

Genetic Signatures

Transforming
Molecular
Diagnostics

Investor Presentation

March 2019

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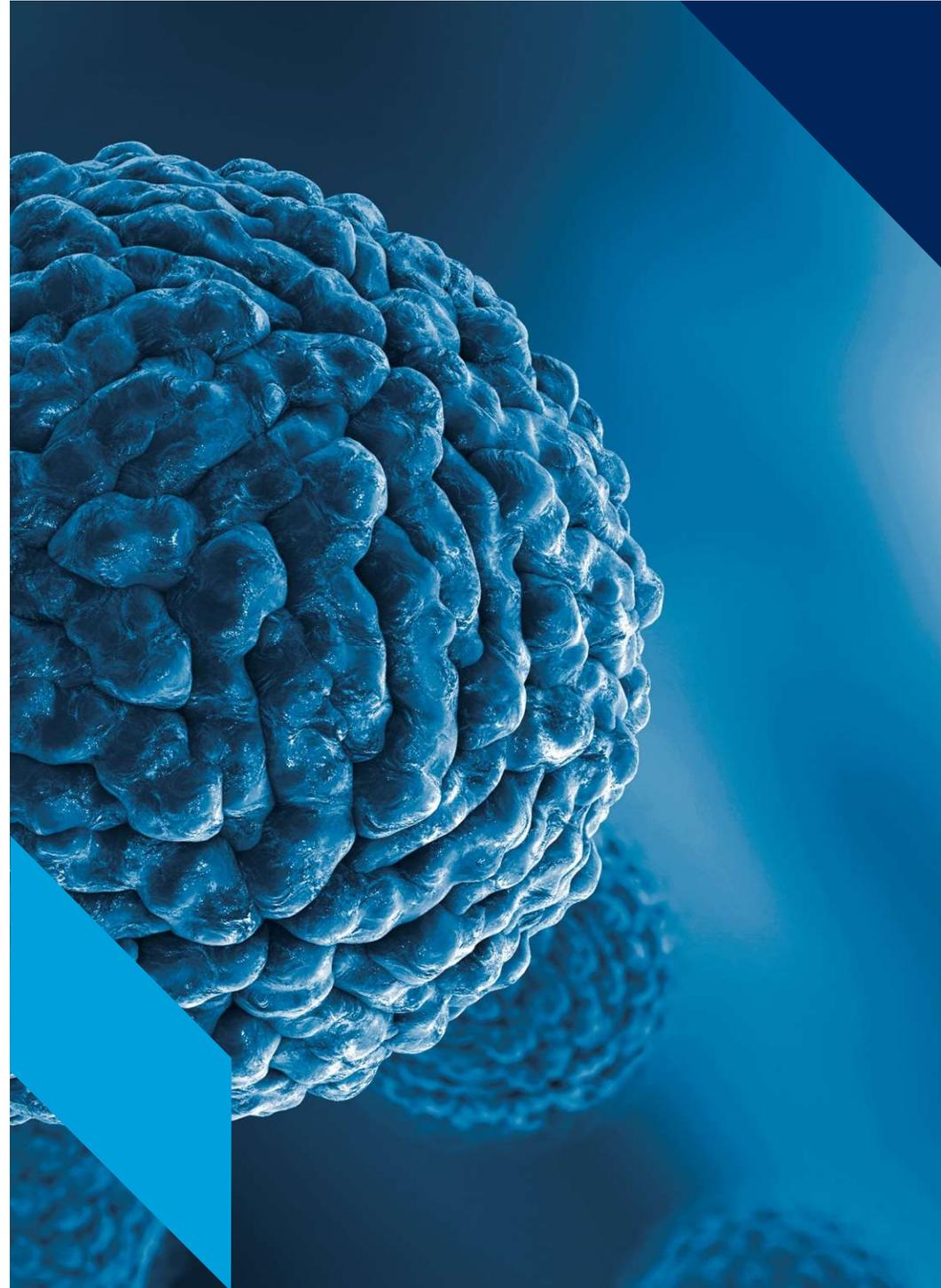
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- 3 Financial and share price growth
- 4 Commercialisation strategy



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 (14-Mar-19) | A\$1.06 |
| Shares on issue | 104.0m ¹ |
| Market capitalisation | A\$110.2m |
| Cash (31-Dec-18) | A\$8.8m |
| Debt (31-Dec-18) | Nil |
| Enterprise value | A\$101.4m |

