

The background of the slide is a microscopic image of cells, possibly cancer cells, rendered in shades of blue. The cells have irregular shapes and some have prominent nuclei. Overlaid on the right side of the image are several blue geometric shapes, including a large triangle and a smaller square, creating a modern, scientific aesthetic.

Genetic Signatures

Transforming
Molecular
Diagnostics

AGM Presentation

29 November 2018

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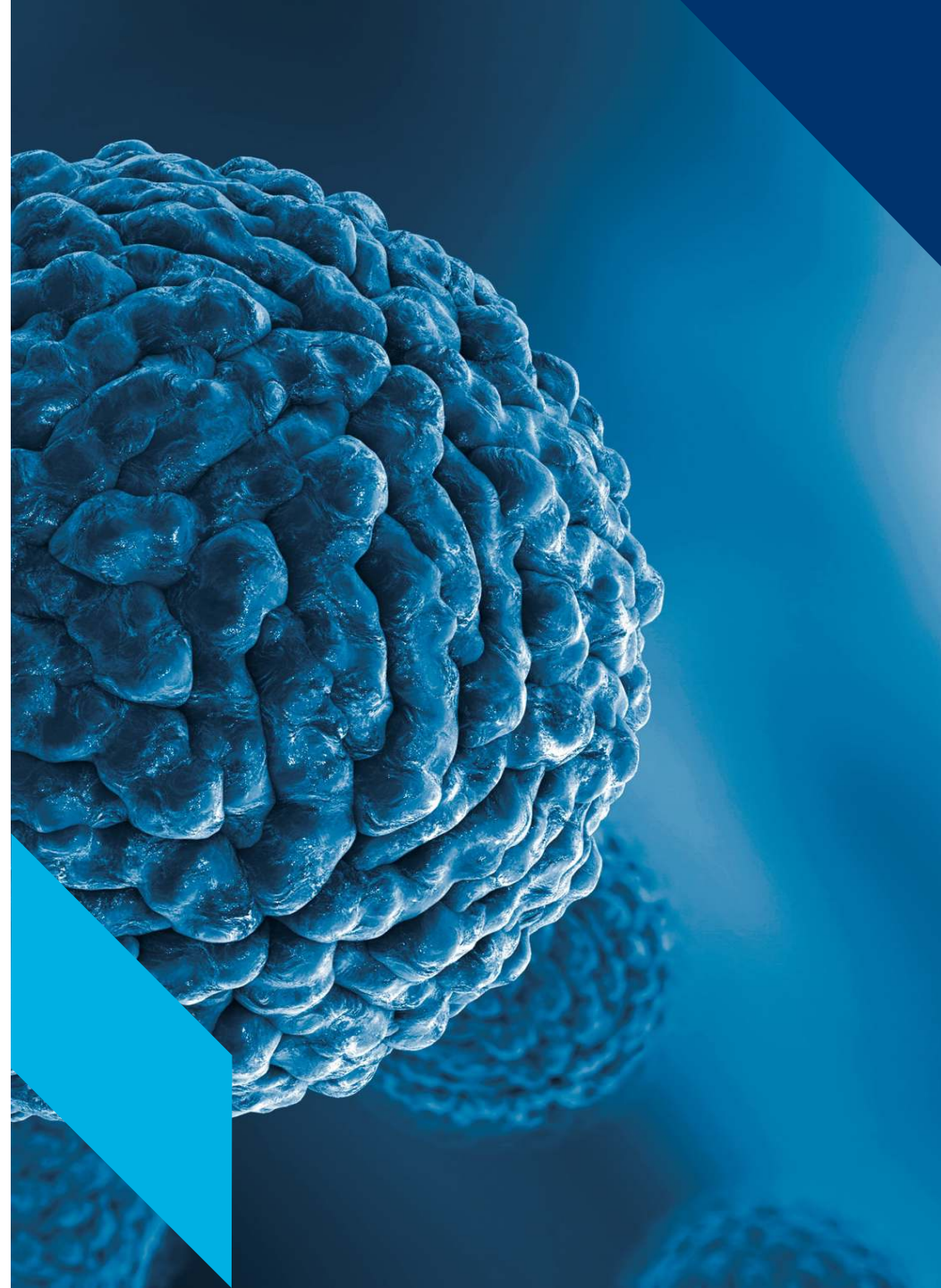
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- 1 Year in review
- 2 Product overview
- 3 Upcoming milestones



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 (23-Nov-18) A\$0.540

Shares on issue 103.9m¹

Market capitalisation A\$56.1m

Cash (30-Sep-18) A\$7.4m

Debt (30-Sep-18) Nil

Enterprise value A\$48.8m

Top shareholders %

Asia Union and Christopher Abbott 39.6%

Karst Peak (HK-based investment manager) 18.2%

Directors, management & advisors >6.0%

Notes:

1: Excludes 1.05m unquoted options (various expiration dates and prices)

Board of Directors

Management team with a proven track record in MDx industry and extensive experience in commercialisation of medical devices



