



# Genetic Signatures

ASX: GSS

**AGM PRESENTATION**

NOVEMBER 2017

## Investment highlights

### ***A REVENUE-STAGE HEALTHCARE COMPANY ACCELERATING THE GLOBAL COMMERCIALISATION OF ITS UNIQUE DIAGNOSTIC PRODUCTS***

- Genetic Signatures (GSS) designs and manufactures Molecular Diagnostic products that have **substantially greater efficacy** than traditional solutions
- **Domestic customer base generated A\$2m+ revenue** in FY17
- **Scalable business model with high gross margins**
- Strong revenue growth pipeline driven by **sale of existing products to new customers** and supported by **complementary new product releases**
- Sales expansion planned in FY18 across North America and Europe to capture part of the **US\$2bn addressable global market opportunity**
- Valuable intellectual property portfolio with **100%-owned 3base™ technology and key patents issued, some expiring 2031**
- **Strong balance sheet** with cash of A\$11.3 million at 30 September 2017

Note: All Medical Diagnostics (MDx) tests are solely focussed on the identification of infectious diseases

## Proprietary technology

All GSS products **underpinned by proprietary 3base™ technology** to enable customers to identify a wider array of infections than standard tests  
**3base™ unique approach optimises DNA analysis** by simplifying the natural sequences resulting in faster and more accurate results

## Growing product set

GSS **manufactures a range of MDx tests<sup>1</sup>** all branded EasyScreen™  
Most advanced product is the EasyScreen™ Enteric (gastrointestinal) tests, **detects 20+ causes of viral, protozoan and bacterial gastroenteritis**

## Clear commercial strategy

**Revenue growth expected from new customers** in Australia, EU and US and the release of new 3base™ products  
Australian expansion in FY18 to set **platform for international sales growth**

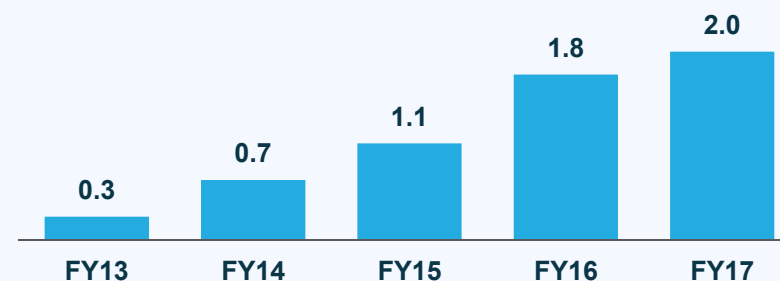
Existing customers generated ...

**A\$2.0m** revenue in FY17 from ...

**3** existing product groups, with ...

**4** new product groups in development

Historical revenues (A\$m)

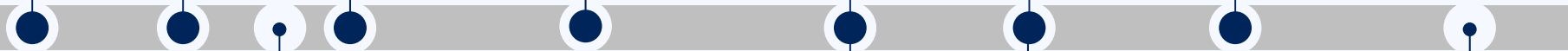


1: All MDx tests are solely focussed on the identification of infectious diseases

# Significant operational progress since IPO in 2015

## Corporate

- Mar-15**  
IPO
- Apr-15**  
First installation of 3base™ respiratory virus kits
- Aug-15**  
Distribution deals in Ireland and Poland
- Nov-15**  
Collaboration with UCLA announced
- Jun-16**  
Launch ASR products in the USA
- Sep-16**  
A\$14m placement announced
- Mar-17**  
Launch and first sales of STI Genital Pathogen Detection Kit



- Jul-15**  
FDA listing of EasyScreen™ clinical concentrators
- Sep-16**  
Trial of STI Kit commenced
- Jun-16**  
UCLA completes trial of 3base™ technology with successful results
- Oct-17**  
Beta-release 2<sup>nd</sup>-generation Respiratory Detection Kit

