

Genetic Signatures

Investor Update – July 2017

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Company Overview

- Genetic Signatures Limited (GSS) designs and manufactures proprietary molecular diagnostic (MDx) test solutions for **rapid and specific identification of diseases and infections**
- GSS fully owns its proprietary molecular *3base*[™] technology with **multiple patents issued**, expiring in 2031
- *EasyScreen*[™] products have an estimated **US\$2.1B addressable global market** in 2017
- **Large pipeline** of **new 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 delivering shareholder returns

Commercial Progress

- June quarter **Sales revenue growth of 16%** on the previous corresponding period
- **\$13.2M cash** as of 30 June 2017
- **Growing global profile** through participation at EU, AU and US industry events coincides with **offshore expansion**
- **New sales and marketing appointment** supports overall strong foundation for future growth
- Completion of **oversubscribed \$15M capital raising** in September allowing for further investment in offshore expansion

Product Progress

- Successful launch of new **3base™ EasyScreen™** STI detection kit: global addressable STI testing market estimated at US\$550M in 2017
- First sale and delivery of beta-release **3base™ EasyScreen™** Flavivirus and Alphavirus detection kit
- First product trial of new **3base™ EasyScreen™** Extended Spectrum Beta-Lactamase (ESBL) and Carbapenemase-producing organisms (CPO) Detection Kit for rapid antibiotic resistance detection of bacteria such as *E.coli* and *Klebsiella*
- Full EU regulatory approval for complete enteric suite allows unrestricted sales in 22% of global molecular diagnostics market
- **3base™** patent approval in US where focus is on completing scientific validation for FDA product approval



EasyScreen™ STI Detection Kit Progress

- Successful launch of *3base*™ *EasyScreen*™ Sexually Transmitted Infection (STI) Detection Kit — simultaneously detects the 12 most commonly encountered STIs and has superior multiple infection detection over existing hospital testing techniques
- **First commercial customer secured** — SydPath, a fully accredited private Pathology Lab of St. Vincent's hospital in Sydney will use the new STI Kit on an ongoing basis
- **Potential market** — 1 million people contracting an STI daily (World Health Organisation)

EasyScreen™ Flavivirus Detection Kit Progress

- GSS exhibited at the 27th European Congress of Clinical Microbiology and Infectious Diseases in April — Highlighting the improved detection of Flaviviruses with GSS' **3base™** technology following a successful Vanuatu Dengue Detection Clinical Trial with Port Villa Central Hospital
- **Results demonstrate strong performance** — The success of the trial shows the global potential of the **3base™ EasyScreen™ Flavivirus and Alphavirus Detection Kit** to aid in preventing the spread of disease, including Zika and West Nile
- **First commercial customer secured** — Ahead of product launch first significant offshore customer using beta-release on a trial basis
- **Potential market** — Flavivirus' and Alphavirus' cause widespread morbidity and mortality in developed and developing world

Upcoming Activities

- Focus remains on sales growth, product range expansion and market share expansion
- New global product trials underway or commencing this quarter
- Research and development on new kits and assays continues, including kits for atypical respiratory infections, antibiotic resistance and meningitis
- Preparation of two new products for commercial release (Flavirus and ESBL/CPO)
- GSS continues to work on securing regulatory approvals for STI and respiratory products whilst ongoing regulatory developments in the \$1.26B US market remain on course



Corporate Summary

Financial Information (A\$)	
ASX Code	GSS
Shares on Issue	104.6M
Market Capitalisation	\$45M
Share Price (at market close 25 July 2017)	\$0.43
Cash at 30 June 2017	\$13.2M

Top Shareholders	%
Asia Union Investment Pty Limited	35.4%
Citicorp Nominees Pty Ltd	16.2%
UBS Nominees Pty Ltd	6.5%
Directors, Management and Advisors	>6.0%

Genetic Signatures

Transforming Global Molecular Diagnostics



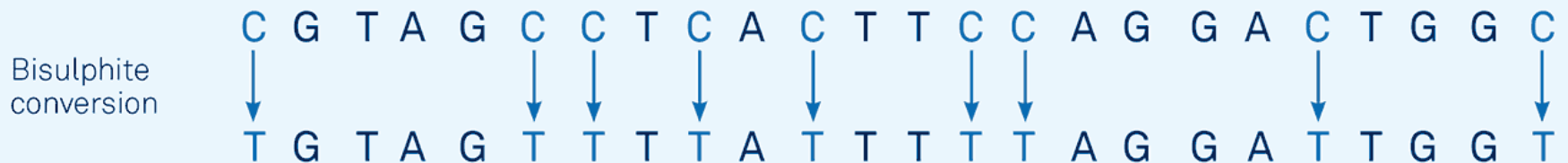
Genetic Signatures - 3Base™ Technology

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

- GSS' 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
- Significant reduction in complexity and enhanced detection of multiplexed assays - multiple targets are detected in one tube