Nick Samaras
Non-Executive Chairman

- Significant experience in leading international sales expansions of biotech companies
- Former Managing Director of **Applied Biosystems** (acquired by ThermoFisher, US\$76.8bn market cap)
- Held senior roles with **Perkin Elmer** and **AMRAD Corporation** (now part of CSL)



John Melki
Managing Director & CEO

- **Led global commercialisation efforts of GSS since 2011** and the product development team since 2003
- Successfully **commercialised seven products globally**
- Authored 20 peer-reviewed articles and listed as an inventor on eight patent applications



Michael Aicher
Executive Director

- Founder and former CEO of **National Genetics Institute** (subsidiary of LabCorp, US\$15.3bn market cap)
- Led Lab-Corp's Esoteric Business Units which generated over US\$1b revenue p.a.
- Former executive roles at **Central Diagnostics Laboratory**
- Recipient of Ernst & Young "**Entrepreneur of the Year**" award for emerging technologies



Tony Radford AO
Non-Executive Director

- Former Co-Founder and CEO of **Cellestis** (ASX:CST, acquired by QIAGEN for c.A\$350m in 2011)
- Former member of CSIRO team that invented QuantiFERON
- Former Head of Development at **AMRAD** (later acquired by CSL)



Phillip Isaacs
Non-Executive Director

- Former Managing Director of Australian subsidiary of **Technicon Equipment**
- Former Managing Director of **Beckman Instruments** in Australia
- Vice President of Asia Pacific for **Cytec Corporation**
- Founding Chairman of Australian Proteome Analysis Facility

GSS snapshot

Genetic Signatures is globally commercialising the 3base™ technology which underpins its EasyScreen™ molecular diagnostic kits

Genetic Signatures' 3base™ technology

- World-first, proprietary platform technology **significantly simplifies genetic detection of microbial organisms**
- Technology **reduces the four bases of nucleic acid that make up DNA to just three**
- **3base™** is the science **behind the EasyScreen™ Kits**

Global strategy for commercialisation

Australia

- Continued compounding revenue growth driven by new customers and new product releases

Europe

- Expand revenue with recently established local sales team

North America

- Continue to drive direct sales of ASRs and progress FDA submission of EasyScreen™ Kits

Genetic Signatures EasyScreen™ Portfolio



Enteric

Detects 20+ gastro-enteritis pathogens (e.g. Salmonella and Cryptosporidium)



Respiratory

Detects 14 common respiratory infections (e.g. Influenza A & B, Rhinovirus and M. pneumonia)



ESBL & CPO

Identifies antibiotic resistant 'superbugs'



STI / Genital

Detects 12 of the most common sexually transmitted infections (e.g. Chlamydia, Gonorrhoea and Syphilis)



Flavivirus / Alphavirus

Detects complex viruses primarily spread by insects causing widespread morbidity (e.g. Dengue Fever)



Meningitis

Detects life-threatening infection surrounding the brain and spinal cord



Respiratory Atypical

Simultaneous detection of leading causes of bacterial respiratory infection



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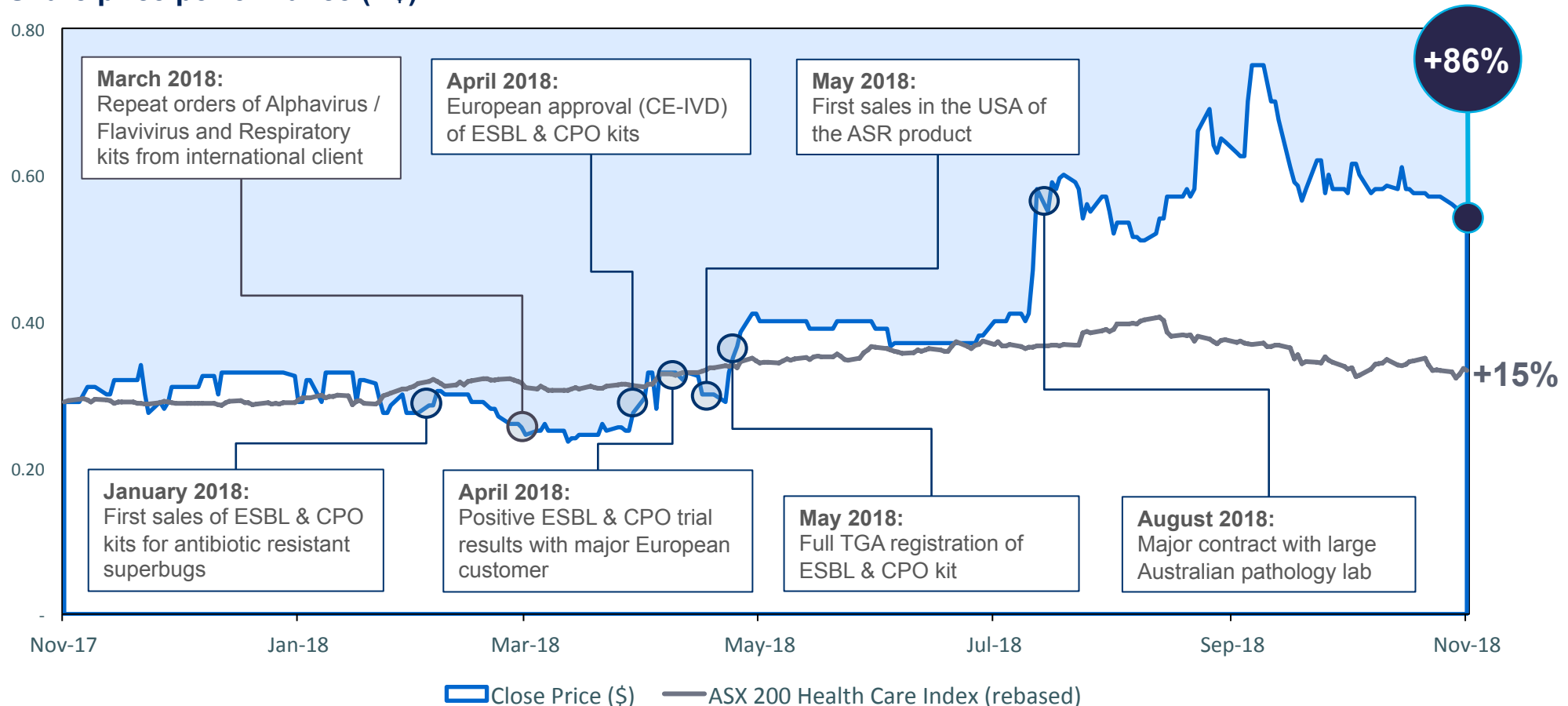
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1 Year in Review

