

Genetic Signatures

Annual General Meeting – 2016

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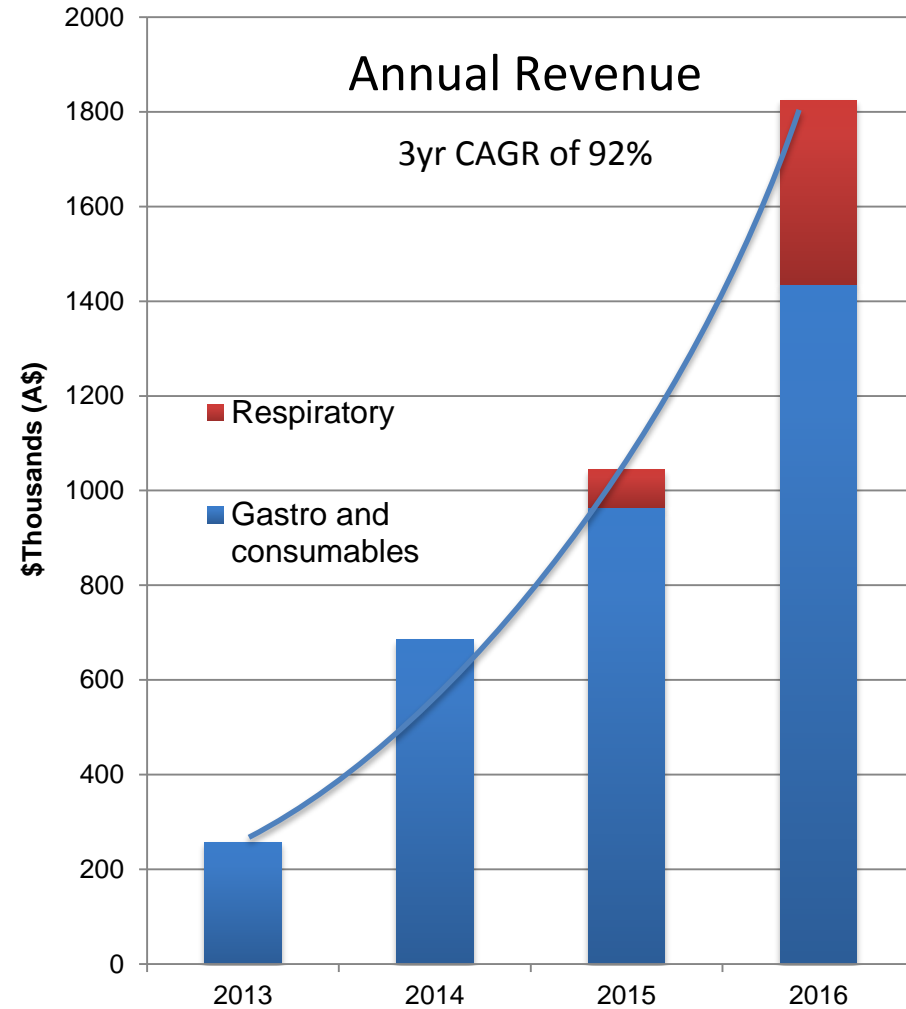
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Company Overview

- 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
- **FY16 sales revenue up 75% to A\$1.83M - 92% 3yr CAGR**
- *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

Recent Achievements

- Strong sales growth with a 3yr CAGR of 92%
- FY16 revenue of A\$1.83M, split ~80% Gastroenteritis and ~20% Respiratory specialist sales
- Recently completed oversubscribed \$15M capital raising
- Advancing R&D development of 5 new diagnostic products
- New product for STI infections – preliminary results reported, strong performance noted
- Offshore expansion underway in EU and the US
- Strong foundation for future growth



Corporate Summary

Financial Information (A\$)	
ASX Code	GSS
Shares on Issue	104.6M
Market Capitalisation	\$50.2M
Share Price (at market close 25 November 2016)	\$0.48
Cash at 31 October 2016	\$16.5M

Top Shareholders	%
Asia Union Investment Pty Limited	35.3%
Pan Australian Nominees Pty Ltd	14.2%
UBS Nominees Pty Ltd	6.5%
Directors, Management and Advisors	7.0%

Experienced Board and Management

Nick Samaras - Non-Executive Chairman

More than 25 years experience in the global life sciences industry, including Applied Biosystems (now part of Thermo Fisher) and Perkin Elmer. Founder of consulting firm Australis Biosciences and Director of the AGRF and MuriGen Therapeutics.

