

# Genetic Signatures

Transforming  
Molecular  
Diagnostics

## Investor Presentation

7 November 2019

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**A specialist molecular diagnostics (MDx) company focused on the commercialisation of its proprietary platform technology, 3base™....**



**Proprietary 3base™ technology with a strong competitive advantage**



**Strong foothold in the domestic market backed by an attractive revenue model**



**Well funded to enter a rapid phase of global expansion**



**Multiple upcoming catalysts to drive value upside**

**...Genetic Signatures is well positioned to execute on its global expansion strategy**

# Global market dynamics

GSS has consistently grown its revenue quarter-on-quarter over the last 4 year and current revenue is derived almost entirely from Australia (~97%)

## GSS is at the forefront of significant growth opportunities

### International expansion

- Australia represents ~1% of the global MDx market for infectious diseases
- US and Europe represent ~75% of global MDx market

### Rapidly growing global infectious disease IVD market

- MDx is rapidly replacing traditional testing with market growth estimated at ~8.2% p.a.<sup>1</sup>
- Respiratory test market is expected to grow at 12.0% CAGR over next 5 years<sup>1</sup>
- Global STI and women’s health market is expected to grow at 10.1% CAGR over next 5 years<sup>1</sup>

### Significant M&A activity in the diagnostic sector<sup>3</sup>

- Significant strategic interest from large diagnostic companies in multiplex panels / assays
- Larger acquisitions were valued at nearly US\$4bn
- M&A activity within the sector expected to continue

**EasyScreen™ Kits** currently registered for sale (TGA, CE-IVD):



Enteric



Respiratory



ESBL & CPO

**~US\$820m**

**Global market share (p.a.)<sup>2</sup>**

**GSS is expecting multiple TGA, CE-IVD and FDA product registrations in FY20, expanding the Company’s addressable market**

1. Kalorama Information – Molecular Testing Market of Infectious Diseases  
 2. Kalorama and Company estimates  
 3. Refer to slide 15 for further information on M&A activity

# The 3base™ technology behind our EasyScreen™ tests



World-first, proprietary platform technology significantly simplifies genetic detection of microbial organisms in current urine, blood or stool tests

- 1 **3base™** platform technology converts original 4-base microbial genome to 3-base
- 2 Conversion occurs during standard procedures with no additional steps for the technician
- 3 **3base™** MDx can identify a wider array of patient infections and provide greater testing accuracy by reducing complexity

**1,048,576** combinations for a 10 digit number with 4-base



**59,049** combinations for a 10 digit number with 3-base

## Benefits for labs / hospitals

**3base™** technology creates a clear *competitive advantage* relative to other MDx products for its high throughput, target customer base

- ✓ Cost saving for labs – less time spent evaluating samples
- ✓ More results per patient specimen
- ✓ Reduced complexity in molecular testing

## Benefits for patients

- ✓ 83% more infections detected than current tests<sup>1</sup>
- ✓ Results in 1 day instead of 4 days – quicker path to treatment
- ✓ Accelerated path to treatment reduces mortality and morbidity

## Benefits for government

- ✓ Reduced hospital stays from more accurate infection detection
- ✓ Faster turnaround speeds up costly treatment and reduces risk of spread of disease
- ✓ Reduced repeat doctor visits
- ✓ Reduces overuse and misuse of antibiotics

# Attractive revenue model

## ✓ Large throughput with predictable orders

- Target customers are **large throughput** pathology groups, hospitals or government run programs.
- Customers **secure long-standing contracts** with set prices and **relatively predictable volumes**

## ✓ High margins and sticky annuity revenue:

- **Consumable revenue model** for 3base™ test where customers pay per test
- **Tests become embedded in workflow** and typically request **monthly orders** with **fast payment terms** – relatively low working capital needs
- Customers receptive to **adoption of new tests** once workflow established

## ✓ Attractive return on investment:

- Potential to fund new customer installations to **speed up customer acquisition**, particularly offshore
- “Printer & cartridge” model: by offering equipment, GSS can **recoup a multiple of initial outlay** via long term consumable revenue

## Model validated by strong foothold in the domestic market

- ✓ 500k+ patients tested to date
- ✓ 100% customer retention since 2016
- ✓ 65% gross margin
- ✓ High “bottom line” impact with 3-5 year contracts