## Clinical / regulatory

# 1Q FY18 trading update

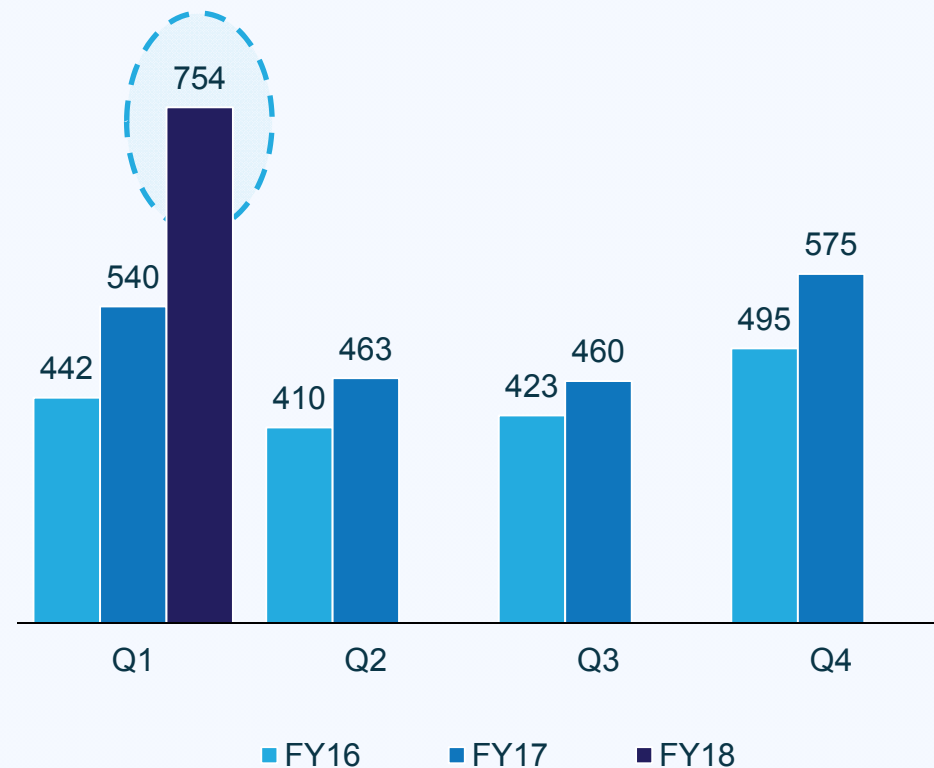
## STRONG REVENUE GROWTH CONTINUES WITH SOME SEASONALITY

### 1Q FY18 Revenue Update

- ✓ **Record quarterly revenues** achieved in Q1 FY18 of A\$754k
- ✓ **Some seasonality** in revenue due to strong demand for respiratory kits across the winter flu season

1Q performance continues **consistent quarter-on-quarter revenue growth** since listing in 2015

Quarterly revenue (A\$000)



# 3base™ enables a step-change in MDx efficacy

## GSS owns the proprietary 3base™ technology

- ✓ Unique and innovative approach simplifies the DNA and RNA sequences of bacterial, viral, protozoan and fungal pathogens
- ✓ The resultant simplified genetic sequences enables a step-change in efficacy in molecular diagnostics (**MDx**)
- ✓ Underlying 3base™ technology covered by multiple patents including workflow

## 3base™ MDx testing is focused solely on the detection of infectious diseases

- ✓ 3base™ MDx can identify a **wider array** of patient infections than current diagnostics
- ✓ Reduces **time to results** (5 vs 24 hours for conventional methods)
- ✓ Provides greater testing **accuracy**



# EasyScreen™ products built on 3base™ technology

GSS is commercialising a range of **MDx tests** based on **3base™** and branded **EasyScreen™**

**EasyScreen™** kits offer faster and more effective detection of infectious disease

- ✓ Three product families available covering **enteric microorganisms, respiratory viruses, and STIs**
- ✓ Target customers are high-volume hospitals and pathology laboratories



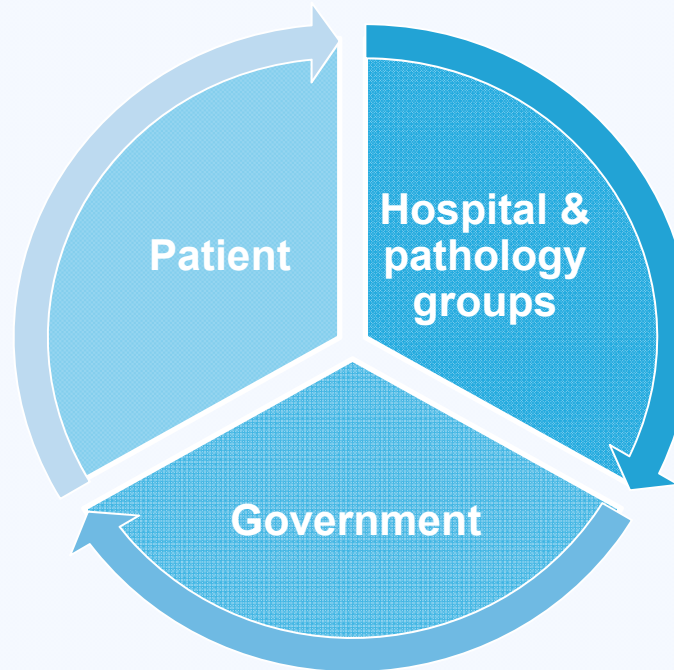
- ✓ **Platform agnostic** – compatible with common existing laboratory equipment
- ✓ **High specificity** – superior accuracy of results
- ✓ **Rapid time to result** (4 - 5 hours) – would have traditionally taken 4 - 5 days
- ✓ **Common Workflow** – all tests work under identical conditions

**EASYSscreen™ KITS IDENTIFY MORE PATHOGENS IN LESS TIME**

# 3base™ offers significant benefits to all parties

## Saves lives

- ✓ **More accurate** test results
- ✓ **Faster turnaround**  
4-5 hours (vs 4-5 days)
- ✓ **Improved efficacy & breadth of detection**



