Genetic Signatures

ASX Announcement 26 April 2022

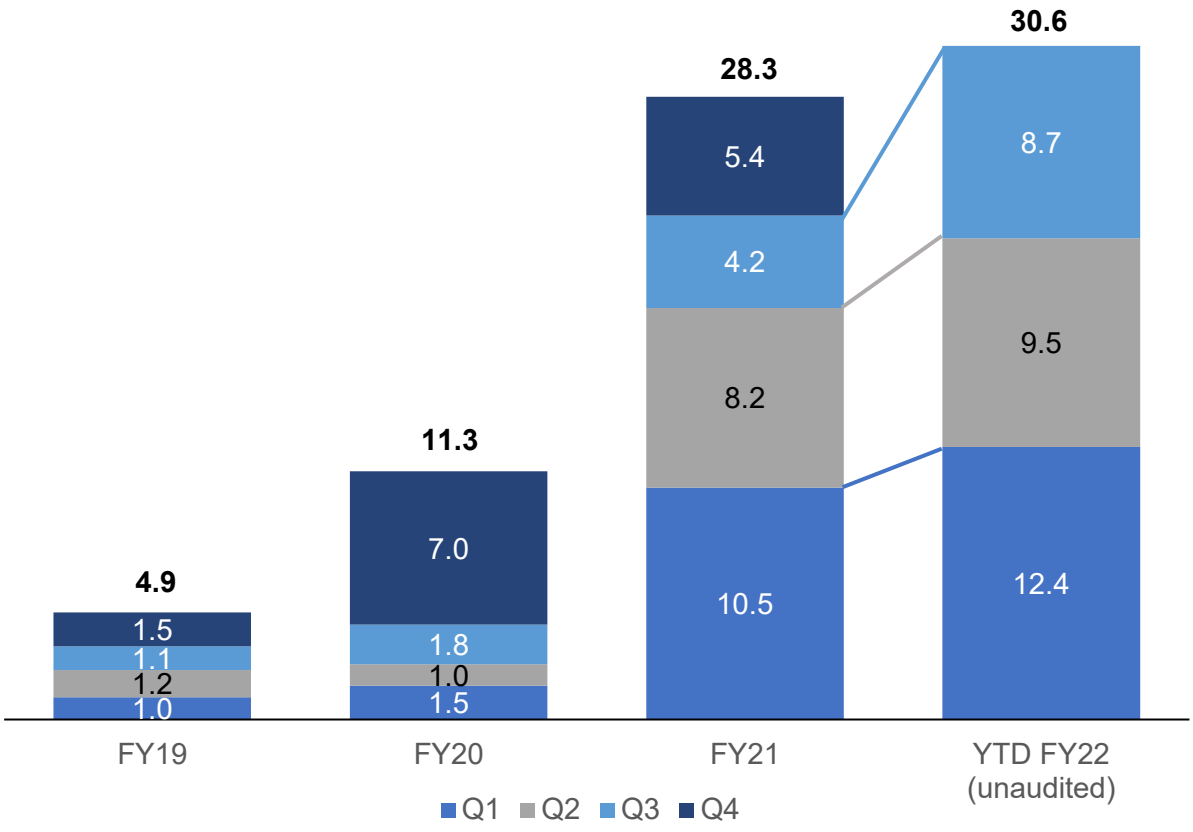
Quarterly Activities Report and Appendix 4C

Highlights

- Quarterly sales of $8.7 million, up 108% on Q3 FY2021
- Cash receipts of $11.8 million during the quarter
- $30.6 million year to date sales, a 34% increase on the previous year to date
- International sales account for 19% of total sales in Q3 FY2022
- *EasyScreen*™ Enteric Detection Kit selected as national test for Public Health Wales
- Clinical trial component for Enteric Protozoan Detection Kit FDA 510(k) product clearance application nearing completion

Genetic Signatures Limited (ASX: GSS) recorded further strong quarterly sales of $8.7 million, a 108% increase on Q3 FY2021. Total year to date sales were $30.6 million (unaudited), 34% higher than the same period last year, and already 8% higher than full FY2021 sales.

