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%

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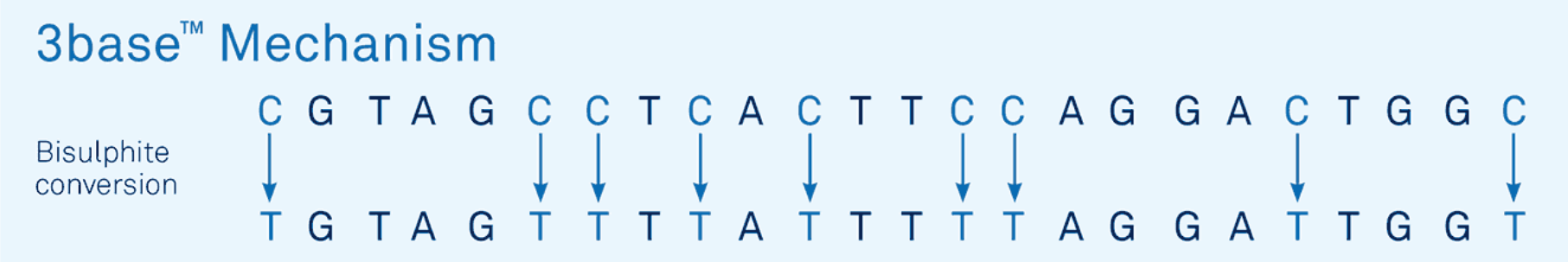
Transforming Global Molecular Diagnostics

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



- 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 C G A T A T G G T T G A C A C	G A T G G T G A T A T G G T T G A T A T
Seq 2	G A T G G T G A C A T G G T A G A T A C	G A T G G T G A T A T G G T A G A T A T
Seq 3	G A T G G T G A T A T G G T G G A C A C	G A T G G T G A T A T G G T G G A T A T
Seq 4	G A T G G T G A T A T G G T A G A T A T	G A T G G T G A T A T G G T A G A T A T
Seq 5	G A T G G T G A T A T G G T G G A C A C	G A T G G T G A T A T G G T G G A T A T
Seq 6	G A T G G C G A C A T G G T T G A T A T	G A T G G T G A T A T G G T T G A T A T
Seq 7	G A T G G T G A T A T G G T G G A C A C	G A T G G T G A T A T G G T G G A T A T
Seq 8	G A T G G T G A C A T G G T A G A T A C	G A T G G T G A T A T G G T A G A T A T
Seq 9	G A T G G T G A T A T G G T A G A T A C	G A T G G T G A T A T G G T A G A T A T
Seq 10	G A T G G T G A T A T G G T G G A T A C	G A T G G T G A T A T G G T G G A T A T
Consensus	G A T G G Y G A Y A T G G T D G A Y A Y	G A T G G T G A T A T G G T D 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

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SYDPATH
ST VINCENT'S PATHOLOGY

- 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	*EasyScreen*™	Hospital Traditional
C. trachomatis	48	31
N. gonorrhoeae	24	27
LGV	1	1*
M. genetalium	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

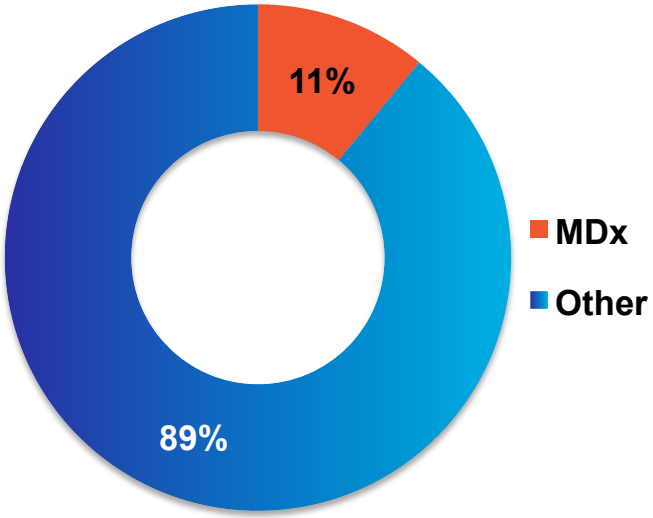
- Product expansion will drive revenue and market share growth
- Product development pipeline includes tests for:
  - 2nd generation respiratory virus
  - Atypical pneumonia
  - Meningitis
- Additional products being readied for sale:
  - Antibiotic resistance panel
  - Flavivirus (including Chikungunya,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

