

A photograph of a family in a clinical setting. A doctor in a white lab coat is on the left, facing a woman and a young girl. The woman is smiling and has her hand raised, and the girl is also smiling and has her hand raised towards the doctor. The background shows a bookshelf with books and a small potted plant.

# Genetic Signatures

## Investor presentation

August 2020



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# Investment highlights



## Trusted and proven technology

- 100% customer retention since 2016 and the accuracy of the technology has been clinically validated<sup>1</sup>



## Competitive advantage

- Underpinned by novel 3base™ technology providing increased throughput capacity, reduced time to results and significant cost savings



## Significant opportunity created by COVID-19

- Leverage internal capabilities to develop a new test for SARS-CoV-2 and scale up manufacturing capacity to meet the significant COVID-19 related increase in customer demand



## Global expansion strategy

- Increasing international recognition through the SARS-CoV-2 launch creates new avenues to expand customer base



## Attractive and scalable

- Business model with favourable unit economics expected to underpin growth through FY21 and beyond

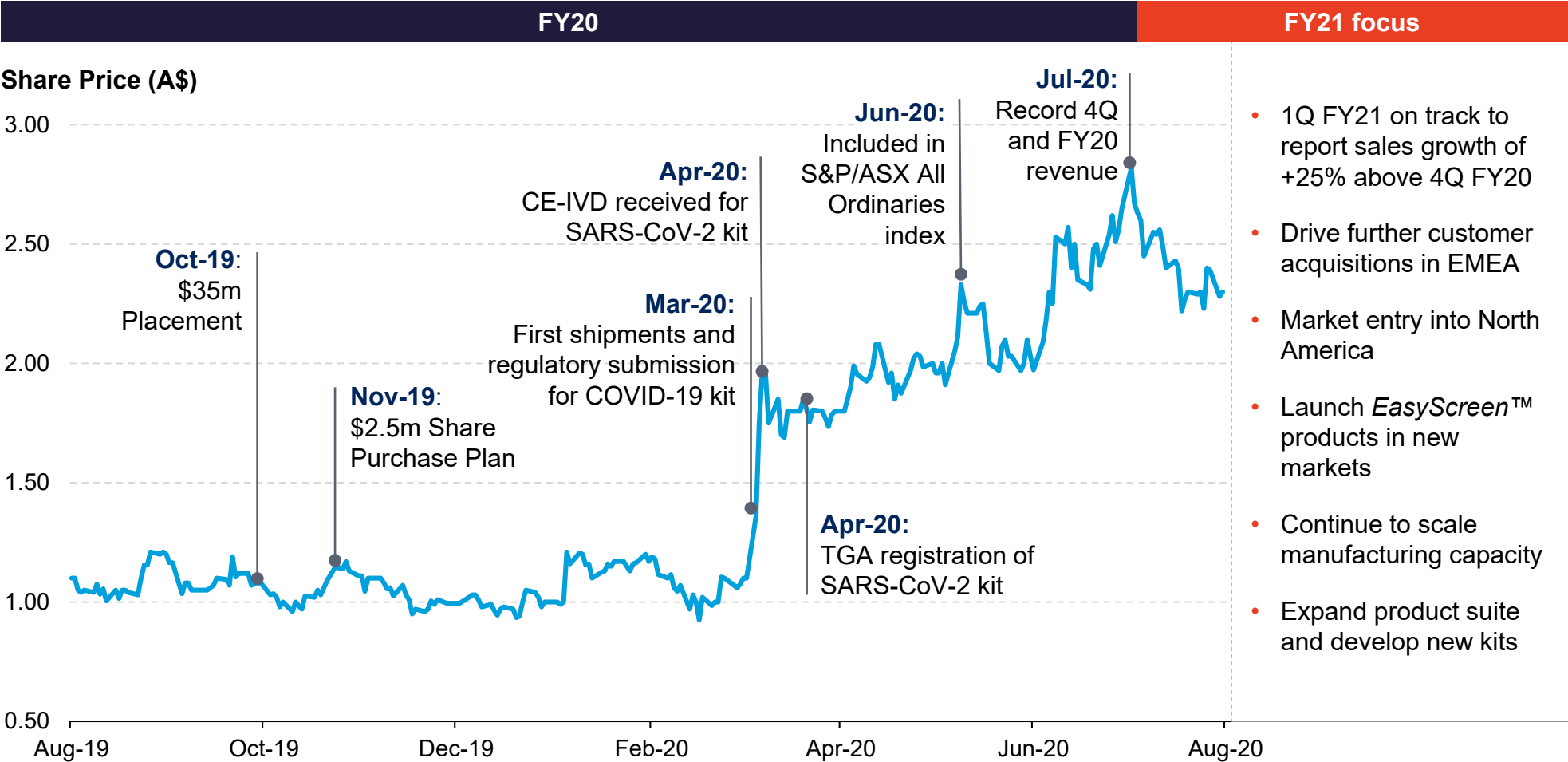


## Multiple upcoming catalysts in FY21

- Multiple global growth opportunities to be pursued in tandem, each representing potential upside

