

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*TM SARS-CoV-2 Detection Kit. This demand has accelerated the interest in other *EasyScreen*TM 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) or contact us as below:

Dr John Melki
Chief Executive Officer

john.melki@geneticsignatures.com

T: +61 (0)2 9870 7580

Peter Manley
Chief Financial Officer

peter.manley@geneticsignatures.com

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**[™]. 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*[™] brand. Genetic Signatures' proprietary MDx **3base**[™] 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.



Annual General Meeting

19 November 2021



This presentation has been prepared by Genetic Signatures Limited ACN 095 913 205 (the Company or GSS) and comprises written materials/slides for a verbal presentation concerning the Company and should be read in that context. This presentation is proprietary to GSS. It may not be reproduced, disseminated, quoted or referred to, in whole or in part, without express consent of GSS.

No representation or warranty, express or implied, is or will be made in relation to, and no responsibility or liability (whether for negligence, under statute or otherwise) is or will be accepted by the Company or by any of its officers, directors, shareholders, employees or advisers as to or in relation to the accuracy or completeness of the information, statements, opinions or matters (express or implied) arising out of, contained in or derived from this presentation or any omission from this presentation or of any other written or oral information or opinions provided now or in the future to any interested party or its advisers. In particular, no representation or warranty is given as to the achievement or reasonableness of any plans, future projections, management targets, prospects or returns and nothing in this presentation is or should be relied upon as a promise or representation as to the future.

The Company expressly disclaims all liability for any loss or damage of whatsoever kind (whether foreseeable or not) which may arise from any person acting on any information and opinions relating to the Company contained in this presentation or any information which is made available in connection with any further enquiries, notwithstanding any negligence, default or lack of care. In furnishing this presentation, the Company undertakes no obligation to provide any additional information.

Subject to any continuing obligation under applicable law or relevant listing rules of the ASX, the Company disclaims any obligation or undertaking to disseminate any updates or revisions to any forward-looking statements in these materials to reflect any change in expectations in relation to any forward-looking statements or any change in events, conditions or circumstances on which any statement is based. Nothing in these materials shall under any circumstances create an implication that there has been no change in the affairs of the Company since the date of the presentation.

This presentation is for information purposes only and does not constitute or form part of any offer or invitation to acquire, sell or otherwise dispose of, or issue, or any solicitation of any offer to sell or otherwise dispose of, purchase or subscribe for, any securities, nor does it constitute investment advice, nor shall it or any part of it nor the fact of its distribution form the basis of, or be relied on in connection with, any or contract or investment decision. Without limiting the foregoing, this presentation does not constitute an offer to sell, or a solicitation of an offer to buy, any securities in the United States. The securities of Genetic Signatures have not been, and will not be, registered under the U.S. Securities Act of 1933, as amended (Securities Act) or the securities laws of any state or other jurisdiction of the United States, and may not be offered or sold in the United States except in compliance with the registration requirements of the Securities Act and any other applicable securities laws or pursuant to an exemption from, or in a transaction not subject to, the registration requirements of the Securities Act and any other applicable securities laws.

The receipt of this presentation by any person and any information contained herein or subsequently communicated to any person is not to be taken as constituting the giving of investment advice by the Company or any other person to any such person. No such person should expect the Company or any of its officers, directors, shareholders, employees or advisers to owe it any duties or responsibilities and should take its own professional advice. The Recipient must rely solely on its own knowledge, investigation, judgement and assessment of the matters which are the subject of this presentation and to satisfy itself as to the accuracy and completeness

