ASX Code: GSS
16 November 2022

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 2022 Annual General Meeting. On behalf of the Board, I would like to thank you all for attending and for your ongoing support.

The 2022 financial year was another landmark year for Genetic Signatures and one where we continued to lay down a solid foundation for our long-term growth on the global stage. As you will be aware, the need for accurate and rapid molecular testing for the SARS-CoV-2 virus during the pandemic resulted in a rapid acceleration of our sales trajectory over the last couple of years. I am pleased to say that in FY2022, not only were we able to consolidate this growth, but in fact delivered an additional 25% to our top line revenue. However, what is particularly pleasing is that a growing proportion of this has come from being able to leverage the increased awareness of our technology and products that arose from the initial use of our 3base COVID tests. This has resulted in several customers trialing and adopting our non-COVID kits following their positive experience using 3base technology for COVID testing.

Our proprietary 3base technology reduces the complexity of genetic material—which ultimately makes our molecular assays more informative and easier to combine into a single test. This is becoming more important as clinicians are wanting to use "syndromic tests" when patients present with symptoms that could result from infection from a variety of different pathogens. The similarity of symptoms can make identification of the infecting pathogen difficult and often this requires the use of diagnostic tests for each of the different pathogens or using less reliable and slower culturing methodologies. Our 3base technology means that we are able to accurately test for up to 20 different pathogens, including many variants, from a single sample within a few hours. As syndromic testing can have a significant impact on the ability to promptly provide appropriate treatment for patients, it is increasingly being adopted as a more effective and efficient way to manage patients who present with infectious disease. Because of this trend, global diagnostic companies are increasingly focusing on syndromic tests—something that we have been doing for over 15 years using our proprietary 3base technology.

Before handing over to our CEO and Managing Director, Dr John Melki, I would like to provide a very high-level overview of some of significant achievements Genetic Signatures has made during the financial year 2022, and—more importantly—the great prospects I see for the company as we head into 2023.

As your Chairman, it pleases me greatly to report that Genetic Signatures generated sales revenue of A$35.4 million during the 2022 financial year. This represents 25% growth on the previous year during which we benefited from the unprecedented demand for molecular tests for the SARS-CoV-2 virus. This financial year, we benefitted from initial high demand for our COVID products which, as anticipated, declined towards the end of the year as public health initiatives for molecular testing were wound back. Furthermore, we were able to deliver our second consecutive year of profitability, with net income for the year of $3.1 million.

While the future course and consequences of the COVID pandemic remain unknowable, Genetic Signatures expects to continue to play an important role in the management of future outbreaks. One of the significant benefits of Genetic Signatures' 3base approach is it is less susceptible to the genetic changes that are found in new, emerging variants which is becoming recognised as a significant problem with some other approaches to molecular testing.

The accelerated commercial ramp-up of Genetic Signatures' 3base technology arising from the COVID pandemic has put the company in a solid position for its future growth.

First, it has resulted in broader and more rapid exposure of customers to the benefits our 3base platform provides for multi-pathogen testing. Customers who initially used our 3base approach to ensure variants of the SARS-CoV-2 virus were detected, have started to trial or use our other syndromic test kits. Significantly, in the most recent quarter, over half of our sales came from non-COVID specific products.

Second, the strong positive cash flows have provided the company with a strong balance sheet, that includes a cash balance of $32.4 million at 30 September and no debt, to support this future growth. Even taking into account the expected volatility around future revenue from COVID-based products, the company's balance sheet is able to support and fully fund its planned and anticipated investments in future growth opportunities.

During the year, the company completed recruitment for the clinical trial to support its first regulatory clearance in the US. Subject to completion of the remaining data analysis, validation, and verification, Genetic Signatures expects to file a 510(k) application for its EasyScreen Enteric Protozoan Syndromic Kit in the coming months. This is a significant opportunity for the company and will also establish a commercial beachhead for our other 3base products in the US market.

Additionally, Genetic Signatures is continuing to invest in its product pipeline with clinical studies for a second product for the US market expected to commence before the end of the calendar year. The company is also progressing the development of a number of new syndromic tests as well as a fully integrated next-generation instrument that will offer high-throughput, low-input 3base molecular testing. As well as addressing the volume and scale economics that high-volume customers require, this next generation instrument has the potential to embed 3base technology into their workflow and diagnostic test offering.

And with this exciting future ahead of us, it was a pleasure to welcome Ms. Caroline Waldron as a Non-Executive Director in May this year. As a Board, we have already benefitted from the depth of her significant legal and corporate experience.

