Genetic Signatures

Transforming Molecular Diagnostics

# AGM Presentation

29 November 2018

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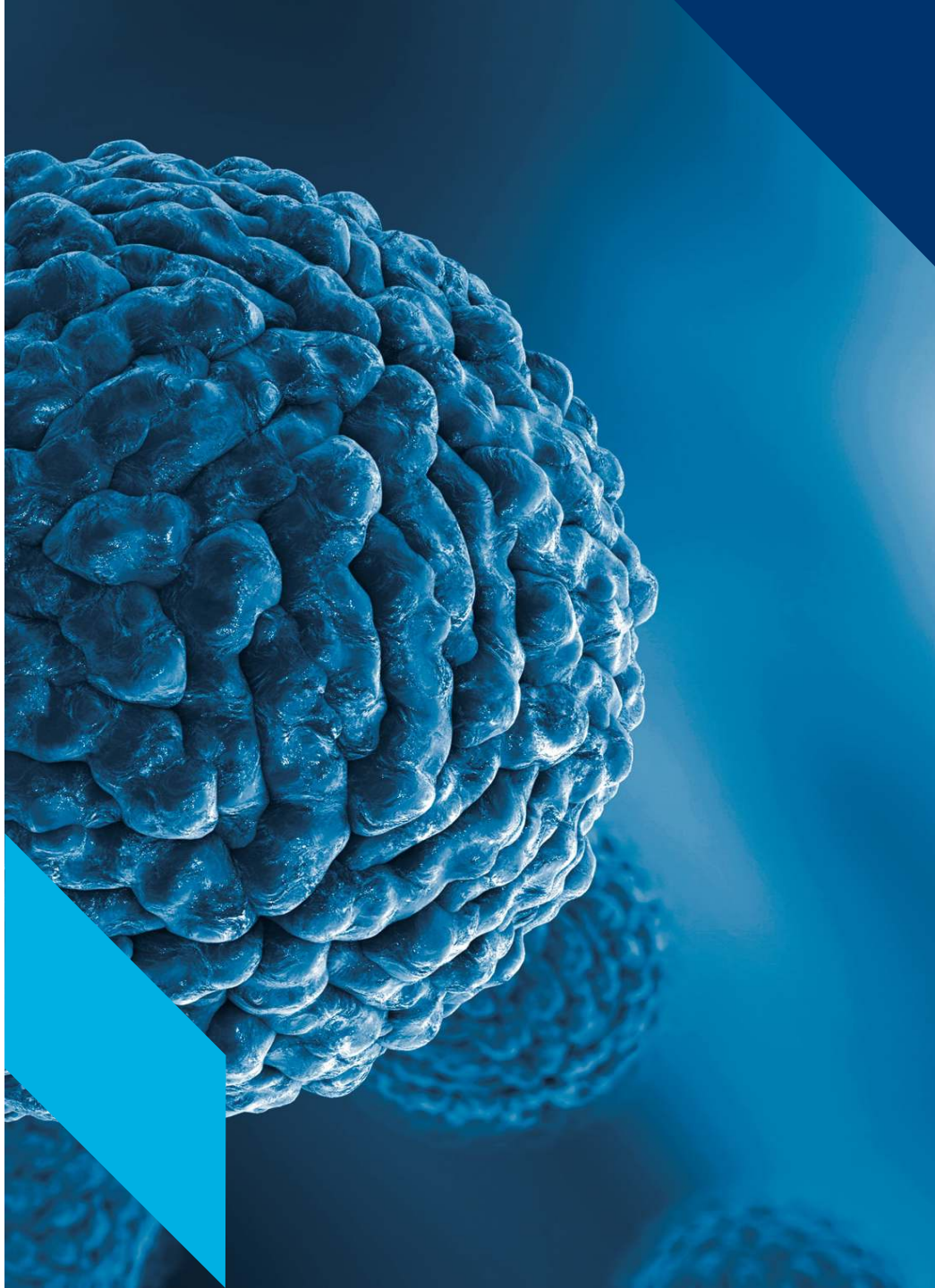
# Contents