*Rapid growth supported by expanding pipeline of new customers / tenders*

# Significant revenue growth

Genetic Signatures has made strong progress on its commercialisation strategy during the year

## Key FY19 achievements

- ✓ Key management and sales team appointments

### Australia

- ✓ Major new contract with large pathology service
- ✓ Launched two new products
- ✓ Received TGA registration for *EasyScreen™* Respiratory Kit

### Europe

- ✓ CE-IVD registration for *EasyScreen™* Respiratory Kit
- ✓ First sale of reagent kit to UK customer
- ✓ Increased investment sales activities

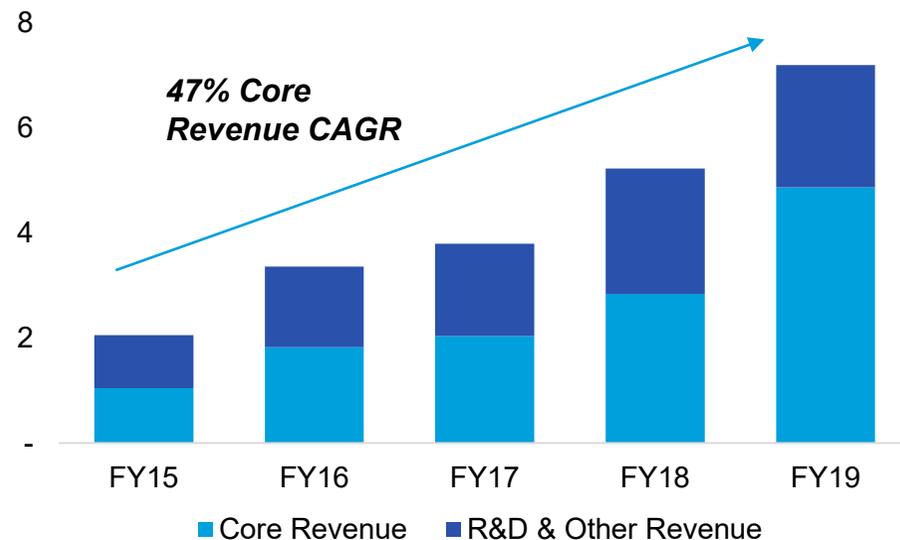
### North America

- ✓ Progress towards securing FDA clearance
- ✓ Several labs assessing the potential for ASR products

## Strong revenue performance in FY19

- **97%** of FY19 core revenue generated in **Australia** from **3 products**
- First **material sales out of Europe and the Americas** is anticipated in 2H FY20
- **New products** in development

## Statutory revenue (A\$m)



# Easyscreen™ product portfolio



3 products selling in Australia and EU. Major new registrations and product launches imminent in US, AU and EU

	Enteric 	Respiratory 	ESBL & CPO 	STI / Genital 	Alphavirus / Flavivirus 	Meningitis 	Atypical Respiratory 
<b>Asia Pacific</b>	TGA	TGA	TGA	TGA and CE-IVD in early 2020. First sales to exempt customers			
<b>EMEA</b>	CE IVD	CE IVD	CE IVD			Currently in development	
<b>Americas</b>	FDA expected in ~mid-2020			ASRs available for sales			
<b>Global market size<sup>1</sup> (A\$m p.a.)</b>	\$573m	\$627m	Emerging market, ripe for molecular disruption	\$1,891m	\$69m	\$156m	See Respiratory

Notes:

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

# Powerful evidence of efficacy from clinical trials

Comparative studies confirm superior performance of Genetic Signatures' technology