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**
- 3Base™ delivers greater sensitivity and specificity in a rapid assay

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

Advantages of 3Base™ Technology

Patient

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

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

- Reduces 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

Significant benefits to the health system:
minimise work, maximise results and drives value

EasyScreen™ Testing Kits

- First products to market:
 - 22 gastroenteritis pathogens including viral, bacterial and protozoan
 - 15 common respiratory infections
 - 12 common sexually transmitted infections
- Being adopted by major hospitals and pathology laboratories for detection of infectious diseases
- Deliver a wider array of highly specific results in 4-5 hours that would traditionally take 4-5 days
- Works on existing equipment found in any diagnostic laboratory
- A 1ml product volume is sufficient for 50 individual tests, driving an attractive and operationally leveraged business model
- Scalable manufacturing not limiting growth

Case Study:

St Vincent's Hospital Evaluation Study on Gastroenteritis

- *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

Case Study:

Evaluation Study on STI Detection Kit

- Results from 846 Specimens

- 846 patient samples compared to current testing, includes culture, and other molecular tests
- Identified 503 infections that were missed with current testing methods – almost 3 times more**

Pathogen detected	<i>EasyScreen™</i>	Hospital Traditional
C. trachomatis	48	31
N. gonorrhoeae	24	27
LGV	1	1*
M. genitalium	10	Not tested
T. vaginalis	8	4
Ureaplasma spp.	296	Not tested
Candida spp.	153	95
M. hominis	71	Not tested
S. agalactiae	98	51
T. pallidum	2	2, Confirmed by reference lab
HSV-1	32	25
HSV-2	19	15
Total	762	259

* Confirmed by sequencing

EasyScreen™ Products in Development

- Product expansion will drive revenue and market share growth
- Product development pipeline includes tests for:
 - 2nd generation respiratory virus
 - Atypical pneumonia
 - Meningitis
- Additional products being readied for sale:
 - Antibiotic resistance panel
 - Flavivirus (including Chikungunya, Zika, Dengue, West Nile, Yellow Fever etc.)

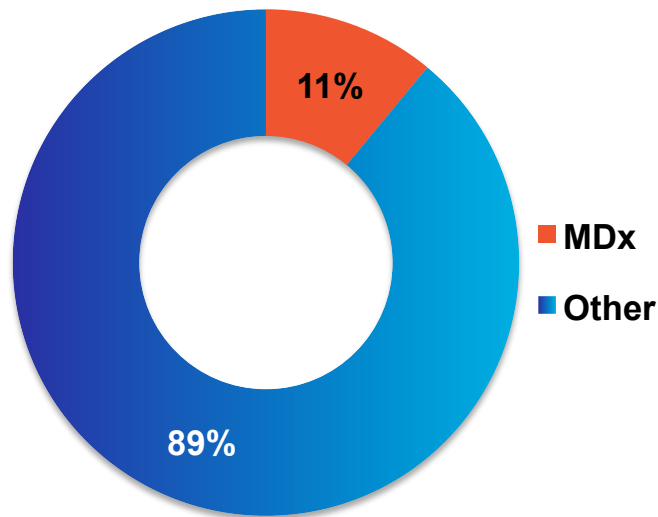
Global Growth Strategy and Commercial Progress