Share price performance

Genetic Signatures has made significant operational progress which has been recognised by positive share price performance in the last 12 months

Share price performance (A\$)



Source: IRESS

Major Australian contract and product launch

New domestic customer and product launch creates immediate boost to the domestic revenue base

Step change in domestic revenue following product launch and new major contract

- Sales contract signed with **a large Australian pathology services provider** for **two new products**:
 - *Second generation EasyScreen™* Respiratory Pathogen Detection Kit
 - GS1-HT Instrument
- New customer creates an opportunity to supply up to **1,000 tests per day during peak flu season**, and **~100-200 test per day outside of flu season**
- Single new contract creates a notable **jump in revenue for Genetic Signatures**
- Significant size of customer **validates Genetic Signatures technology**

1

Second generation *EasyScreen™* Respiratory Pathogen Detection Kit

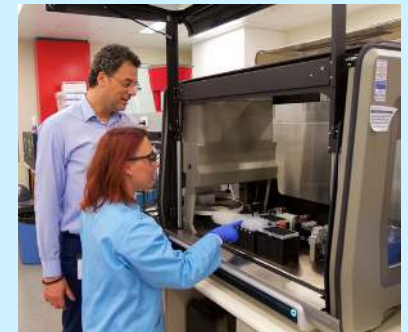
- ✓ Increased throughput with the ability to simultaneously detect **15 common respiratory pathogens** in patients
- ✓ Rapid detection in approximately 4.5 hours



2

GS1-HT Instrument

- ✓ Automates sample processing and amplification setup
- ✓ **Increases throughput by up to 15%** relative to existing instrumentation, offering **a more consolidated and efficient workflow**



New customer and product launch expected to help accelerate sales growth

First sales of ASRs in the US

Increasing traction with ASR approach and early revenue out of the US highlights the commercial potential of 3base™ technology

Important milestone for Genetic Signatures

- Received its **first US sales order of Analyte Specific Reagents (ASRs)** in the June 2018 quarter
 - Customer nearing completion of validation work
- Customer is a **well respected pathology lab** that offers extensive services to a large number of patients
- Launch **followed a successful ASR trial period**

What is an ASR?

- Building blocks of *EasyScreen™* kits that utilise the Company's proprietary **3base™** technology
- Can be purchased by eligible customers¹ to develop and validate proprietary tests for the diagnosis of infectious diseases
- ASRs are offered to more than 11,000² eligible labs and hospitals in the US
- ASRs are used to make LDTs (laboratory-developed tests), and represent ~20% of the US MDx market³

Estimated MDx market size (2017, US\$)⁴

Australia



\$0.1bn

North America



\$4.6bn

+9.3%

*global forecast
CAGR to 2020*

A major US contract should significantly increase Genetic Signatures' group revenue

Notes:

- US Laboratories regulated by the Clinical Laboratory Improvement Act (CLIA) may purchase and use ASRs,
- <https://www.acla.com/wp-content/uploads/2014/09/Alan-Mertz-Written-Statement-for-21st-Century-Cures-Hearing-2014-09-09.pdf>
- DeciBio Consulting
- Molecular Diagnostics Market by Application, Forecast to 2020. Markets and Markets, November 2015 and Global In Vitro Diagnostics (IVD) Market Forecast 2013-2020. Allied Market Research, June 2014.

