

ASX Code: GSS 29 November 2018

Chairman's Address at Annual General Meeting

Good morning and welcome to the Genetic Signatures (ASX: GSS) Annual General Meeting,

On behalf of the Board, I would like to thank you all for coming and for your ongoing support over the last 12 months.

The last 12 months have been an exciting year for Genetic Signatures and we are pleased to be sharing with you, some of the exciting achievements the Company has made since the last AGM and to also provide an update on what you can expect from the Company in the coming year.

Before I get into the details of last 12 months, I would like to spend some time reiterating our purpose and vision at Genetic Signatures. Our proprietary **3base™** technology (the cornerstone of our *EasyScreen™* Pathogen Detection Kits), enables hospitals and pathology facilities to use standard equipment and procedures to more accurately screen for a wide array of infectious diseases and deliver enhanced results in hours, not days, as compared to traditional methods.

Improving patient outcomes is ultimately at the center of what we do at Genetic Signatures and we are pleased to be offering solutions that create an opportunity to provide timely accurate diagnosis, that reduce costs and save lives.

The company has made significant progress over the past year and I am delighted to be able to share some of these achievements with you today.

Our sales revenue demonstrates the growing success of our products. Genetic Signatures' domestic revenue base continued to grow significantly to A\$2.8 million in FY18, up from A\$2.0 million in FY17. We are proud to see that the Company continues to achieve growth on each corresponding quarter and in 1Q FY19 we recorded record quarterly revenue exceeding A\$1 million, a 34% increase on the prior corresponding period.

This revenue growth is a strong indicator of the commercial potential of our products in both domestic and international markets. Our expanding product line also enhances our commercial potential and we are pleased to have progressed our *EasyScreenTM* ESBL & CPO (antibiotic resistance) Detection Kit through to both Australian (TGA) and European (CE-IVD) registration in 2018. We have also submitted TGA and CE-IVD applications for our *EasyScreenTM* Respiratory Kit and we anticipate receiving approval before the end of the year.

Towards the end of the financial year Genetic Signatures progressed a new commercial relationship with a large Australian pathology service provider. This has resulted in a new customer contract (officially signed in early FY19) for our $EasyScreen^{TM}$

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Respiratory Pathogen Detection Kit (second generation) and new laboratory Instrumentation: Genetic Signatures Automation System (GS1-HT). The new customer may use up to 1,000 tests per day during the peak of the Australian flu season, depending on seasonal flu severity.

Similar positive momentum has been made in the US, including the first sale and repeat order of our ASR product offering in the US, and an extended study of our early release *EasyScreen*TM Respiratory and Flavivirus / Alphavirus Detection Kits to a US customer based in Kenya,

FDA work for the Company's Enteric Protozoan Kit is also well advanced, and we expect that it will achieve full FDA clearance during 2019. With a robust North American infrastructure and intellectual property measures in place, Genetic Signatures is ready to scale up its commercial operations once US approval is secured.

A key focus over the past 12 months has been on establishing experienced teams in key jurisdictions and progressing our portfolio towards achieving the regulatory approvals needed to accelerate sales of our *EasyScreenTM* Kits. We expect to see Genetic Signatures' sales in Europe and the US grow throughout the next 12 months as we continue to expand our product range, and further implement our strategy of delivering multiple products into multiple jurisdictions, reducing reliance on any one product.

Our current diagnostic products and pipeline accounts for more than 50 per cent of the overall microbiology diagnostics segment, with an total global addressable market estimated to be 2.1 billion US dollars in 2017.

Our products also continue to perform well in clinical trials and we were particularly pleased with the results of the trial that Ireland's National CPE Reference Laboratory presented in April. The validation results for our *EasyScreen*™ ESBL & CPO Detection Kit, confirmed the ESBL & CPO assay is promising as a sensitive and specific alternative to culture for the rapid detection of carbapenemase producing organisms. Compared to culture, which could take days, the assay can be carried out in less than 3 hours with minimal hands-on time required. These results complement the strong potential for **3base**™ technology to gain commercial traction in Europe.

We believe the Company is well positioned to pursue key milestones in FY19, including:

- Financial growth, product range expansion and global market share expansion
- New global product trials already underway or commencing soon
- Continued research and development on new kits and assays, including kits for atypical respiratory infections and meningitis
- Securing regulatory registrations for STI and respiratory products and preparation of commercial release
- Capitalising on recent enteric product suite regulatory listings in Europe following Australian growth trajectory
- Increasing Genetic Signatures' presence in the US market through sales of its extended ASR range and participation at industry events
- Progression of required scientific validation and clinical trials for full FDA listing



We are pleased to have you, our shareholders, accompany us on this journey as we move forward with our aggressive growth strategy into international markets.

On behalf of the board and management, I would like to take this opportunity to thank our shareholders for their ongoing support.

I will now handover to our CEO, John Melki to provide more detail on the operations and developments at Genetic Signatures.

Nick Samaras Chairman

- END -

Genetic Signatures

For further information, see our website (<u>www.geneticsignatures.com</u>) 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™*. 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.