## Saves costs

- ✓ **More results** per patient specimen
- ✓ **Easy to use** common workflow between tests
- ✓ **Compatible** with existing equipment (no CAPEX required)

## Better system outcomes

- ✓ **Reduces hospital stays** through more effective infection detection
- ✓ Rapid detection **reduces spread of infectious diseases**
- ✓ **Reduced repeat doctor visits**



# Powerful evidence of efficacy from clinical trials

## Clinical trials demonstrate efficacy

Evaluation study conducted at St Vincent's Hospital, Sydney in 2014

221 patient samples tested and compared to traditional culture, microscopy, and antibody based tests

Results highlight the efficacy of 3base™ technology and GSS products

- ✓ **Faster screening:** Generated results in 4 hours, compared to up to 120 hours for traditional testing methods
- ✓ **Greater accuracy:** Identified 44 infections that existing testing missed

## St Vincent's Hospital Evaluation Study results

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>

**Significantly greater efficacy**

# 7 products underpinned by 3base™ technology

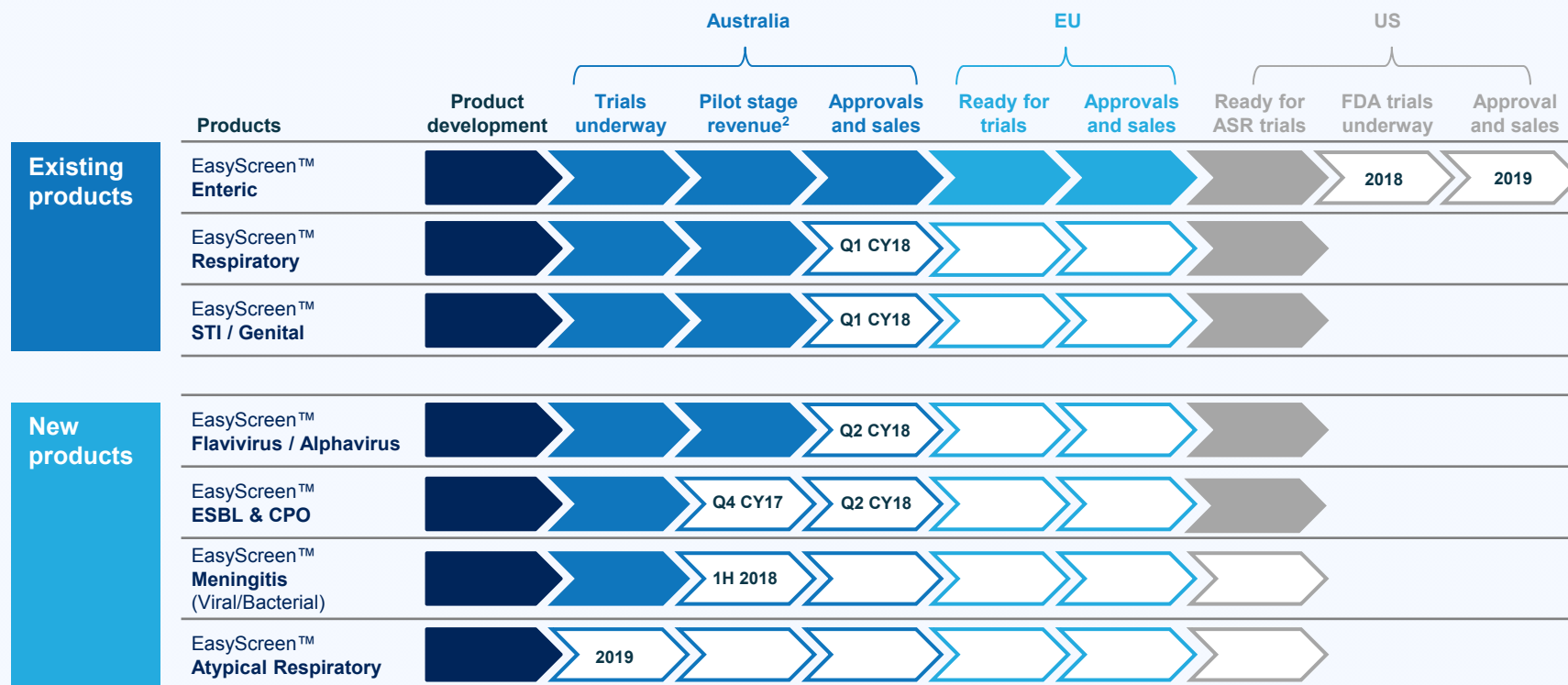
	Product group	Target pathogens	Key highlights
<b>Three existing products groups</b>  <b>Commercial sales underway</b>	EasyScreen™ <b>Enteric</b>	<b>20+ enteric pathogens</b> Includes Salmonella, <i>C. difficile</i> Bacteria, Protozoan and Viral Detection Kits and <i>C. difficile</i> reflex kits	All tests have full regulatory approval in Europe (10-20x the size of Aus market)
	EasyScreen™ <b>Respiratory</b>	<b>15 respiratory pathogens</b> (including influenza A & B, Rhinovirus and M. pneumonia)	Approval in Australian and European markets currently in progress
	EasyScreen™ <b>STI / Genital</b>	<b>12 most commonly encountered STIs</b> (including chlamydia, gonorrhoea and syphilis)	Offers superior test efficacy for pathogens contracted by 1m people daily <sup>1</sup> (market worth ~US\$550M <sup>2</sup> )
<b>Four new product groups</b>  <b>Trials underway</b>	EasyScreen™ <b>Flavivirus / Alphavirus</b>	<b>Multiple Flavivirus/Alphavirus viral families</b> (including Zika and West Nile virus)	Offers testing for complex viruses causing widespread morbidity and mortality but historically labour-intensive to detect
	EasyScreen™ <b>ESBL &amp; CPO</b>	<b>Extended Spectrum Beta-Lactamase and Carbapenemase Producing Organisms</b>	Beta trials underway; rapid alternative for conventional antibiotic-resistant bacterial detection
	EasyScreen™ <b>Meningitis (Viral and Bacterial)</b>	<b>Multiple strains of Meningitis</b> (viral and bacterial infections)	In final development stages – offers rapid diagnosis for life-threatening bacterial meningitis
	EasyScreen™ <b>Respiratory Atypical Pathogen</b>	Simultaneous detection of <b>leading causes of bacterial respiratory infection</b>	In development

