Genetic Signatures

Bioshares Presentation July 2015

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THE GSS IPO EXPERIENCE:

- Why IPO?
- Who to Use?
- Once in…
- Take 2

INVESTMENT HIGHLIGHTS

Genetic Signatures is a molecular diagnostics (MDx) company operating in the global IVD (*in vitro* diagnostics) industry. **Primary focus on supplying major hospitals and pathology laboratories in testing for infectious diseases.**

- Products already available in Australia with GSS set to launch into large global markets worth **US$1.11 billion** in 2012 growing to **US$1.77 billion in 2017**
- Proprietary technology driving product development for large customers in multiple markets
- Experienced management team and board with track record in global molecular diagnostics industry

CORPORATE SNAPSHOT

Capital Structure	
ASX Code	**GSS**
Shares on Issue	**72.9m**
Market Capitalisation	**$32.8m**
Share Price (at market close 17 July, 2015)	**$0.45**

Directors & Chief Executive	
Nick Samaras	Non-Executive Chairman
John Melki	Director & CEO
Mike Aicher	Executive Director - US
Phillip Isaacs	Non-Executive Director
Pat Noland	Non-Executive Director
Robert Birrell	Director & CFO

TECHNOLOGY – 3BASE™

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
- Patent-protected chemical transformation of DNA and RNA sequences to reduce genetic code complexity
- Process can enhance detection of multiplexed assays where multiple targets are detected in the one tube
- Achieved by allowing a simpler design of molecular assays for the simultaneous detection of multiple targets

Case Study: Major Hospital, Sydney, Australia: Pilot Study 2013 – *EasyScreen*™ vs Traditional

METHODS:

- Primary focus of this study was to assess the clinical utility of *EasyScreen*™ in detecting infectious agents in 279 patient samples as compared to their existing methods
- ***Results generated in approximately 4 hours, which compares to up to 4 days*** when using traditional microbiology techniques
- ***Additional 79 pathogens detected*** (last column) that would not have been detected using traditional microbiology testing methods

Pathogen detected	*EasyScreen*™	Sensitivity %	Specificity %	Additional pathogens
Viruses (Noro, Rota, Adeno, Astro)	69	100	97.1%	25
C. difficile	58	84.8	99.4	9
Campylobacter spp.	48	100	100	0
Salmonella spp.	42	97.7	100	1
Shigella spp.	11	100	99.5	0
L. monocytogenes	1	NA	NA	1
Y. enterocolitica	3	100	100	2
D. fragilis	10	100	100	10
B. hominis	17	100	100	16
G. intestinalis	12	92.3	100	7
Cryptosporidium spp.	3	100	100	3
Entamoeba complex	5	NA	NA	5
Totals	279			79

Table 2: Major Hospital Pilot Study 2013 – EasyScreen™ versus Traditional Methods

"I find that the fast turnaround time and the number of targets tested in the EasyScreenTM 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)**

Case Study: St Vincent's Hospital (SydPath), Sydney Australia: Evaluation Study 2014 – *EasyScreen*™ vs Traditional Methods

METHODS:

- Primary focus of study was to assess the clinical utility of *EasyScreen*™ in detecting infectious agents in 221 patient samples as compared to traditional methods
  - ***Identified 44 infections that existing testing would have missed.***
  - Missed infections within the hospital environment can have substantial downstream consequences such as the 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**

Table 3: St Vincents Hospital (SydPath) Evaluation Study 2014 - *EasyScreen* versus Traditional Methods

COMPETITOR ENVIRONMENT

Table 1 opposite explores the global competitive environment in which GSS operates for infectious disease products, focusing on enteric (otherwise known as or gastroenteritis) screening.

Table 1 incorporates the major criteria utilised by global customers in assessing products for gastroenteritis screening.

GSS is unique in supplying products that

- Screen over 20 pathogens, including RNA and DNA viruses, whilst
- Using the latest technology and being compatible with existing equipment (open platform)
- ease of use and automation