1. <https://geneticsignatures.com/au/publications/>

# Genetic Signatures has had an outstanding year against the backdrop of the COVID-19 pandemic, reflected by positive share price performance



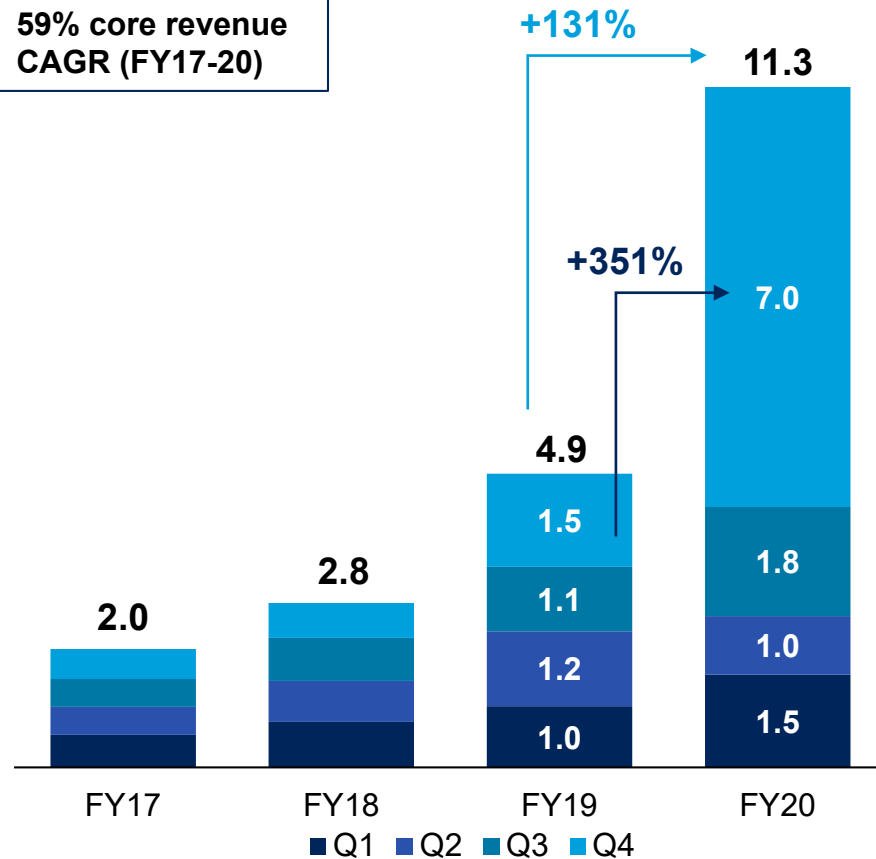
- 1Q FY21 on track to report sales growth of +25% above 4Q FY20
- Drive further customer acquisitions in EMEA
- Market entry into North America
- Launch *EasyScreen*™ products in new markets
- Continue to scale manufacturing capacity
- Expand product suite and develop new kits

# Significant revenue growth and continued to achieve strong year-on-year revenue growth and a milestone quarter in 4Q FY2020



## Revenue (A\$m)

59% core revenue CAGR (FY17-20)



## Exceptional year for Genetic Signatures

- ✓ Revenue for **FY20 of \$11.3m**, a **+131%** on pcp
- ✓ Record quarterly revenue in 4Q FY20 of **\$7.0m**, a **+351%** on pcp, includes instrument sales of **~\$1.0m**
- ✓ Rapid development of **SARS-CoV-2 kit** driving significant domestic and international sales
- ✓ Sales to European customers represented **~10% of total sales for the year and strong demand** from existing domestic customers
- ✓ **Increased manufacturing capacity** within existing infrastructure to cater for the increased demand
- ✓ Significantly **increased inventory holdings** to meet growing demand
- ✓ Considerable **investment in instrumentation**
- ✓ Strong cash balance as at 30 June 2020 of **\$31.2m**