Sources:

1: <http://www.who.int/mediacentre/factsheets/fs110/en/>

2: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 168

# Clear path to global commercialisation for all products



Notes:

- 1: Each of the product suites may contain multiple different individual products, indicating that multiple regulatory approval applications and approvals may be required for a suite of products
- 2: Pilot stage revenue generated from sales for research use only (medical professionals may use products for diagnosis only where they validate results with independent testing)
- 3: Sold as individual Analyte Specific Reagents (ASR) for a number of pathogens in the USA

**GSS HAS MADE SUBSTANTIAL PROGRESS ON ALL PRODUCTS SINCE IPO**

## EasyScreen™ customers are strong advocates

*“We use EasyScreen™ at ACL for its **robust user friendly automation, higher levels of specificity** for clinical samples and our confidence in delivering **clinically significant results** to our clinicians.*

**Tony Field**

Operations Manager  
Australian Clinical Labs

*“Same day results and triage options for urgent requests help potentially **save lives**. And we get a high level of service and support from the GSS team!”*

*“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**.”*

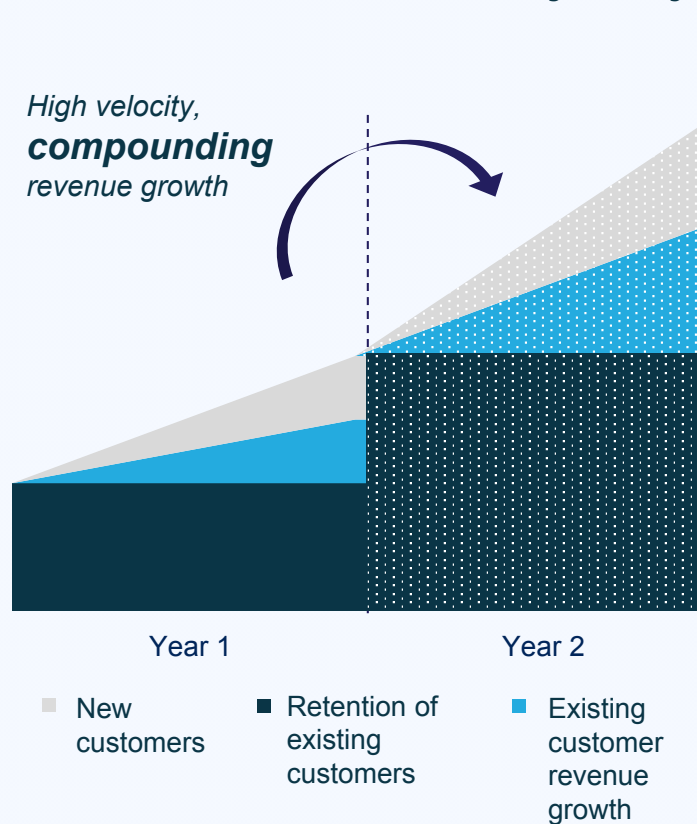
**Dr Damien Stark**

KOL and Senior Microbiologist  
St Vincent's Hospital Sydney

# GSS has multiple levers to grow revenues

## Illustrative GSS revenue trajectory

High velocity,  
**compounding**  
revenue growth



### New customer growth

- Continue to acquire new customers in Australia
- European sales recently enabled by key regulatory CE-IVD approvals
- In US, multiple products now seeking regulatory approvals to enable sales to US-based customers