Promising clinical trial results

The National CPE Reference Laboratory in Ireland presented successful results from the trial of the *EasyScreen*TM ESBL & CPO Detection Kit

Successful *EasyScreen*TM ESBL & CPO trial results

- The trial was undertaken by Ireland's National CPO Reference Laboratory
- Trial results highlight that:
 - ✓ The automated sample extraction and the *EasyScreen*TM ESBL & CPO Detection Kit has **strong results in the rapid detection of antibiotic resistant organisms**
 - ✓ Provides a **sensitive and specific** alternative to culture
 - ✓ Diagnostic results **in less than 3 hours**, compared to culture, which takes days
 - ✓ Requires **minimal hands-on-time**
- Positive trial results validate the *EasyScreen*TM ESBL & CPO Detection Kit



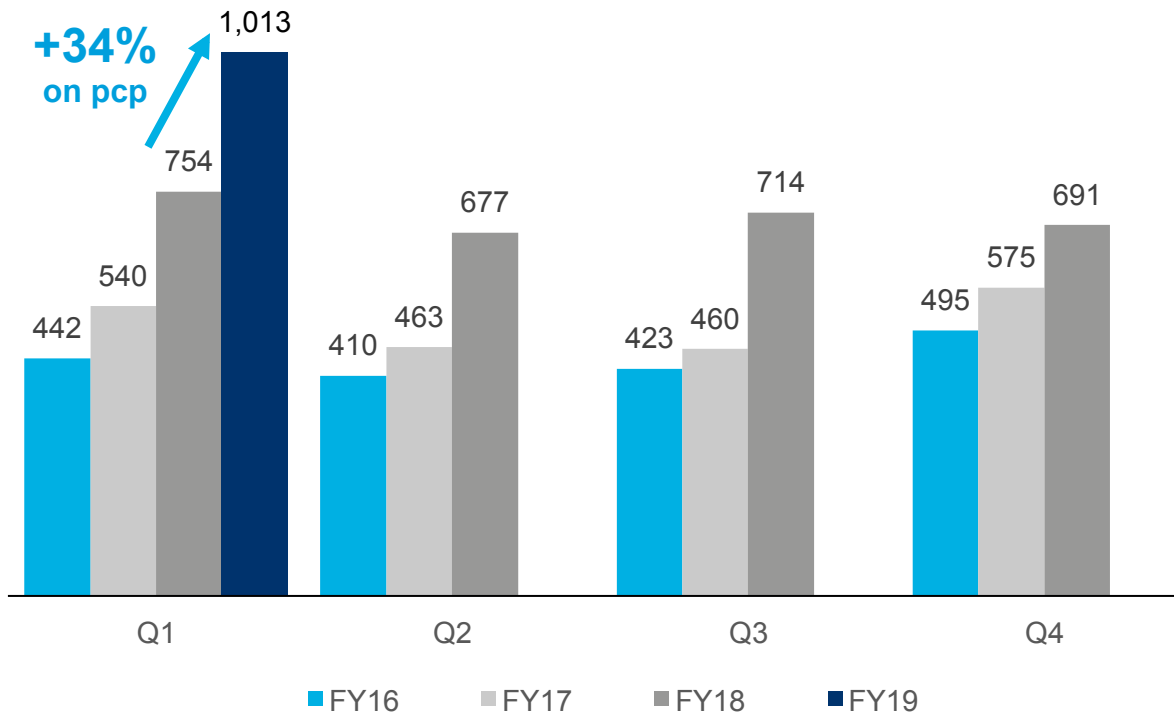
In April 2018, successful trial results were presented at ECCMID in Madrid, educating labs about how they can tackle antimicrobial resistance

Growing interest in *EasyScreen*TM ESBL & CPO as a result of global outbreaks

Strong revenue uplift in 1Q FY19

GSS continues to deliver consistent quarter-on-quarter revenue growth since listing

Quarterly revenue (A\$k)



Key Highlights

- Despite a relatively soft flu season, Genetic signatures achieved **record quarterly revenues of A \$1.0m**
- Strong revenue is reflective of the sales traction Genetic Signatures is building across its **expanding product range in both domestic and key international markets**
- A **new major customer contract** was also signed during the quarter, which further boosted domestic sales, and is expected to **help accelerate future global sales**

Financial performance

A\$000	Year ending 30 June 2017	Year ending 30 June 2018
Sales revenue	2,038	2,840
Other income	2,275	2,384
Total revenue	4,313	5,224
Cost of goods sold	(602)	(1,000)
Employee benefits expense	(3,056)	(3,724)
Other expense items	(2,847)	(3,122)
EBITDA	(2,192)	(2,622)
Depreciation and amortization	(479)	(632)
EBIT	(2,671)	(3,254)
Finance costs	-	-
(Loss) / profit before tax expenses	(2,671)	(3,254)
Income tax benefit / (expense)	-	-
Net (loss) / profit after tax	(2,671)	(3,254)
Basic and diluted earnings per share (Acps)	(2.78)	(3.13)