# Financial performance

A\$000	Year ending 30 June 2020	Year ending 30 June 2019
Sales revenue	11,263	4,866
Other income	2,910	2,327
<b>Total revenue</b>	<b>14,173</b>	<b>7,193</b>
Cost of goods sold	(4,305)	(1,686)
Employee benefits expense	(6,671)	(4,933)
Other expense items	(4,367)	(3,594)
<b>EBITDA</b>	<b>(1,170)</b>	<b>(3,020)</b>
Depreciation and amortization	(883)	(471)
<b>EBIT</b>	<b>(2,053)</b>	<b>(3,491)</b>
Finance costs	(33)	(1)
<b>(Loss) / profit before tax expenses</b>	<b>(2,086)</b>	<b>(3,492)</b>
Income tax benefit / (expense)	-	-
<b>Net (loss) / profit after tax</b>	<b>(2,086)</b>	<b>(3,492)</b>
Earnings per share (cents)	(1.64)	(3.36)

- Revenue of \$11.3m ,**+131% on pcp** driven by **demand for SARS-CoV-2 test**
  - Other revenue includes R&D tax rebate of \$2.6m
- Expense up ~35% relative to pcp with:
  - **Additional personnel** added to the teams in Europe, USA and locally across all functions
  - Scientific consumables increased 50% on pcp, reflecting the **work on SARS-CoV-2**
  - R&D projects and initial clinical trial activity for the **FDA Enteric Protozoan submission**
- Net loss of \$2.1m in FY20, a **+\$1.4m improvement** over FY19
  - **2H FY20 was a maiden profit** of \$0.3m, showing the impact of higher sales

*A strong cash balance of \$31m positions the Company well to drive future growth*

Trusted and proven technology – the *EasyScreen*<sup>TM</sup> products are built on **3base**<sup>TM</sup> technology



## Our Products

Transforming **molecular diagnostics** via streamlined sample processing methods linked to highly **multiplexed real-time PCR screening assays**.

Our automated **sample preparation** method is suitable for **bacterial, protozoan and viral** (DNA & RNA) targets.

The *EasyScreen*<sup>TM</sup> Detection assays **simultaneously detect a larger number of pathogen targets** in a shorter time than conventional methods.



GS-mini



GS1-HT

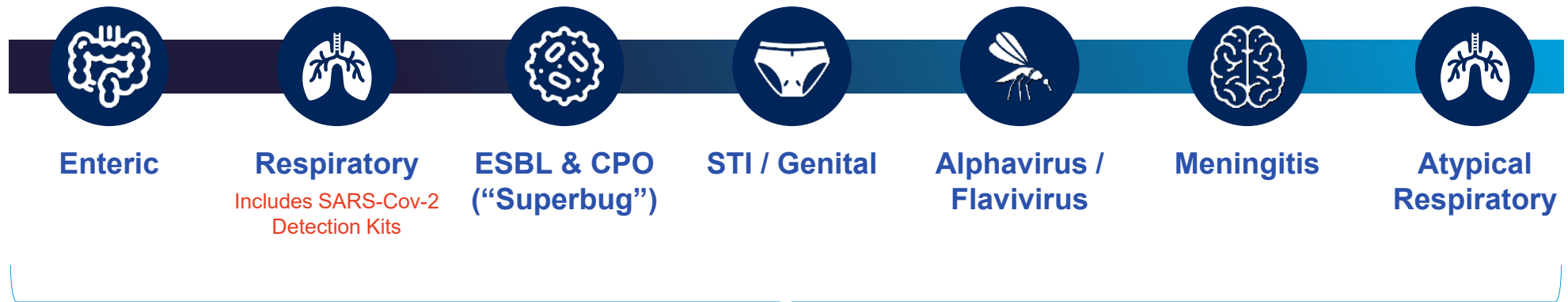


GS-1000

# Broad suite of EasyScreen™ Detection Kits targeting significant addressable markets



## EasyScreen™ Products



**Global market size of  
~A\$10bn per annum**

Sources: World Market for Molecular Diagnostics, 5th. Edition (Infectious Disease, Oncology, Blood Screening, Pre-Natal and Other Areas) Kalorama Information, Published: 1/9/2013 & company estimates; Molecular Diagnostics Markets in the COVID-19 Era (Markets for Molecular COVID-19 IVD Tests, Respiratory Tests, Blood Screening, Cancer Markers and Other IVD Tests), Published: 9/7/2020



