



# 1H FY21 Results and Update

February 2021



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# Introducing Genetic Signatures

## Genetic Signatures Limited (ASX: GSS)

*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 direct teams and distributors across Australia, Europe and North America

## Range of *EasyScreen™* Kits



### Enteric

*Detects 20+ gastroenteritis pathogens including Salmonella, Giardia and Norovirus*



### Respiratory

*Detects 14 common respiratory infections including Influenza types A&B, Rhinovirus and SARS-CoV-2)*



### ESBL & CPO

*Detection of antibiotic resistant pathogens also colloquially known as “superbugs”*



### STI / Genital

*Detects the most prevalent pathogen infections (Chlamydia, Gonorrhoeae, Syphilis and Trichomoniasis) plus many others*



### Flavivirus / Alphavirus

*Refers to mosquito born pathogens including Dengue fever, Zika virus, West Nile virus and others*



### Meningitis

*Detects 8 viral meningitis pathogens, a life-threatening infection surrounding the brain and spinal cord*



### Respiratory Atypical

*Additional targets under the Respiratory banner*

# Executive Summary

## Unique molecular 3base™ technology

- Resistant to naturally occurring mutations (variants)
- Screens for large number of organisms from one patient specimen.
- High throughput solution
- **IP protection** until 2031

## Total available market<sup>1</sup> - >\$3.0bn pa

- Enteric, respiratory (excl. COVID-19) and STI

## Solid history of growth

- YoY growth since listing
- 4 year **CAGR – 59%** (2017-2020)
- 638% increase in sales 1H21 vs 1H20
- **Labs** using *EasyScreen™* tests in AU, EU, US

## Well funded to pursue growth

- Cash balance @ 31 Dec 2021 - \$36.3m
- **Positive operating cashflow** last 2 qtrs.

## High throughput with predictable orders

- Target customers are **high throughput** pathology groups, hospitals or government run programs
- Customers **secure long-standing contracts** with set prices and **relatively predictable volumes**
- **Regular orders** with **fast payment terms** – relatively low working capital needs

## Sticky annuity revenue:

- **“Printer & cartridge”** model - tests become embedded in workflow
- Customers may **adopt new tests** once workflow established

## Attractive return on investment:

- Potential to fund new customer installations to **speed up customer acquisition**, particularly offshore
- **Consumable revenue model** - customers pay per test

1. Global market size (A\$m per annum) - Kalorama Information, Molecular Testing Markets for Infectious Diseases (Sepsis, Respiratory Diseases, HIV, Hepatitis, TB Testing, STIs and Other Tests), July 2019, and company estimates