## Clinical trials demonstrate efficacy



Evaluation study conducted at St. Vincent's Hospital, Sydney



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<sup>1</sup>

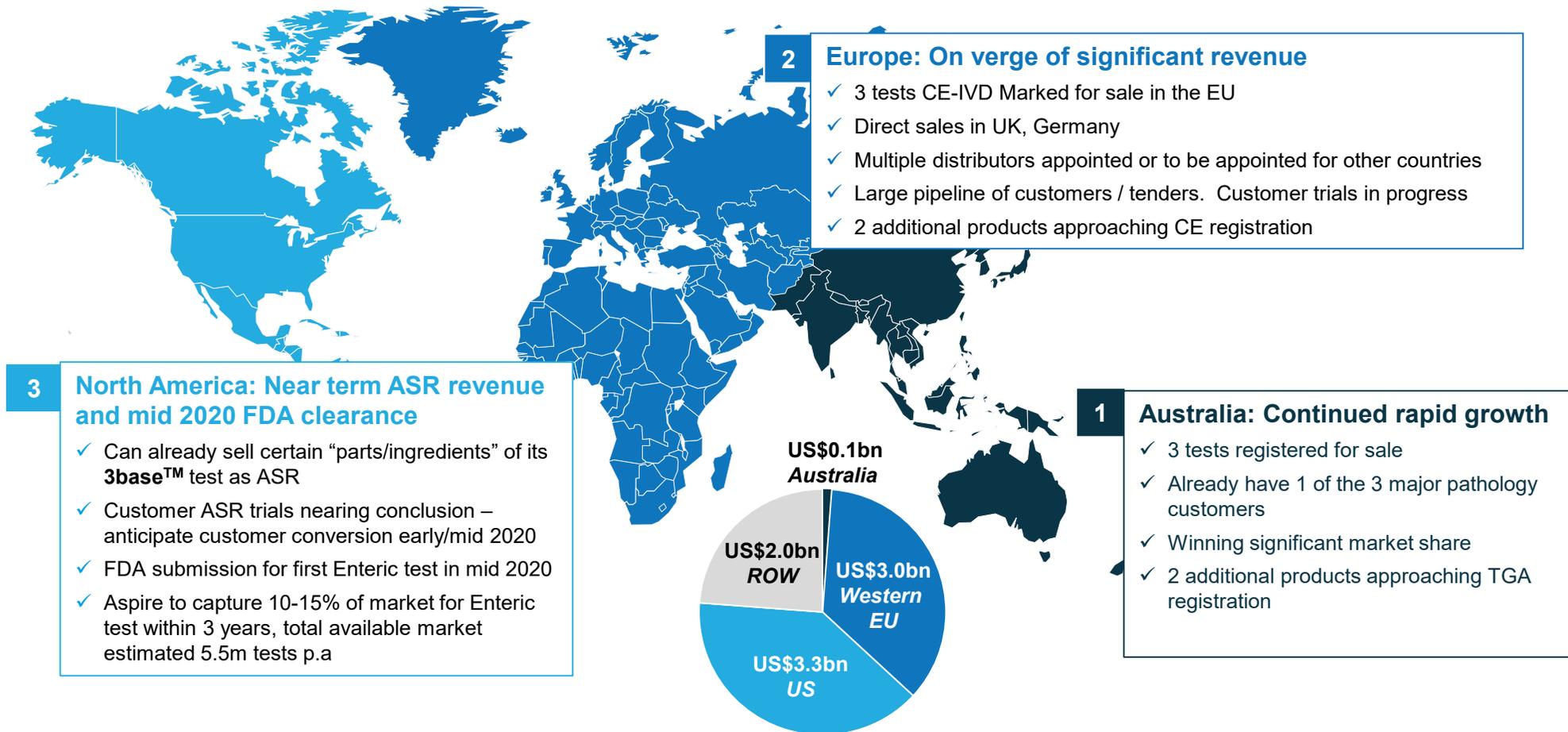
Pathogen	Conventional Methods*	EasyScreen™
<i>Campylobacter</i>	7	9
<i>Salmonella</i>	8	9
<i>Shigella</i>	5	6
<i>C. difficile</i>	3	7
<i>Yersinia</i>	-	1
<i>Cryptosporidium</i>	-	1
<i>Giardia</i>	9	12
<i>Dientamoeba fragilis</i>	4	20
<i>Blastocystis hominis</i>	16	21
<i>Entamoeba histolytica</i>	1	1
<i>Norovirus group 2</i>	-	7
<i>Adenovirus</i>	-	1
<i>Adenovirus 40/41</i>	-	1
<i>Sapovirus</i>	-	1
<b>Total</b>	<b>53</b>	<b>97</b>

▲  
Significantly greater efficacy  
(+83% more infections detected)

Notes:  
1. Diagnostic Microbiology and Infectious Diseases 78(2): 149-152, February 2014. St Vincent's Hospital (SydPath) Evaluation Study – EasyScreen™ versus traditional methods