# Rapid development of SARS-CoV-2 kit and scaled up manufacturing capacity to meet a significant increase in customer demand



## Strongly positioned to test for SARS-CoV-2



The SARS-CoV-2 Test can be used **alone or in conjunction** with the broader *EasyScreen™* Respiratory Kit



**3base™** provides **resistance to genetic drift** or mutations of pathogens over time allowing **preservation of clinical specificity**



**High throughput** allows **testing** of up to 1,500 samples in a 24-hour period in batches of 94 to 188 samples per run

## *EasyScreen™* SARS-CoV-2 Detection Kit update



**CE-IVD and TGA received** – kits available for sale in Europe and Australia



**FDA EUA<sup>1</sup> application submitted** and awaiting clearance. Can now sell to select customers in the US under a Section IVc exemption<sup>2</sup>



**Testing underway** in Australia and EMEA with customers using the kits for routine testing



**Driving global sales** - international sales team and distributors in place in key regions



**Expanded sales force** - new appointments made to promote kits globally

***Genetic Signatures can proudly claim that none of its customers has been without product to undertake testing to date***

1. Emergency Use Authorisation  
2. The FDA is permitting manufacturers that have or will submit an EUA for a SARS-CoV-2 test to supply their test prior to receiving the EUA. The FDA describes this marketing route in Section IV.C. of their Policy for Coronavirus Disease-2019 (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>)

# Competitive advantage - Genetic Signatures' 3base™ technology creates potential benefits for multiple key stakeholders



## Patients

- ✓ **qPCR<sup>1</sup> detection methodology** used, the gold standard for infectious disease diagnosis
- ✓ **Rapid time to results**, with results processed from 4 hours, for up to 188 specimens
- ✓ Screening for **more targets** per patient specimen **increases accuracy of diagnosis**
- ✓ **Accelerates treatment path** and **reduces mortality and morbidity**



## Laboratories

- ✓ **Clear competitive advantage** for target customer base of **high throughput labs**
- ✓ **Reduces customer costs** through accurate detection and minimising hands on time
- ✓ **Reduced complexity** in molecular testing



## Governments

- ✓ **Reduced hospital stays** with **broad and accurate** detection of infectious disease
- ✓ Fast turnaround and accurate detection **reduces the spread of disease**
- ✓ Testing for **more targets per specimen** **reduces repeat doctor visits**
- ✓ **Reduces overuse and misuse of antibiotics**

1. Real-time polymerase chain reaction (real-time PCR), also known as quantitative polymerase chain reaction (qPCR)

# Growth underpinned by scalable revenue model and attractive unit economics supported by expanding pipeline of new customers / tenders



## Attractive revenue model



### High throughput with predictable orders

Target **high throughput** pathology groups, hospitals or government run programs