# 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 | 103.9m[1] |
| **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 **Cytyc 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 r**educes 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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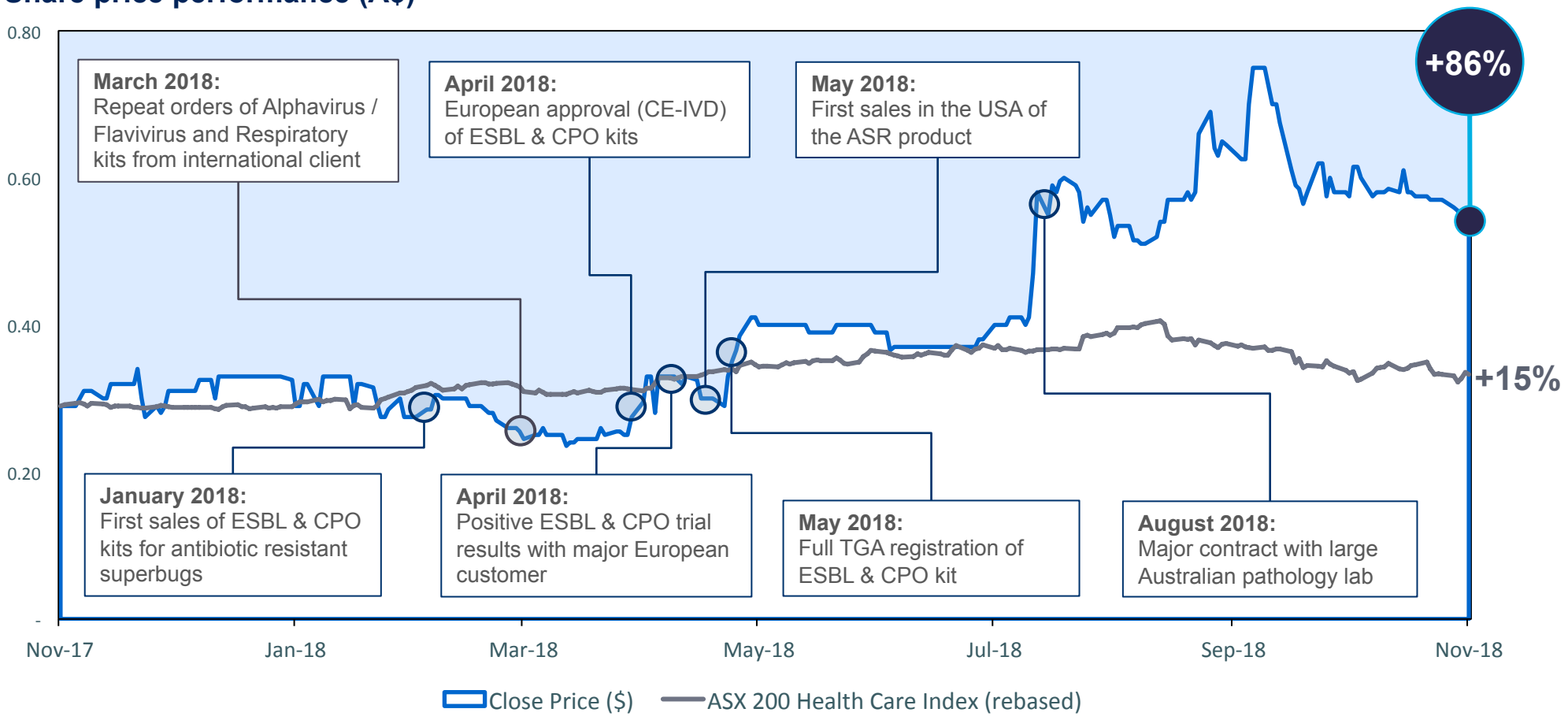
# 1 Year in Review