John Melki - Managing Director & CEO

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

More than 30 years 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 US\$1B+ in annual revenue.

Tony Radford, AO - Non-Executive Director

Part of CSIRO team that invented QuantiFERON, the worldwide benchmark for tuberculosis infection diagnosis. Founding CEO of Cellestis until its acquisition by QIAGEN NV in 2011 for ~\$400m.

Phillip Isaacs - Non-Executive Director

More than 30 years of industry experience, including Beckman Instruments and 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



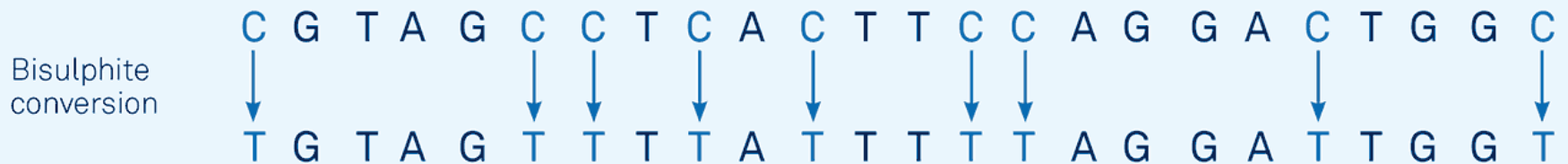
Genetic Signatures - 3Base™ Technology

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

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
- 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

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
 - STIs with clinical evaluation trial announced in September
 - Antibiotic resistance panel
 - Meningitis
 - Flavivirus (including Zika, Dengue, West Nile, Yellow Fever etc.)
- Two new products to be released in next 6-12 months
- Preliminary STI results presented at Molecular Conference in October

EasyScreen™ STI Detection Kit

Panel A	Panel B	Panel C	Panel D
C. trachomatis	M. genitalium	Candida spp.	T. pallidum
N. gonorrhoeae	T. vaginalis	M. hominis	HSV-1
LGV	Ureaplasma spp.	S. agalactiae	HSV-2
Extraction Control			

- STIs significantly impact sexual and reproductive health with WHO reporting **1 million+ STIs contracted daily** basis
- The *EasyScreen*™ STI Detection Kit is designed to cater for the **large addressable STI testing market estimated to be US\$550M** in 2017
- Aim is to screen 12 of the top causative agents of bacterial antiviral infections in one workflow solution

Traditional STI Testing Methods

Test	Amplification	Run frequency
C. trachomatis	Cobas 4800	Mon-Fri
N. gonorrhoeae	Cobas 4800	Mon-Fri
HSV 1/2	Simplexa	Mon, Wed, Fri
LGV	Send away test	Weekly
T. palladium	Send away test	Weekly
T. vaginalis	Wet prep only	Daily
Mycoplasma spp.	Send away test	Weekly
Ureaplasma spp.	Send away test	Weekly
Candida spp.	Routine culture	24-48 hours
S. agalactiae	Routine culture	24-48 hours

Results from 729 Specimens

Pathogen detected	<i>EasyScreen</i> TM	Hospital Traditional
C. trachomatis	38	31
N. gonorrhoeae	24	27
LGV	3 (7.9%)	To be confirmed*
M. genitalium	8	Not tested
T. vaginalis	8	4
Ureaplasma spp.	263	Not tested
Candida spp.	149	94
M. hominis	64	Not tested
S. agalactiae	84	51
T. pallidum	2	Confirmed by reference lab
HSV-1	30	25
HSV-2	19	15
Total	692	247