# Trusted and Proven 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.



# 12 Months in Review

## March 2020:

First shipments and regulatory submission for COVID-19 kit

## April 2020:

CE-IVD received for SARS-CoV-2 kit

## April 2020:

TGA registration of SARS-CoV-2 kit

## June 2020:

Included in S&P/ASX All Ordinaries index

## June 2020:

Record quarterly revenue up 351% on pcip

## September 2020:

Record quarterly revenue up 585% on pcip

## December 2020:

Supply agreement with Boston Medical Center – 1<sup>st</sup> US customer

## January 2021:

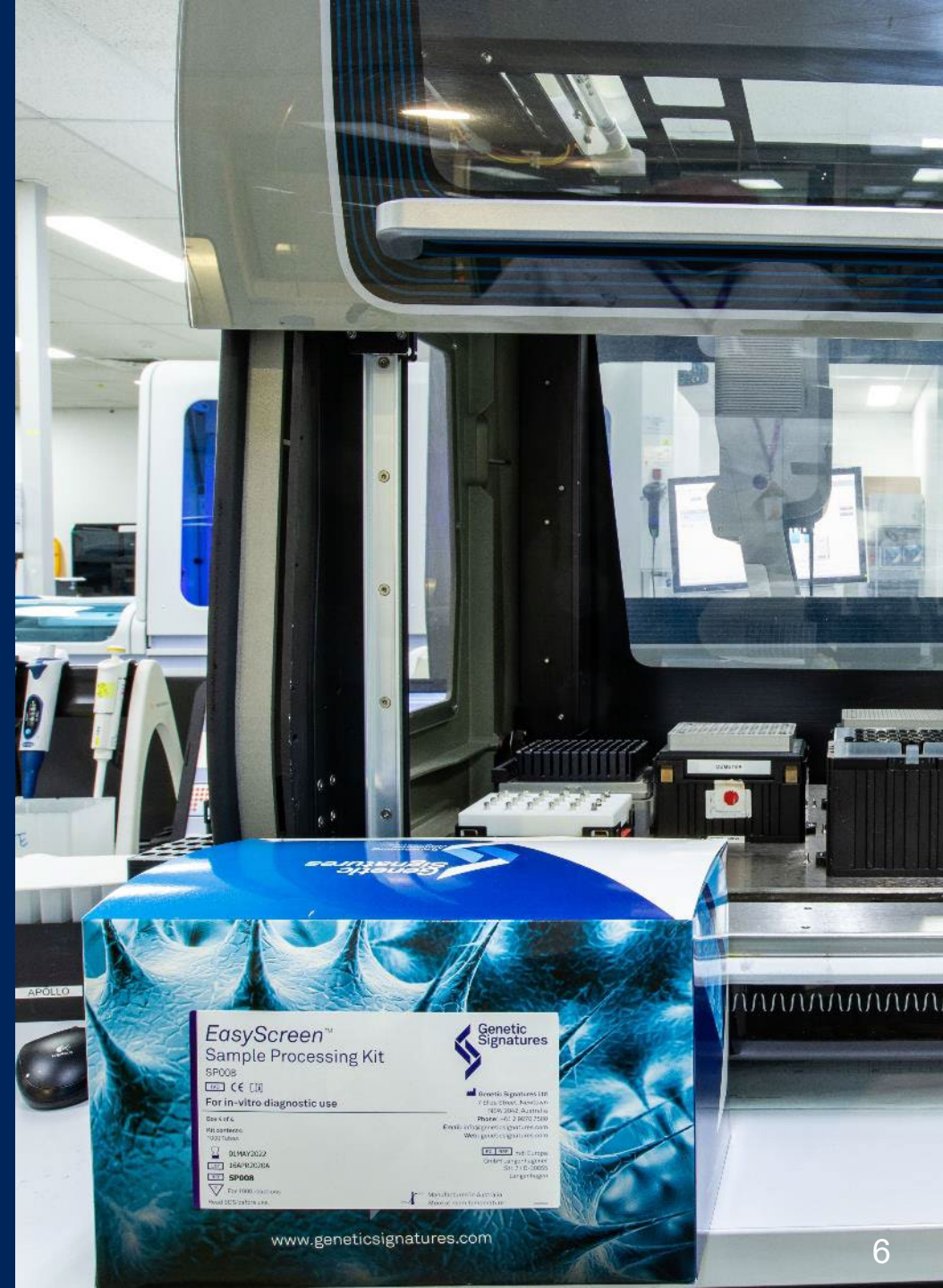
Quarterly revenue up 744% on pcip

## January 2021:

CE-IVD received for *EasyScreen*<sup>TM</sup> STI Genital Pathogen Detection Kit