# Share price performance

## Genetic Signatures has made significant operational progress which has been recognised by positive share price perfomance 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**

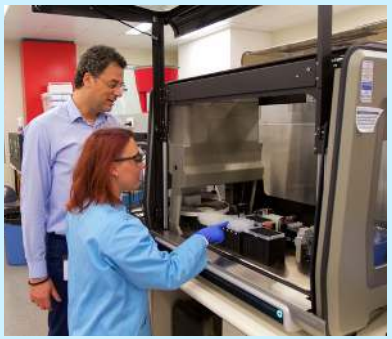
**1**

### 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

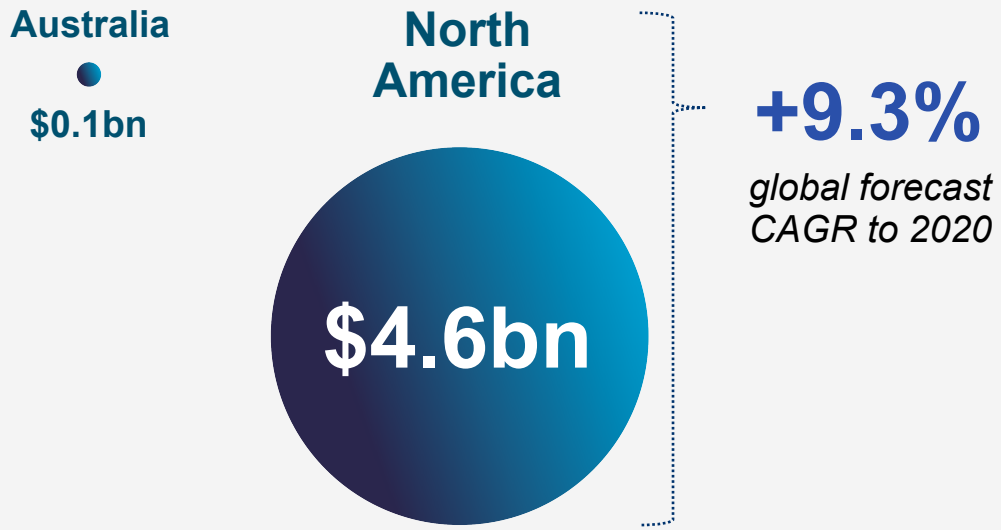
### Important milestone for Genetic Signatures

- 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 customers[1] to develop and validate proprietary tests for the diagnosis of infectious diseases
- ASRs are offered to more than 11,000[2] eligible labs and hospitals in the US
- ASRs are used to make LDTs (laboratory-developed tests), and represent ~20% of the US MDx market[3]

### Estimated MDx market size (2017, US$)[4]




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

Notes:
1. US Laboratories regulated by the Clinical Laboratory Improvement Act (CLIA) may purchase and use ASRs,
2. https://www.acla.com/wp-content/uploads/2014/09/Alan-Mertz-Written-Statement-for-21st-Century-Cures-Hearing-2014-09-09.pdf
3. DeciBio Consulting
4. 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™* ESBL & CPO Detection Kit

### Successful *EasyScreen™* 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™* 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*™ 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***