* Clinical presentation suggested LGV infection

Results - 25.9% of the samples had mixed infection (≥2 pathogens detected)

Pathogen detected	Specimen type	EasyScreen™	Hospital Traditional	Confirmatory test	Sensitivity (%) ^ψ	Specificity (%) ^ψ
<i>C. trachomatis</i>	Genital Swab (n = 550)	17	11 [⌘]	17	100.0	100.0
	Throat Swab (n = 19)	1	1	1	100.0	100.0
	Urine (n = 159)	19	18	19	100.0	100.0
	Thin Prep (n = 1)	1	1	1	100.0	100.0
<i>N. gonorrhoeae</i>	Genital Swab (n = 550)	12	12	12	100.0	100.0
	Throat Swab (n = 19)	7	10	8	87.5 (100.0)*	100.0
	Urine (n = 159)	5	5	5	100.0	100.0
	Thin Prep (n = 1)	0	0	0	N/A	100.0
HSV-1	Genital Swab (n = 550)	26	23 ^φ	25	100.0	100.0
	Throat Swab (n = 19)	0	0	0	N/A	N/A
	Urine (n = 159)	4	2 ^φ	4	100.0	100.0
HSV-2	Genital Swab (n = 550)	17	14 ^Δ	17	100.0	100.0
	Throat Swab (n = 19)	1	0	1	100.0	100.0
	Urine (n = 159)	1	1	1	100.0	100.0

* Throat swabs are not recommended for CT/NG nucleic acid amplification technology (NAAT)

^ψ Sample is regarded as positive when at least 2 out of 3 of the methods tested is positive

[⌘] 5 samples were not tested for CT/NG

^φ 2 swab and urine samples were not tested for HSV-1

^Δ 2 genital swab samples were not tested for HSV-2

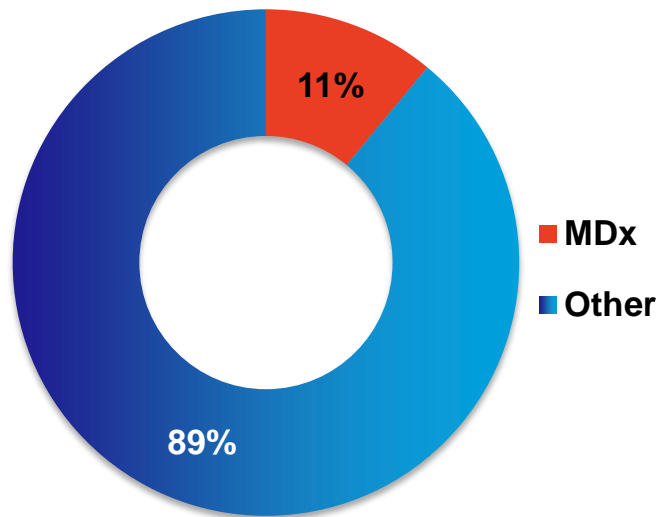
Global Growth Strategy and Commercial Progress



Growing Global Molecular Diagnostics Market

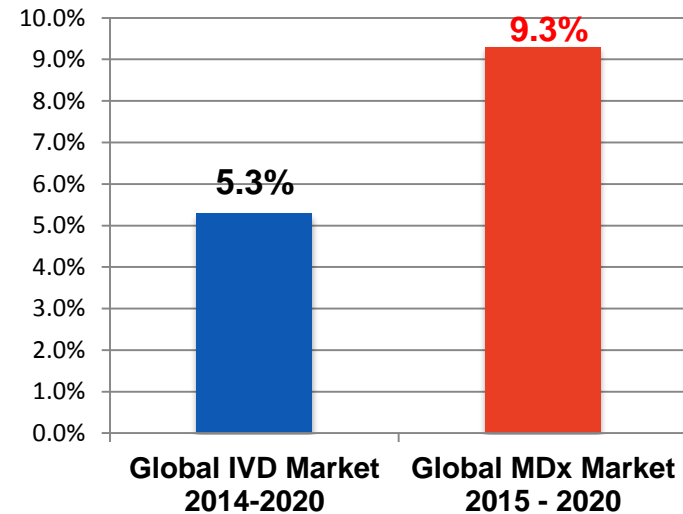
- Molecular Diagnostics (MDx) Market estimated to be US\$7.6B in 2017 representing 11% of the overall *in vitro* Diagnostics (IVD) market of \$US69B
- MDx market forecast to grow at an above system CAGR of 9.3% exceeding overall IVD market growth as MDx techniques replace traditional diagnostics