Global Growth Strategy and Commercial Progress

Growing Global Molecular Diagnostics Market

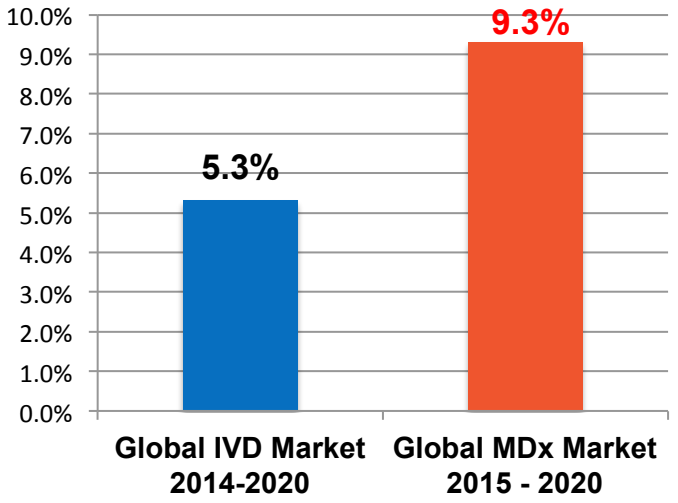
- Molecular Diestimatedics (MDx) Market estimated to be US$7.6B in 2017 representing 11% of the overall *in vitro* Diagnostics (IVD) market of $US69B
- MDx market forecast to grow at an above system CAGR of 9.3% exceeding overall IVD market growth as MDx techniques replace traditional diagnostics

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



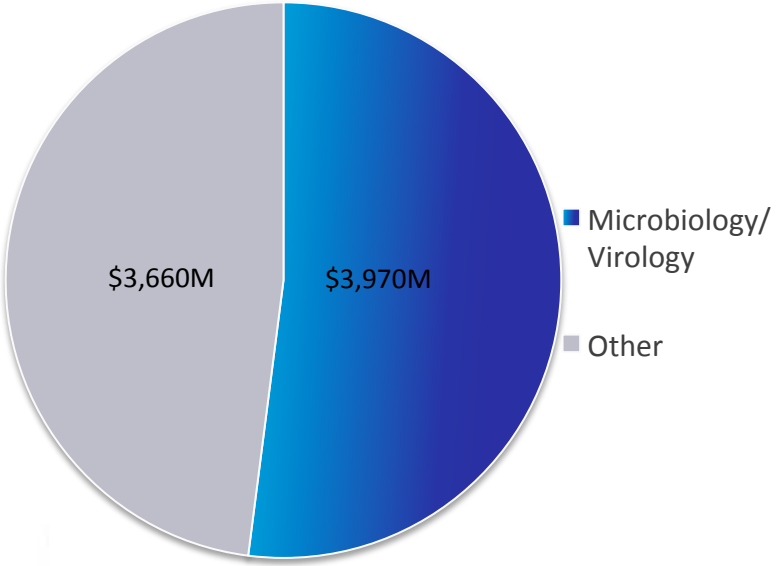
Source: www.marketsandmarkets.com/PressReleases/molecular-diagnostic.asp and www.researchbeam.com/in-vitro-diagnostic-ivd-market