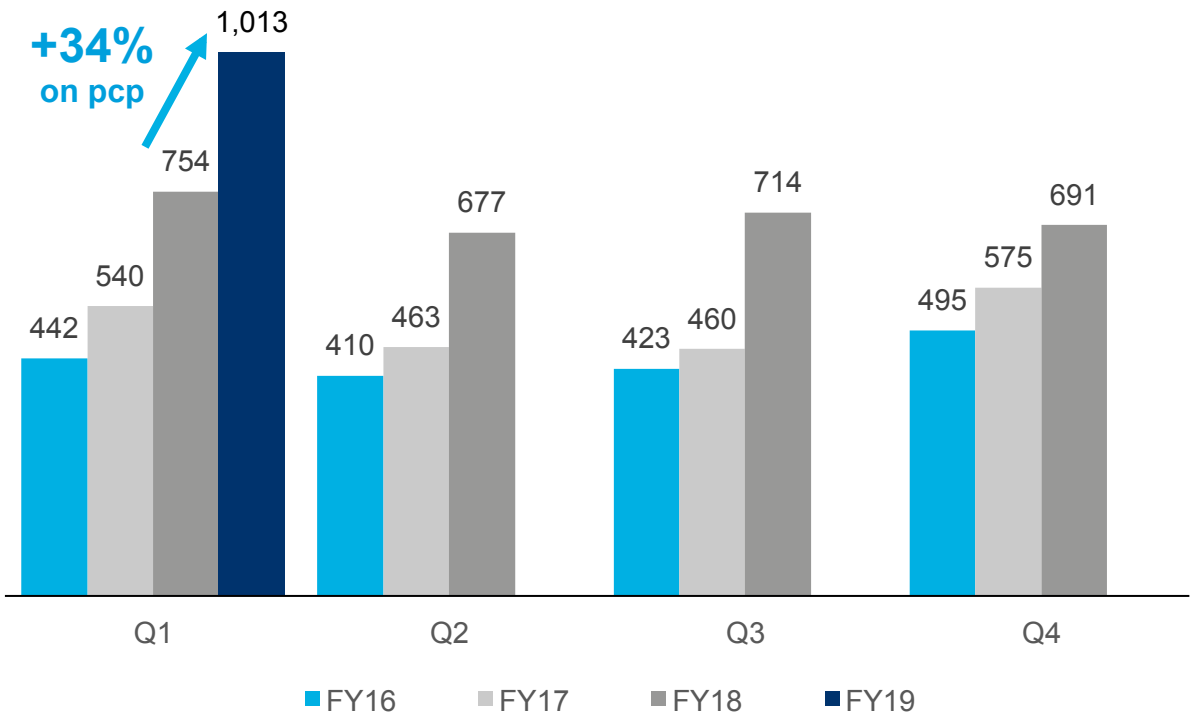
**Growing interest in *EasyScreen™* ESBL & CPO as a result of global outbreaks**

1. CPE: *Carbapenemase Producing Enterobacteriaceae*

# 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

| | | Australia | | | | EU | | US | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Products | 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 | *EasyScreen*™ **Enteric** | ● | ● | ● | ● | ● | ● | ● | **2018/2019** | **2019** |
| | *EasyScreen*™ **ESBL & CPO** | ● | ● | ● | ● | ● | ● | ● | | |
| | *EasyScreen*™ **Respiratory** | ● | ● | ● | **2H CY18 (submitted)** | **2H CY18** | **2H CY18 (submitted)** | ● | | |
| | *EasyScreen*™ **STI / Genital** | ● | ● | ● | **1H CY19** | **1H CY19** | **1H CY19** | ● | | |
| New products | EasyScreen™ **Flavivirus / Alphavirus** | ● | ● | ● | **1H CY19** | **1H CY19** | **1H CY19** | ● | | |
| | *EasyScreen*™ **Meningitis** (Viral/ Bacterial/fungal) | ● | ● | **2H CY18** | ○ | ○ | ○ | ● | | |
| | *EasyScreen*™ **Atypical Respiratory** | ● | **2019** | ○ | ○ | ○ | ○ | ○ | | |