In closing, I would like to thank each and every one of our employees for helping create the successes we have enjoyed over the past year. I would also like to thank my fellow Directors for the support and guidance they have provided to me over the year. 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

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Genetic Signatures

Transforming Molecular Diagnostics

2022 Annual General Meeting

16 November 2022

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Investment highlights

- **Proprietary 3base® technology platform** that provides a revolutionary approach for molecular diagnostics
- **Dramatically simplifies multiple pathogen testing** from a single sample (multiplexing)
  - More informative – detect related pathogens/genes using fewer tests;
  - Simpler – fewer reagents with better matched, ideal reaction conditions.
- **Strong commercial adoption** in Australian market – expanding into European and US markets
  - 4 Diagnostic Test Kits cleared in one or more markets – 5 new kits completing development;
  - Strong continued revenue growth – FY22 revenue A$35.4 million (+25% yoy), cash flow positive ($6.7M) and profitable ($3.1M).
- **Multiple drivers for growth** – funded from anticipated future cash flow and existing balance sheet
  - Commercial expansion – into large international markets (Europe and US);
  - Product expansion – multiple new products completing development or registration;
  - Instrument expansion – embed 3base® technology in high-volume customers sites.

Company Snapshot

Financial information

Share price (15-Nov-22)	A$0.70
Shares on issue	143.4m
Market capitalisation	**A$100.4m**
Cash (30-Sep-22)	A$32.4m
Debt (30-Sep-22)	Nil
Enterprise value	**A$68.0m**

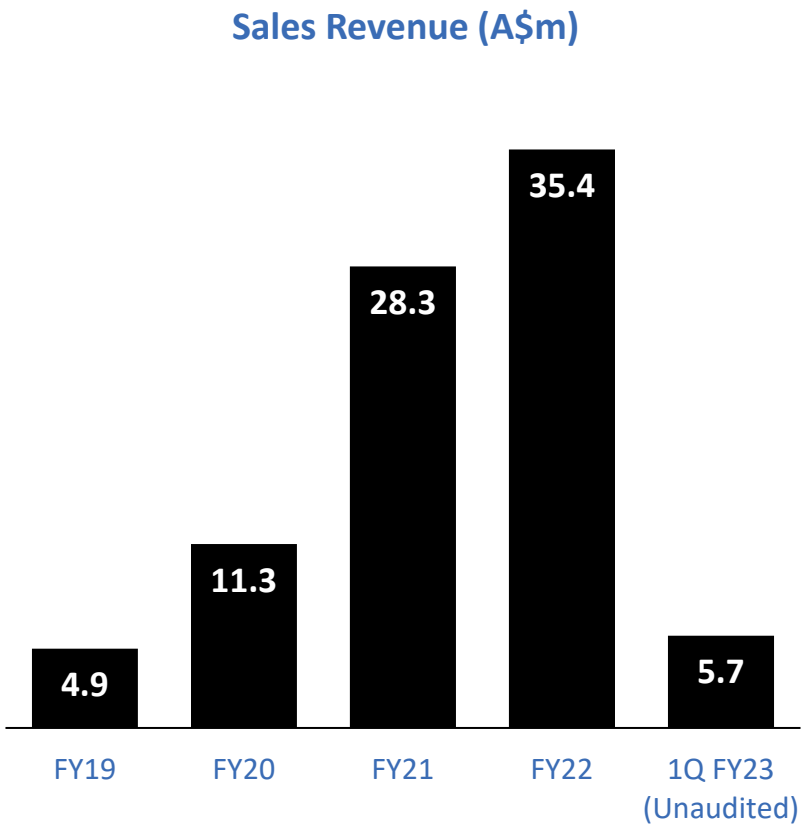
Top shareholders %

Asia Union (Chris Abbott private investment)	26.2%
Perennial Value Management	15.0%
Fidelity International	6.9%
Directors & management	3.0%

Research reports

	Target price
MST Access (28-Oct-22)	$1.45
Bell Potter (27-Oct-22)	$0.90

Track record of continued, strong revenue growth



- **FY22 sales revenue of $35.4 million**
  - 25% growth yoy, 89% 4yr CAGR
  - Q1 FY23 sales up 16% from preceding quarter
- **Growing contribution from international sales**
  - Leveraging experience in Australian market;
  - European orders for non-Covid Syndromic Kits;
  - Significant US contributions to come once FDA clearance secured.
- **Strong demand for SARS-CoV-2 tests during FY21 & FY22**
  - Scale-back of molecular testing programs;
  - Growing contribution from other *EasyScreen*™ Kits;
  - Shifting from COVID only testing to Syndromic Respiratory.
- **Successful strategy of targeting high-volume customer groups**
  - High-throughput labs
  - Multi-hospital groups
  - Private pathology chains
  - Government-led programs