# Executing a global strategy for commercialisation

GSS remains focused on growth in 3 major markets



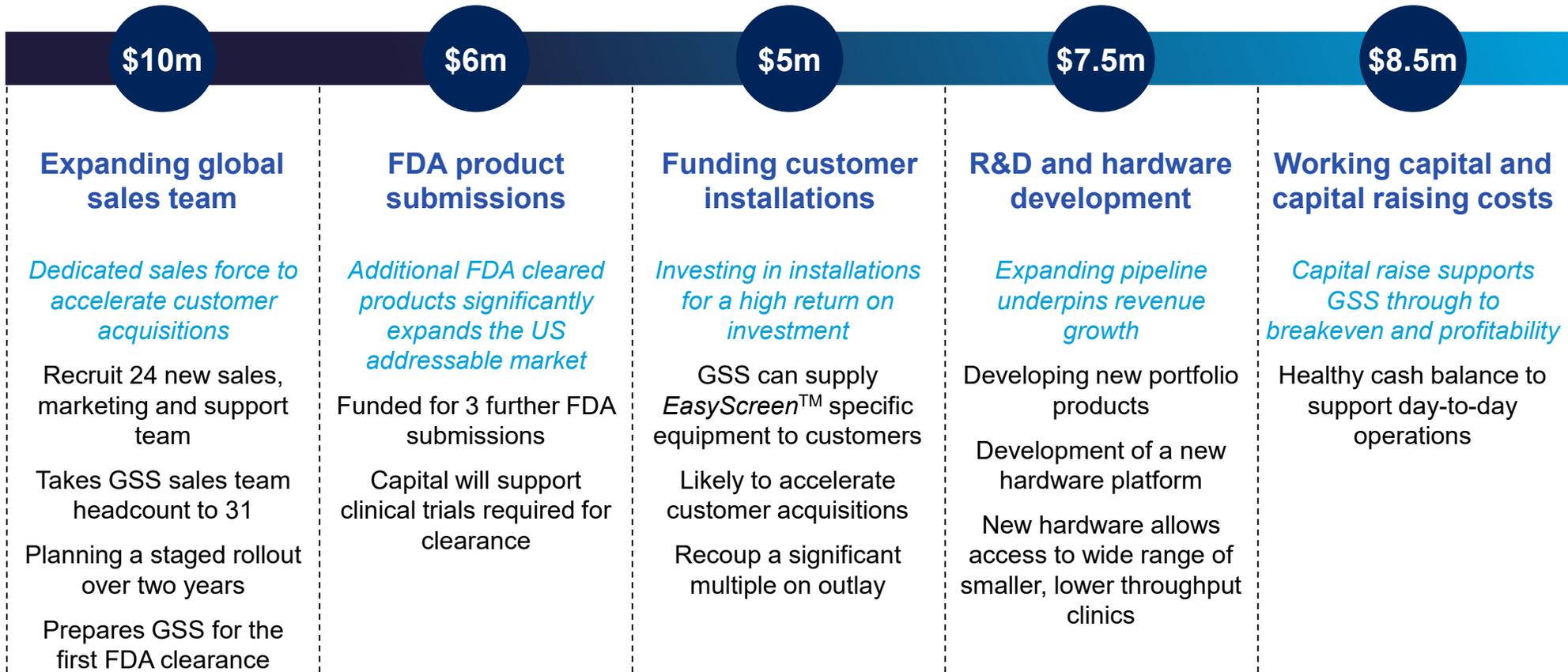
Infectious disease MDx market size (2018)<sup>1</sup>

Source:  
 1. Bell Potter Securities Estimates (Initiation of Coverage Report) and World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas)  
 Kalorama Information, Published: 1/9/2013.

# Fully funded to execute on commercialisation strategy

Following the A\$35m placement completed and \$2m SPP offered, Genetic Signatures is well positioned to execute on its global expansion strategy

## Use of funds from capital raising



## Commercialisation success in Australia. Further growth via new customers and new products



### Australian Market Dynamics

- Market comprises private centralised labs, government and hospital networks
- Private labs **dominated by 3 large pathology groups** (Sonic, Healius, Australian Clinical Labs) - ~58% of total test market
- We estimate market size to be **A\$47m p.a** across our 3 currently registered tests<sup>1</sup>

### Regulatory registrations (TGA)

- ✓ Enteric range (bacterial, viral, protozoan)
- ✓ Respiratory
- ✓ ESBL & CPO (antibiotic superbugs)

