

ASX Code: GSS  
20 November 2024

## 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 2024 Annual General Meeting. On behalf of the Board, I would like to thank you all for attending and for your ongoing support.

Today's AGM will be my final address to you, our valued shareholders. I am immensely proud of what we have achieved over my 16 years of tenure with Genetic Signatures, and it has been a great privilege to serve as Chair since 2010. Caroline Waldron, our incoming Chair, has worked closely with me to facilitate a smooth transition, and on behalf of the Board, I welcome her to the next chapter of contribution to Genetic Signatures.

In the 23 years since Genetic Signatures was established, the Company has undergone a transformative journey. When I assumed the role of Chairman, we had a vision to revolutionise molecular diagnostics for infectious diseases and improve patient outcomes through our proprietary 3base® technology. Today, that vision has become a reality. We now have a number of diagnostics that have been cleared and are being sold and used in different markets. Our technology and tests were used extensively in the management of the recent COVID pandemic due to their ability to detect related pathogens with a single test. And, this year, we secured the FDA clearance for our *EasyScreen*™ Gastrointestinal Parasite Detection Kit in the US – the largest single market for molecular diagnostics. As well as providing a revolutionary solution to a very poorly met diagnostic need, this will provide a beachhead for establishing our 3base® with pathology providers throughout the US.

The reason healthcare providers are adopting our innovative solutions is that they enable the more rapid and accurate diagnosis of infectious diseases, which in turn results in timely medical interventions, improved patient outcomes, and the containment of disease spread within the community. These tangible impacts on public health are at the heart of our mission and what drives our relentless commitment to excellence.

Before handing over to our CEO, Allison Rossiter, I would like to provide a high-level overview of some of the significant achievements Genetic Signatures has made during the financial year 2024, and more importantly, the great prospects I see for the company as we head into 2025.

Achieving FDA clearance for our *EasyScreen*™ Gastrointestinal Parasite Detection Kit and workflow has been a pivotal moment in the Company's history. This milestone would not have been possible without the team's passion, hard work and innovative spirit.

In April, the Australian TGA authorised the Company to recommence supply of our leading respiratory diagnostic solution in Australia following some modifications that were required to improve the detection of the influenza B virus in a small class of samples. I am pleased to say that this came before the commencement of the Australian respiratory infection season, and we have seen sales in the most recent two quarters return to their historical levels indicating that our customers were keen to resume using the test once it became available.

And finally, during FY24, we raised a total of \$45.9M via two capital raisings. This has provided the Company with a very solid balance sheet for growth from the launch and sale of our *EasyScreen*<sup>™</sup> Gastrointestinal Parasite Detection Kit in the US, and to invest in other initiatives to drive growth for the Company. As the outgoing Chair, I would like to sincerely thank you, our shareholders for your commitment and confidence in supporting these capital raisings which have put us in a very strong position to deliver robust growth going forward.

In April 2024, we farewelled Dr. John Melki, whose two-decade-long tenure with Genetic Signatures saw him rise from a Senior Scientist to the role of CEO of the Company. His scientific acumen and executive leadership were pivotal in transforming the Company from a research-focused entity to a commercial company. The Board and I would like to extend our deepest gratitude to Dr. Melki for his invaluable contributions and leadership over this time.

In addition, on behalf of the Board, I sincerely thank my fellow board member, Dr. Neil Gunn, for stepping into the Interim CEO role at a crucial time for the Company, and for providing invaluable leadership and guidance during this time.

Allison Rossiter recently commenced with Genetic Signatures in September 2024. Allison brings a wealth of experience from her distinguished career at Roche Diagnostics. Her commercial expertise and strategic vision will support Genetic Signatures' next phase of commercial growth. We are confident that under her leadership, Genetic Signatures will continue to thrive and expand to become recognised as a significant player in the global diagnostics market.

As a Board, we have embarked on a process of board renewal. In addition to the transition of leadership from myself to Caroline Waldron as Chair, we welcome Anne Lockwood and Jenny Harry to the Board, and thank Tony Radford and Stephane Chatonsky for their contributions to the Company. I would like to personally thank Tony and Stephane for their valuable contributions on the Board. Their input has been critical to getting the Genetic Signatures to the exciting stage that we find ourselves today.

In closing, I extend my gratitude to all employees for their contributions to our successes in the past year despite the challenges we faced. Additionally, I appreciate the support and guidance from my fellow Directors, which has made my role as Chairman both enjoyable and fulfilling.

Finally, let me take this opportunity to thank you, the shareholders, for your continuing support of this wonderful company. It really has been a privilege to be part of Genetic Signatures for the past 16 years and I look forward to continuing to share this exciting journey with you.

