

## **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**<sup>TM</sup> 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



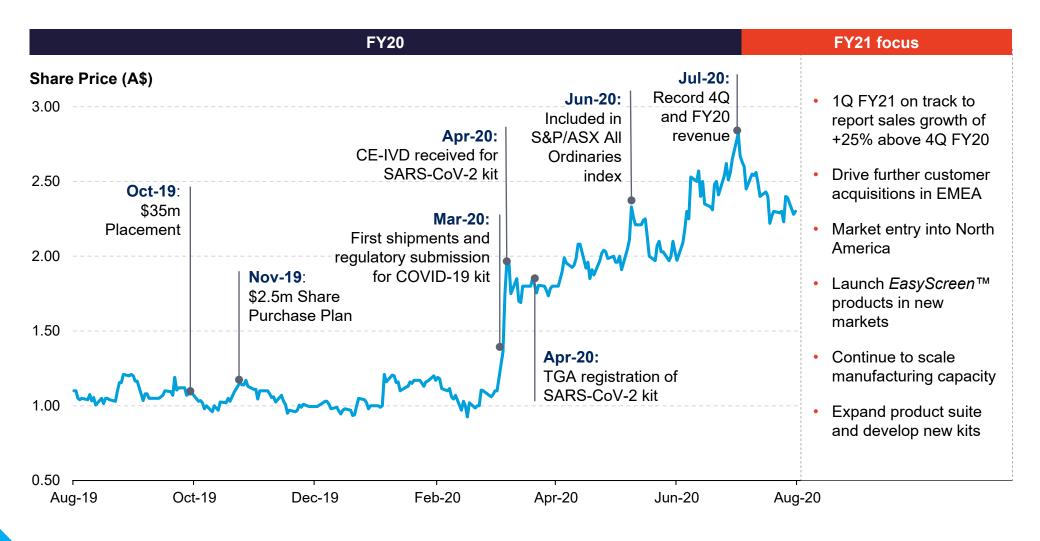
## Multiple upcoming catalysts in FY21

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

<sup>1.</sup> 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

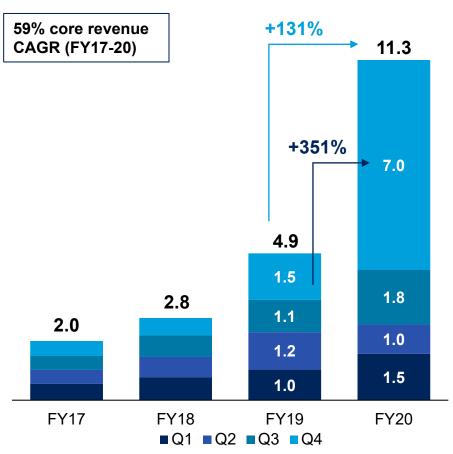




# **Significant revenue growth** and continued to achieve strong year-on-year revenue growth and a milestone quarter in 4Q FY2020



#### Revenue (A\$m)



### **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
Total revenue	14,173	7,193
Cost of goods sold	(4,305)	(1,686)
Employee benefits expense	(6,671)	(4,933)
Other expense items	(4,367)	(3,594)
EBITDA	(1,170)	(3,020)
Depreciation and amortization	(883)	(471)
EBIT	(2,053)	(3,491)
Finance costs	(33)	(1)
(Loss) / profit before tax expenses	(2,086)	(3,492)
Income tax benefit / (expense)	-	-
Net (loss) / profit after tax	(2,086)	(3,492)
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™* products are built on **3base™** 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™ Detection assays simultaneously detect a larger number of pathogen targets in a shorter time than conventional methods.



## Broad suite of EasyScreen<sup>™</sup> Detection Kits targeting significant addressable markets



## *EasyScreen™* Products















**Enteric** 

Respiratory

Includes SARS-Cov-2 Detection Kits ESBL & CPO ("Superbug")

STI / Genital

Alphavirus / Flavivirus

Meningitis

Atypical Respiratory

# 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<sup>™</sup> 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<sup>™</sup> 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

**Emergency Use Authorisation** 

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





- ✓ qPCR¹ 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



- ✓ 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



- ✓ 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

<sup>1.</sup> 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

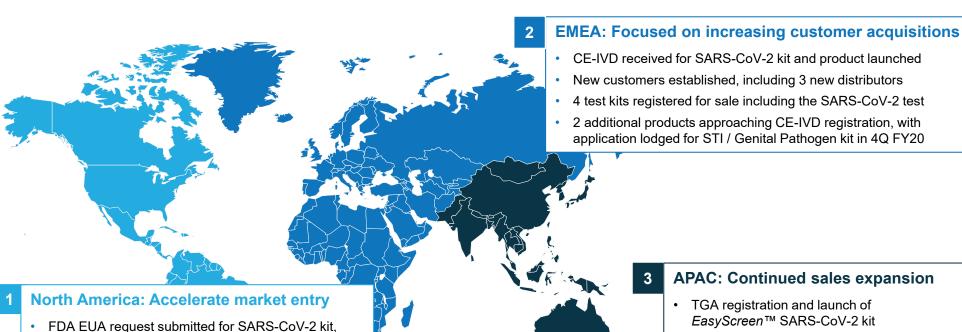
Potential to fund new customer installations

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





- New customers adopt *EasyScreen*™ 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

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

awaiting final clearance

industry

Initial clinical work has now commenced for FDA clearance of the *EasyScreen*™ Enteric Protozoan **Detection Kit** 

<sup>1.</sup> 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

# 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<sup>TM</sup> multiplex kits and facilitate new contracts in US and Europe

<sup>1.</sup> 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)

## Genetic Signatures

Transforming Molecular Diagnostics

## **Appendices**

## 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**

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

#### 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%

<sup>1:</sup> Excludes 3.28m unquoted options (various expiration dates and prices)

# **Novel proprietary technology** - proprietary **3base<sup>TM</sup>** platform technology underpins the *EasyScreen<sup>TM</sup>* product range



#### Our proprietary 3base<sup>™</sup> solution...

- 3base<sup>™</sup> platform technology converts original
   4-base microbial genome to 3-base
- Conversion occurs during standard procedures with no additional steps for the technician
- 3 3base<sup>™</sup> 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



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, antimicrobial resistance, sexual health and tropical diseases

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





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 Cardiex) 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

Dr John Melki

**Genetic Signatures** 

Chief Executive Officer

P: +61 (0)2 9870 7580

E: john.melki@geneticsignatures.com

**Peter Manley** 

Genetic Signatures

Chief Financial Officer

P: +61 (0)2 9870 7580

E: peter.manley@geneticsignatures.com

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