Notes:

1: Excludes 2.51m unquoted options (various expiration dates and prices)

Top shareholders %

| | |
|--|-------|
| Asia Union and Christopher Abbott | 36.4% |
| Karst Peak (HK-based investment manager) | 14.4% |
| Directors, management & advisors | >6.0% |

GSS snapshot

Genetic Signatures is commercialising its 3base™ technology, targeting large international markets

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
- Launchpad/platform for global expansion

Europe

- Expand revenue opportunities with recently established local sales team and distributor network

North America

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

Genetic Signatures EasyScreen™ Portfolio



Enteric

Detects 20+ gastroenteritis 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

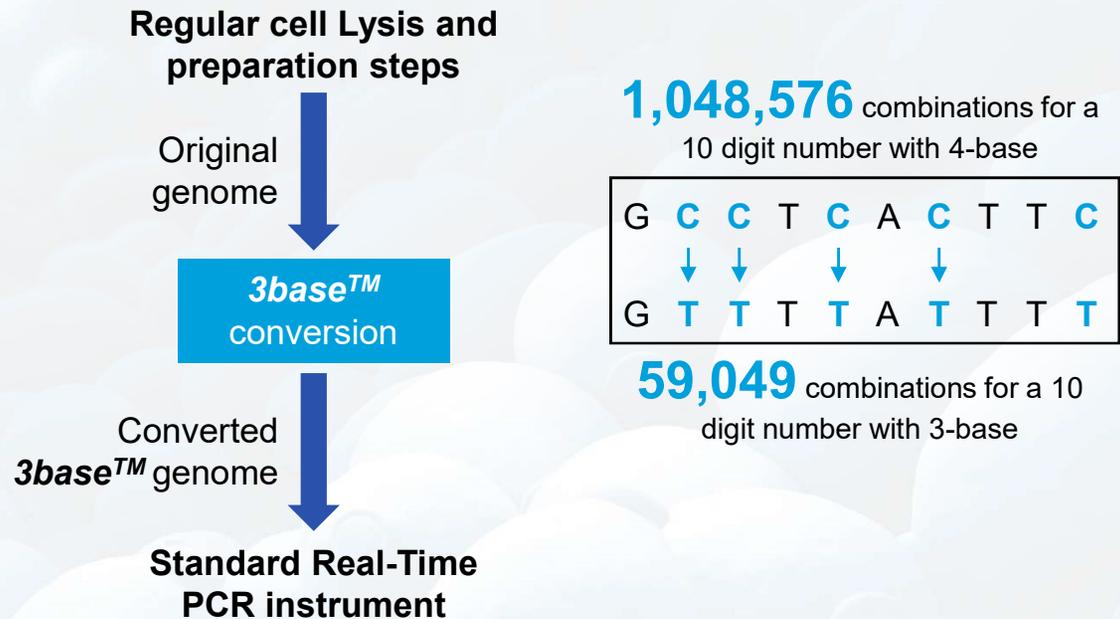
The science behind 3base™ technology

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

3base™ technology

- 1 **3base™** platform technology converts original 4-base microbial genome to 3-base
- 2 Conversion occurs during standard procedures with no additional steps for the technician
- 3 **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



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

every 4-5 hours

+83%

more infections detected than traditional methods¹

4-5 hours

until result, compared to 4-5 days with traditional methods

All tests

use compatible workflow

Low setup cost

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

Comparative studies confirm superior performance of Genetic Signatures' technology

