

**ASX Code: GSS**  
19 November 2021

## **Chairman's Address and CEO Presentation at Annual General Meeting**

Genetic Signatures Limited (ASX:GSS) is pleased to release the Annual General Meeting Chairman's Address and CEO presentation.

### **Chairman's Address:**

Good morning, and welcome to the Genetic Signatures 2021 Annual General Meeting. On behalf of the Board, I thank you all for attending and for your ongoing support.

Your company is fast becoming a leader in the fight against infectious diseases. And, while COVID has placed challenges in front of us it has also helped build our strong reputation as a global supplier of molecular diagnostic tests. As a consequence of delivering a COVID testing product we have seen awareness of Genetic Signatures grow substantially with its consequent materially positive financial impact from product sales.

Let me turn our attention to the Company's recent achievements before handing the microphone to our CEO and Managing Director, Dr John Melki, to provide additional detail on the company's strategy and the milestones we will strive to reach in the 2022 financial year.

As your Chairman it pleases me greatly to be able to report that Genetic Signatures generated sales revenue of A\$28.3 million in the 2021 financial year, representing a 150% increase on the previous year. This is an outstanding result showing strong revenue growth across the year. It is worth noting that revenue remains strong with a very solid result of A\$12.4 million in the first quarter of the 2022 financial year, up by almost \$2 million on the prior corresponding period, which was the previous record.

The increase in revenue over the 2021 financial year also helped deliver our first full year profit, which is a very important milestone for a company such as ours.

I am pleased that the continued strong financial performance and higher media profile of your company is generating a new, and deeper, pool of investors as evidenced by increased trading activity.

I mentioned earlier that COVID has had a positive effect on our business. We continue to see solid demand for the *EasyScreen*<sup>TM</sup> SARS-CoV-2 Detection Kit. This demand has accelerated the interest in other *EasyScreen*<sup>TM</sup> indications from new customers in Europe and the USA who had previously been slow to convert in the past. Our instruments have been acquired in many laboratories around the world and will consequently cement future sales.

This new interest fits well with our strategy of focusing on syndromic testing, where users of our technology can test for a broad range of clinically important pathogens. Syndromic testing will also protect our revenue base as a result of a decline in COVID testing. It is inevitable that we will start to see some reduction in COVID testing over the coming years. How far and how quickly this reduction occurs remains to be seen but, for the time being, demand for COVID tests is still being driven by outbreaks around the world.

During the year Dr Neil Gunn joined your Board and I warmly welcome Neil to his first Genetic Signatures Annual General Meeting. Neil joins the Board after a long and successful career in diagnostics business in Europe and the USA. His experience is very valuable and his insights into the industry in which we operate are providing solid guidance in the discussions around the boardroom. Neil, we look forward to your ongoing contribution to the company.

The company has a dynamic and highly experienced Board that governs this business very capably. In saying that, I have two important near-term aims. First, I would like to drive debate on how Genetic Signatures can become a more sustainable business. Second, we are actively engaged in a search that will address diversity on the Board and I expect to be able to make an

announcement concerning this in the near future. These aims are important to me and I firmly believe they will be important elements in the ongoing success of the company.

Genetic Signatures is looking beyond the pandemic with a clear focus on expanding the range of diagnostic products available for sale across Europe, the USA and Australia. We have been successful in obtaining CE-IVD registration for our enteric, respiratory, anti-microbial resistance, and sexually transmitted infection kits in Europe. Our enteric protozoan test is in clinical trials in the USA with a view to obtaining FDA clearance. And, locally, our enteric and respiratory tests, and others, have been registered with the TGA.

These product registration efforts represent years of work by many dedicated employees. A lot has been achieved. But we plan to continue our product development effort so we can see continued growth in the company. The company has healthy cash reserves, \$33 million as at 30 September 2021 and is debt-free with positive cashflow. This says we are in a position to fund product development and our substantial growth plans.

In closing, I thank each and every one of our employees for helping create the successes we have enjoyed over the past year.

I also thank my fellow Directors for the support and guidance they have provided to me. It has made my job as your Chairman enjoyable and immensely fulfilling.

Finally, let me take this opportunity to thank you, the shareholders, for your continuing support of this wonderful company. I look forward to continuing to share this exciting journey with you.

Dr John Melki, our Managing Director and CEO, will now provide a review on Genetic Signatures' operations, corporate strategy and milestones in the coming year.

