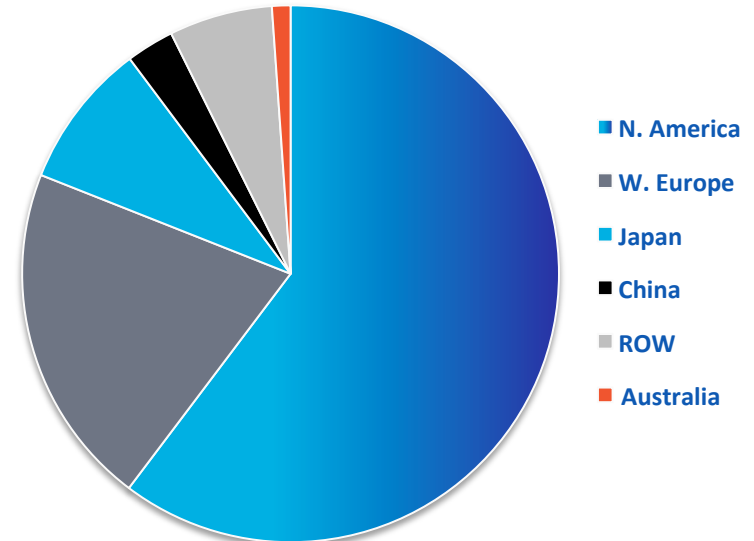


All numbers refer to US\$M

Regulatory approvals already gained in large portion of US\$7.6Bn global market - driving revenue

- **Full regulatory approval for ~22% of the global market** in Gastroenteritis testing, with partial approval (Clinical Concentrators, Analyte Specific Reagents) in the USA
- Validation of company strategy with revenues ramping quickly following approvals (see slides 5 and 20); European & North American revenues expected to contribute in FY17
- Further molecular diagnostic approvals sought for new products in key global markets, driving further revenue in other product categories - driving shareholder value
- Multiple products and multiple jurisdictions are de-risking the commercialisation process

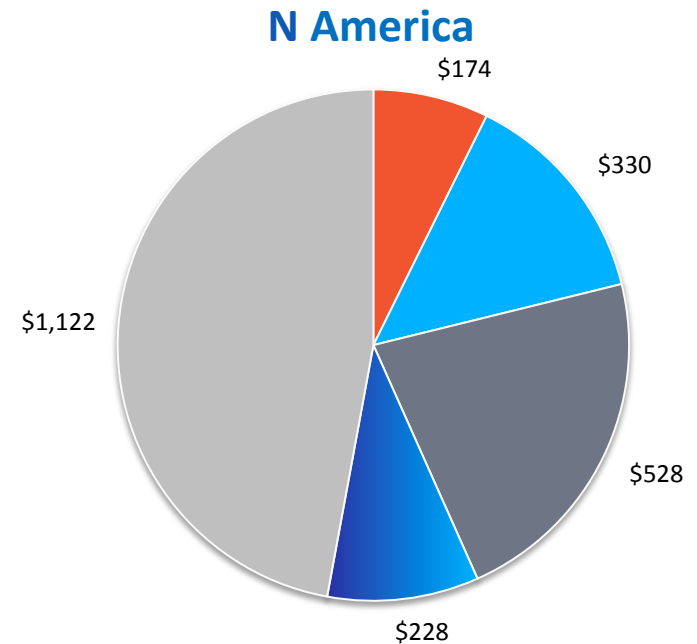
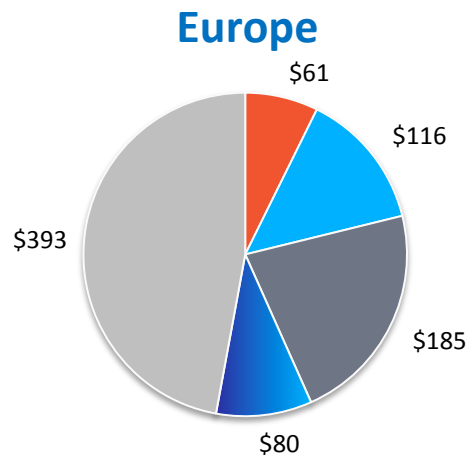
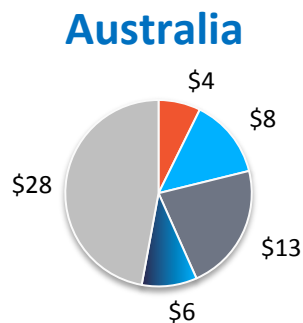
2017 Estimate MDx Market Size by Region (USD)



Source: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 94 .