● Complete ○ Upcoming

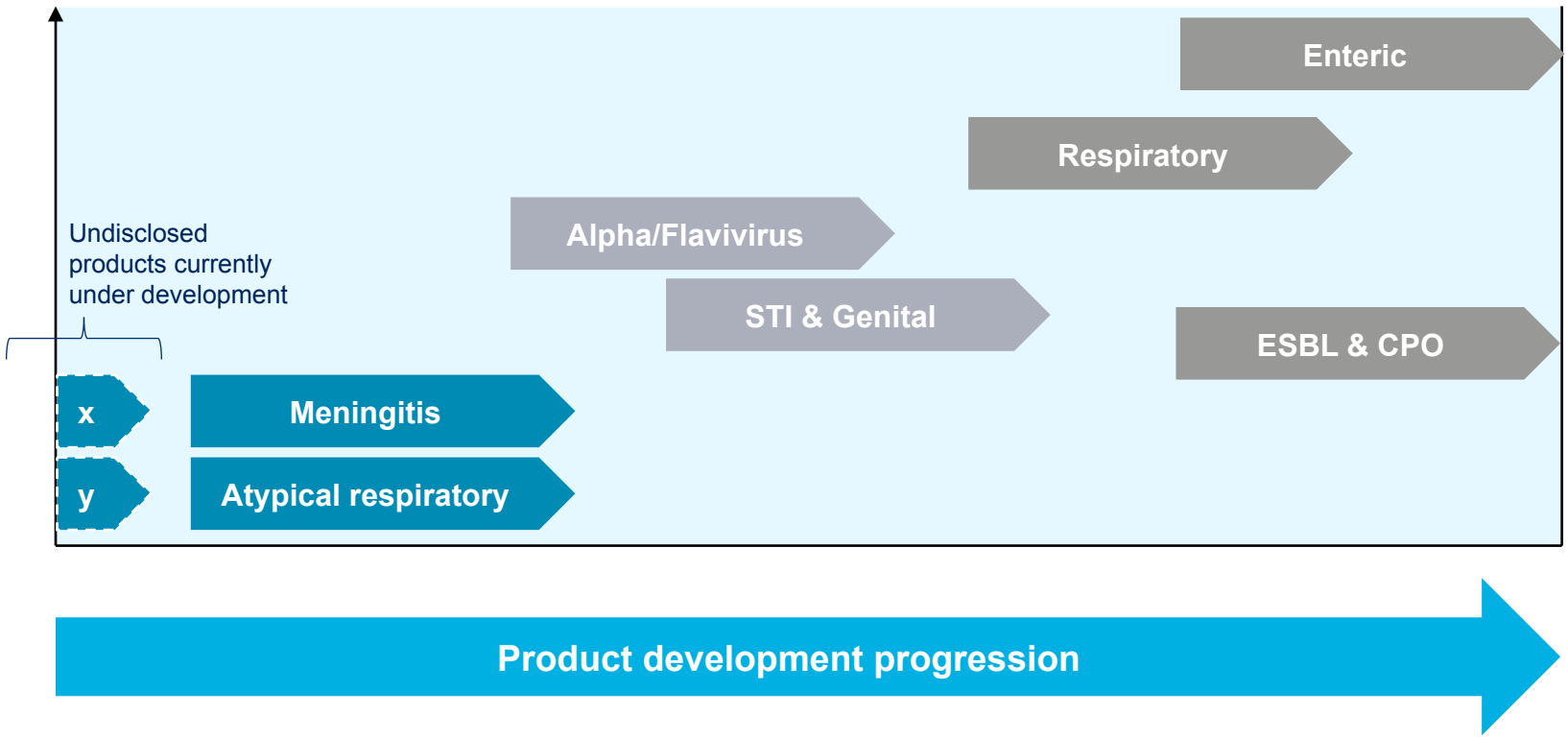
**GSS has made substantial progress on all products since IPO**

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 families[1]




1. Image not to scale. Provides an approximate depiction of Genetic Signatures' portfolio. Revenue contibution 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$228m[1] 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

# *EasyScreen*™ Respiratory Pathogen Detection Kit

## 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 year[1]
  - 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