Other income includes R&D rebates received (A\$2.1m in FY2018) and interest received

Includes scientific consumables, rental, travel etc

No interest bearing liabilities on balance sheet

Total amount of unused tax losses for which no deferred tax asset has been recognised is A\$7.6m (A\$2.3m at tax effected rate of 30%)

Financial performance - cash

A\$000	Year ending 30 Jun 2018	Qtr ending 30 Sep 2018
Receipts from customers	2,902	1,066
Payments to suppliers & employees	(8,447)	(2,448)
Interest received	253	4
R&D tax concession received	1,598	-
Net cash used in operating activities	(3,694)	(1,378)
Purchase of plant & equip	(519)	(181)
Net cash used in investing activities	(519)	(181)
Net cash flows from financing activities	-	-
Net decrease in cash & equivalents	(4,213)	(1,559)
Cash at beginning of period	13,193	8,955
Foreign exchange differences	(25)	(3)
Cash & equivalents at end of period	8,955	7,393

▪ Increase in line with sales

▪ R&D refund of \$2.6m expected in 2Q19



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2 Product overview

Clear path to global commercialisation for all products

	Products	Australia				EU		US		
		Product development	Trials underway	Pilot stage revenue ²	Registration and sales	Ready for trials	Registration and sales	Ready for ASR trials	FDA trials initiated	Clearance and sales
Existing products	<i>EasyScreen</i> ™ Enteric	●	●	●	●	●	●	●	2018/2019	2019
	<i>EasyScreen</i> ™ ESBL & CPO	●	●	●	●	●	●	●		
	<i>EasyScreen</i> ™ Respiratory	●	●	●	2H CY18 (submitted)	2H CY18	2H CY18 (submitted)	●		
	<i>EasyScreen</i> ™ STI / Genital	●	●	●	1H CY19	1H CY19	1H CY19	●		
New products	<i>EasyScreen</i> ™ Flavivirus / Alphavirus	●	●	●	1H CY19	1H CY19	1H CY19	●		
	<i>EasyScreen</i> ™ Meningitis (Viral/ Bacterial/fungal)	●	●	2H CY18	●	●	●	●		
	<i>EasyScreen</i> ™ Atypical Respiratory	●	2019	●	●	●	●	●		

● Complete ● Upcoming

GSS has made substantial progress on all products since IPO

Notes:

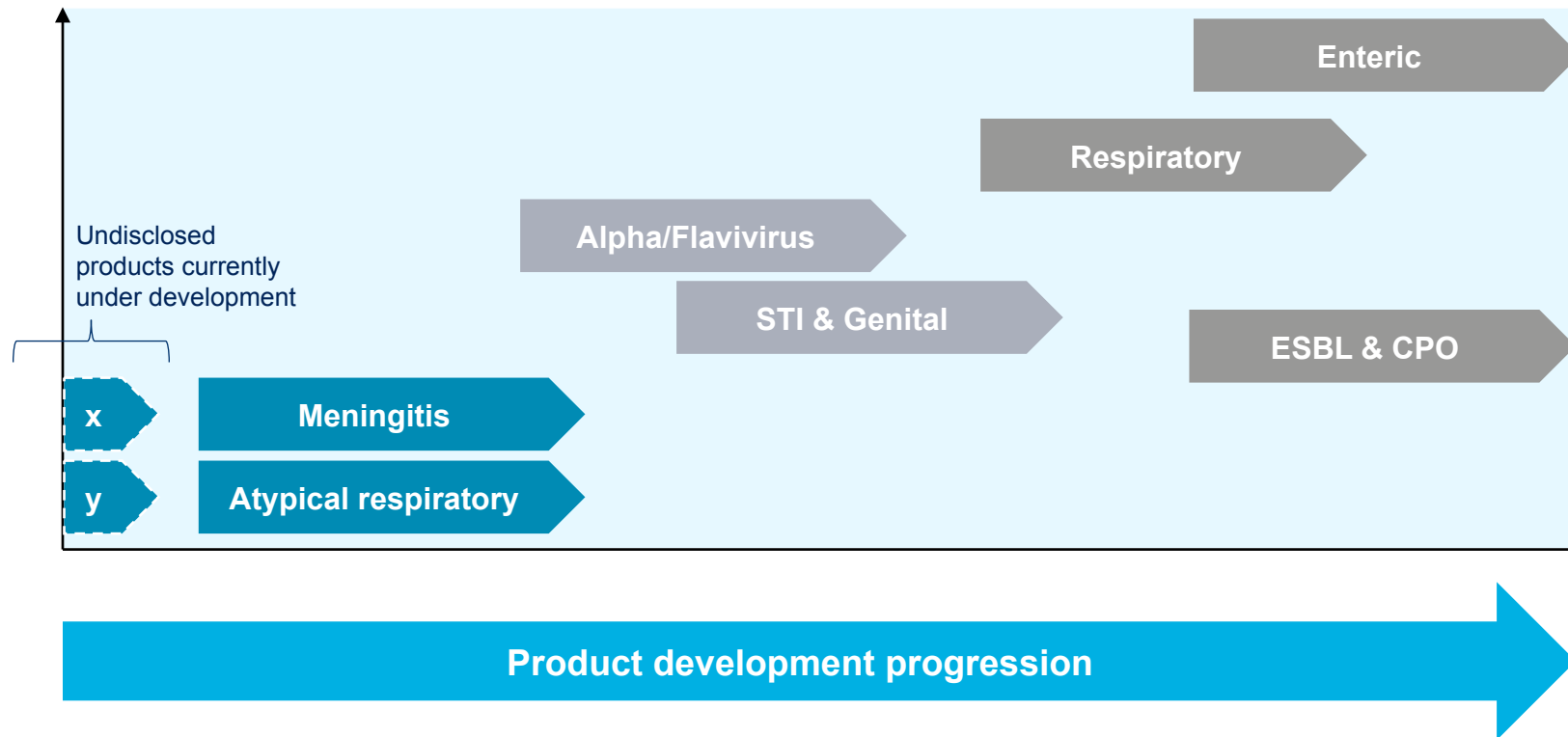
- 1: Each of the product suites may contain multiple different individual products, requiring multiple regulatory submissions and registrations for a suite of products
- 2: Pilot stage revenue generated from sales for research use only (medical professionals may use products for diagnosis only where they validate results with independent testing)
- 3: Sold as individual Analyte Specific Reagents (ASR) for a number of pathogens in the USA