Significant Offshore Opportunity

- Strong revenue growth in Australia validates commercial potential of products in offshore markets
- Enteric products have **full approval in Europe** which is 10-20x Australian market
- Specialist clinical sales of Enteric ASR tests into N. America commencing in FY17
- Specialist respiratory sales commenced in Australia (~20% of FY16 revenue) with imminent availability in the US



■ Respiratory
 ■ STI
 ■ Hospital acquired infections
 ■ Gastroenteritis
 ■ Other

All numbers refer to US\$M

Experienced 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 seven 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 US\$1 billion in annual revenue
- Director on boards of Kinetic Diagnostics Inc and Omicia, Inc

Experienced Board and Management

Tony Radford, AO - 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

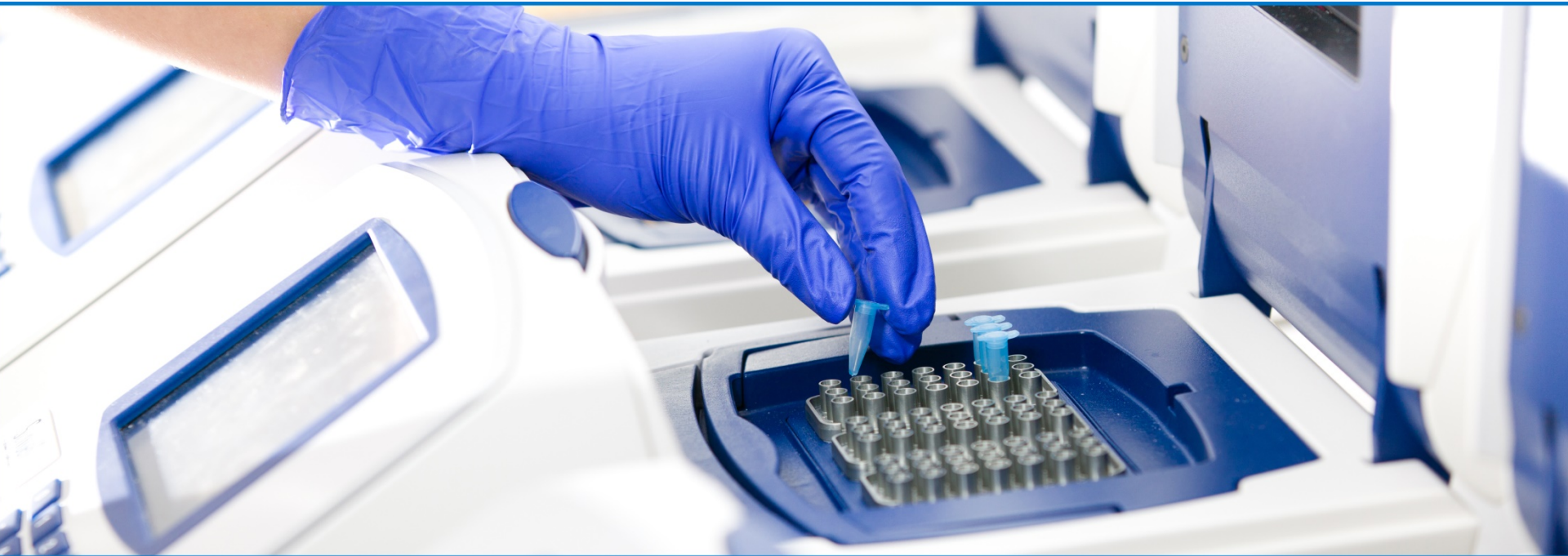
Phillip Isaacs - Non-Executive Director

MSc, JP

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

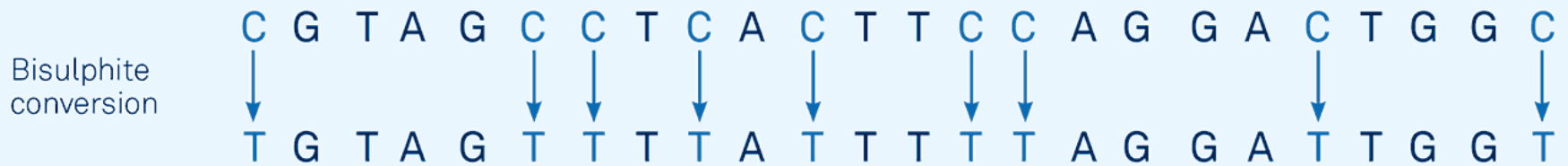
Genetic Signatures

Transforming Global Molecular Diagnostics



Unique 3Base™ Technology

3base™ Mechanism



- GSS' unique 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
- The conversion occurs during standard procedures and there are no additional steps for the end user