## Genetic Signatures

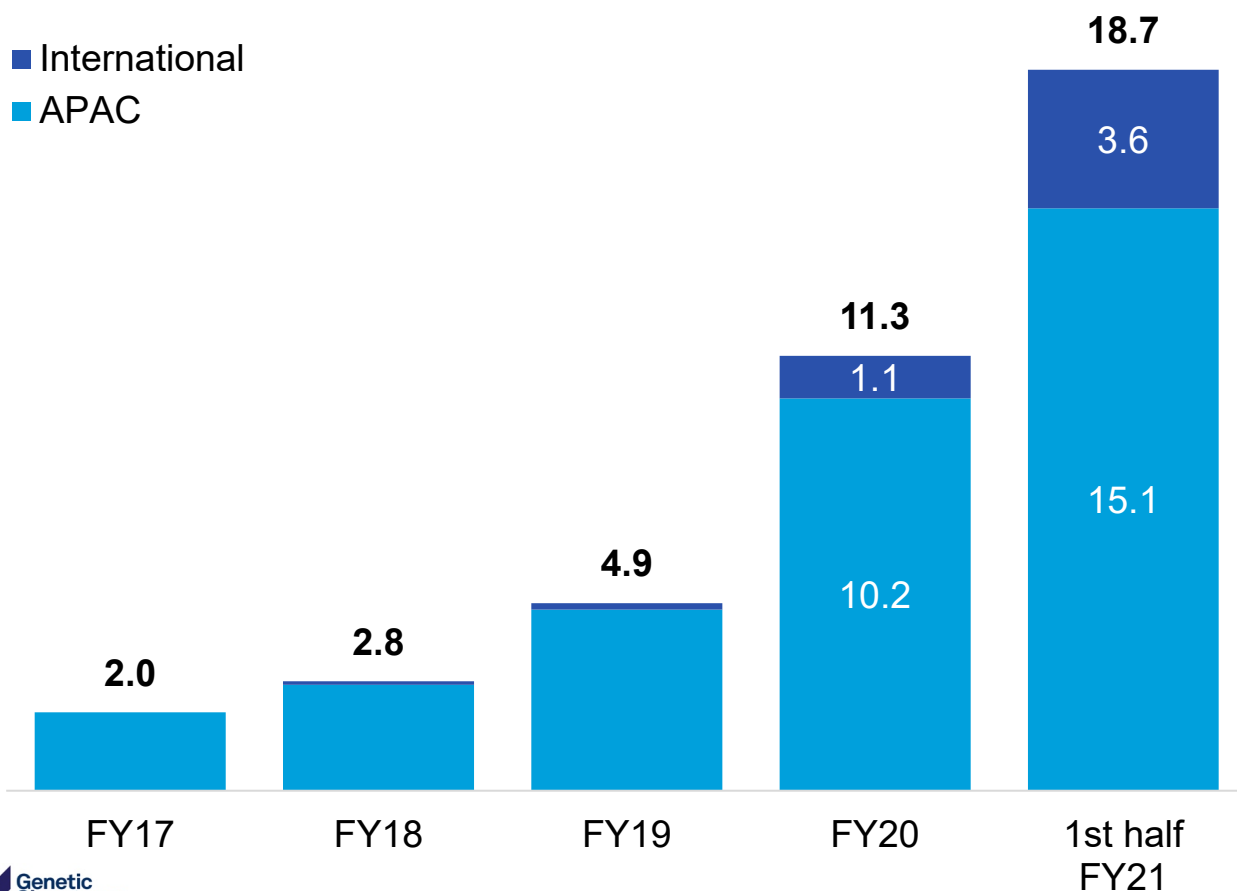


# Continued Strong Revenue Growth

Increasing contribution from international business

## Revenue (unaudited) from operations (A\$m)

■ International  
■ APAC



- **+744%** on qtrly pcp and **+638%** vs 1H FY20
- **Strong demand for tests** in 1HFY21 following second wave of COVID-19 in Australia
- **Multiple new instruments** installed across FY20 and FY21
- New instrument placements will continue to support **future demand for tests**
- **2<sup>nd</sup> positive cash quarter** 2QFY21 and cash balance of **\$36m** positions the Company well to **drive future growth**
- **More than 1.8m patient samples** analysed using at least one *EasyScreen™* test