Product development

High calibre product development team executing on a clear strategy of commercialisation

Overview of Genetic Signatures current infectious disease portfolio of 7+ product families¹

Revenue focus



1. Image not to scale. Provides an approximate depiction of Genetic Signatures' portfolio. Revenue contribution changes over time as a result of a number of factors including seasonality and regularity of purchase orders.



EasyScreen™ Enteric Detection Kits

Targets 20+ pathogens that affect the intestines and often result in gastroenteritis or other severe illnesses

Enteric range overview

- Flagship product is comprised of 3 key kits:
 - Bacterial, Protozoan and Viral
 - Kits can be purchased separately or together, maintaining both **flexibility** and **broad coverage** for customers
- Approved for sale in Australia (TGA) and the EU (CE-IVD)
- In market with major hospital and pathology customers, including St. Vincent's Sydney and Australian Clinical Labs

Commercialisation status

- Total addressable market in US is **~US\$228m¹ to be targeted with FDA clearance expected in 2019**
 - Preparing for US clinical trial for the Protozoan kit
 - On course to attain FDA clearance for our Enteric Protozoan Detection Kit in 2019
- The total addressable market in EU is **~US\$80m**
- Seegene is a market leading MDx competitor
 - However *EasyScreen™* Enteric Detection Kit has the highest level of throughput per run

Pathogen targets

- **Bacterial targets** - targets 6 common Bacterial pathogens including *Salmonella* spp.
- **Protozoan targets** - targets 6 common Protozoan pathogens including *Giardia* intestinalis
- **Viral targets** - targets 9 common viral pathogens including Norovirus GI and GII and Rotavirus

Infection overview and implication



Target pathogens can result in severe illness and similar symptoms often manifest across pathogens



Symptoms including diarrhoea, stomach pain, loss of appetite, nausea and fatigue



Rapid and accurate detection can optimise the course of treatment – drastically improving patient outcomes

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

Respiratory infections represent a substantial global burden in terms of lost productivity and morbidity

Respiratory Pathogen Detection Kit overview

- Detection Kit targeting a large addressable market, where increased throughput is required in peak flu season
- Already achieving repeat customer orders across key markets
- Major new domestic customer in August 2018 – creates an opportunity to supply up to 1,000 tests per day during peak flu season, and ~100-200 test per day outside of flu season

Commercialisation status

- Total addressable market in US is **~US\$174m**
- The total addressable market in EU is **~US\$61m**
 - Advancement of existing trials, in addition to the establishment of several new trials
 - CE-IVD application has been submitted with anticipated approval in 2H CY18
- Seegene is a market leading MDx competitor
 - However *EasyScreen*™ Respiratory Pathogen Detection Kit has the highest level of throughput per run

Pathogen targets

- *EasyScreen*™ Respiratory Pathogen Detection Kit can simultaneously and rapidly detect 14 common respiratory pathogens, including:
 - Influenza A & B, Rhinovirus and *M. pneumonia*

Infection overview and implication

- Respiratory viral infections are responsible for the deaths of an estimated 3.9 million people per year¹
 - Particularly dangerous for children, older adults, and people with immune system disorders
 - At risk patients can be prescribed an antiviral for influenza if correctly diagnosed



Genetic Signatures *EasyScreen*™ Respiratory Pathogen Detection Kit has the potential to:

- ✓ Simultaneously screen for multiple targets reduces possibility of misdiagnosis and mistreatment
- ✓ Reduce antibiotic overprescribing, which drives the development of resistant bacteria