Technology - 3Base™

- **Massive reduction in complexity**
- 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**
- **Reduces complexity by 97% yet maintains or increases accuracy**

	Before	After
Seq 1	G A T G G <u>C</u> G A <u>T</u> A T G G T <u>T</u> G A <u>C</u> A <u>C</u>	G A T G G T G A T A T G G T <u>T</u> G A T A T
Seq 2	G A T G G <u>T</u> G A <u>C</u> A T G G T <u>A</u> G A <u>T</u> A <u>C</u>	G A T G G T G A T A T G G T <u>A</u> G A T A T
Seq 3	G A T G G <u>T</u> G A <u>T</u> A T G G T <u>G</u> G A <u>C</u> A <u>C</u>	G A T G G T G A T A T G G T <u>G</u> G A T A T
Seq 4	G A T G G <u>T</u> G A <u>T</u> A T G G T <u>A</u> G A <u>T</u> A <u>T</u>	G A T G G T G A T A T G G T <u>A</u> G A T A T
Seq 5	G A T G G <u>T</u> G A <u>T</u> A T G G T <u>G</u> G A <u>C</u> A <u>C</u>	G A T G G T G A T A T G G T <u>G</u> G A T A T
Seq 6	G A T G G <u>C</u> G A <u>C</u> A T G G T <u>T</u> G A <u>T</u> A <u>T</u>	G A T G G T G A T A T G G T <u>T</u> G A T A T
Seq 7	G A T G G <u>T</u> G A <u>T</u> A T G G T <u>G</u> G A <u>C</u> A <u>C</u>	G A T G G T G A T A T G G T <u>G</u> G A T A T
Seq 8	G A T G G <u>T</u> G A <u>C</u> A T G G T <u>A</u> G A <u>T</u> A <u>C</u>	G A T G G T G A T A T G G T <u>A</u> G A T A T
Seq 9	G A T G G <u>T</u> G A <u>T</u> A T G G T <u>A</u> G A <u>T</u> A <u>C</u>	G A T G G T G A T A T G G T <u>A</u> G A T A T
Seq 10	G A T G G <u>T</u> G A <u>T</u> A T G G T <u>G</u> G A <u>T</u> A <u>C</u>	G A T G G T G A T A T G G T <u>G</u> G A T A T
Consensus	G A T G G <u>Y</u> G A <u>Y</u> A T G G T <u>D</u> G A <u>Y</u> A <u>Y</u>	G A T G G T G A T A T G G T <u>D</u> G A T A T
	75% homology over 20 bases	95% homology over 20 bases
	48 possible primer combinations	3 possible primer 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 trial showed superior performance vs. Digene assay in reducing false positives (J. Clin. Virol. 42:22-6. 2008)
- 3Base™ delivers greater Sensitivity and Specificity, in a rapid assay

EasyScreen™ Testing Kits

- GSS' suite of *EasyScreen*™ products are being adopted **by major hospitals & pathology laboratories in Australia** for detection of infectious diseases
- Products work 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**
- 1mL product volume is sufficient for 50 individual tests, driving an attractive and operationally leveraged business model
 - Scalable manufacturing, not limiting growth
- **First Products to Market**
 - Enteric Pathogen Detection Kit detects up to **22 gastroenteritis pathogens, including viral, bacterial and protozoan agents**
 - Respiratory Pathogen Detection Kit detects up **to 15 of the most common respiratory infections**

Case Study:

St Vincent's Hospital Evaluation Study

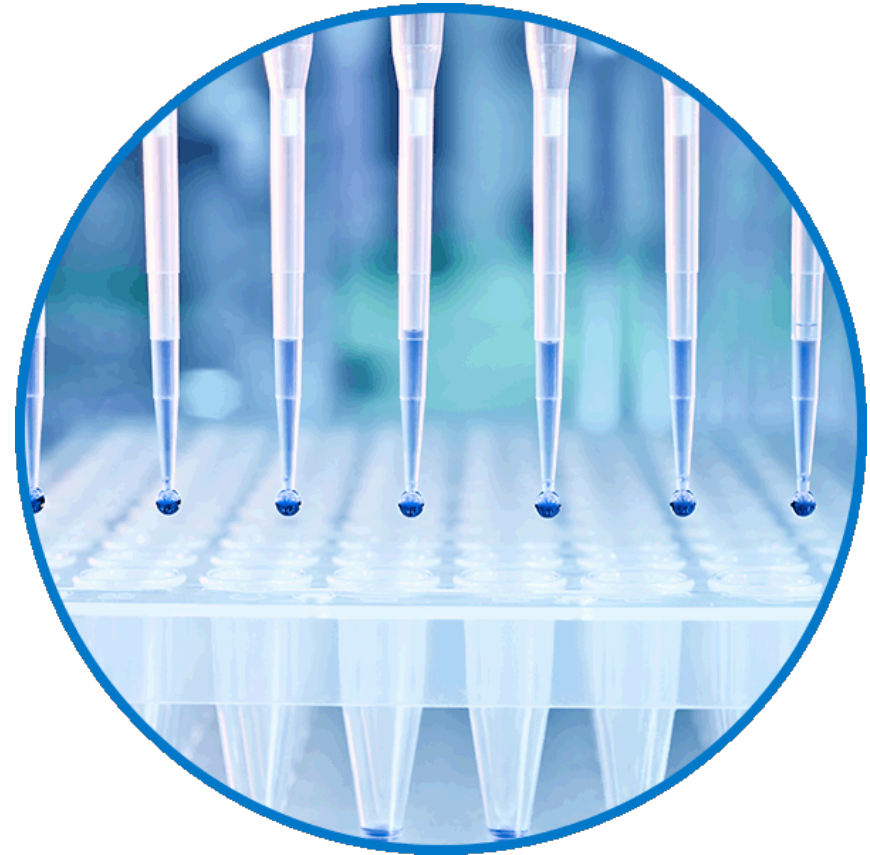
- *Powerful evidence of efficacy*

- 221 patient samples compared to traditional culture, microscopy and antibody based tests
- Results in 4 hours**, compared to up to 120 hours for traditional
- Identified 44 infections that existing testing missed – 83% more than traditional testing**
- Missed infections have substantial downstream consequences, such as 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,
KOL and Senior Microbiologist, St. Vincent's
Hospital Sydney



Advantages of 3base™ Technology

Significant benefits to the health system

Patient

- Patients receive more accurate test results
- Faster turn around time; 4-5 hours vs 4-5 days under existing methods
- Improved efficacy and breadth of infection detection leading to improved patient experience

Pathology Groups / Hospitals

- Cost savings due to decreased time spent evaluating samples
- Delivers greater sensitivity and specificity
- More results per patient specimen
- Reduces complexity in molecular testing
- Common workflow between tests
- Compatible with existing equipment i.e. no CAPEX requirement
- Point of differentiation

Government

- Reduce hospital stays through more effective infection detection
- Fast turnaround time allows rapid detection and reduces spread of infectious diseases
- Reduced sick leave for nursing staff
- Reduces repeat doctor visits

Minimise work, Maximise results, Drive value


Global Growth Strategy and Commercial Progress



Global Growth Strategy

- Focus on regions with regulatory approvals
 - Australia, Europe and US, together account **for >80% of world MDx market**
- **Extend footprint in both Europe and US**
 - Europe has unique testing and reimbursement strategies – local knowledge is critical
 - Full distributor model in select countries, with local support
 - US growth via direct sales and support
- **Realise early revenue** from specialist products (e.g ASRs in the US)
 - Larger revenues to follow with additional approvals
- Expand product range and complete regulatory approvals for new products
- Prepare first products for FDA approval to achieve full regulatory approvals

Commercialisation Progress - Australia

- Currently in market with major hospital and pathology group customers, including St. Vincent's Sydney and Australian Clinical Labs
 - Driving strong revenue growth for Australian sales, 92% 3yr CAGR
 - FY16 Sales revenue up 75% to AU\$1.83M
 - Revenue split ~ 80% gastroenteritis, 20% respiratory
 - Revenue accounts for 2% of total Australian molecular market (AU\$58M)
 - 6% of Australian addressable molecular market (AU\$31M)
 - **Two new products to be released** in next 6-12 months
 - Australia forms base for EU and US approvals and release
 - Product expansion will drive revenue and market share growth
 - Product development pipeline includes tests for 2nd generation respiratory virus, atypical pneumonia, STIs, antibiotic resistance panel, meningitis and flavivirus (including Zika, Dengue, yellow fever, etc)
- 