**Dr Nick Samaras**  
Chairman

- END -

For further information, see our website ([www.geneticsignatures.com](http://www.geneticsignatures.com)) or contact us as below:

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**About Genetic Signatures Limited:** Genetic Signatures is a specialist molecular diagnostics (MDx) company focused on the development and commercialisation of its proprietary platform technology, **3base**<sup>™</sup>. Genetic Signatures designs and manufactures a suite of real-time Polymerase Chain Reaction (PCR) based products for the routine detection of infectious diseases under the *EasyScreen*<sup>™</sup> brand. Genetic Signatures' proprietary MDx **3base**<sup>™</sup> platform technology provides high-volume hospital and pathology laboratories the ability to screen for a wide array of infectious pathogens, with a high degree of specificity, in a rapid throughput (time-to-result) environment. Genetic Signatures' current target markets are major hospital and pathology laboratories undertaking infectious disease screening.



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# The year in review – FY2021

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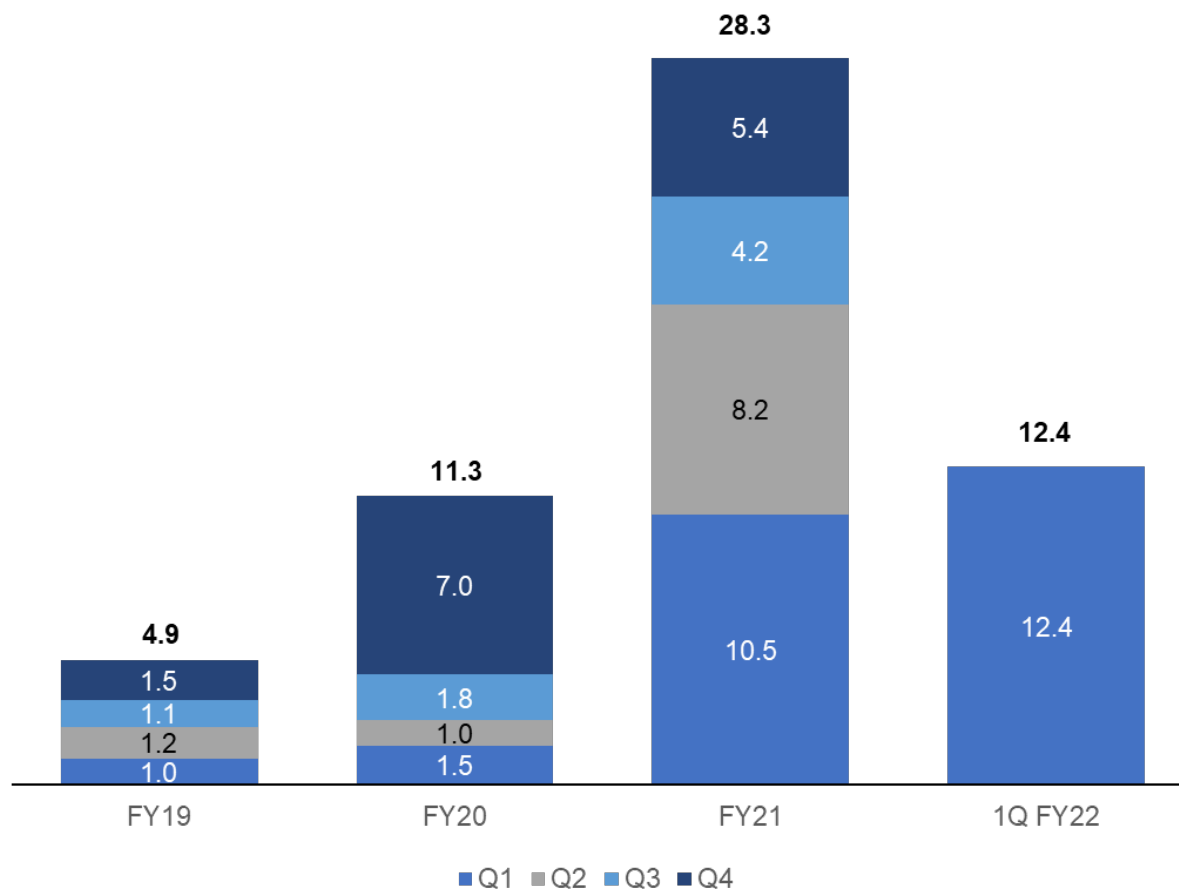