# 1H FY21 Financial Summary

A\$000	Half year ending 31 Dec 2020	Half year ending 31 Dec 2019
Revenue from operations	18,693	2,532
Other income	235	1,106
<b>Total revenue</b>	<b>18,928</b>	<b>3,704</b>
Cost of materials & freight	(6,086)	(879)
Employee benefits expense	(4,913)	(2,953)
Other expense items	(2,757)	(1,808)
<b>EBITDA</b>	<b>5,172</b>	<b>(1,936)</b>
Depreciation and amortization	(655)	(395)
<b>EBIT</b>	<b>4,517</b>	<b>(2,331)</b>
Finance costs (AASB 16 leases)	(20)	(15)
<b>Profit / (loss) before tax expenses</b>	<b>4,497</b>	<b>(2,346)</b>
Income tax benefit / (expense)	-	-
<b>Net profit / (loss) after tax</b>	<b>4,497</b>	<b>(2,346)</b>
Basic earnings per share (cents)	3.15	(2.10)
Diluted earnings per shares (cents)	3.09	(2.10)

- Revenue of \$18.7m , **+638% on pcp** driven by **demand for SARS-CoV-2 test**
  - Other revenue includes R&D tax rebate in 1HFY20, nothing in 1HFY21
- Gross margin up to **67%**
  - 2% improvement over pcp
- Expense up ~61% relative to pcp with:
  - **Additional personnel** added to the teams in Europe, USA and locally across all functions
  - Scientific consumables increased 82% on pcp, reflecting continued **work on SARS-CoV-2** plus other projects
- First significant profit of \$4.5m, a **+\$6.8m turnaround** over 1HFY20
  - Higher sales and improving gross margin



# 1H FY21 Cashflow

A\$000	Half year ending 31 Dec 2020	Half year ending 31 Dec 2019
Receipts from customers	20,316	2,871
Payments to suppliers and employees	(15,358)	(5,961)
R&D grant	2,554	2,147
Other	284	38
<b>Net operating cash</b>	<b>7,796</b>	<b>(905)</b>
Payment for plant & equipment	(2,558)	(512)
<b>Net investing cash</b>	<b>(2,558)</b>	<b>(512)</b>
Net proceeds from issue of shares	128	35,656
Principal elements of lease payments	(169)	(105)
<b>Net financing cash</b>	<b>(41)</b>	<b>35,551</b>
<b>Net increase in cash and cash equivalents</b>	<b>5,197</b>	<b>34,134</b>
Opening cash and cash equivalents	31,176	6,312
Effects of exchange rate changes on cash	(100)	(5)
<b>Closing cash and cash equivalents</b>	<b>36,273</b>	<b>40,441</b>

- Collections **up 7-fold** vs pcp
- Payment up due to investments in additional personnel and inventory
- 5-fold increase in capital expenditure
  - Increased manufacturing capacity
  - Instrumentation to place with customers
- Capital raise in October 2019 provided funds to enable current growth

# Asia Pacific Update

- ✓ 1H21 revenue **increased 519% to \$15.1m** (1H20: \$2.4m) and includes instrument sales of \$0.2m
- ✓ Received TGA registration and **launched *EasyScreen*™ SARS-CoV-2 Detection Kit** across Australia – Apr 20
- ✓ Underpinned by **strong demand for *EasyScreen*™ SARS-CoV-2 Detection Kit** – which is currently being used both as a standalone test and in combination with the broader ***EasyScreen*™ Respiratory Pathogen Detection Kit** by new and existing customers
- ✓ Significantly **increased production capacity** to meet current demand and **more production expansion underway**
- ✓ Application lodged with **TGA for *EasyScreen*™ STI / Genital Pathogen Detection Kit**

# EMEA Update

- ✓ **European Union and UK are a key focus** through FY21 and beyond
- ✓ **Achieved European registration** (CE-IVD) for the *EasyScreen*™ SARS-CoV-2 Detection Kit – Apr 20
- ✓ 1H21 revenue **3.0m**, (1H20: \$0.1m), including instrument sales of \$0.6m, representing 16% of global 1H FY21 revenue
- ✓ **New customers established – strategically partnering** with customers interested in the broad range of *EasyScreen*™ Detection Kits
- ✓ European registration for *EasyScreen*™ STI / Genital Pathogen Detection Kit