Commercialisation Progress - Australia (Cont)

- Dedicated R&D labs and network of clinical partners driving **new product development**
- 4 *EasyScreen*™ products for Gastroenteritis have TGA approval
 - *C. difficile* detection and reflex kits; Enteric Protozoan & Bacterial Kits
- 2 more *EasyScreen*™ kits are being validated for TGA approval
 - Respiratory and Enteric Viral infections
- TGA approved manufacturer
 - dual ISO 9001 and 13485 certifications
 - Approval allows products to come to market quicker
- Dedicated validation team, performing validation experiments for TGA, CE-IVD and FDA
- Anticipate new products and increased market share will drive strong revenue growth

Commercialisation Progress - Europe

- Western European market ~20% of the global molecular diagnostics market
 - **Addressable market of ~US\$435M**
- Targeting first significant recurring revenues in FY17
- Full distributors appointed in Italy, Israel, Poland and Ireland
 - Currently setting up trials and applying for hospital tenders
- 4 *EasyScreen*™ kits have CE-IVD approval
 - *C. difficile* detection and reflex kits; Enteric Protozoan and Bacteria infections



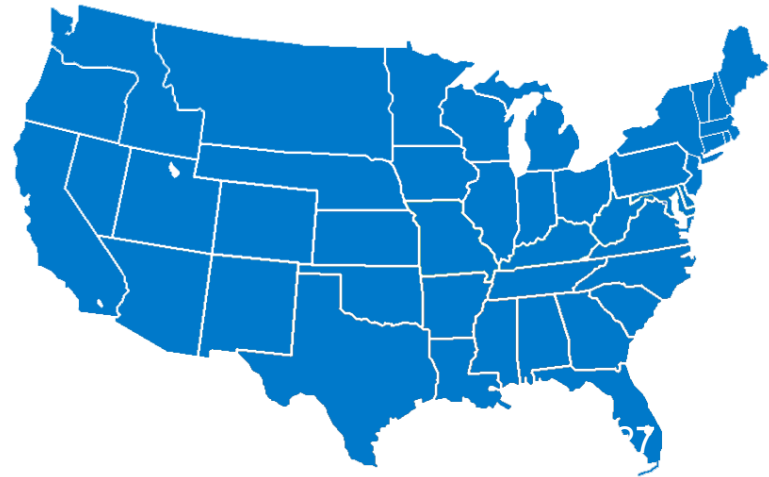
Commercialisation Progress - Europe

- 2 more *EasyScreen*[™] kits are being validated for CE-IVD approval
 - For Respiratory and Enteric Viral infections
- European Director, Sales and Support, appointed, based in the Netherlands
- Establishing direct Sales and Support in Europe
 - Mix of Direct sales and distributors, similar to Cellestis model
- Also providing local support for the existing European distribution network
- Strong client engagement established for upcoming products



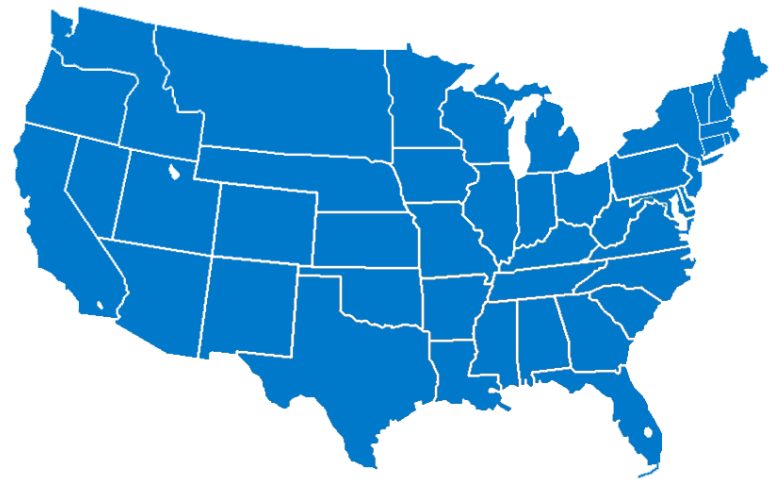
Commercialisation Progress – North America