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

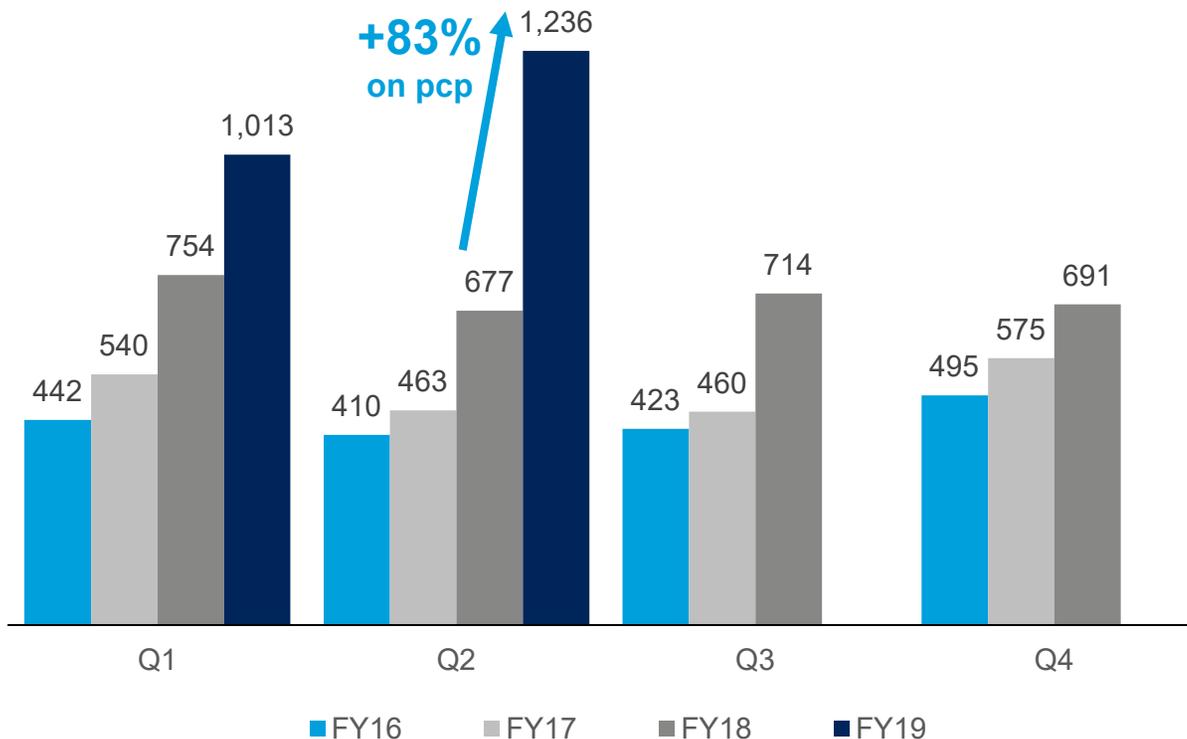
| Pathogen | Conventional Methods* | EasyScreen™ |
|------------------------------|-----------------------|-------------|
| <i>Campylobacter</i> | 7 | 9 |
| <i>Salmonella</i> | 8 | 9 |
| <i>Shigella</i> | 5 | 6 |
| <i>C. difficile</i> | 3 | 7 |
| <i>Yersinia</i> | - | 1 |
| <i>Cryptosporidium</i> | - | 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)

Continued revenue growth in 2Q FY19

GSS continues to consistently deliver strong quarter-on-quarter revenue growth over the previous 4 financial years

Quarterly revenue (A\$k)



Key Highlights

- Existing domestic customers executing **repeat orders and purchasing new products within GSS' expanding product range**
- Increasing sales traction throughout Europe**, bolstered by the expanding sales team and key management appointments
- EasyScreen*[™] Respiratory Pathogen Detection Kit **receiving positive customer interest** following recent approval and commercial launch in Europe

Financial performance



| A\$000 | Half year ended 31-Dec-18 | Half year ended 31-Dec-17 |
|---|------------------------------|------------------------------|
| Total sales and other income | 3,456 | 2,458 |
| Cost of materials used | (789) | (521) |
| Employee benefits expense | (2,398) | (1,857) |
| Other expense items | (1,796) | (1,478) |
| EBITDA | (1,527) | (1,399) |
| Depreciation and amortization | (222) | (302) |
| EBIT | (1,749) | (1,700) |
| Finance costs | - | - |
| (Loss) / profit before tax expenses | (1,749) | (1,700) |
| Income tax benefit / (expense) | - | - |
| Foreign currency loss on translation | (8) | (12) |
| Net (loss) / profit after tax | (1,757) | (1,712) |
| Basic and diluted earnings per share (Acps) | (1.68) | (1.64) |

- Income includes R&D tax concession (A\$1.1m in 1H FY2019) and interest received (A\$0.1m in 1H FY2019)