Growing Global Molecular Diagnostics Market

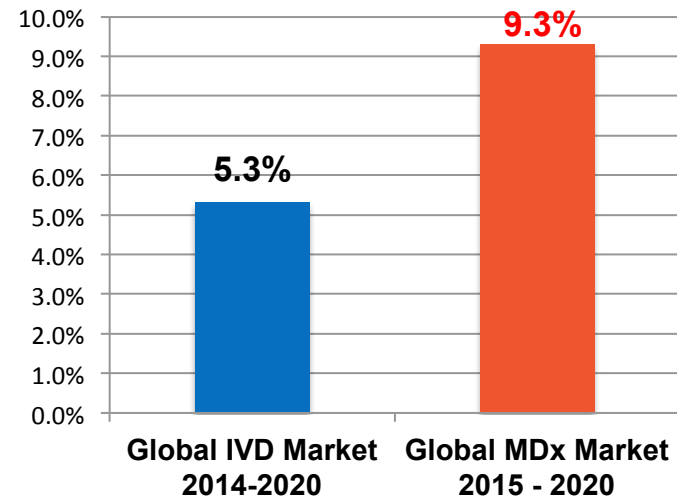
- Molecular Diagnostics (MDx) Market estimated to be US\$7.6B in 2017 representing 11% of the overall *in vitro* Diagnostics (IVD) market of \$US69B
- MDx market forecast to grow at an above system CAGR of 9.3% exceeding overall IVD market growth as MDx techniques replace traditional diagnostics

Breakdown of US\$69B Global (IVD) Market as at 2017



Source: www.mddionline.com/article/global-vitro-diagnostics-market-grow-691-billion-2017

CAGR of the Global IVD Market & Global MDx Market



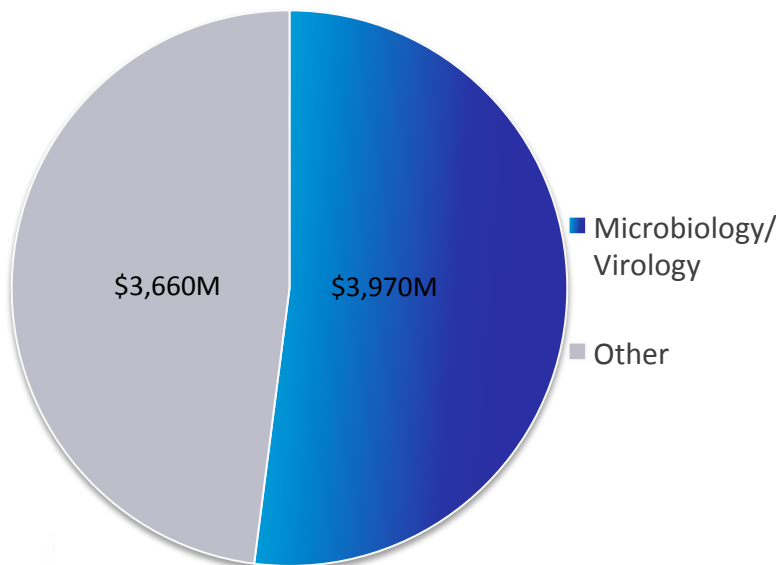
Source: www.marketsandmarkets.com/PressReleases/molecular-diagnostic.asp and www.researchbeam.com/in-vitro-diagnostic-ivd-market

MDx growth expected to drive IVD market demand

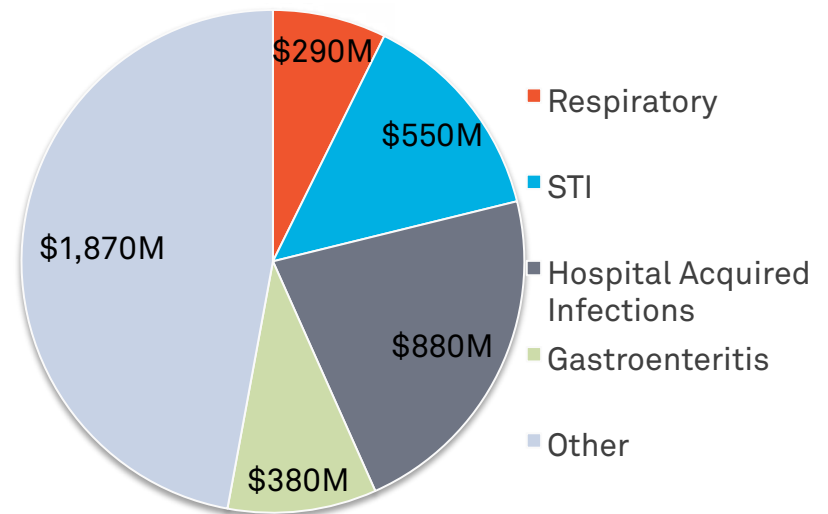
Large Addressable Markets

- GSS' current diagnostics products and pipeline products account for >50% of microbiology/virology diagnostics segment
- This total addressable market was **\$US1.1B in 2012** and estimated to be worth **US\$2.1B by 2017**