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



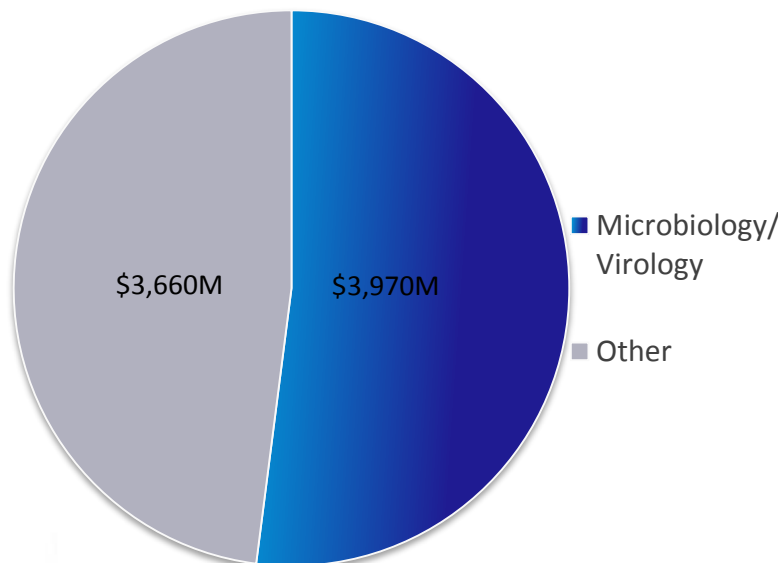
Source: www.marketsandmarkets.com/PressReleases/molecular-diagnostic.asp and www.researchbeam.com/in-vitro-diagnostics-ivd-market