Exp. 2020 STI / Genital Pathogen

Exp. 2020 Flavivirus / Alphavirus

### Growth drivers and commentary

- Currently generating 90%+ of group core revenue
- Significant volumes from 1 of top 3 centralised labs
- Leverage current **strong foothold in the Australian market**
- **Continue growth** of the domestic business in FY20
- Launch **two new products in 2020** – STI/Genital Pathogen and Flavi/Alpha
- Develop & release new higher throughput systems and next generation platform
- Develop new 3base™ test kits – not yet disclosed
- Significant IP and learnings from early sales efforts that will accelerate our growth in offshore markets

1. [http://medicarestatistics.humanservices.gov.au/statistics/mbs\\_item.jsp](http://medicarestatistics.humanservices.gov.au/statistics/mbs_item.jsp) and company estimates. Australia is more advanced in its adoption of MDx test than other countries.

# Europe

European Union and United Kingdom represents ~35% of global molecular diagnostics market<sup>1</sup>



## Market Dynamics

- Focus on selling direct in UK & Germany
- **85% of testing in UK managed under NHS** – mixed between Public Health England labs (7 centralised labs) and hospital trusts
- Germany **dominated by 5 large pathology groups** with some smaller university clinics
- Remaining countries – distributor model

## Regulatory registrations (CE-IVD)

- ✓ Enteric range (bacterial, viral, protozoan)
- ✓ Respiratory
- ✓ ESBL & CPO (antibiotic superbugs)

Exp. 2020 STI / Genital Pathogen

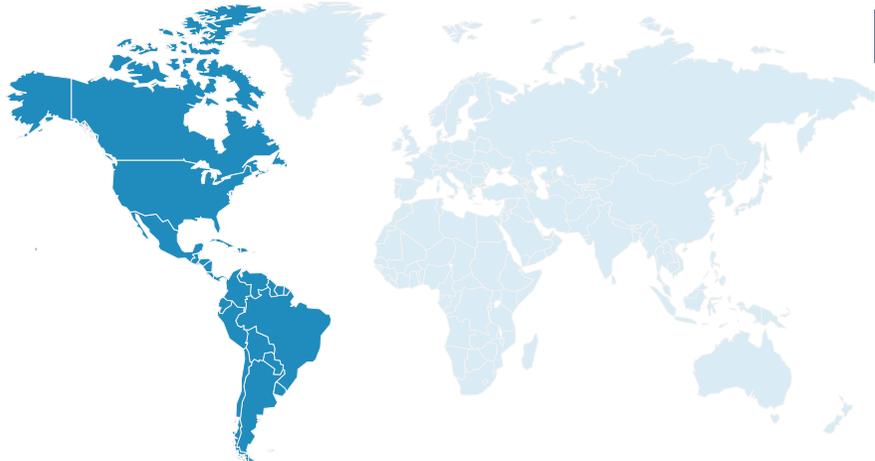
Exp. 2020 Flavivirus / Alphavirus

## Growth drivers and commentary

- Targeting first major sale in Europe early/mid 2020 – also becomes reference site for other potential customers
- **Increased investment into European sales** to coincide with regulatory improvements and expanding customer pipeline
- Further build **sales and technical team**
- Additional distributors and managed warehouse **allowing rapid delivery; expanding local footprint**

# Americas

North America is the largest market opportunity globally, accounting for an estimated 40% of molecular diagnostics revenue<sup>1</sup>



## Market Dynamics

- Est. 5.5m Enteric Protozoan tests p.a in the US
- Initial focus on **largest 30 “high throughput” centralised labs**
- Smaller decentralised labs more accessible with development of new testing hardware
- Whilst awaiting clearance, GSS can sell “parts/ingredients” of **3base™** kits to centralised labs under ASR program

## Regulatory Clearance (FDA)

- Exp. 2020 Enteric Protozoan anticipated in mid 2020.
- Exp. 2020/1 Additional tests (not identified for competitive purposes)

## Enteric (Protozoan) revenue potential p.a.<sup>2</sup>

Revenue per test	10% Market Share	15% Market Share	20% Market Share
<b>A\$22 (US\$15)</b>	A\$12.1m	A\$18.2m	A\$24.2m
<b>A\$37 (US\$25)</b>	A\$20.4m	A\$30.5m	A\$40.7m
<b>A\$51 (US\$35)</b>	A\$28.1m	A\$42.1m	A\$56.1m