- Includes scientific consumables, rental, travel etc

- No interest bearing liabilities on balance sheet

Financial performance - cash



| A\$000 | Half year ended 31-Dec-18 | Half year ended 31-Dec-17 |
|---|------------------------------|------------------------------|
| Receipts from customers | 2,302 | 1,437 |
| Payments to suppliers & employees | (4,872) | (4,313) |
| Interest received | 92 | 146 |
| R&D tax concession received | 2,561 | 1,598 |
| Net cash used in operating activities | 83 | (1,132) |
| Purchase of plant & equip | (259) | (327) |
| Net cash used in investing activities | (259) | (327) |
| Net cash flows from financing activities | 50 | - |
| Net decrease in cash & equivalents | (127) | (1,459) |
| Cash at beginning of period | 8,955 | 13,193 |
| Foreign exchange differences | (8) | (12) |
| Cash & equivalents at end of period | 8,821 | 11,722 |

- Increase in receipts from customers in line with revenue increases

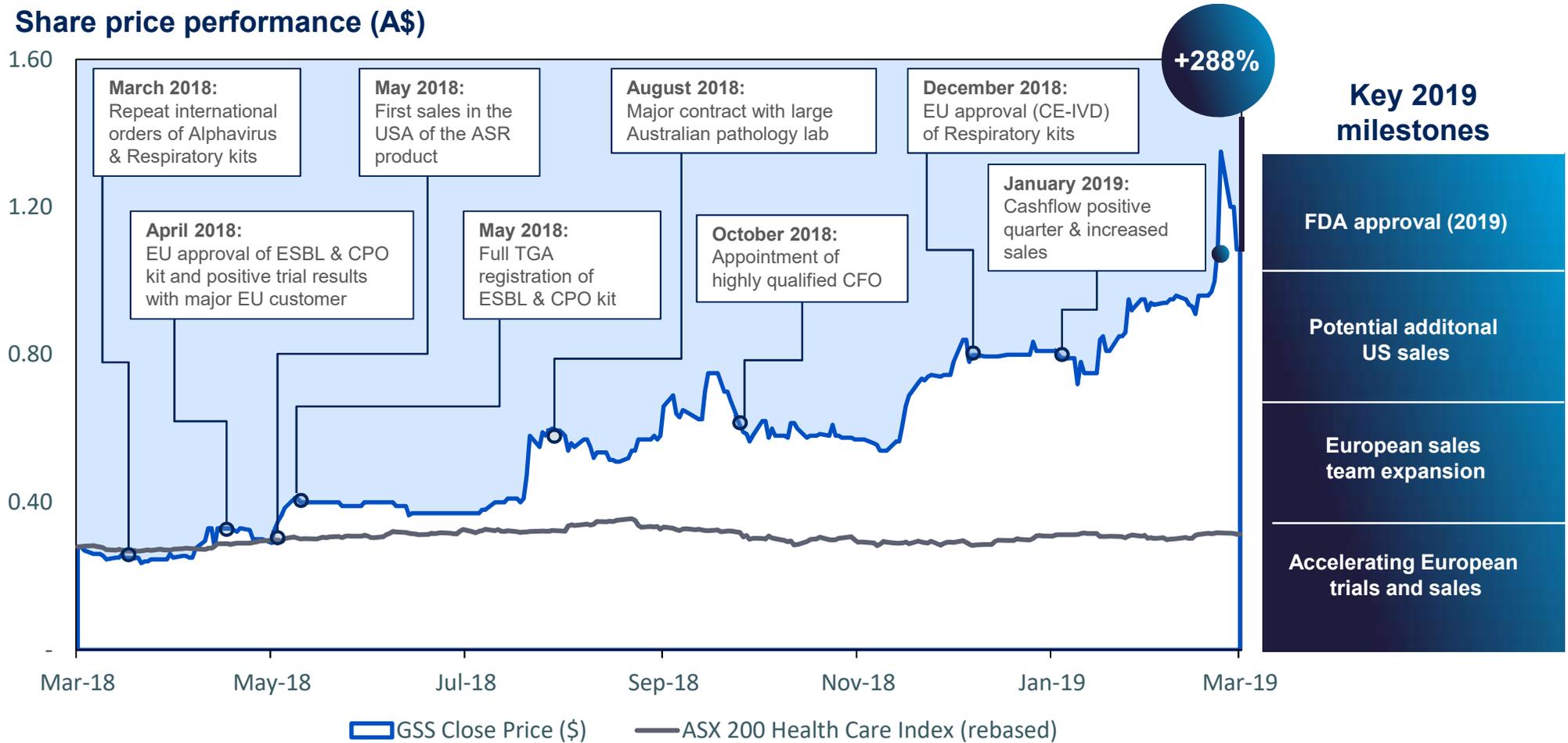
- Proceeds from issue of shares/options (net A\$50k in 1H FY2019)

- Decrease in cash burn as strong revenue growth continued in 1H FY2019

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

Infectious disease – a growing global concern

WHO launches new global influenza strategy



11 March 2019 | News Release | Geneva

WHO today released a Global Influenza Strategy for 2019-2030 aimed at protecting people in all countries from the threat of influenza. The goal of the strategy is to prevent seasonal influenza, control the spread of influenza from animals to humans, and prepare for the next influenza pandemic.