I will now hand you over to Allison Rossiter, Chief Executive Officer, who will provide a review on Genetic Signatures' operations, corporate strategy and milestones in the coming year.

**Dr Nick Samaras**  
Chairman

- END -

#### **Authorisation and Additional Information**

This announcement was authorised by the Board of Directors of Genetic Signatures Limited.



CEO Presentation  
2024 Annual General Meeting  
20 November 2024

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Commenced as Genetic Signatures CEO 23 September 2024



2002 - 2024



2000 - 2002





**Genetic Signatures' 3base® is a unique extraction technology which brings key benefits to molecular diagnostics tests:**

- Simplifies the genome of a sample to reduce the impact of mutations in viruses, bacteria, fungi & parasites. Such mutations occur at a much higher rate in viruses:
  - As an example, Genetic Signatures' SARS-CoV-2 assay has never had to be modified despite the number of variants during the pandemic
  - The 3base® lysis technique enables hard-to-lyse targets such as parasites to be analysed
- Enables **“syndromic testing”** – simultaneous screening for the majority of pathogens that could be responsible the same set of symptoms in a patient



## Why focus on Infectious disease?

- Infectious diseases are caused by viruses, bacteria, fungi and parasites, and can be transmitted through person to person, insect/animal to person or through contaminated food or water
  - Early diagnosis reduces the spread of disease
  - Accurate diagnosis ensures appropriate treatment
  - Antimicrobial Resistance (AMR) is one of the top global public health and development threats. It is estimated that bacterial AMR was directly responsible for 1.27 million global deaths in 2019 and contributed to 4.95 million deaths <sup>(1)</sup>

1. Antimicrobial Resistance Collaborators. (2022). Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis. The Lancet; 399(10325): P629-655. DOI: [https://doi.org/10.1016/S0140-6736\(21\)02724-0](https://doi.org/10.1016/S0140-6736(21)02724-0)



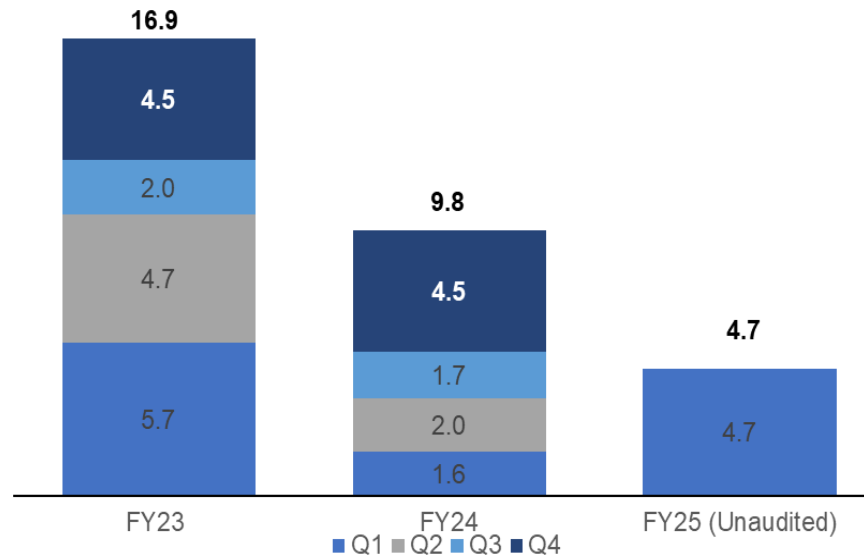
- Revenue from operations of A\$9.8M: 10.7% from EMEA, gross margin of 53%
- Completed **two capital raisings** with net proceeds totaling \$45.9M (before costs)
  - **\$15.9M** Placement and Rights Issues in December 2023
  - **\$30.0M** Placement and Entitlement Offer in June 2024
- Secured authorisation to supply redesigned Respiratory Kit from TGA (April 2024)
- Secured **US FDA clearance** for *EasyScreen*™ Gastrointestinal Pathogen Detection Kit (May 2024)
- **Board renewal** announced including:
  - **Retirement** of Chair Nick Samaras and appointment of Ms Caroline Waldron at AGM
  - **Resignation** of Non-Executive Directors Dr Tony Radford and Mr Stephane Chatonsky
  - **Appointment** of Ms Anne Lockwood and Dr Jenny Harry
- Cash and cash equivalents at 30 September 2024 of **\$41.3M** (\$36.3M at 30 June 2024)





## Return to strong quarterly revenue following TGA authorisation for supply of the modified respiratory assay in April 2024