## Growth drivers and commentary

- First material ASR order anticipated in early/mid 2020 – becomes reference site for other potential customers
- Several **labs now trialling the ASR products**, which incorporate the Company’s proprietary **3base™** technology
- ASR trials presented at key conferences
- With customer relationships established and expanding sales force we are “game ready” for our first FDA regulatory clearance for Enteric Protozoan
- Aiming to win 10-15% of Enteric Protozoan market within 3 years
- Additional regulatory clearances for additional tests to drive growth

1. Bell Potter Securities Estimates (Initiation of Coverage Report) and World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) | Kalorama Information, Published: 1/9/2013.  
 2. Assumes 5.5 million Enteric Protozoan tests undertaken p.a. in US

# M&A activity in the diagnostic sector

Strong strategic interest from large diagnostic companies in multiplex panels/assays such as GSS' 3base™ technology. M&A activity within the sector expected to continue

Date	2018	2018	2018	2017	2016	2011
Company						
	Private	(NASDAQ:CPHD)	(Private)	(Private)	(NYSE:DGX)	(ASX:CST)
Acquired by						
	(NYSE:QGEN)	(NYSE:DHR)	(ETR:SIE)	(NYSE:PKI)	(BIT:DIA)	(NYSE:QGEN)
Transaction	Takeover	Takeover	Takeover	Takeover	Acquired molecular and immunoassay business	Takeover
Size	US\$147m upfront US\$44m milestone	US\$4bn	Not disclosed	US\$1.3bn	US\$300m	~US\$400m

# Catalysts and newsflow

Expected to announce a significant amount of news flow and major catalysts by end of 2020



- TGA registration to begin selling STI / Genital Pathogen Kits in Australia – targeting early 2020
- TGA registration to begin selling Flavi / Alpha Kits in Australia – targeting early 2020
- Ongoing announcements of key contract wins



- CE registration to begin selling STI / Genital Pathogen Kits in Europe – targeting early 2020
- CE registration to begin selling Flavi / Alpha Kits in Europe – targeting early 2020
- First material customer win in Europe – targeting early/mid 2020