"The threat of pandemic influenza is ever-present," said WHO Director-General Dr Tedros Adhanom Ghebreyesus. "The on-going risk of a new influenza virus transmitting from animals to humans and potentially causing a pandemic is real. The question is not if we will have another pandemic, but when. We must be vigilant and prepared – the cost of a major influenza outbreak will far outweigh the price of prevention."

GOV.UK

News story

Government promises more funding to fight superbugs

The government has agreed an extra £10 million to fight antimicrobial resistance (AMR) at home and abroad.

Published 19 November 2018

From: Department for International Development and Department of Health and Social Care

9NEWS

News / Health

Superbugs killing 33,000 a year in Europe

1:30pm Nov 6, 2018

SA NEWS

South Australia facing worst flu year with a record start to 2019

Brad Crouch, Sue Dunlevy, The Advertiser
March 6, 2019 10:08pm

The Advertiser
WERE FOR SA

S.T.D. Diagnoses Reach Record 2.3 Million New Cases in U.S. **The New York Times**

By Karen Zraick

Aug. 28, 2018



"Most people with these S.T.D.s do not know they are infected," said Dr. Gail Bolan, director of the C.D.C.'s division of sexually transmitted disease prevention. "They don't realize that these diseases are spreading silently through the country."

Are we ready for pandemics and antibiotic resistance?

Listen now Download audio



Wednesday 20 February 2019 9:06AM (view full episode)

Some researchers argue that the world is overdue for an influenza pandemic. In that event Australian lives would depend on a robust response from health authorities to any deadly new virus.

Meanwhile, what risk does antibiotic resistance pose to our health into the future? And are there other threats looming on the horizon?



IMAGE: HEALTH WORKERS PICTURES IN A SIMULATION OF AN OUTBREAK OF H7N9 AVIAN FLU IN HEBEI, CHINA IN 2017. (FEATURE

LIFESTYLE > HEALTH

Gonorrhoea is on the rise, with few options to treat it



Insist on condoms if you are unsure of your partner's status for gonorrhoea or if you are in non-monogamous relationship. (Berenice Manzano/Mosaic)

By JEN GUNTER | JI correspondent
November 11, 2018 at 12:00 pm

Gonorrhoea (*Neisseria gonorrhoeae*) is a sexually transmitted infection (STI) that has been with us for a long time. There are descriptions of conditions that fit with gonorrhoea — penile burning, discharge and scarring — dating as far back as biblical times. Whether those descriptions were actually gonorrhoea or not is not possible to know as the bacteria that causes gonorrhoea was not identified until 1879, but as approximately 80 to 85 percent of men with gonorrhoea develop symptoms these historical descriptions, also recounted by ancient Greek physicians, do fit.

Over the centuries there have been a variety of therapies to treat the infection and its complications, many of which are too horrible and graphic to describe here. The therapies were also largely ineffective. And so men and women suffered severe complications of an untreatable bacterial infection that caused abscesses and scarred the reproductive tract. That suffering came to an end with the introduction of antibiotics in the 1940s.