FY22 Financial Summary – Cashflow

A'000s	FY22
Receipts from customers	39,405
Payments to suppliers and employees	(29,706)
Other	27
Net operating cashflow	**9,806**
Payment for plant & equipment	(1,714)
Payment for intangibles	(1,275)
Net investing cashflow	**(2,989)**
Net proceeds from option exercise	264
Principal elements of lease payments	(365)
Net financing cashflow	**(101)**
Net increase in cash and cash equivalents	**6,716**
Opening cash and cash equivalents	30,121
Effects of exchange rate changes on cash	60
Closing cash and cash equivalents	**36,897**

Planned investment in growth opportunities

Funded from existing cash and anticipated future cash flows:

- International markets;
- New products;
- Regulatory clearances;
- Product launches;
- Internal capabilities (clinical, regulatory);
- Technology improvements;
- Sample-to-result instrument

Robust pipeline with multiple products cleared for sale

Enteric Protozoan kit will provide entry to North America

North America accounts for 40% of the global molecular diagnostics market

- **High need for Enteric Protozoan Kit**
  - 5.5 million tests conducted in the US pa;
  - Primarily culture/microscopy: slow, labour intensive, unreliable;
  - Detects leading protozoan infections;
- **Enteric Protozoan Screening Kit**
  - Completed recruitment for 1,500 subject clinical trial;
  - Targeting 510(k) submission in Q4 CY2022;
  - First *EasyScreen*™ product for US;
  - Reimbursement code in place (CPT 87506 US$262.99).
- **US Market preparation activities underway**
  - KOL webinars;
  - Sales & marketing presence in US;
  - Warehousing facility in Los Angeles;
  - Initial focus on 30 high-throughput, centralised labs.
- **First 3base® product for the US**
  - Regulatory dossier relevant for other *EasyScreen*™ products.

Recent Events

- **US FDA clinical trial recruitment completed**
  - Targeting 4Q CY2022 application for clearance
- **3base® kit for antimicrobial resistance shows high detection rate**
  - Independent study[1] showed excellent biological performance for the 5 most common carbapenemases
  - WHO has declared AMR as one of the top 10 global public health threats facing humanity > 5m deaths pa[2]
- **GSS commences commercial sales in Western Australia**
  - Two new sites trialling respiratory & gastrointestinal targets; first sales into WA
- ***EasyScreen*™ Enteric Protozoan Detection Kit - Health Canada registration**
  - Canadian market ~2.5% of world IVD market
  - 3rd *EasyScreen*™ Detection Kit registered

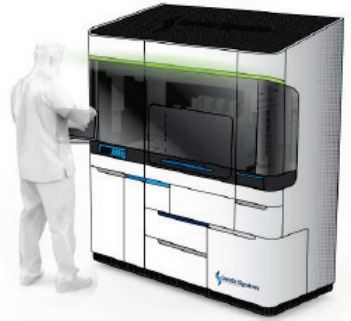
[1] Gonzales, C et al, (2022), *Diagnostics* **2022**, *12*(9), 2223; **https://doi.org/10.3390/diagnostics12092223**
[2] Antimicrobial Resistance Collaborators (2022), The Lancet: https://doi.org/10.1016/ S0140-6736(21)02724-0

Growth initiatives

- **Leverage experience in Australian market to grow international sales**
  - Europe – drive adoption of other 3base® products;
  - US – build 3base® franchise once Protozoan Detection Kit is cleared.
- **Build and expand portfolio of commercially-available *EasyScreen*™ products**
  - Expand menu of 3base® tests;
  - Develop new *EasyScreen*™ Syndromic Test Kits;
  - Secure registration for new *EasyScreen*™ products.
- **Embed 3base® technology in high-value customer's workflow**
  - Increase adoption of *EasyScreen*™ kits for more applications;
  - Broader range of commercial arrangements with customers.

New products and instruments

- **Expand available *EasyScreen*™ Syndromic Kits**
  - 3 kits research use only (RUO) – tropical diseases, MMR & meningitis;
  - Other kits in development (tick-borne, skin infections, etc.);
  - Advance additional 3 products through the FDA process
- **Improve and enhance 3base® technology platform**
  - Saliva-based protocol for SARS-CoV-2 cleared by TGA;
  - Process improvements for amplification and time-to-result
- **Next-generation, "sample-to-result" instrument**
  - Highly automated, high-throughput;
  - Ideally suited for high-volume commercial users;
  - Embed use of 3base® with customers;
  - Facilitates different commercial models;



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Upcoming milestones – 12 months

- **US Enteric Protozoan Kit**
  - File 510(k) application by end of CY2022;
  - Launch product once clearance is granted.
- **Increase sales and presence in UK and European markets**
  - Contracts with new customers;
  - Direct sales force and distributor appointments.
- **Initiation of US clinical trial for next *EasyScreen*™ product**
- **R&D initiatives for new products**
  - New tests and *EasyScreen*™ kits;
  - Technology improvements;
  - Development of Next Generation instrument prototype.
- **Quarterly sales updates and progress reports**

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