MDx growth expected to drive IVD market demand

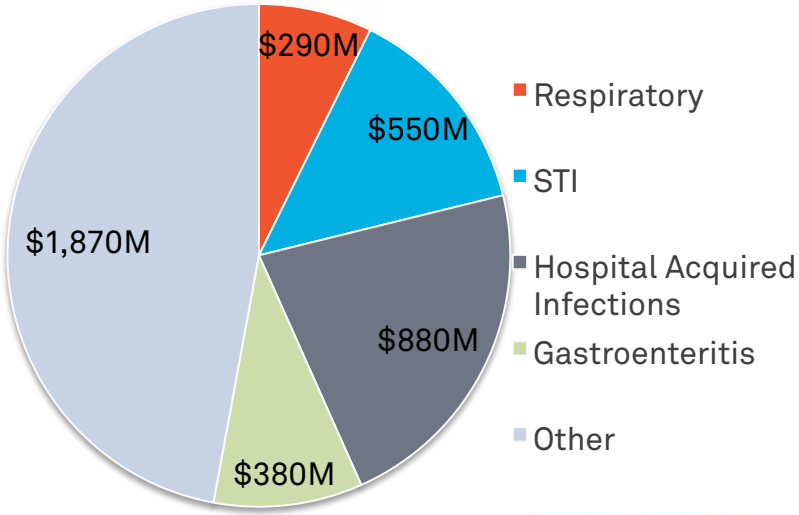
Large Addressable Markets

- 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

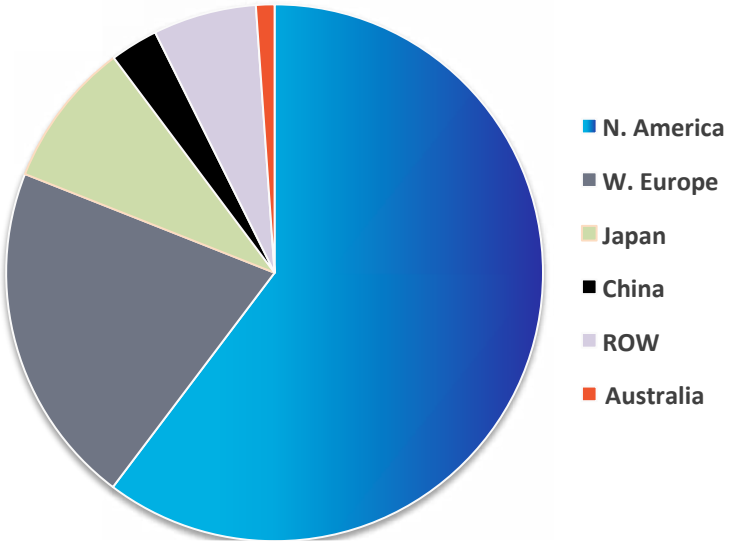


Source: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013, page 168 and
www.transparencymarketresearch.com/pressrelease/global-enteric-disease-testing-market.htm