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



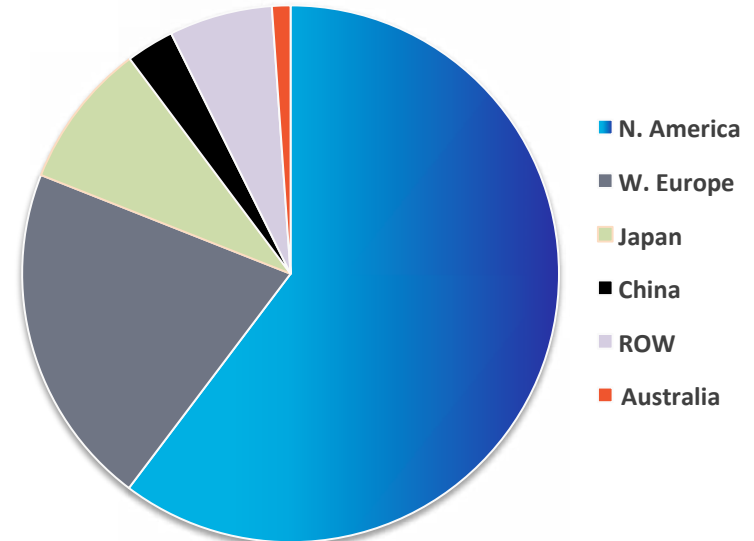
2017 Estimate of GSS Microbiology/Virology Addressable Market of US\$2.1B



Regulatory Approvals Now Secured in Large Portion of 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 Australia); 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

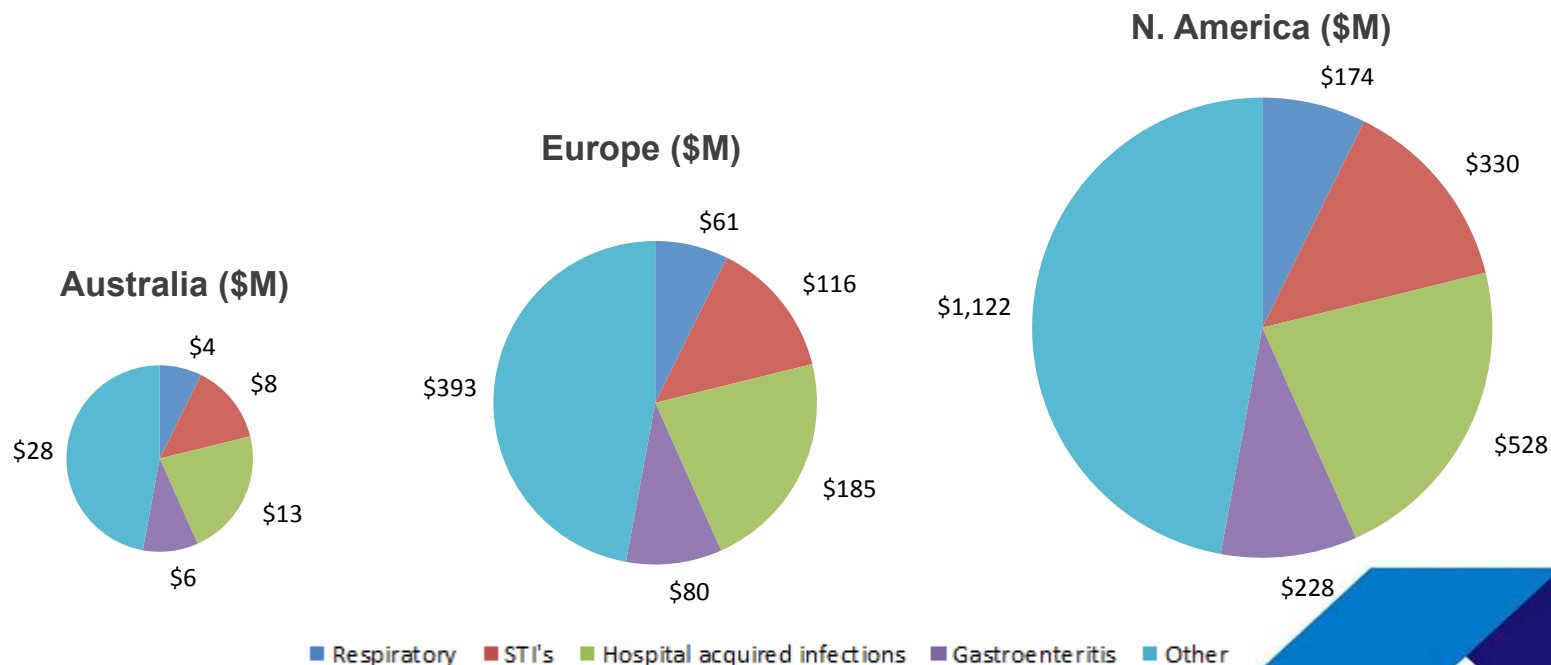
2017 Estimate MDx Market Size by Region (USD)