¹ World Health Organisation (2015), Battle against Respiratory Viruses (BRaVe) initiative, http://www.who.int/influenza/patient_care/clinical/brave/en/



EasyScreen™ ESBL & CPO Detection Kit

The “superbug” detection kit has advanced rapidly with regulatory approval achieved in the EU and Australia, and trials underway in the US (ASRs)

ESBL & CPO Detection Kit overview

- Product was fast-tracked in response to increasing customer demand
- Received full regulatory registration in Europe (CE-IVD) in April and Australia (TGA) in May

Commercialisation status

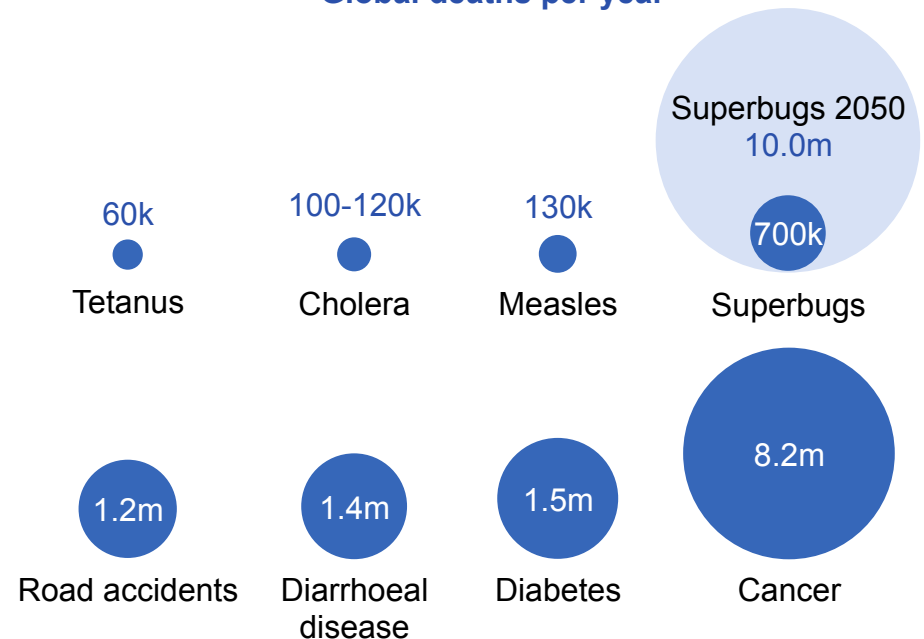
- Economic impact related to antimicrobial resistance is expected to **cost over ~\$105bn annually** worldwide¹
- First sales of ASRs in the US in June 2018 quarter
- Maiden sales from large European health care entity
- Positive trial results from Ireland’s National CPE Reference Laboratory
 - Trials currently underway in the US for the ESBL & CPO range, with results anticipated in 2019
- Cepheid is a market leading MDx competitor
 - Cepheid’s superbug kits only detect for CPO
 - Low throughput: 1 test performed at a time (POC²)
 - *EasyScreen™* ESBL & CPO Detection Kit outperforms on both breadth of targets and throughput

Pathogen targets

- *EasyScreen™* ESBL & CPO Detection Kit can simultaneously and rapidly detect more antibiotic resistant targets than any other commercial kit

Large and growing global impact of antibiotic resistance³

Global deaths per year



1. Codjoe, F. S., & Donkor, E. S. (2017). Carbapenem Resistance: A Review. Medical sciences (Basel, Switzerland), 6(1), 1. doi:10.3390/medsci6010001

2. POC: Point of care

3. Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations. The Review on Antimicrobial Resistance Chaired by Jim O'Neill December 2014



EasyScreen™ STI Detection Kit

The STI diagnostics market is set for a rapid growth and the simultaneous testing of multiple targets can reduce the spread of infection

STI Detection Kit overview

- Innovative STI Detection Kit testing for a range of pathogens that are not always tested for with routine screening
- Revenue generated from sales in Australia for research use only version
- Domestic commercial customer secured, a fully accredited private Pathology Lab

Commercialisation status

- Total addressable market in US is **~US\$330m**
 - ASRs currently available in the USA
- The total addressable market in EU is **~US\$116m**
 - Anticipated to achieve CE-IVD approval in FY19
- Seegene is currently a market leading MDx competitor
 - *EasyScreen™* STI Detection Kit screens for a broader range of targets in a single kit
 - *EasyScreen™* STI Detection Kit has the highest level of throughput when screening across a broad range of targets

Pathogen targets

- Detects 12 of the most commonly encountered STIs
 - Including chlamydia, gonorrhoea and syphilis
- Also detects a number of less common STIs, which often go undiagnosed

Large and growing global impact of antibiotic resistance



1 million STIs are contracted daily worldwide¹



Majority of STIs have no symptoms or only mild symptoms that may not be recognised¹



Laboratories routinely test for chlamydia and gonorrhoea but others are often not tested