- US market 50-60% of the global molecular diagnostics market
 - **Up to ~US\$1,265M addressable market**
- Anticipate first sales in FY17
- Direct sales and support model with established and experienced US team
- Early revenue underpinned by US FDA listing for Clinical Sample Concentrator achieved in FY16. *EasyScreen*™ Sample Processing Kits can now be legally sold to laboratories in the US to yield 3base nucleic acids from patient specimens
- **Analyte Specific Reagents (specialist sales) launched in the US at the largest US microbiology conference** (June 2016)
 - further step towards full product suite commercialisation
 - Allows 3base™ products to be sold to **~11,000 CLIA certified laboratories**



Commercialisation Progress – North America

- **UCLA evaluation concluded with successful product trial, publication to follow and progressing to adopt into routine use**
- First products are being prepared **for full FDA approval, allowing unrestricted sales in the US**
 - FDA approval opens pathway to a broader group of clinical laboratories, where sales are not restricted to specialist laboratories
 - FDA pre-submission meeting is being planned
 - First product is the Enteric Protozoan kit
- Genetic Signatures now certified by Health Canada, clearing the way for **registering *in vitro* diagnostics (IVD) sales into the Canadian market**



Outlook

- **Significant progress made during FY16 & further strong growth expected in FY17**
- FY16 sales revenues of AU\$1.83M, representing a 3 year CAGR of 92%
- Launch of specialist products for sale into Australia and prepared for US
- Alliances made with leading KOL and health laboratories in the US (UCLA) and globally
- **Progressing significant offshore opportunities**
- Expect to capture a similar % of sales in Europe, similar to Australian growth trajectory
 - **Addressable market of ~US\$435M**
- Commence sales of ASRs into the US market
 - **Addressable market up to ~US\$1265M**
- Launch FDA approval process for two products including Enteric Protozoan Kit
- Target commencing FDA work for 3 products
- **Driving Shareholder value**
- Accelerate revenues through distribution and direct sales activities globally
- Accelerate R&D and approval activities globally, unlocking further revenues and strategic value within molecular test portfolio
- Targeting cash flow breakeven in FY18

Appendix



Comparable companies demanding large valuations

- Comparable companies within the molecular diagnostics field trade on an average revenue multiple of 8.6x
- This multiple exists under the spectre of the 3 year CAGR of the three closest comparable companies being an average of 9.1%
- GSS' 3 year CAGR has been 92%. With strong growth to continue driven by expanded product range and new geographies

	Stock code	Market Capitalisation (\$US m)	2016 Consensus Revenue (\$US m)	Market Capitalisation/ Revenue	3 Year Revenue CAGR
Seegene	KOSDAQ: 096530	\$840.9	\$64.1	13.1x	1.6%
Genmark	NASDAQ: GNMK	\$419.3	\$47.7	8.8x	15.9%
Cepheid	NASDAQ: CPHD	\$2,405.0	\$621.7	3.9x	9.8%
			Average	8.6x	9.1%
			Median	8.8x	9.8%