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

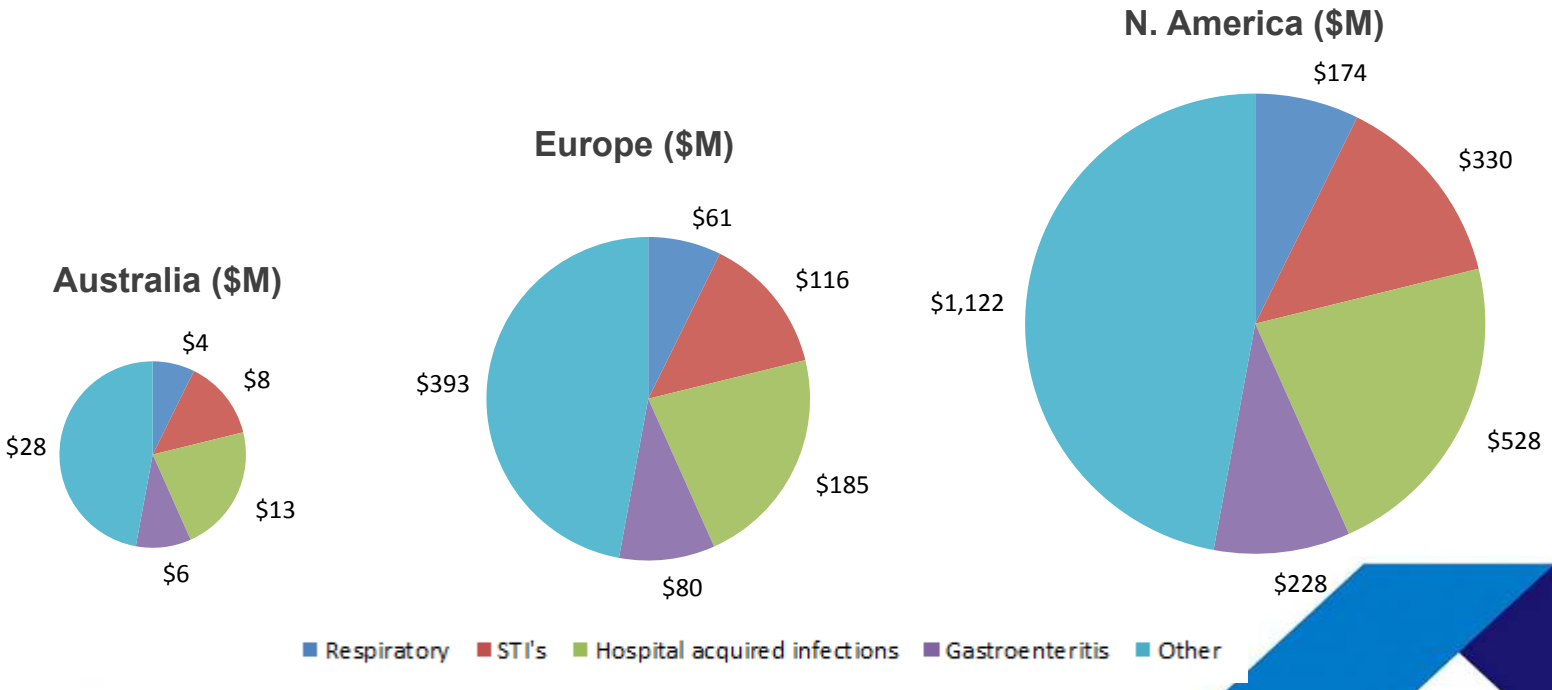
2017 Estimate MDx Market Size by Region (USD)



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

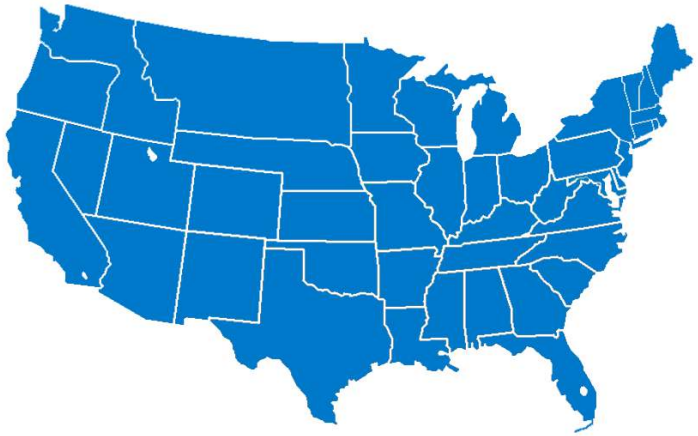
- Major hospital and pathology group customers including St. Vincent's Sydney and Australian Clinical Labs
- New Sales and Marketing Director appointment to support growth
- Two new products to be released
  - Australia forms base for EU and US approvals and release
  - Product expansion will drive revenue 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

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