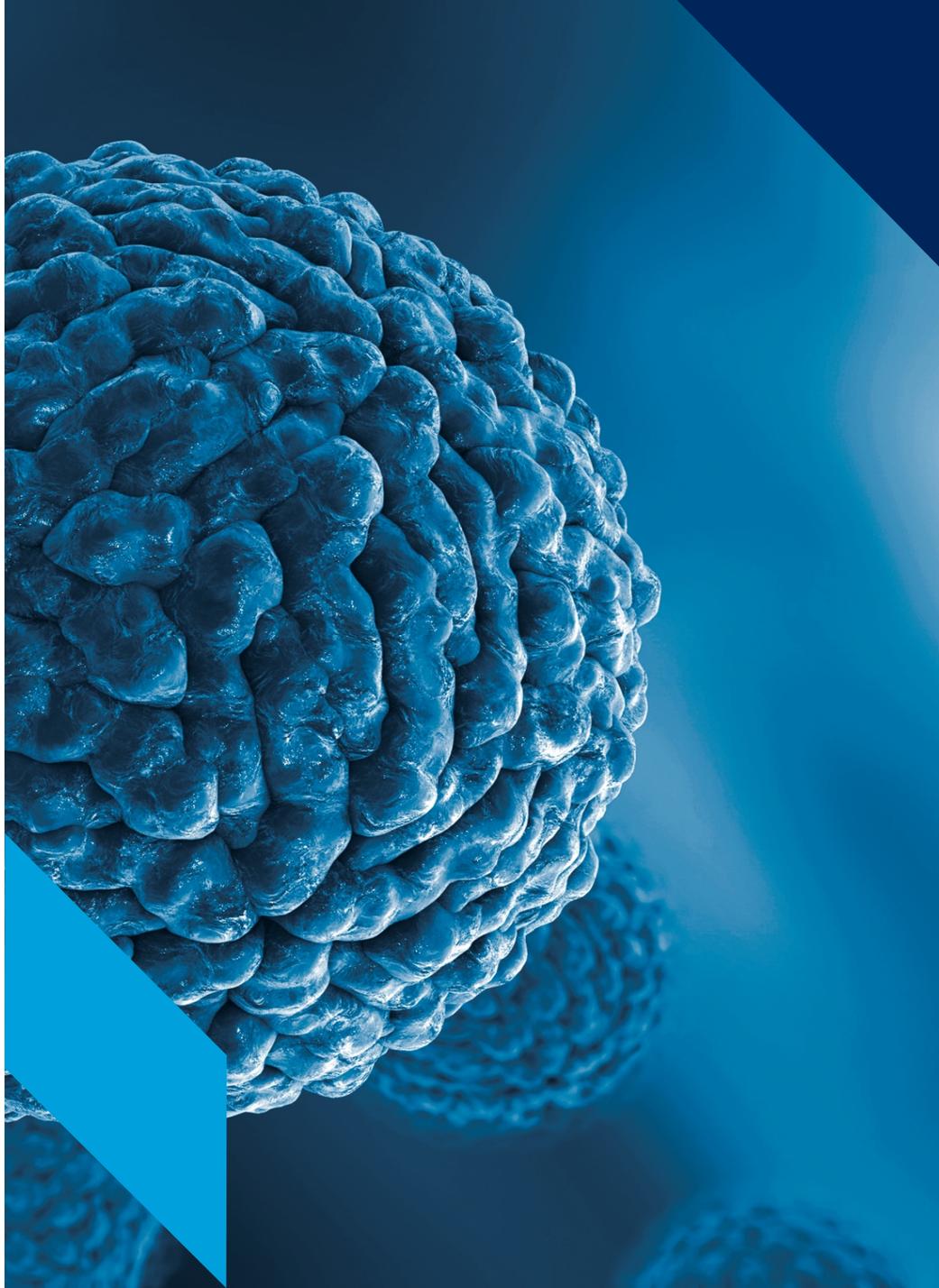


- First material ASR contract in US – targeting early/mid 2020
- FDA submission for Enteric Protozoan test – expected mid 2020
- FDA clearance for Enteric Protozoan test – 90+ days post submission
- Announcement of first US Enteric Protozoan sales – anticipated 2H 2020



- GS-Call software launched 1H 2020
- Planning additional FDA submissions
- Ongoing quarterly revenue and operations reports

# Appendix



# Corporate summary



Revenue stage healthcare company listed on the ASX

## Genetic Signatures Limited (ASX: GSS)

### A specialist molecular diagnostics company



Focused on becoming a global leader in the supply of molecular diagnostic solutions



Developing and commercialising its proprietary platform technology, **3base™**



Implementing its commercial strategy through a team of 30+ across Australia, Europe and North America



### Financial information

Share price (6-Nov-19)	A\$0.985
Shares on issue <sup>1</sup>	119.6m
<b>Market capitalisation<sup>1</sup></b>	<b>A\$118.7m</b>
Cash (Pro forma 30-Sep-19 post offer)	A\$41.9m
Debt (30-Sep-19)	Nil