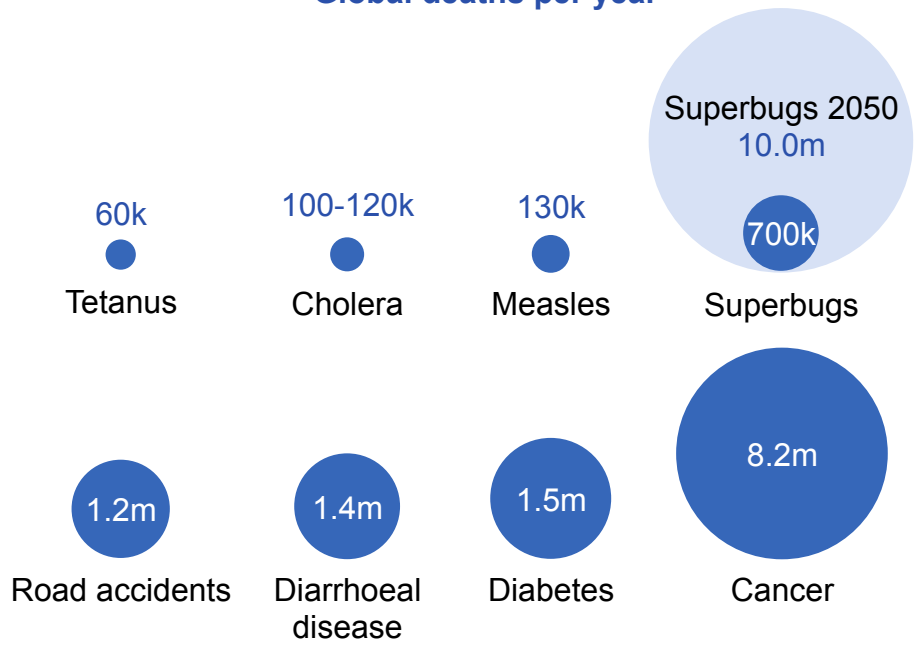
- Economic impact related to antimicrobial resistance is expected to **cost over ~$105bn annually** worldwide[1]
- First sales of ASRs in the US in June 2018 quarter
- Maiden sales from large European health care entity
- Positive trial results from Ireland's National CPE Reference Laboratory
  - Trials 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 (POC[2])
  - *EasyScreen™* ESBL & CPO Detection Kit outperforms on both breadth of tagets 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 resistance[3]

**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 worldwide[1]
- Majority of STIs have no symptoms or only mild symptoms that may not be recognised[1]
- 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)

# 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

**Regular cell Lysis and preparation steps**

Original genome

***3base*™ conversion**

Converted ***3base*™** genome

**Standard Real-Time PCR instrument**

**1,048,576** combinations for a 10 digit number with 4-base

| G | C | C | T | C | A | C | T | T | C |
|---|---|---|---|---|---|---|---|---|---|
| G | T | T | T | T | A | T | T | T | T |

**59,049** combinations for a 10 digit number with 3-base

# The EasyScreen™ competitive advantage

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

### High throughput

Ability to test multiple samples simultaneously maximises pathogen testing capacity

### High specificity

Superior accuracy relative to traditional testing methods, ability to detect more specimen types simultaneously

### Rapid time to result

Provides optimised solution for high-volume hospitals and pathology laboratories

### Common workflow

Four product families currently available covering enteric microorganisms, respiratory pathogens (including influenza), ESBL & CPO "Superbugs" and STIs

### Platform agnostic

Compatible with common existing laboratory equipment, specialised hardware not required

| 200+ samples | +83% | 4-5 hours | All tests | Low setup cost |
|---|---|---|---|---|
| every 4-5 hours | more infections detected than traditional methods[1] | until result, compared to 4-5 days with traditional methods | use compatible workflow | with *EasyScreen*™ detection kits |

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*™ |
|---|---|---|
| *Campylobacter* | 7 | 9 |
| *Salmonella* | 8 | 9 |
| *Shigella* | 5 | 6 |
| *C. difficile* | 3 | 7 |
| *Yersinia* | - | 1 |
| *Cryptosporidium* | - | 1 |
| *Giardia* | 9 | 12 |
| *Dientamoeba fragilis* | 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** |

**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

# Contact us

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