**Secure long-standing customer relationships** with **predictable volumes**

Customers typically have **regular ordering patterns**



### Sticky annuity revenue

“**Printer & cartridge**” model - tests become **embedded in workflow**

Customers may **adopt new tests** once workflow established

**100% customer retention** since 2016



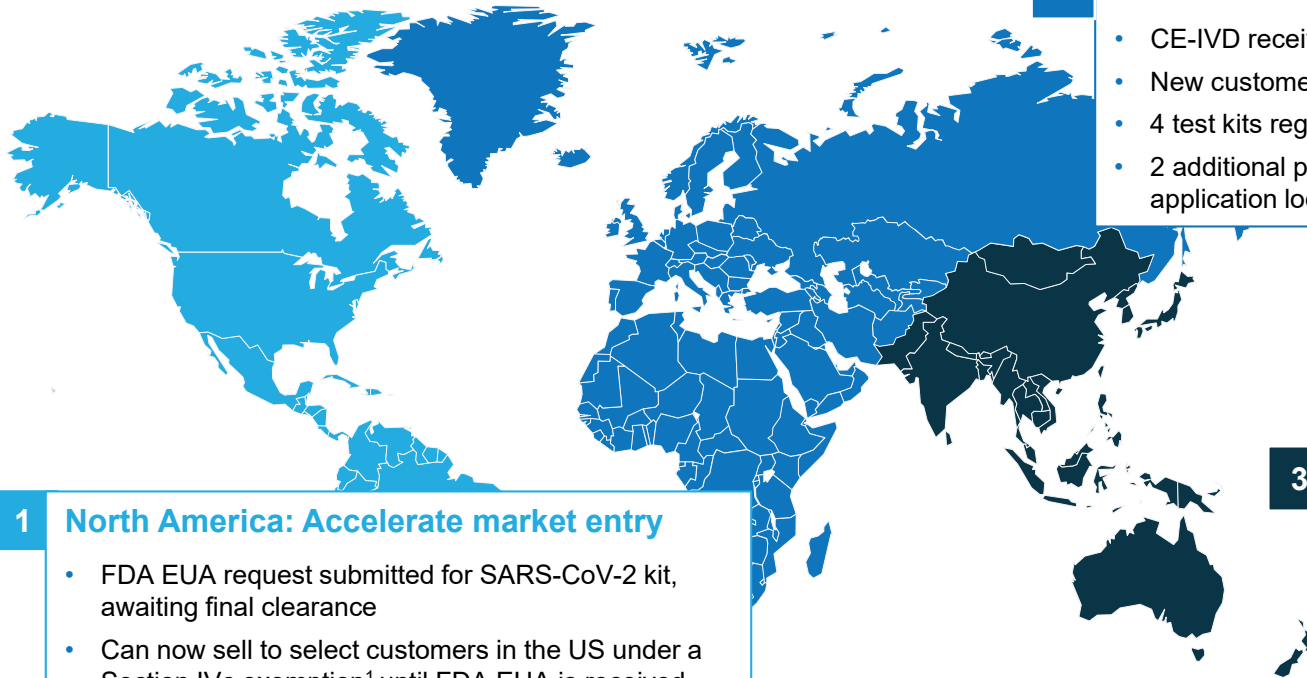
### Attractive return on investment

Potential to **fund new customer installations**

**Speeds up customer acquisition**, particularly offshore

**Consumable revenue model** - customers pay per test

# Global strategy for commercialisation - COVID-19 pandemic has created an opportunity to accelerate international expansion



## 1 North America: Accelerate market entry

- FDA EUA request submitted for SARS-CoV-2 kit, awaiting final clearance
- Can now sell to select customers in the US under a Section IVc exemption<sup>1</sup> until FDA EUA is received
- New sales team appointed with strong pedigree in the industry
- Initial clinical work has now commenced for FDA clearance of the *EasyScreen*<sup>™</sup> Enteric Protozoan Detection Kit

## 2 EMEA: Focused on increasing customer acquisitions

- CE-IVD received for SARS-CoV-2 kit and product launched
- New customers established, including 3 new distributors
- 4 test kits registered for sale including the SARS-CoV-2 test
- 2 additional products approaching CE-IVD registration, with application lodged for STI / Genital Pathogen kit in 4Q FY20

## 3 APAC: Continued sales expansion

- TGA registration and launch of *EasyScreen*<sup>™</sup> SARS-CoV-2 kit
- New customers adopt *EasyScreen*<sup>™</sup> SARS-CoV-2 test
- Production capacity increased to meet current demand and further expansion underway
- Application lodged with TGA for STI / Genital kit to be included on ARTG

1. The FDA is permitting manufacturers that have or will submit an EUA for a SARS-CoV-2 test to supply their test prior to receiving the EUA. The FDA describes this marketing route in Section IV.C. of their Policy for Coronavirus Disease-2019 (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>)

# On track to achieve multiple commercial milestones in FY21 that could accelerate revenue growth



## Near term opportunities for SARS-CoV-2 commercialisation

- ✓ **CE-IVD received** allowing marketing of the kit in Europe with **orders received**
- ✓ TGA registration received allowing marketing of the kit in Australia with **orders received**
- FDA EUA has been submitted for SARS-CoV-2 kit, **awaiting final clearance**
- **Targeting first US customer contract** for SARS-CoV-2 product<sup>1</sup>

## Launching EasyScreen™ products in new markets

- TGA / CE-IVD submission for the STI / Genital kit filed in 4Q FY20 **with clearance anticipated in the coming months**
- Well positioned to progress regulatory applications when COVID-19 restrictions lift:
  - Clinical trials initiated for the FDA submission for the Enteric Protozoan kit
  - TGA / CE-IVD submissions for the Flavivirus / Alphavirus kit