- ✓ Continued sales growth, supported by SARS-CoV-2 and other testing
  - 151% growth over pcp
  - 4 year CAGR 93%
- ✓ Profitable and positive operating cashflow
- ✓ 4-fold increase in instruments at customer sites
- ✓ Expansion in Europe and 1<sup>st</sup> US customer
- ✓ New products – *EasyScreen™* STI received CE-IVD
- ✓ Appointed Dr Neil Gunn as Director
  - Ex President, Roche Sequencing Systems and VP Roche Molecular



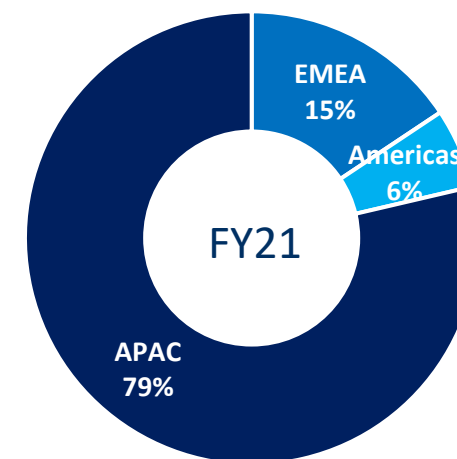


## Revenue from sales (A\$m)



## Continued Strong Revenue Growth

- Record revenue - \$28.3m FY21, \$12.4m 1QFY22
- Demand for COVID tests continues due to ongoing outbreaks, though demand fluctuates with outbreaks
- New instrument placements continue to support future demand for tests



# Financial Summary – Profit & Loss Statement

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| A\$000                            | Year ending<br>30 June 2021 | Year ending<br>30 June 2020 |
|-----------------------------------|-----------------------------|-----------------------------|
| Revenue from operations           | 28,284                      | 11,263                      |
| Other income                      | 435                         | 2,910                       |
| <b>Total revenue</b>              | <b>28,719</b>               | <b>14,173</b>               |
| Cost of materials & freight       | (9,804)                     | (4,305)                     |
| Employee benefits expense         | (10,024)                    | (6,671)                     |
| Other expense items               | (5,674)                     | (4,367)                     |
| <b>EBITDA</b>                     | <b>3,217</b>                | <b>(1,170)</b>              |
| Depreciation and amortisation     | (1,425)                     | (883)                       |
| <b>EBIT</b>                       | <b>1,792</b>                | <b>(2,053)</b>              |
| Finance costs (AASB 16 leases)    | (36)                        | (33)                        |
| <b>Profit before tax expenses</b> | <b>1,756</b>                | <b>(2,086)</b>              |
| Income tax benefit / (expense)    | -                           | -                           |
| <b>Net profit after tax</b>       | <b>1,756</b>                | <b>(2,086)</b>              |
| Basic EPS (cents)                 | 1.23                        | (1.64)                      |
| Diluted EPS (cents)               | 1.21                        | (1.64)                      |

- **Sales revenue** - \$28.3m, +151% vs pcp
  - Other income includes interest earned, FY20 includes R&D tax rebate
- **Gross margin** on materials improved to **70%** from 67% in FY20
- Expenses up ~43% relative to pcp
  - Growth in personnel, particularly sales and production teams
  - Scientific consumables up 56% - increased projects and Enteric Protozoan US FDA trials
  - Higher depreciation reflecting increased instrumentation in the field plus production expansion
- **Maiden full year profit**



## Market Dynamics

- Leading global cause of death of children under 5
- In the USA 350m acute cases annually with 200,000 children under 5 hospitalized
- Molecular testing not yet widely adopted in Europe or USA
  - Current diagnosis limited & time consuming (culture, microscopy & antibody-based tests)

## Enteric Protozoan

- ~5.5m Enteric Protozoan tests per annum in the US
- CPT code 87506 – Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen; 6-11 targets (\$262.99)

## US FDA 510(k) Clearance Status

- 3 sites running FDA trials for GSS. Minimum 500 samples per site required
- Goal to complete sample collection by end CY2021, dependent on patient recruitment rate
- Aiming to win 40% market share within 5 years post FDA clearance