Figure 1: GSS Quarterly revenue (A$m)



Genetic Signatures welcomes continued strong sales growth underpinned by further expansion into key global markets and diversification of sales across their product portfolio.

"*Genetic Signatures remains profitable while continuing its strategy for investing in long-term growth. Strong demand for our EasyScreen™ SARS-CoV-2 Detection Kits lifted the profile of the Company and demonstrated the benefits of our 3base® technology in the normally conservative pathology sector,"* **said Genetic Signatures CEO, Dr John Melki.**

"As COVID-19 testing tapers with the Omicron outbreak waning, we are pleased to report increasing sales of a more diverse array of EasyScreen™ detection kits. International sales are contributing a growing proportion of revenue with strong interest across Europe."

"*This validates our strategy of targeting high throughput hospitals, pathology laboratories and government programs to drive revenue and to demonstrate the speed, accuracy, and cost benefits of our 3base® EasyScreen™ platform to improve patient health. Customers in Europe can now choose from an array of flexible, syndromic, and fully registered kits that test for gastrointestinal, respiratory, and sexually transmitted disease pathogens, as well as testing for more than 20 antimicrobial resistant gene targets.*"

During the quarter, Genetic Signatures made progress on many initiatives that position the company well for a post-pandemic future. Europe and the United Kingdom (UK) notably made substantial progress securing new sites and saw customers trialing and buying new test kits. This region accounted for almost 19% of revenue in the quarter, up from 10% in 2Q FY2022.

Further supporting expected growth, Genetic Signatures recently won the Public Health Wales national tender for molecular detection of enteric pathogens across 7 different hospital sites in Wales. This contract, announced in March 2022, is worth up to A$1.8 million per annum. Public Health Wales will use Genetic Signatures unique **3base®** technology for the syndromic testing of more than 20 pathogenic bacteria, protozoan and viral microorganisms that cause gastrointestinal disease. The TGA registered and CE-IVD marked *EasyScreen*™ Enteric Detection Kit supports accurate, flexible, and rapid testing to enable earlier, appropriate patient management, and drive significant cost savings for health systems. Installation and training is underway, and the first sites will officially begin processing patient samples in June 2022**.**

In the United States (US), clinical trials for the FDA application for registration of the *EasyScreen*™ Protozoan Detection Kit have progressed well. Final collection of 1,500 samples will be done this quarter, after which data analysis will be undertaken and the submission completed. Once cleared by the FDA, Genetic Signatures will be free to market its *EasyScreen*™ Enteric Protozoan Detection Kit in the US. In preparation, Genetic Signatures' expanded US sales team has identified key high-throughput laboratories as potential customers, and is aiming to supply 40% of the available US gastrointestinal protozoan testing market within five years of FDA clearance, with a revenue potential of up to US$88 million per annum.

Australia currently remains the largest contributor to sales revenue as Genetic Signatures' most mature market. However, Australia's share of total revenue is expected to change, with further growth projected in key North American and European markets over the next few years. Australian sales of *EasyScreen*™ SARS-CoV-2 Detection Kits were strong in January 2022 during the last Omicron wave. PCR testing demand for SARS-CoV-2 has subsequently tapered as the quarter progressed. A shift to syndromic testing for a range of respiratory pathogens is now evident, as Australian customers increase their requirement for the broader *EasyScreen*™ Respiratory Pathogen Detection Kit, in preparation for a projected seasonal increase in winter respiratory diseases.

Genetic Signatures also advanced its research and development (R&D) projects, including commencing the next development phase of the next generation instrument. As previously disclosed, this new instrument has been designed to address the diagnostic laboratory's need for a fast, automated sample to result solution that retains high throughput capabilities. This new instrument will firmly position Genetic Signatures unique products and instrumentation at the forefront of molecular testing of infectious diseases.

During the quarter Genetic Signatures also joined the BioHub Birmingham® as the first physical footprint for the Company within the UK and Europe. The BioHub laboratory will support the expanding European operation to develop protocols, processes, and quality performance materials for planned growth. The site will also offer customers training and technical support opportunities through hands-on learning using Genetic Signatures' various diagnostic kits and automated platforms. An equivalent facility for the US team has been in operation in California for the last 2 years.