# North America Update

- ✓ **Largest market opportunity globally**, representing an estimated **42%** of the global molecular testing market<sup>1</sup>
- ✓ **First customers in USA**, including Boston Medical Center – 1<sup>st</sup> orders supplied in December 2020
- ✓ 1H FY21 revenue **\$0.6m** – 1<sup>st</sup> notable sales in USA
- ✓ Initial **clinical trials have commenced** for FDA clearance of the **EasyScreen™ Enteric Protozoan Detection Kit**, despite disruptions caused by COVID-19
- ✓ **Canadian distributor** appointed – Somagen Diagnostic, Inc
- ✓ **New warehouse facility** established and stocked in Los Angeles



1. Global market size (A\$m per annum) - Kalorama Information, Molecular Testing Markets for Infectious Diseases (Sepsis, Respiratory Diseases, HIV, Hepatitis, TB Testing, STIs and Other Tests), July 2019, and company estimates; 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 Tests During the Public Health Emergency (Revised)<sup>2</sup> Under the exemption the manufacturer must have validated the kit and is required to notify the FDA of their intent to supply the test. The use of the test is limited to laboratories that have been certified under CLIA (Clinical Laboratory Improvement Amendments) to perform high complexity testing and the laboratory is required to disclaim the status of the test on all results that are issued using the test. (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>)



# Multiple *EasyScreen*<sup>TM</sup> Kits Targeting Significant Addressable Markets

*Commercial products available...*



**Enteric**  
TGA / CE-IVD  
~\$537m p.a<sup>1</sup>



**Respiratory**  
TGA / CE-IVD  
~\$627m<sup>1</sup> / \$6.3bn  
SARS-CoV-2 p.a<sup>2</sup>



**ESBL & CPO**  
TGA / CE-IVD  
Emerging market



**STI / Genital**  
CE-IVD  
Submitted TGA  
~A\$1.9bn p.a<sup>1</sup>

*...and continued development of new products*



**Alpha / Flavivirus**  
~\$69m p.a<sup>1</sup>



**Meningitis**  
\$156m p.a<sup>1</sup>



**Atypical Respiratory**  
See Respiratory



**Undisclosed**  
Products under development



1. Global market size (A\$m per annum) - Kalorama Information, Molecular Testing Markets for Infectious Diseases (Sepsis, Respiratory Diseases, HIV, Hepatitis, TB Testing, STIs and Other Tests), July 2019, and company estimates; 2. 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) Kalorama Information, Published: 9/7/2020

# Looking Forward

Multiple growth opportunities to be pursued in tandem, creating significant upside potential



## Focus on long-term customer contracts and customer satisfaction

- Focus on securing long-term customer contracts with high throughput pathology groups, hospitals or government run programs
- Provide reliable and quality customer service to build strong customer relationships
- Favourable unit economics expected to underpin growth through FY21 and beyond



## Leverage COVID-19 momentum and promote new tests to existing customers

- Increasing international recognition through the *EasyScreen*<sup>TM</sup> SARS-CoV-2 launch creates new avenues to expand the customer base
- Tests become embedded in workflow and customers typically adopt new tests once workflow established leading to favourable unit economics
- Targeting additional North American and European contracts



## Development of new *EasyScreen*<sup>TM</sup> Kits

- FDA submission for the *EasyScreen*<sup>TM</sup> Enteric Protozoan Detection Kit
- TGA registration for *EasyScreen*<sup>TM</sup> STI / Genital Pathogen Detection Kits (CE-IVD received Jan-21)
- CE-IVD and TGA registration for *EasyScreen*<sup>TM</sup> Flavivirus / Alphavirus Detection Kits
- Continued development of other new kits



## Contact us

**Dr John Melki**

Genetic Signatures

Chief Executive Officer

P: +61 (0)2 9870 7580

E: [john.melki@geneticsignatures.com](mailto:john.melki@geneticsignatures.com)

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