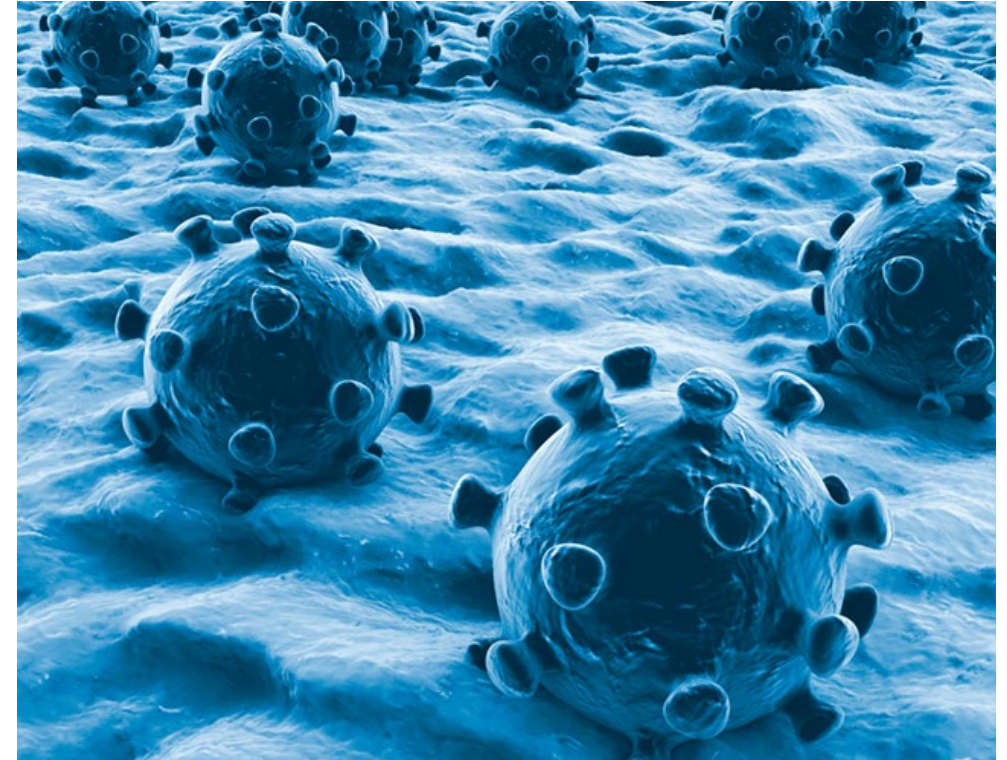
## Enteric Protozoan Revenue Potential - USA

| Revenue per test | 20% Market Share | 30% Market Share | 40% Market Share |
|------------------|------------------|------------------|------------------|
| US\$20           | \$22.0m          | \$33.0m          | \$44.0m          |
| US\$30           | \$33.0m          | \$49.5m          | \$66.0m          |
| US\$40           | \$44.0m          | \$66.0m          | \$88.0m          |





- Initially developed **SARS-CoV-2 test** based on existing expertise in seasonal coronaviruses
- **Driving global sales** – new customers in Europe and USA previously difficult to convert. Now interested in other *EasyScreen™* tests
- Developed new **“fast” PCR test** that reduces batch processing times by 1.5 - 2 hours; incorporated into *EasyScreen™* SARS-CoV-2 Detection Kit and in use in customer labs with very positive feedback
- Conversion of other *EasyScreen™* tests to fast methodology underway – **significant benefit to laboratories**





## Leverage COVID-19 – new customers, new tests

- Continue building interest in *EasyScreen*<sup>™</sup> kits in US & EU markets using new sales teams and SARS-CoV-2 experience as leverage
- Targeting high throughput pathology groups, hospitals & govt programs
- Build long-term reliable customer contracts/relationships
- Embed *EasyScreen*<sup>™</sup> workflows & demonstrate favourable unit economics
- Promote & place GSS branded instruments



## Product Development

- Progress product registrations
  - FDA submission: Enteric Protozoan Detection Kit
  - TGA registration for STI/Genital Pathogen Detection Kits
- Next generation **3base**<sup>™</sup> ‘sample to result’ instrument
- Develop new test kits including flavivirus, measles, mumps & rubella, tick-borne diseases and dermatophytes



\*Aspirational illustration only



# Genetic Signatures

Transforming Molecular Diagnostics

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