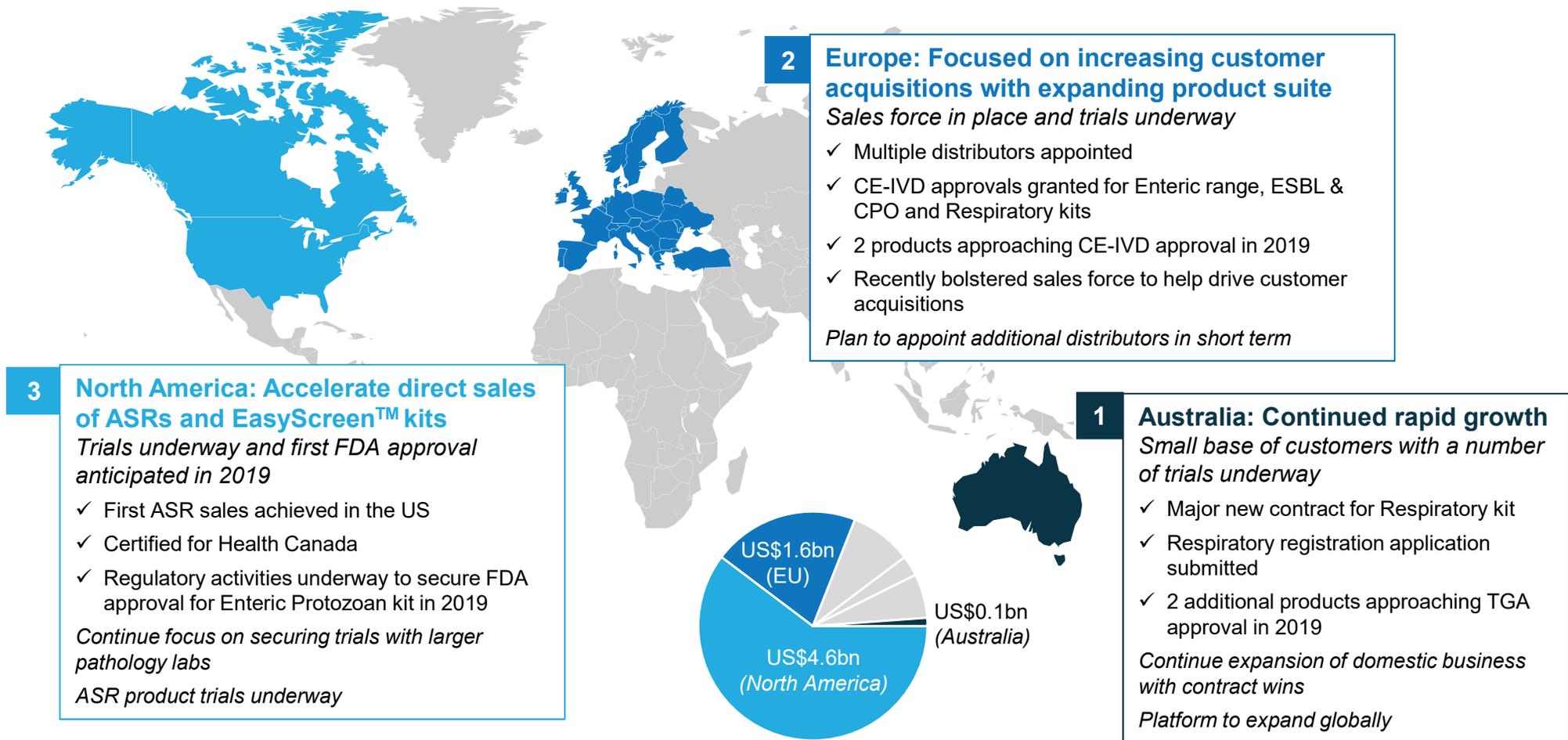


Rapid and comprehensive detection of pathogens is an important strategy in reducing the spread of infectious disease.

Genetic Signatures' EasyScreen™ Detection kits identify a larger number of pathogen targets in a shorter time frame than conventional methods.