### Existing customer growth

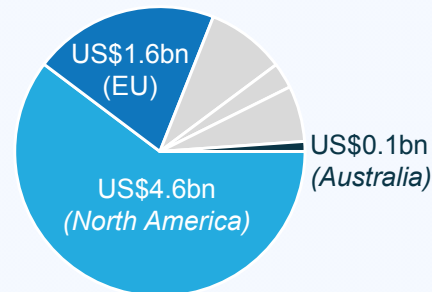
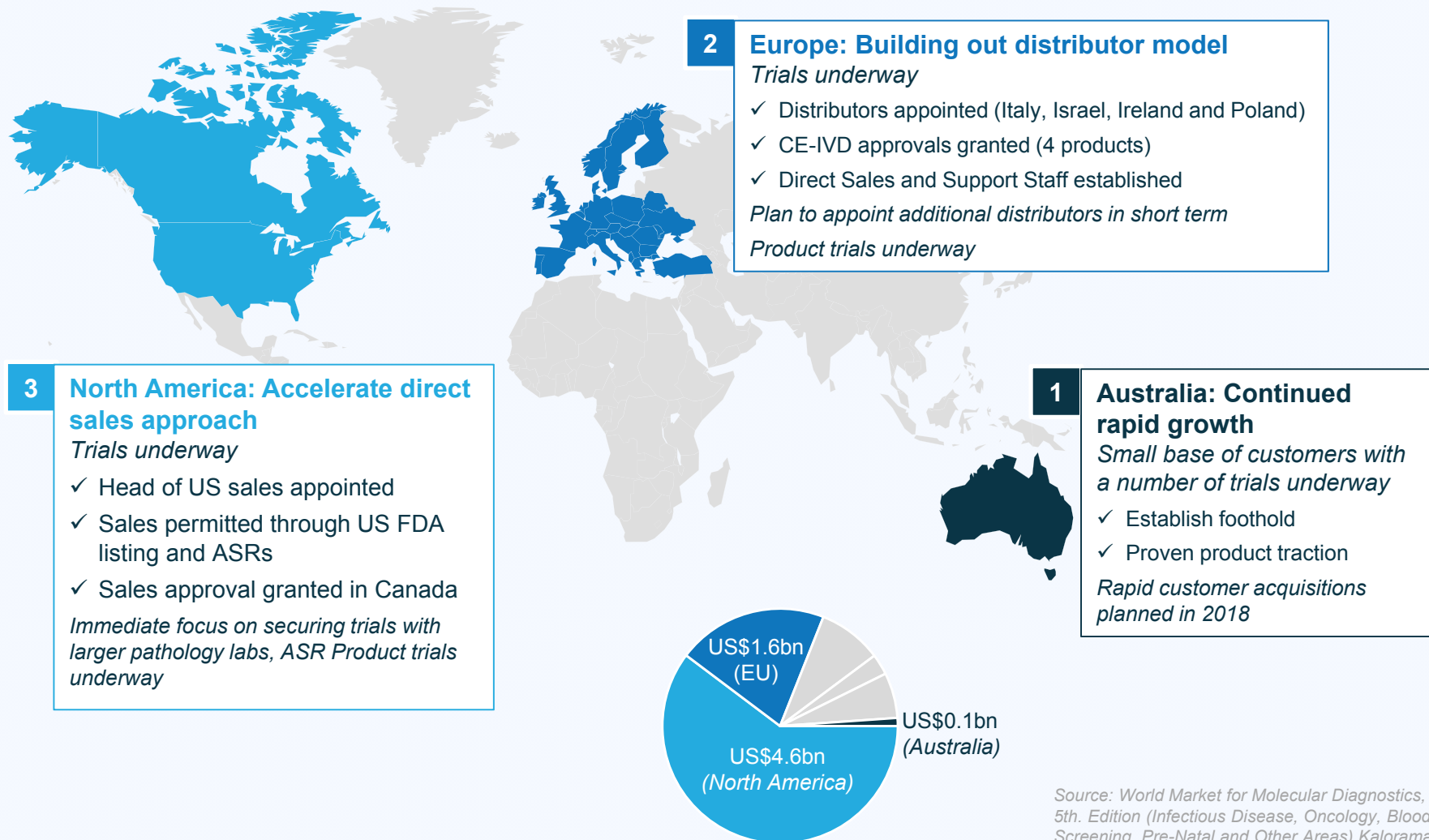
- Further product sales to be driven by the commercial release of 3 new products in development
- Sales team to leverage established customer network and relationships
- Offers a high gross margin revenue growth opportunity