MDx growth expected to drive IVD market demand

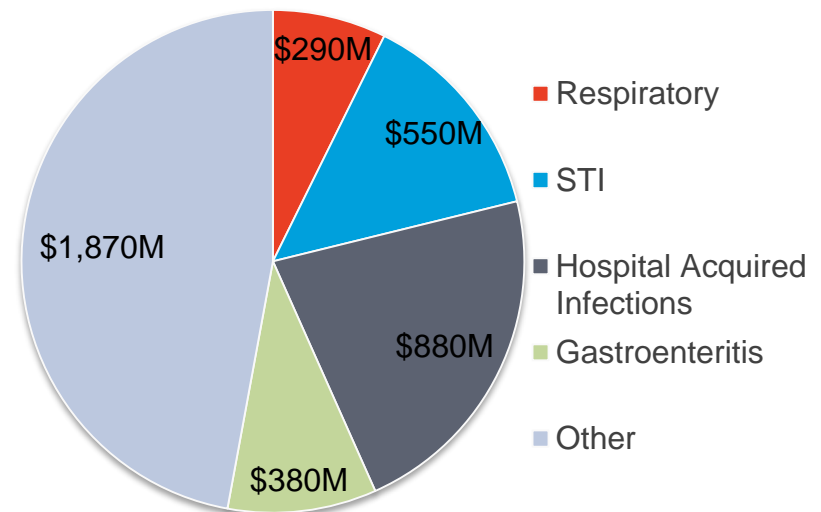
Large Addressable Markets

- 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



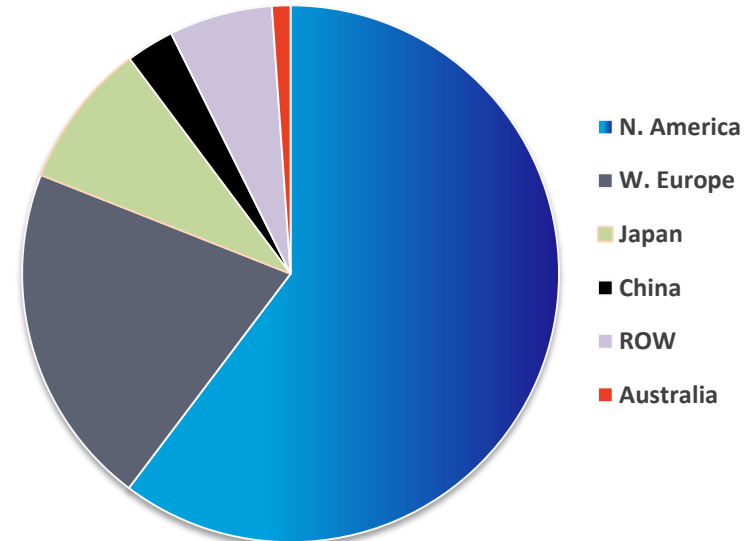
2017 Estimate of GSS Microbiology/Virology Addressable Market of US\$2.1B



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

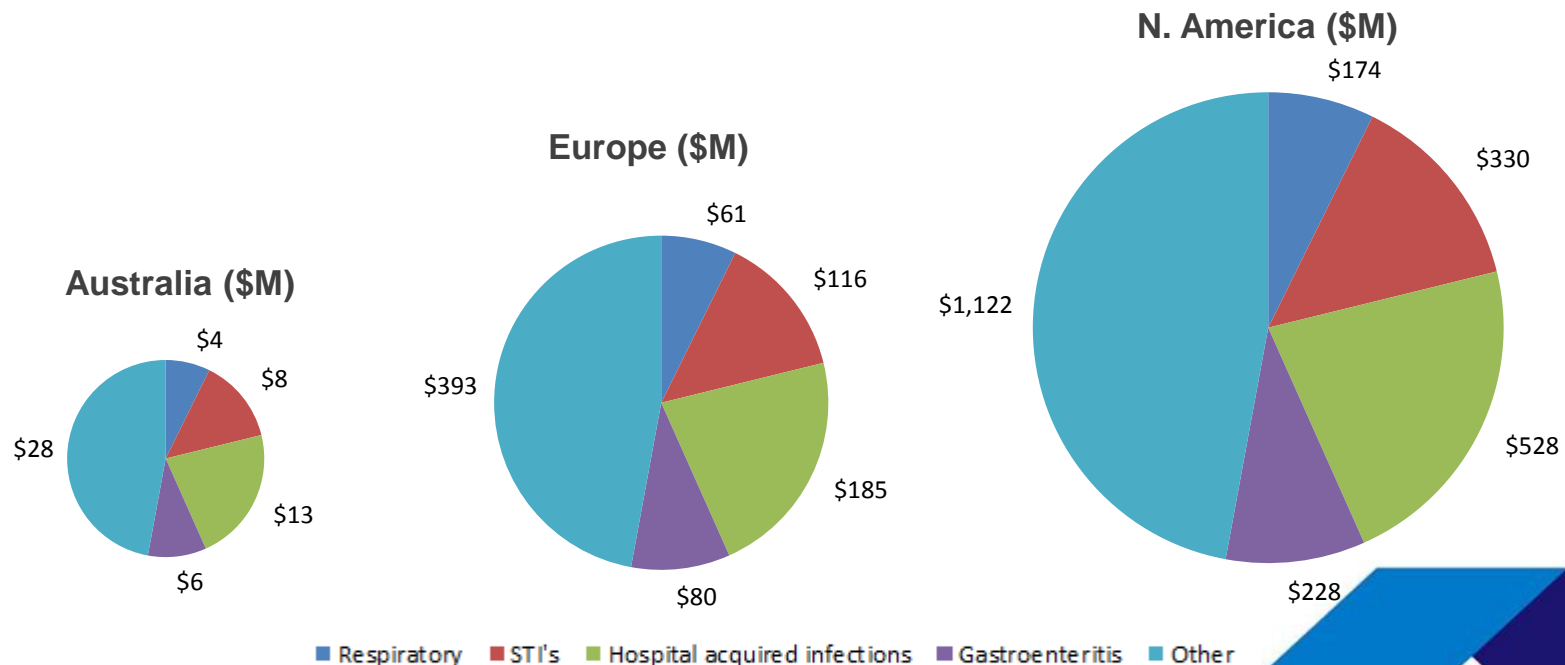
2017 Estimate MDx Market Size by Region (USD)