## Leverage growing international exposure to drive new contract wins

- ✓ COVID-19 pandemic has given Genetic Signatures an opportunity to **demonstrate its technology** and broader syndromic testing platform to a greater range of customers
- Interest in the SARS-CoV-2 products likely to drive interest in broader range of *EasyScreen™* multiplex kits and facilitate **new contracts in US and Europe**

1. The FDA is permitting manufacturers that have or will submit an EUA for a SARS-CoV-2 test to supply their test prior to receiving the EUA. The FDA describes this marketing route in Section IV.C. of their Policy for Coronavirus Disease-2019 (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>)



# Appendices







**Genetic  
Signatures**

Transforming  
Molecular  
Diagnostics

# A global leader in the supply of molecular diagnostic solutions

## 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 teams in Australia, Europe and North America
-  Scalable business which has achieved strong core revenue growth



## Financial information

Share price (26-Aug-20)	A\$2.30
Shares on issue	142.6m <sup>1</sup>
<b>Market capitalisation</b>	<b>A\$328.0m</b>
Cash (30-Jun-20)	A\$31.2m
Debt (30-Jun-20)	Nil
<b>Enterprise value</b>	<b>A\$296.8m</b>

## Top shareholders %

Asia Union (Chris Abbott private investment)	26.7%
Karst Peak (HK-based investment manager)	11.2%
Perennial Value Management	9.4%
Fidelity International	7.7%
Directors, management & advisors	3.5%

1: Excludes 3.28m unquoted options (various expiration dates and prices)

# Novel proprietary technology - proprietary 3base™ platform technology underpins the EasyScreen™ product range



## Our proprietary 3base™ solution...

- 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 pathogens and provide greater testing accuracy by reducing complexity in a multiplex environment



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

↓

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

## ...improves workflow and increases throughput



**EasyScreen™ kits are compatible with most existing** automated nucleic acid extraction and real-time PCR instruments and **streamline the preparation process**



High throughput labs can achieve **further workflow automation** with compatible hardware. Creates **workflow efficiencies and reduce costs**



**Currently offering over 100 pathogen targets** across enteric, respiratory, anti-microbial resistance, sexual health and tropical diseases

# Board of Directors with proven track records of commercialisation success across key geographic regions

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**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 &  
Chief Executive Office**

- **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)

# International management team of highly skilled researchers and executives bring a broad array of experience and knowledge



**Dr. Doug Millar**  
Chief Scientific Officer

- One of the pioneers of the bisulphite genomic sequencing protocol with a PhD in Molecular Genetics
- Key inventor on over **30 patents** or pending patent applications held by the company
- Authored **23 peer reviewed scientific papers** and presented at 20+ international conferences



**Peter Manley**  
Chief Financial Officer  
& Company Secretary

- Led the recent Genetic Signatures capital raise, successfully securing \$37.5m
- Served as CFO and Company Secretary for **AtCor Medical** (now Cardiac) and **Sirtex Medical**
- Senior financial positions including 8 years with **Dow Chemical** and 4 years at **Goodman Fielder**



**Jackson Jones**  
Director of Global  
Sales & Marketing

- **20+ years experience** in clinical diagnostics, blood banking, and life sciences sector
- Joined Genetic Signatures in 2017 and brings significant commercial experience from working with **several large US multinationals** and roles across **Australasia, Europe, and North America**



**Derek Joesting**  
Director of Sales -  
North America

- **20+ years of medical sales experience** with broad sector experience
- Previously held **leadership roles in molecular diagnostics** and pathology sales in North America
- Holds a Bachelor of Science degree in Biology from Syracuse University



**John Buckels**  
Director of Sales &  
Support - Europe

- **20+ years' experience** in molecular biology and sales across the EMEA
- Former **Senior Director and Head of Infectious Diseases sales at QIAGEN** and 13 years experience in sales and marketing



**Neralie Coulston**  
Regulatory Affairs  
Manager

- Supported Genetic Signatures since 2002 and **brings significant experiences in Quality System and Regulatory Affairs**
- Former roles at the **CSIRO and UNSW** on both **therapeutic development and research** programs



# Contact us

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# Genetic Signatures

Transforming  
Molecular  
Diagnostics

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