The year in review – FY2021

Annual General Meeting
19 NOVEMBER 2021

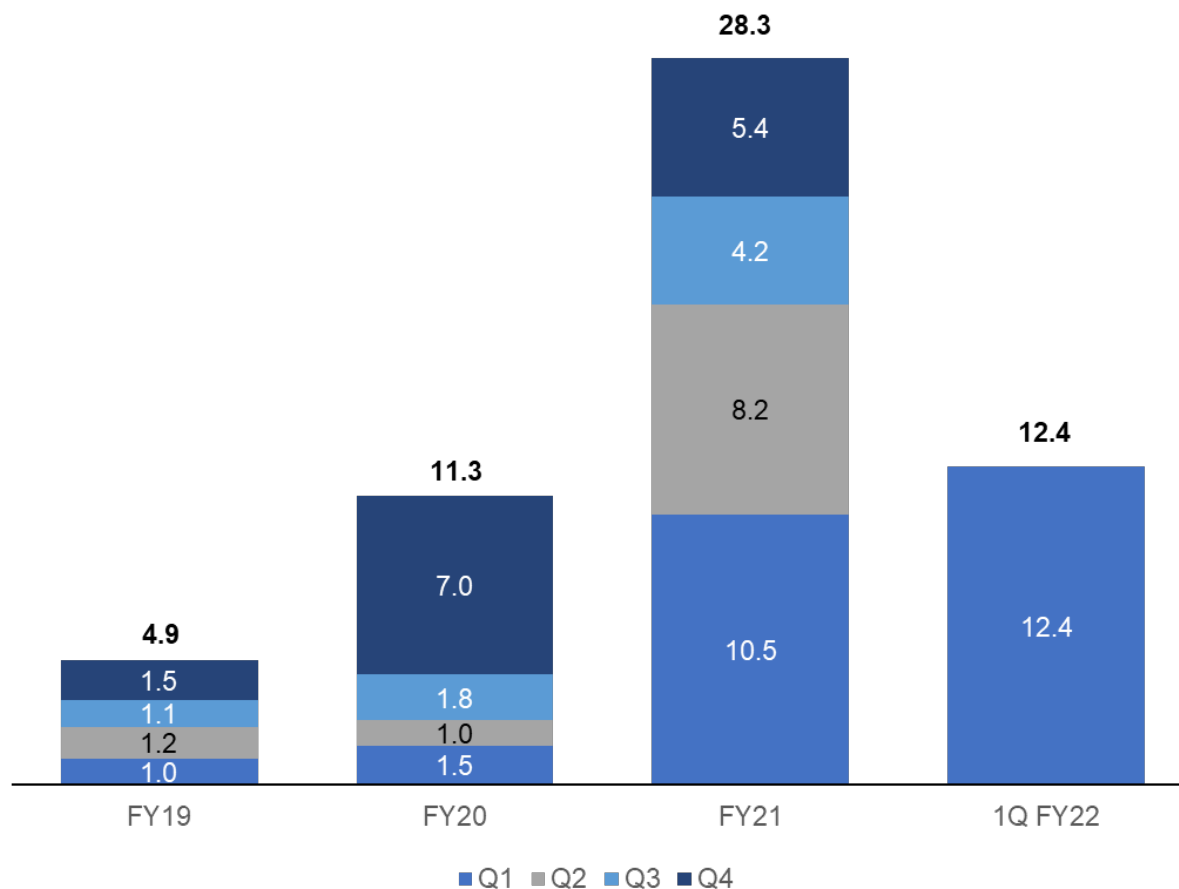


- ✓ Continued sales growth, supported by SARS-CoV-2 and other testing
 - 151% growth over pcp
 - 4 year CAGR 93%
- ✓ Profitable and positive operating cashflow
- ✓ 4-fold increase in instruments at customer sites
- ✓ Expansion in Europe and 1st US customer
- ✓ New products – *EasyScreen*[™] STI received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



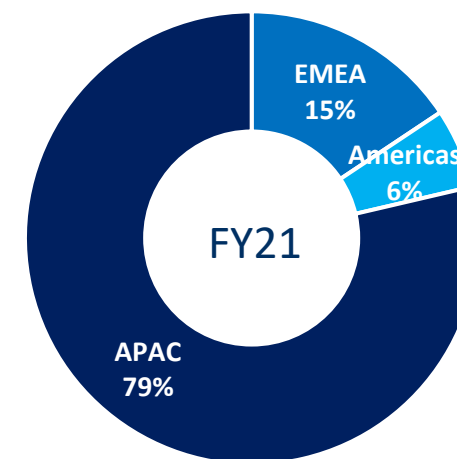


Revenue from sales (A\$m)



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

Annual General Meeting
19 NOVEMBER 2021



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

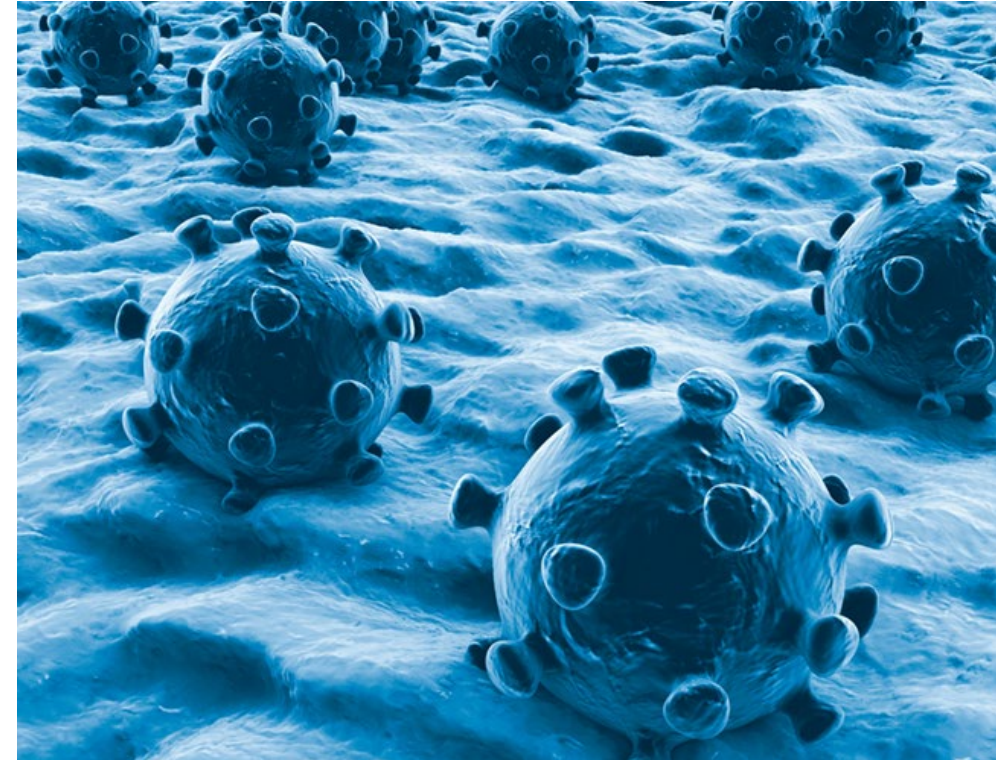
- 3 sites running FDA trials for GSS. Minimum 500 samples per site required
- Goal to complete sample collection by end CY2021, dependent on patient recruitment rate
- Aiming to win 40% market share within 5 years post FDA clearance

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*[™] 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*[™] 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**[™] ‘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

Contact us

Dr John Melki

Genetic Signatures

Chief Executive Officer

P: +61 (0)2 9870 7580

E: john.melki@geneticsignatures.com

Visit us

www.geneticsignatures.com

Follow us