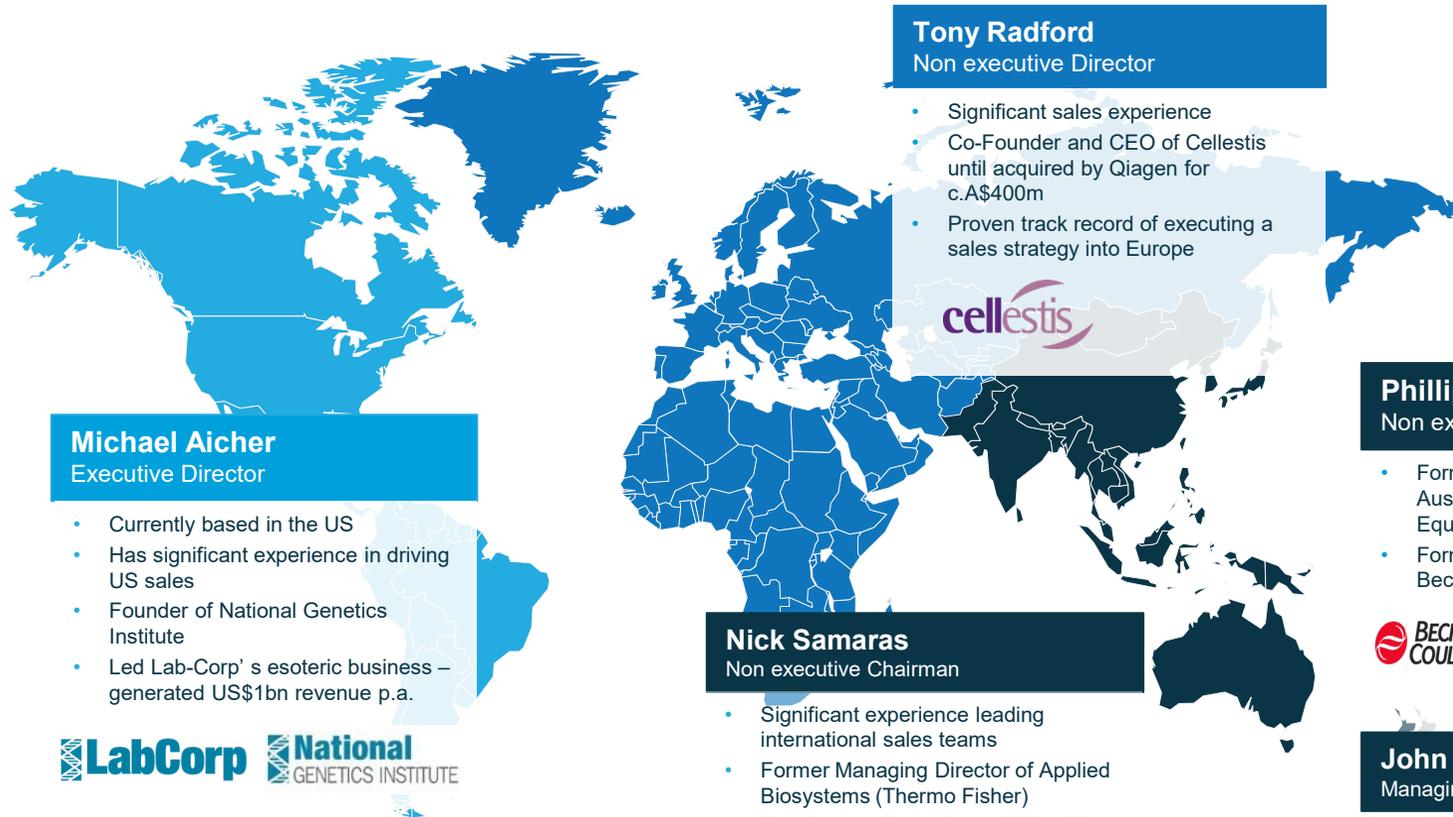
Notes:

1: Shares on issue includes shares to be issued under the 15% rule but excludes shares not yet issued and subject to shareholder approval, all part of the recently announced capital raising. Excludes 2.68m unquoted options (various expiration dates and prices)

### Top shareholders %

Asia Union and Christopher Abbott	31.6%
Karst Peak (HK-based investment manager)	15.8%
Directors, management & advisors	>5.0%

# Board of Directors have a track record of success



**Michael Aicher**  
Executive Director

- Currently based in the US
- Has significant experience in driving US sales
- Founder of National Genetics Institute
- Led Lab-Corp's esoteric business – generated US\$1bn revenue p.a.



**Tony Radford**  
Non executive Director

- Significant sales experience
- Co-Founder and CEO of Cellestis until acquired by Qiagen for c.A\$400m
- Proven track record of executing a sales strategy into Europe



**Nick Samaras**  
Non executive Chairman

- Significant experience leading international sales teams
- Former Managing Director of Applied Biosystems (Thermo Fisher)
- Senior executive roles at Perkin Elmer and AMRAD Corporation (CSL)



**Phillip Isaacs**  
Non executive director

- Former Managing Director of Australian subsidiary of Technicon Equipment
- Former Managing Director of Beckman Instruments in Australia



**John Melki**  
Managing Director and CEO

- Led global commercialisation efforts of GSS since 2011 and the product development team since 2003
- Led the commercialisation of two research products worldwide and seven diagnostic products in Australia and Europe

# 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
<b>Consensus</b>	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
	<b>48</b> possible primer combinations	<b>3</b> possible primer combinations

- Sufficient information is retained for genotyping equivalent to native (4Base) genomic assays
- No loss of clinical specificity is observed during 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

# Contact us

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