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
- Full regulatory approval for ~22% of the global market (Australia and Europe) - Enteric products have full CE-IVD approval in Europe which is 10-20x Australian market
- Specialist clinical sales of Enteric ASR tests into North America commencing FY17
- Specialist respiratory sales commenced in Australia (~20% of FY16 revenue) with imminent availability in the US
- Multiple products/jurisdictions de-risking commercialisation



Global Growth Strategy

- Focus on regions with regulatory approvals
 - Australia, Europe and US = >80% of world 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

- Major hospital and pathology group customers including St. Vincent's Sydney and Australian Clinical Labs
- New Sales and Marketing Director appointment to support growth
- Two new products to be released
 - Australia forms base for EU and US approvals and release
 - Product expansion will drive revenue and market share growth
- Dedicated R&D labs and network of clinical partners driving new product development:
 - 5 *EasyScreen*™ products for Gastroenteritis have TGA approval
 - 2 more *EasyScreen*™ kits are being validated for TGA approval

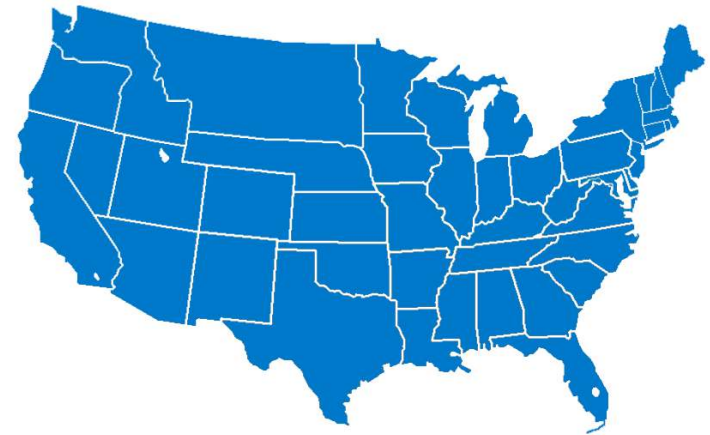
Commercialisation Progress - Europe

- Addressable market of ~US\$435M
- Western Europe = ~20% global molecular diagnostics market
- Expanding team to work with European Director and Distributors
- Trials underway and more planned
- Full EU regulatory approval for complete enteric suite allows unrestricted sales in 31 countries with a market estimated at \$86m per year



Commercialisation Progress – North America

- Up to ~US\$1,265M addressable market
- US = 50-60% global molecular diagnostics market
- **Analyte Specific Reagents (specialist sales) launched** at largest US microbiology conference
- Allows 3Base™ sales to thousands of **CLIA-certified laboratories**
- Trials planned to commence in current quarter
- **3base™ patent approval in US** where focus is on completing scientific validation for FDA product approval
- First products preparing for **full FDA approval**, allowing **unrestricted sales in US**



Outlook

Further strong growth expected in FY18

- Launch of regulatory approved products into Australia and EU
- ASR product trials planned for the US
- Alliances made with leading KOL and health laboratories

Progressing significant offshore opportunities

- Expect to capture a similar % of sales in Europe, following Australian growth trajectory - addressable market of ~US\$435M
- Commence sales of ASRs into the US market - addressable market up to ~US\$1265M
- Continuing FDA work for full regulatory products

Driving shareholder value

- Accelerate revenues through distribution and direct sales activities globally
- Accelerate R&D and approval activates globally, unlocking further revenues and strategic value within molecular test portfolio

The background of the slide is a microscopic image showing numerous rod-shaped bacteria, likely E. coli, with visible flagella. The bacteria are distributed across the frame, with some appearing in sharp focus and others blurred in the background. The overall color palette is a cool blue and green.

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