Executing a global strategy for commercialisation

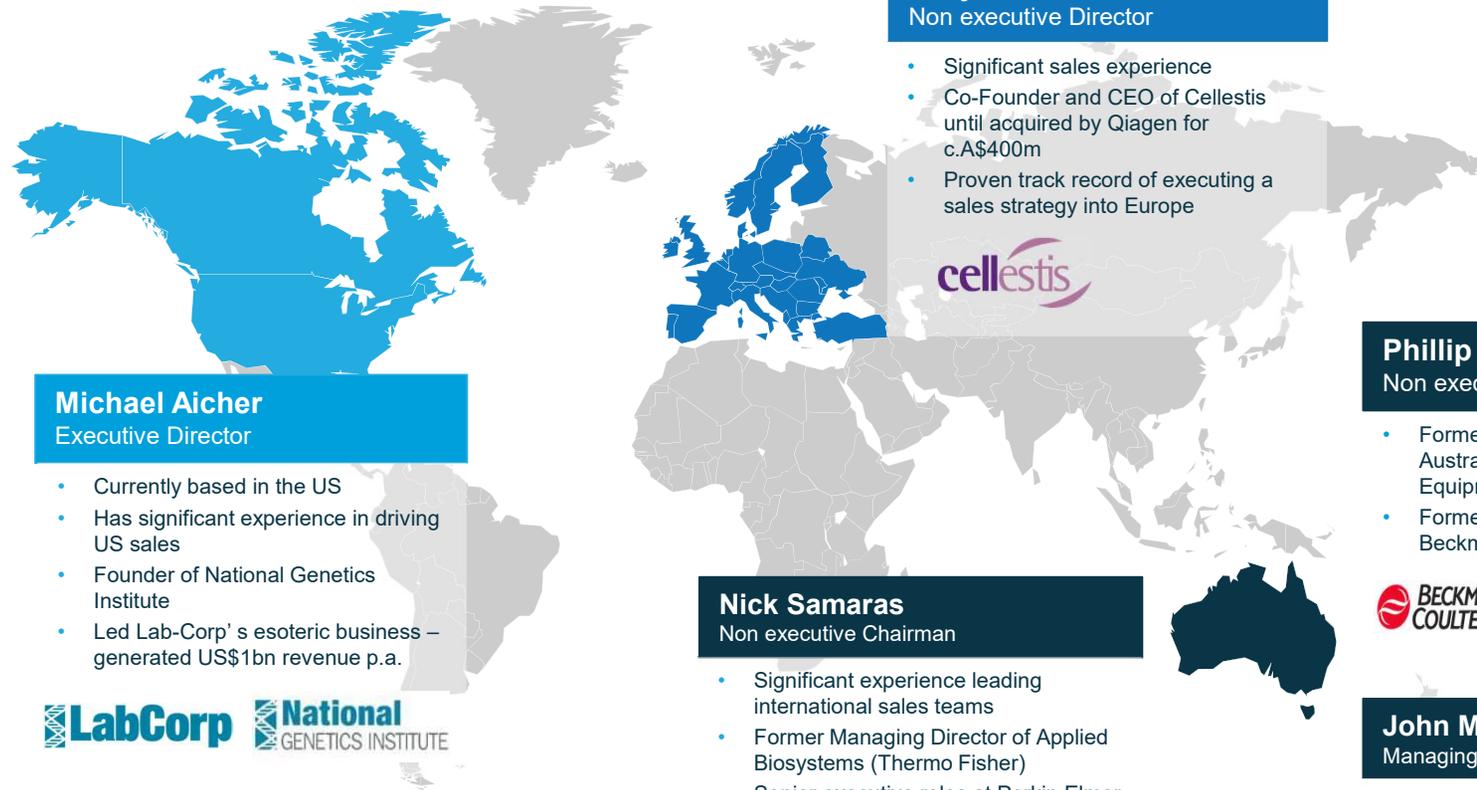
GSS remains focused on growth in both international and domestic markets



Source:

1. 2017 - 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 .

Board of Directors have a track record of success



Michael Aicher
Executive Director

- Currently based in the US
- Has significant experience in driving US sales
- Founder of National Genetics Institute
- Led Lab-Corp's esoteric business – generated US\$1bn revenue p.a.



Tony Radford
Non executive Director

- Significant sales experience
- Co-Founder and CEO of Cellestis until acquired by Qiagen for c.A\$400m
- Proven track record of executing a sales strategy into Europe



Nick Samaras
Non executive Chairman

- Significant experience leading international sales teams
- Former Managing Director of Applied Biosystems (Thermo Fisher)
- Senior executive roles at Perkin Elmer and AMRAD Corporation (CSL)



Phillip Isaacs
Non executive director

- Former Managing Director of Australian subsidiary of Technicon Equipment
- Former Managing Director of Beckman Instruments in Australia



John Melki
Managing Director and CEO

- Led global commercialisation efforts of GSS since 2011 and the product development team since 2003
- Led the commercialisation of two research products worldwide and seven diagnostic products in Australia and Europe

GSS' 3base™ technology is already available in the US

GSS is achieving increasing traction with ASR approach and early revenue out of the US highlights the commercial potential of 3base™ technology