### Existing customers

- Continue to retain and serve existing customer base in Australia

# Executing a global strategy for commercialisation

## 12+ TRIALS PLANNED GLOBALLY INCLUDING 3 DOMESTIC TRIALS



**Estimated MDx market size (2017)**

*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 .*

# 1 Australia: continue rapid growth

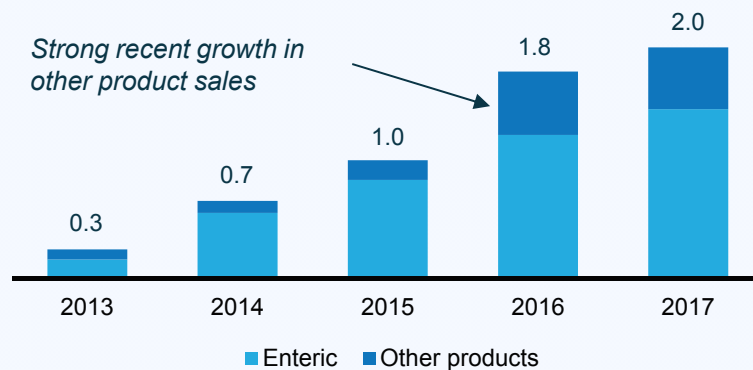
## AUSTRALIA IS THE PLATFORM FOR INTERNATIONAL SALES

### Commercialisation progress

#### Established foothold

- Secured relationships with **top tier customers in NSW and Victoria**
- Established customer relationships **increase ease of new product sales**
- Platform in NSW and Victoria has driven **strong revenue growth over last 4 years**

#### Australian revenue (A\$m)



### Next steps

#### Rapid customer acquisitions

- New Australian Sales Marketing and Support manager appointed
- Focus on **new customer acquisitions**
- Target customers include **pathology labs, hospitals** and large **research laboratories**
- Targeting trials with the largest hospitals and clinical labs in Australia to provide **significant domestic revenue growth**



## 2 Europe: building out distributor model

### STRONG PROGRESS ON MULTIPLE FRONTS TO ACCESS VALUABLE MARKET

#### Commercialisation progress

##### Distributors hired and testing underway

- Full distributors appointed in **Italy, Ireland, Israel and Poland**
- Recently received key patent approvals in **Spain and Israel**
- Currently in discussions with a number of **potential strategic commercial partners** for product distribution
- Enteric product suite has CE-IVD approval allowing for **unrestricted sales in 31 countries**
- Awaiting receipt of regulatory registration for STI and respiratory products in Europe

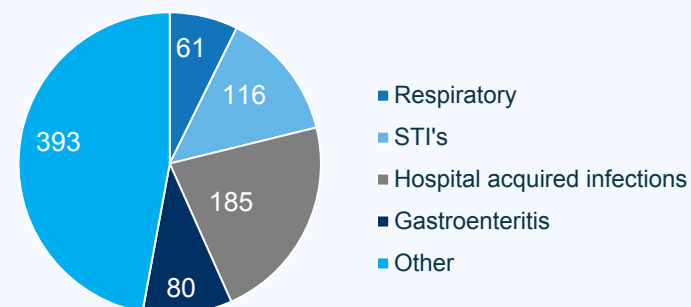
***Genetic Signatures is developing a mix of direct sales and partnerships with distributors across Europe to optimise the sales network***

#### Next steps

##### Strategic market with large opportunity

- Europe has an addressable MDx market of approximately **US\$435m** - *c.20% of the global market*<sup>1</sup>
- GSS continues to participate in industry forums to increase its European profile
- Advanced discussions with new distributors in several European countries

##### European MDx market potential (US\$m)



Sources:

1: 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.



### 3 North America: accelerate direct sales approach

## SALES STRATEGY TO ACCELERATE FOLLOWING FDA APPROVAL

### Commercialisation progress

#### Foothold established

- Hired US Sales Director in November 2016
- Partnership with UCLA for trials and research publication
- Initial trials established with local clinical labs using GSS supplied products in FY17
  - Initial trials now progressing
- Focused on **securing FDA approval** leading to significant revenue growth
- **3base™** technology has patents issued in the US

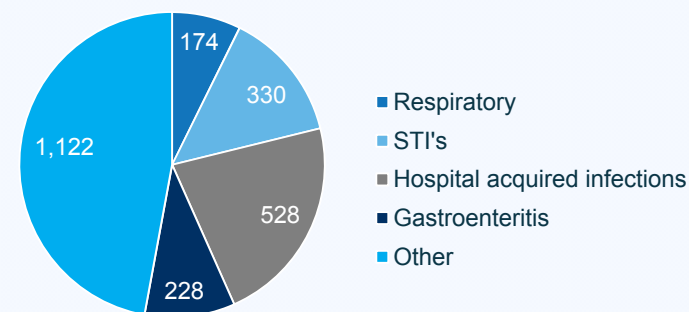


### Next steps

#### Largest market for MDx globally

- Addressable market of approximately **US\$1,265m**, c.55% of the global market
- Over 5,600 registered hospitals in the USA and 11,000 CLA certified laboratories
- FDA listings of Clinical Concentrators in place to allow initial sales