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 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
- Driving strong revenue growth for Australian sales: **92% 3yr CAGR**
- **Two new products to be released** in next 6-12 months
 - STI testing kit in clinical validation trial, preliminary results to be **presented at a molecular conference in October**
 - 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**:
 - 4 *EasyScreen*[™] products for Gastroenteritis have TGA approval
 - 2 more *EasyScreen*[™] kits are being validated for TGA approval

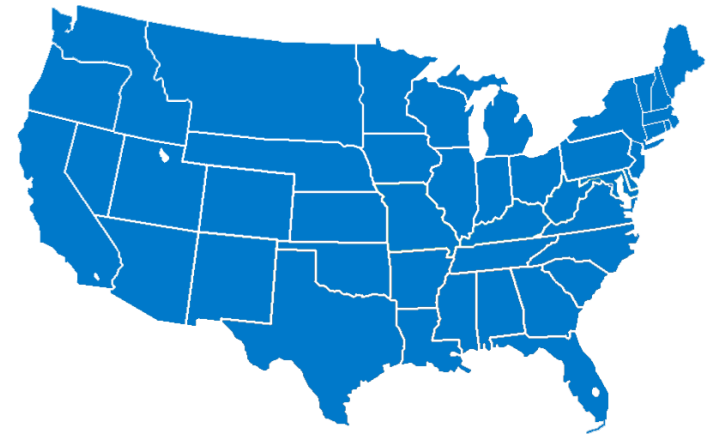
Commercialisation Progress - Europe

- Addressable market of ~US\$435M
- Western Europe = ~20% global molecular diagnostics market
- Anticipate **first significant revenues in FY17**
- European Director appointed
- Distributors in Italy, Israel, Poland & Ireland with hospital tenders and trials underway
- New distributors to be appointed in new jurisdictions
- 4 *EasyScreen*[™] kits have CE-IVD approval
- 2 more *EasyScreen*[™] kits are being validated for CE-IVD approval



Commercialisation Progress – North America

- Up to ~US\$1,265M addressable market
- US = 50-60% global molecular diagnostics market
- Anticipate first sales in FY17
- US FDA listing for Clinical Sample Concentrator achieved in FY16 provides base for future revenue
- *EasyScreen*[™] Sample Processing Kits being sold to US laboratories to yield 3Base nucleic acids from patient specimens
- **Analyte Specific Reagents (specialist sales) launched** at largest US microbiology conference (June 2016)
- Allows 3Base[™] sales to thousands of **CLIA-certified laboratories**
- First products preparing for **full FDA approval**, allowing **unrestricted sales in US**
- GSS certified by Health Canada, leading to **IVD sales in Canada**



Outlook

Further strong growth expected in FY17

- FY16 sales revenues of AU\$1.83m, representing a 3yr 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 and globally

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
- Launch FDA approval process for three products commencing with the Enteric Protozoan Kit

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
- Targeting cash flow breakeven in FY18

A microscopic view of various bacteria, including rod-shaped and spiral-shaped organisms, set against a blue background with a network of fine white lines.

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