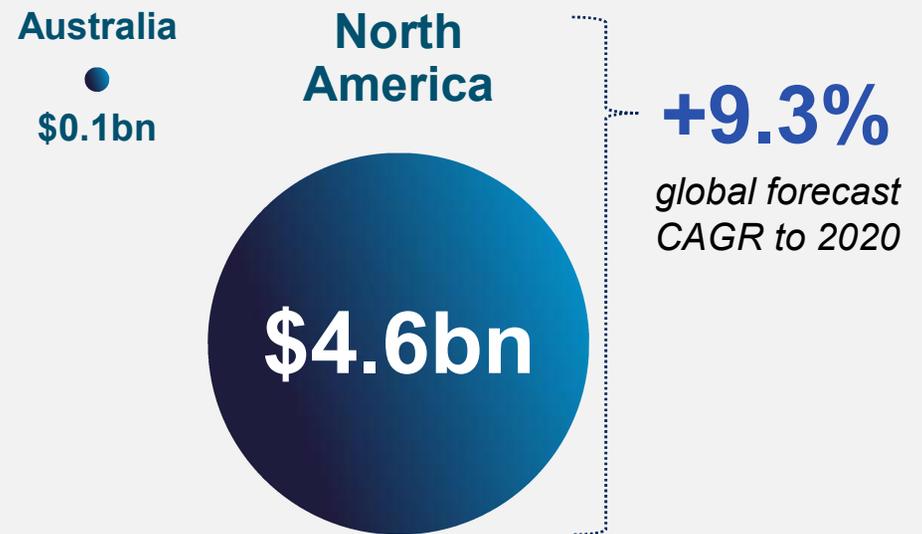
What is an Analyte Specific Reagent (ASR)?

- Components or 'ingredients' of the *EasyScreen™* kits
- Can be purchased by eligible customers¹ to develop and validate proprietary diagnostic tests
- Offered to more than 11,000² eligible labs and hospitals in the US, **represent ~20% of the US MDx market³**

Important milestone for Genetic Signatures

- ✓ GSS received first US sales order of ASRs from a well respected pathology lab in the June 2018 quarter
 - Customer offers extensive services to a large number of patients and is nearing completion of its validation work
- ✓ GSS is increasing its presence in the US market through:
 - Extending the ASR range
 - Participation at key industry events

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



A major US contract should significantly increase GSS' 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.

Major Australian contract and product launch

New customer and product launch created immediate boost to the revenue base

Step change in revenue following product launch and new major contract

- Sales contract signed with a **large Australian pathology services provider** for **two new products**:
 - 1 **Second generation EasyScreen™ Respiratory Pathogen Detection Kit**
 - 2 **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

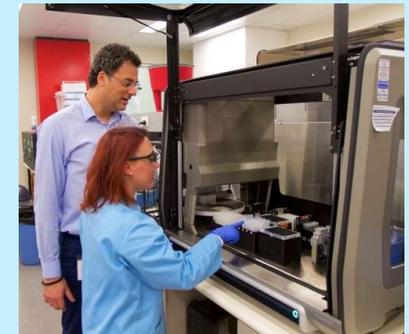
- ✓ Increased throughput with the ability to simultaneously detect **14 common respiratory pathogens in patients**
- ✓ Rapid detection in approximately 4.5 hours



2

Fully automated molecular testing with the GS1-HT

- ✓ 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 global sales growth

Driving awareness at key global conferences

Medical and industry conferences are an important means to drive positive exposure of *EasyScreen™* and the benefits of 3base™ technology

AMP - San Antonio

Nov-2018



Exhibited at the Association for Molecular Pathology Annual meeting, the largest gathering of diagnostic professionals in the world

Sheffield Microbe - UK

Oct-2018



Exhibited the benefits of 3base™ at the Sheffield Microbe 2018, a key industry symposia that attracts delegates from around the world

ESCV Conference – Athens

Sep-2018



Exhibited at the 21st European Society for Clinical Virology Conference, a major event for the Clinical Virology scientific community

ECCMID – Madrid (Apr 2018)

– Amsterdam (Apr 2019)



2018 - The Irish National CPE Reference Laboratory presented results from the successful trial of the *EasyScreen™* ESBL & CPO Detection Kit, educating labs about antimicrobial resistance
2019 – Two customer presentations accepted

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

1. CPE: Carbapenemase Producing Enterobacteriaceae

Multiple upcoming value catalysts

Objectives

2019



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

Dr John Melki

Genetic Signatures

Chief Executive Officer

P: +61 (0)2 9870 7580

E: john@geneticsignatures.com

Peter Manley

Genetic Signatures

Chief Financial Officer

P: +61 (0)2 9870 7580

E: peter.manley@geneticsignatures.com

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