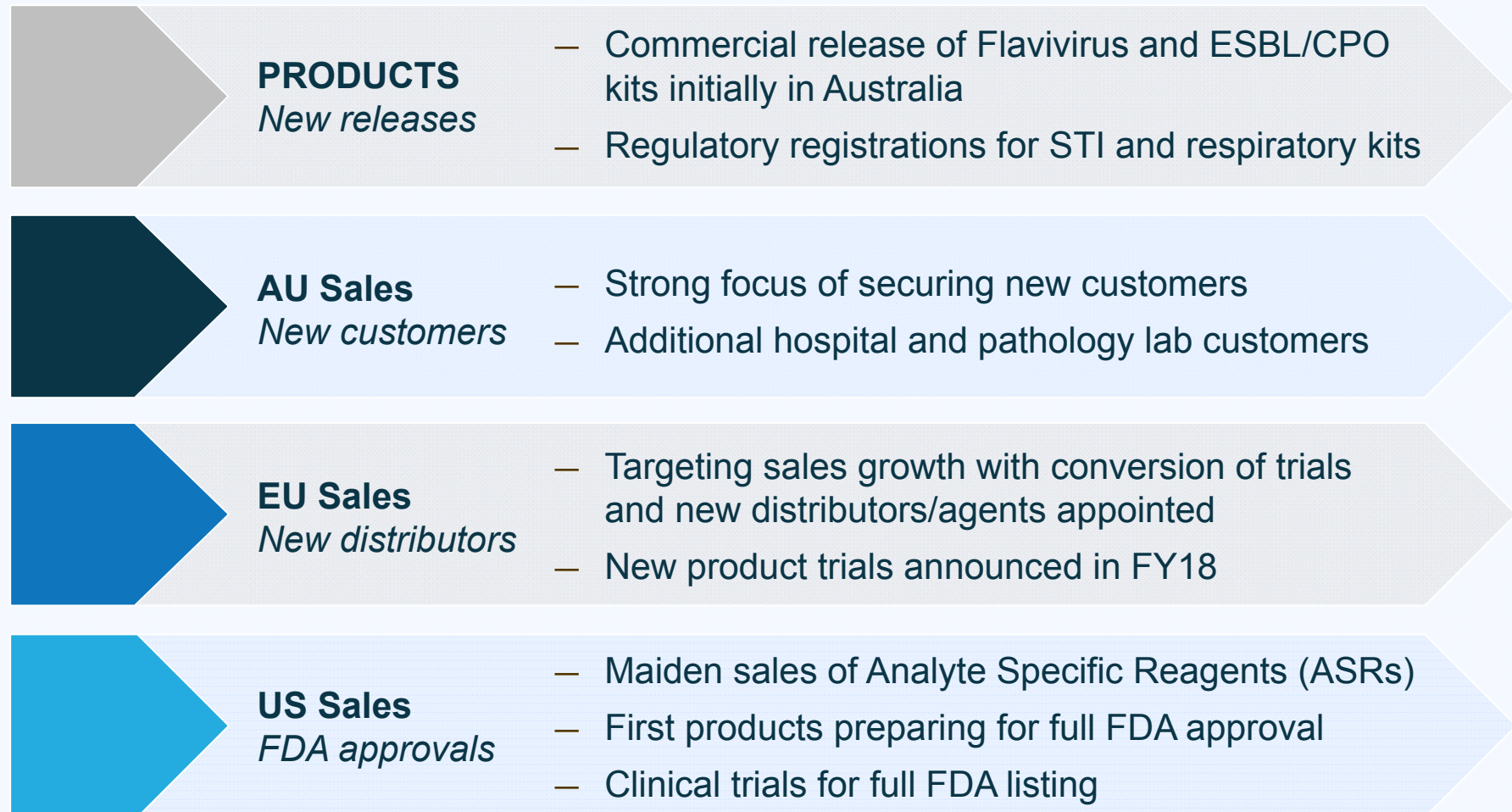
#### North American MDx potential<sup>1</sup> (US\$m)



# Financial performance

A\$000	Year ending 30 June 2016	Year ending 30 June 2017	
Sales revenue	1,825	2,038	
Other income	1,533	1,757	<ul style="list-style-type: none"> <li>Other income includes R&amp;D rebates received (A\$1.5m in FY2017) and interest received</li> </ul>
<b>Total revenue</b>	<b>3,358</b>	<b>3,795</b>	
Cost of goods sold	(462)	(602)	
Employee benefits expense	(3,393)	(3,056)	<ul style="list-style-type: none"> <li>Primarily staff salaries</li> </ul>
Other expense items	(2,130)	(2,846)	<ul style="list-style-type: none"> <li>Other expense items includes scientific consumables (A\$1.1m in FY2017), directors and consultancy fees (A\$0.4m), rental expenses (A\$0.2m), travel and other expenses</li> </ul>
<b>EBITDA</b>	<b>(2,627)</b>	<b>(2,709)</b>	
Depreciation and amortization	(399)	(479)	<ul style="list-style-type: none"> <li>Charged across useful lives of 2.5-13.5 years</li> </ul>
<b>EBIT</b>	<b>(3,026)</b>	<b>(3,188)</b>	
Finance costs	(1)	(0)	<ul style="list-style-type: none"> <li>No interest bearing liabilities on balance sheet</li> </ul>
<b>(Loss) / profit before tax expenses</b>	<b>(3,027)</b>	<b>(3,188)</b>	
Income tax benefit / (expense)	-	-	<ul style="list-style-type: none"> <li>Total amount of unused tax losses for which no deferred tax asset has been recognised is A\$11.0m (A\$3.3m at tax effected rate of 30%)</li> </ul>
<b>Net (loss) / profit after tax</b>	<b>(3,027)</b>	<b>(3,188)</b>	
Basic and diluted earnings per share (Acps)	(4.2)	(3.3)	