Drug resistance, especially for gonorrhoea, is a major threat to reducing the impact of STIs



If left untreated, infections can cause pelvic inflammatory disease, leading to infertility

1. World Health Organisation: [http://www.who.int/en/news-room/fact-sheets/detail/sexually-transmitted-infections-\(stis\)](http://www.who.int/en/news-room/fact-sheets/detail/sexually-transmitted-infections-(stis))

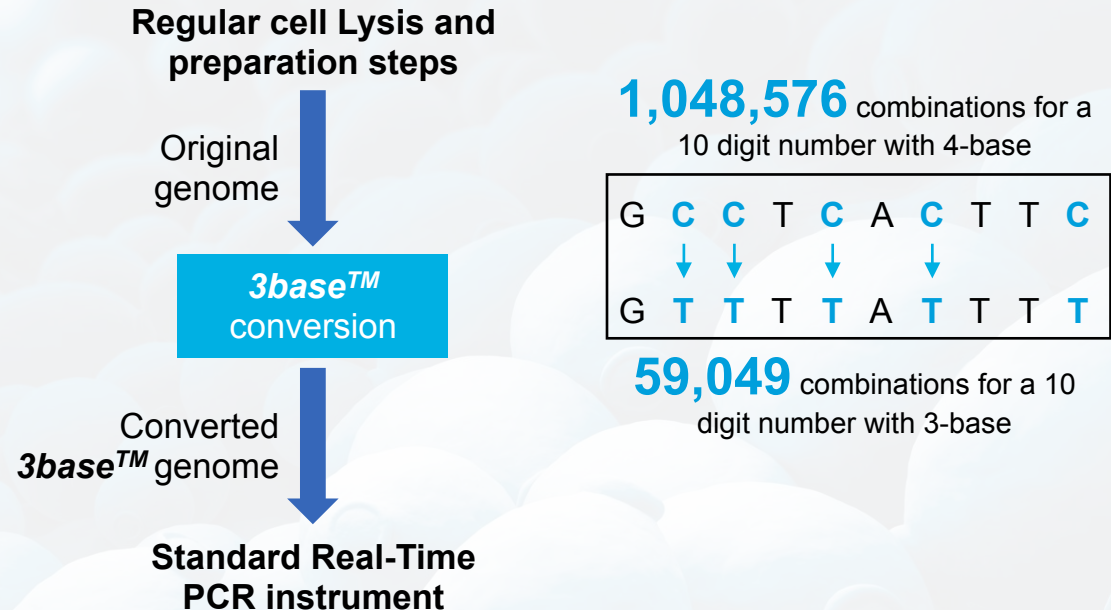
The science behind 3base™ technology

3base™ technology reduces complexity in genetic testing, allowing detection of more pathogens. Extra results, higher accuracy, lower cost

3base™ technology






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

3base™ technology in the detection process



The EasyScreen™ competitive advantage

EasyScreen™ offers faster and more effective detection of infectious disease; optimised for high throughput labs

 <p>High throughput</p> <p>Ability to test multiple samples simultaneously maximises pathogen testing capacity</p>	 <p>High specificity</p> <p>Superior accuracy relative to traditional testing methods, ability to detect more specimen types simultaneously</p>	 <p>Rapid time to result</p> <p>Provides optimised solution for high-volume hospitals and pathology laboratories</p>	 <p>Common workflow</p> <p>Four product families currently available covering enteric microorganisms, respiratory pathogens (including influenza), ESBL & CPO “Superbugs” and STIs</p>	 <p>Platform agnostic</p> <p>Compatible with common existing laboratory equipment, specialised hardware not required</p>
<p>200+ samples</p> <p>every 4-5 hours</p>	<p>+83%</p> <p>more infections detected than traditional methods¹</p>	<p>4-5 hours</p> <p>until result, compared to 4-5 days with traditional methods</p>	<p>All tests</p> <p>use compatible workflow</p>	<p>Low setup cost</p> <p>with <i>EasyScreen™</i> detection kits</p>

Notes:

1: St Vincent's Hospital Evaluation Study results, see below for further details on the study

Powerful evidence of efficacy from clinical trials

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

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
Total	53	97

Significantly greater efficacy
(+83% more infections detected)



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3 Upcoming milestones

Multiple upcoming value catalysts

Objectives

FY19



Domestic

TGA approval and commercial release of 3 products by end of FY19



Europe

CE-IVD registration and sales launch of 3 products by end of FY19



US

FDA clearance of first Enteric kit in CY19
Secure large ASR customers

Ongoing



Continued development

Continue developing Meningitis and Atypical Respiratory products



FDA approval

Progress scientific validation across several products in the US market

Upcoming activities

In addition to key upcoming milestones, GSS will continue to focus on a range of activities delivering value in the near term.

Notable activities include:

- ✓ Securing new customer contracts across several EasyScreen™ products
- ✓ Commercialising Respiratory, STI and Flavivirus kits within Australia and key European markets
- ✓ Continuing to expand international sales and distribution teams

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