- Total revenue of **\$9.8M** recorded for **FY24**:
- **Q1 FY24**: Revenue of **\$4.7M** – Australian customers resumed historical purchasing levels once Kit was available
- Revenue from **international markets** accounted for **10.7%** of sales during the quarter – **expected to grow in FY25**





## FDA clearance to market Genetic Signatures' *EasyScreen*™ Gastrointestinal Parasite Detection Kit in the US received in June 2024

### The product addresses a well-recognised, poorly-met clinical need

- Broadest molecular syndromic test for eight clinically relevant GI parasites

### Product leverages 3base® advantages

### ~5.5M conventional tests conducted in the US each year

- Traditional tests are manual, slow, labour intensive & unreliable
- Current testing is not profitable for pathology laboratories

### Molecular reimbursement code already in place

- Estimated TAM of > \$A500M<sup>1</sup> p.a.
- Higher reimbursement rate than traditional microscopic tests
- Targeting 40% market share in US market within 5 years



**United States**  
**FDA 510(k) cleared**



## *EasyScreen*™ Gastrointestinal Parasite Detection Kit

### 8 parasites detected



*Giardia* spp.



*Cryptosporidium* spp.



*Entamoeba histolytica*



*Cyclospora cayetanensis*



*Dientamoeba fragilis*



*Blastocystis hominis*



*Enterocytozoon bienersi*

*Encephalitozoon intestinalis*

<sup>1</sup>Assumes an indicative selling price of US\$60 per test displacing existing Ova & Parasite (O&P) testing estimated at over 5.5 million p.a.

# Relevant for all key customer segments

2024 – Annual General Meeting

20 November 2024



| Target segments                   | GI parasite testing requirements                                                  | Potential TAM = 5.5M tests | Share of targeted 2.2M tests by segment                                                 |
|-----------------------------------|-----------------------------------------------------------------------------------|----------------------------|-----------------------------------------------------------------------------------------|
| Large commercial reference labs   | High volume<br>LabCorp / Quest = >1500 tests / day<br>Others ~100-300 tests / day | 1.6 M<br>30% of TAM        |  50% |
| IDN / core labs (large hospitals) | Low to medium volume,<br>Some sites high volume<br>Average ~50-100 tests / day    | 3.0 M<br>55% of TAM        |  32% |
| Specialty reference labs          | Medium to high volume<br>Average ~40-100 tests / day                              | 0.3 M<br>5% of TAM         |  12% |
| Independent hospitals             | Low to medium volume,<br>Average ~20-40 tests / day                               | 0.6 M<br>10% of TAM        |  6%  |

Target size and TAM modelled from various data sources listed here

- Morningstar Credit Ratings, LLC 16<sup>th</sup> October 2018. Credit Comparison: LabCorp (BBB+, stable) vs. Quest (BBB+, stable). [Link](#)
- Laboratory Economics, Volume 18, No. 3. March 2023. Jondavid Klipp. [Link](#)
- Genetic Signatures Market Survey Insights. March 2023
- DeciBio ID DX-Book 2022

- Definitive Healthcare, Healthcare Insights, How many IDNs are in the U.S.?, 21/4/23. [Link](#)
- American Hospital Association, Fast Facts. U.S. Health Systems. 2023. [Link](#)
- Lab Florida. Types of Labs in U.S. Medical Diagnostics. Accessed on 13/9/23. [Link](#)
- Australian Medicare Benefits Schedule Book (MBS). [Link](#)



- ✓ Customer experience sites well-advanced in internal review process with several at the final contract stage
- ✓ Established a strong sales pipeline with >60 customer sites at various stages of the evaluation and sales process
- ✓ Engaged with all major commercial reference labs in the US who have expressed interest – 50% target market but also requires longer sales cycle
- ✓ Continue to build brand awareness for technology and products with both the **EasyScreen™ Gastrointestinal Parasite Detection Kit** and **3base® platform** through booth-presence at key conferences in the United States and globally
- ✓ Multiple publishing opportunities with Key Opinion Leaders from Johns Hopkins, Wadsworth, South Dakota and University of Kentucky





- **Our Customers**
  - Several customer experience sites at final contract stage
  - A strong sales pipeline, incl major US reference labs
  - New signed contracts in UK
  - Evaluations underway in UK and Germany
  - Implementing sales excellence methodologies to further strengthen
- **Our Products**
  - Evolution of *EasyScreen*™ detection kits
  - Technology and workflow improvements
  - Development of next generation instrument prototype
- **Our People**
  - Working towards achieving world class employee engagement
  - Strengthening leadership skills
  - Building Emotional Intelligence skills for front line leaders





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