# Near terms focus on product range and sales growth



# Board of Directors

## WELL CREDENTIALLED BOARD WITH SUCCESS IN COMMERCIALISATION

Management team with a proven track record in molecular diagnostics industry and extensive experience in bringing products from clinical development to commercialisation

### Nickolaos Samaras

Non-Executive Chairman

- Significant experience in leading international sales expansions of biotech companies
- Former Managing Director of **Applied Biosystems** (acquired by ThermoFisher, US\$76.8bn market cap)
- Held senior roles with **Perkin Elmer** and **AMRAD Corporation** (now part of CSL)

### John Melki

Managing Director & CEO

- **Led global commercialisation efforts of GSS since 2011** and the product development team since 2003
- Successfully **commercialised two worldwide and five international products**
- Authored 20 peer-reviewed articles and listed as an inventor on eight patent applications

### Michael Aicher

Executive Director

- Founder and former CEO of **National Genetics Institute** (subsidiary of LabCorp, US\$15.3bn market cap)
- Led Lab-Corp's Esoteric Business Units which generated over US\$1b revenue p.a.
- Former executive roles at **Central Diagnostics Laboratory**
- Recipient of Ernst & Young "**Entrepreneur of the Year**" award for emerging technologies

### Anthony Radford

Non-Executive Director

- Former Co-Founder and CEO of **Cellestis** (ASX:CST, acquired by QIAGEN for c.A\$350m in 2011)
- Former member of CSIRO team that invented QuantiFERON
- Former Head of Development at **AMRAD** (later acquired by CSL)

### Phillip Isaacs

Non-Executive Director

- Former Managing Director of Australian subsidiary of **Technicon Equipment**
- Former Managing Director of **Beckman Instruments** in Australia
- Vice President of Asia Pacific for **Cytec Corporation**
- Founding Chairman of Australian Proteome Analysis Facility

# Appendix – the science behind 3base™ technology

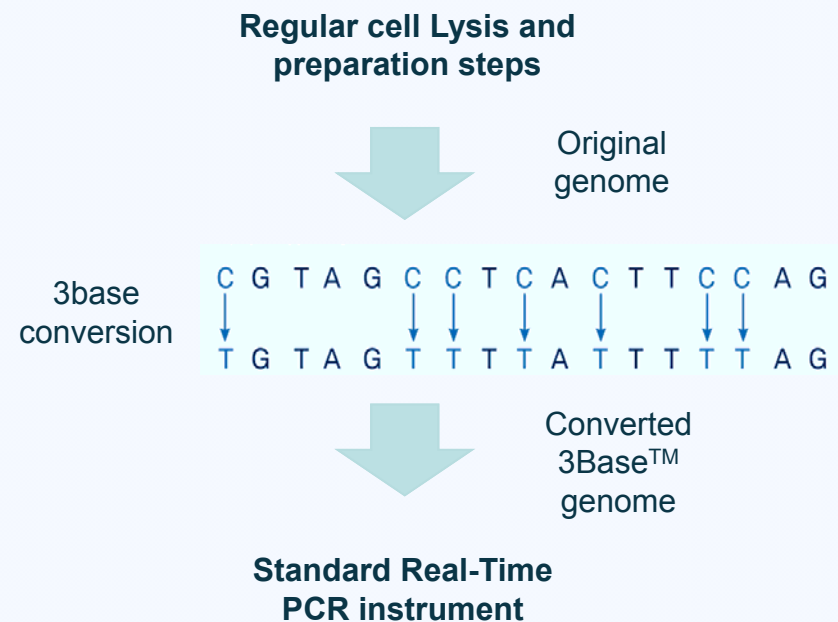
## 3base™ technology in summary

- 3base™ platform technology converts original 4-base microbial genome to 3-base,
  - Reducing complexity in molecular testing
- Conversion occurs during standard procedures and there are no additional steps for the technician

## 3base™ technology influenza example

- The sequence required to detect all sub-types of influenza as a naturally occurring 4-base nucleic acid is comprised of **768 combinations**
- The corresponding sequence after applying 3base™ technology to form a 3base™ nucleic acid has 24 combinations
- Therefore, there is a 32 fold reduction in complexity of the primers required to screen patient samples

## 3base™ technology in the detection process



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