SARS-CoV-2+ Respiratory Testing – Ongoing Demand

In response to the prolonged global COVID-19 pandemic, Genetic Signatures substantially scaled-up its manufacturing capacity and ability to meet ongoing global customer demand for its fast, accurate *EasyScreen*™ SARS-CoV-2 Detection Kits. Genetic Signatures is well placed to rapidly respond to future COVID-19 variant outbreaks, with their unique **3base®** technology demonstrated to detect all known variants to date via *in-silico* analysis, with the **3base®** conversion process improving 'immunity' to mutations. Genetic Signatures continues to further develop its SARS-Cov-2 tests, including TGA registration for use of saliva samples and a specialised variation detection kit being offered for research use.

Leveraging its COVID-19 testing customer base, Genetic Signatures is further marketing its *EasyScreen*™ Respiratory Pathogen Detection Kit, which supports syndromic testing of 14 common respiratory infections, including influenza types A&B, RSV, and rhinovirus. Demand for these respiratory test kits are expected to increase as COVID-19 restrictions continue to ease.

Corporate

As at 31 March 2022 the company has $39.0 million cash at bank. The Genetic Signatures group recorded cash inflows of $1.6 million during the quarter including $11.8m in receipts from customers; net inflows year to date are $9.0 million. This is the third consecutive quarter that Genetic Signatures has reported positive cashflows. Payments of fees to directors, including the CEO, were $199,000 for the quarter and are included in 1.2(e) – staff costs of the Appendix 4C.

– END –

Announcement authorised by Genetic Signatures' Board of Directors

For further information, see our website (www.geneticsignatures.com) or contact us:

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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.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity

GENETIC SIGNATURES LIMITED

ABN	**Quarter ended ("current quarter")**
30 095 913 205	31 March 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (9 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	11,834	34,258
1.2	Payments for		
	(a) research and development	(362)	(2,266)
	(b) product manufacturing and operating costs	(3,654)	(6,534)
	(c) advertising and marketing	(130)	(223)
	(d) leased assets	(71)	(191)
	(e) staff costs	(2,909)	(7,664)
	(f) administration, corporate and other costs	(2,624)	(7,499)
1.3	Dividends received (see note 3)		
1.4	Interest received	22	111
1.5	Interest and other costs of finance paid	(7)	(16)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**2,099**	**9,976**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(54)	(334)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
	(d) investments		
	(e) intellectual property	(390)	(548)
	(f) other non-current assets		
2.2	Proceeds from disposal of:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment		
	(d) investments		
	(e) intellectual property		
	(f) other non-current assets		
2.3	Cash flows from loans to other entities		
2.4	Dividends received (see note 3)		
2.5	Other (provide details if material)		
2.6	**Net cash from / (used in) investing activities**	**(444)**	**(882)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options	21	137
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(3)	(5)
3.5	Proceeds from borrowings		
3.6	Repayment of borrowings		
3.7	Transaction costs related to loans and borrowings		
3.8	Dividends paid		
3.9	Principal element of lease payments	(92)	(272)
3.10	**Net cash from / (used in) financing activities**	**(74)**	**(140)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	37,496	30,121
4.2	Net cash from / (used in) operating activities (item 1.9 above)	2,099	9,976
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(444)	(882)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(74)	(140)
4.5	Effect of movement in exchange rates on cash held	(26)	(24)
4.6	**Cash and cash equivalents at end of period**	**39,051**	**39,051**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	13,865	12,323
5.2	Call deposits	25,186	25,173
5.3	Bank overdrafts		
5.4	Other (provide details)		
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**39,051**	**37,496**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	199
6.2	Aggregate amount of payments to related parties and their associates included in item 2	

Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities		
7.2	Credit standby arrangements		
7.3	Other (please specify)		
7.4	**Total financing facilities**		

7.5	**Unused financing facilities available at quarter end**	

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	2,099
8.2	Cash and cash equivalents at quarter end (Item 4.6)	39,051
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	39,051
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	N/a

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:
Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 26 April 2022

Authorised by: Board of Directors

(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.