Technology - 3Base™

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

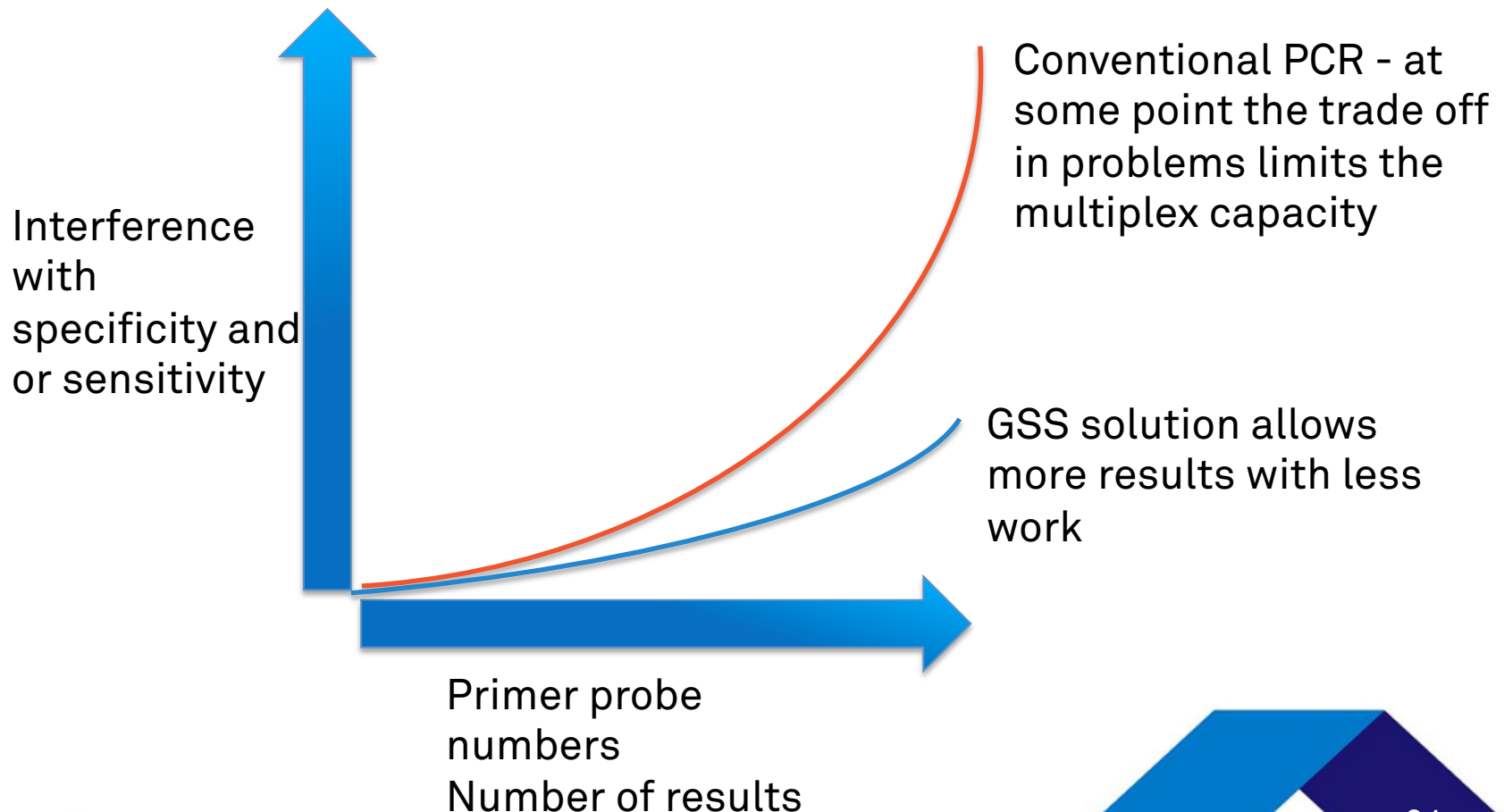
- Genetic Signatures' 3Base™ platform is a proprietary molecular technique which changes naturally occurring DNA and RNA sequences to reduce sequence variation between subtypes
- Patented chemical transformation of DNA and RNA sequences to reduce genetic code complexity
- Process can enhance detection 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

3base™ Simplifying Pathology Testing

- Pathology providers strive to **Minimise work, Maximise results**
 - Desire to get **more results per patient specimen**
 - Thus put more and more primers and probes for more and more diseases in a single tube and sample, to get more answers with less work - multiplexing
- However ---
- Each primer & probe combination has a set of conditions and temperatures that work best. **Non-optimum conditions lead to a loss of specificity, sensitivity, or both**
- The more primers and probes in a tube, the more they can interfere with each other

3base™ Simplifying Pathology Testing

More Primers, more Probes, more Problems



3base™ Advantages

GSS is winning market share due to the following:

- Unique 3base™ products that screen over 20 pathogens, including RNA and DNA viruses, in a probe based real-time format
 - **No post amplification analysis required**
- Uses latest technology compatible with existing equipment (open platform)
 - **No capex required**
- High-Throughput workflow, from sample to result
 - **Scalable, able to manage high volumes, labs performing 200+ specimens/day**
- Separate endogenous extraction and inhibition controls
- Viral, bacterial and protozoan coverage
- Ease of use and automation
- Cost effective



Immense US Market Potential

- US has 5,686 registered hospitals
 - Over 900,000 staffed beds
 - Over 35 million admissions
 - **11,000 CLIA certified laboratories**
- 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”
 - ASRs reduce regulatory barriers
- 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 trial 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
- **ASRs allow access to CLIA certified laboratories**
- Full FDA approval to allow direct marketing of 3 Base benefits is the final goal

The background of the slide is a microscopic image showing numerous rod-shaped bacteria and many smaller, spiky virus-like particles. The entire image has a blue color cast.

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