Comparison of attributes of products for enteric screening

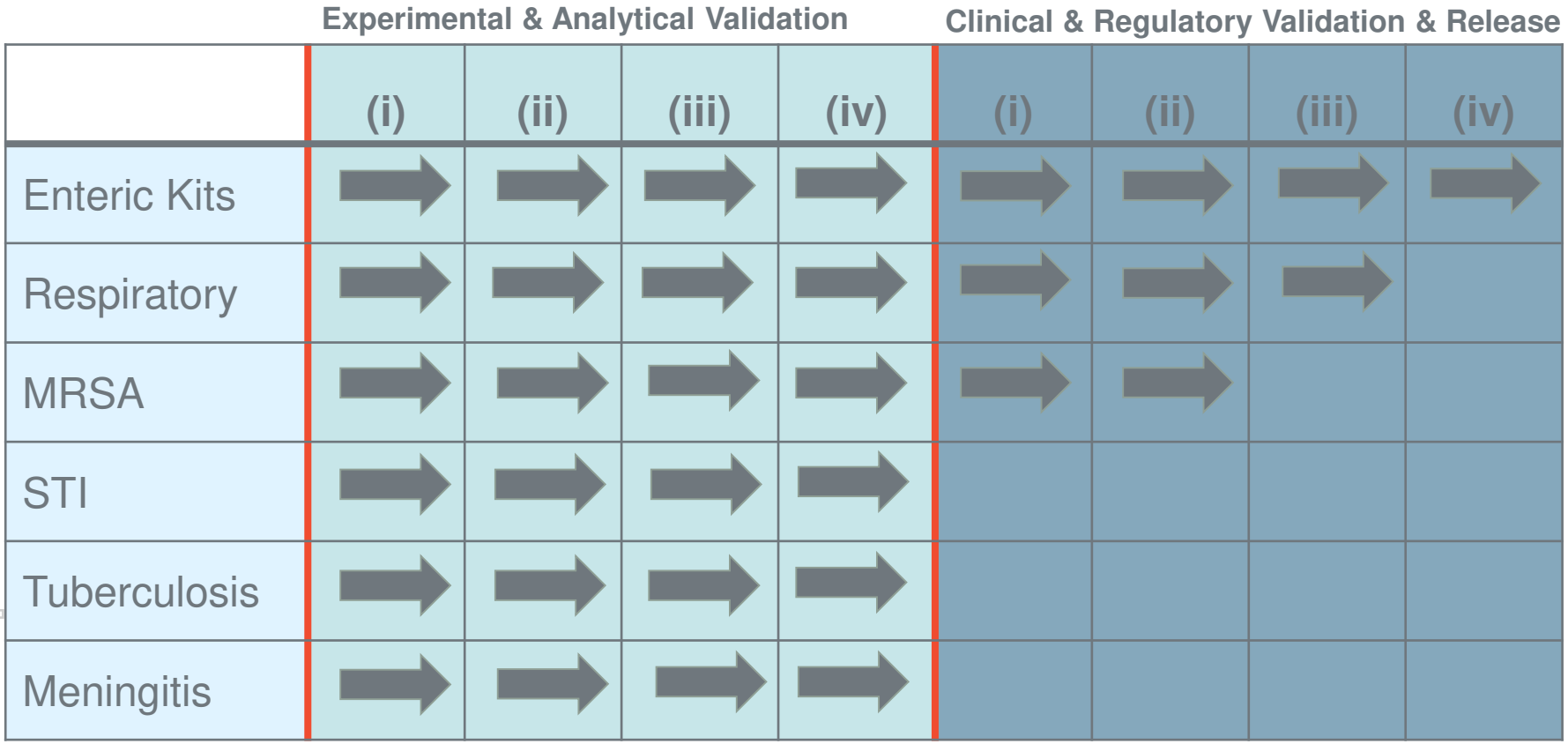
	Genetic Signatures Products for Enteric Screening	Competing Products for Enteric Screening							
	Genetic Signatures (*EasyScreen™*)	Biofire FilmArray	Hologic/ Gen-Probe	BD (BD Max)	Tib Molbiol[1]	Fast Track Diagnos-tics	AusDiag-nostics	Luminex	Seegene[3]
Probe based PCR	●	●	●	●	●	●	●	●	●
Combined extraction and PCR set-up platform provided by supplier of IVD kits[2]	●	●	●*	●	●	●	●	●	●
Rapid Time to Result (<5 hours)	●	●	●	●	●	●	●	●**	●
Thorough Coverage of Common Enteric Pathogens (20 or more targets in a run)	●	●	●	●	●	●	●***	●	●
Separate endogenous extraction and inhibition Controls	●	N/A	●	●	●	N/A	●	N/A	●
Open Platform (Extraction and PCR) from multiple suppliers	●	●	●	●	●	●	●****	●	●
Viral, bacterial and Protozoan coverage	●	●	●	●	●	●	●	●	●
Manufactured in Australia	●	●	●	N/A	●	●	●	●	●

● = Yes; ● = No; N/A = Information not available from company website

Source: Company

[1] Distributed in Australia by Roche Diagnostics
[2] On a single integrated platform
[3] Seeplex End point PCR range
* This test is not compatible with Hologic automated instrumentation
** Does not include pre-treatment time
*** Requires the use of multiple assays with redundant targets under current menu
**** May be compatible with some 3rd party 384-well PCR instrumentation

EASYSCREEN™ PRODUCT DEVELOPMENT PATHWAY



Each product goes through extensive development and beta testing and adheres to rigorous quality management systems & regulatory approach.

- ISO9001 and ISO13485 certified
- Already approved by Australian and European regulators

COMMERCIALISATION PROGRESS

Australia

- Currently in market with major hospital and pathology group customers
- Testing for 22 causes of gastroenteritis
- Testing for 15 causes of viral respiratory disease
- Next new product in beta testing with customer

Western Europe

- Established operations in 2013
- Signed Italian distributor and testing with large pathology laboratories, recurrent revenues commencing
- Signed Israeli distributor agreement
- In discussions with distributors in other jurisdictions

United States

- Established operations in 2014 with appointment of key personnel
- Anticipate entering market in 2015

SUMMARY

- **EasyScreen™ Respiratory & Enteric Pathogen Detection Kits** provide **faster & more accurate screening** for viral, bacterial and protozoan pathogens – **tests are processed in hours instead of days, with fewer false positives and negatives**
- Products already available in Australia with GSS set to launch into global markets worth US$1.11 billion in 2012 growing to **US$1.77 billion in 2017**
- **Established operations in key global markets** of Western Europe and the US over the past year, including appointment of experienced management team
- **Experienced management team and board** with track record in global molecular diagnostics industry
- The 3Base™ platform and products are protected by a **strong patent portfolio** - broad patent protecting the 3Base™ technology platform until 2024, and a more specific patent protecting the use of 3Base™ in each of the Company's products until 2031

MILESTONES - SNAPSHOT

Achieved – CY 2015

- IPO
- Continued sales growth of enteric product line
- Initial Revenues generated from second product line – Respiratory

To lookout for – balance of CY 2015

- Continued sales growth
- Additional EU distributorships
- Release of third product line – MRSA ("Golden Staph")
- Initial US Revenues targeted around end CY2015

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