Genetic Signatures

ASX Announcement 27 July 2022

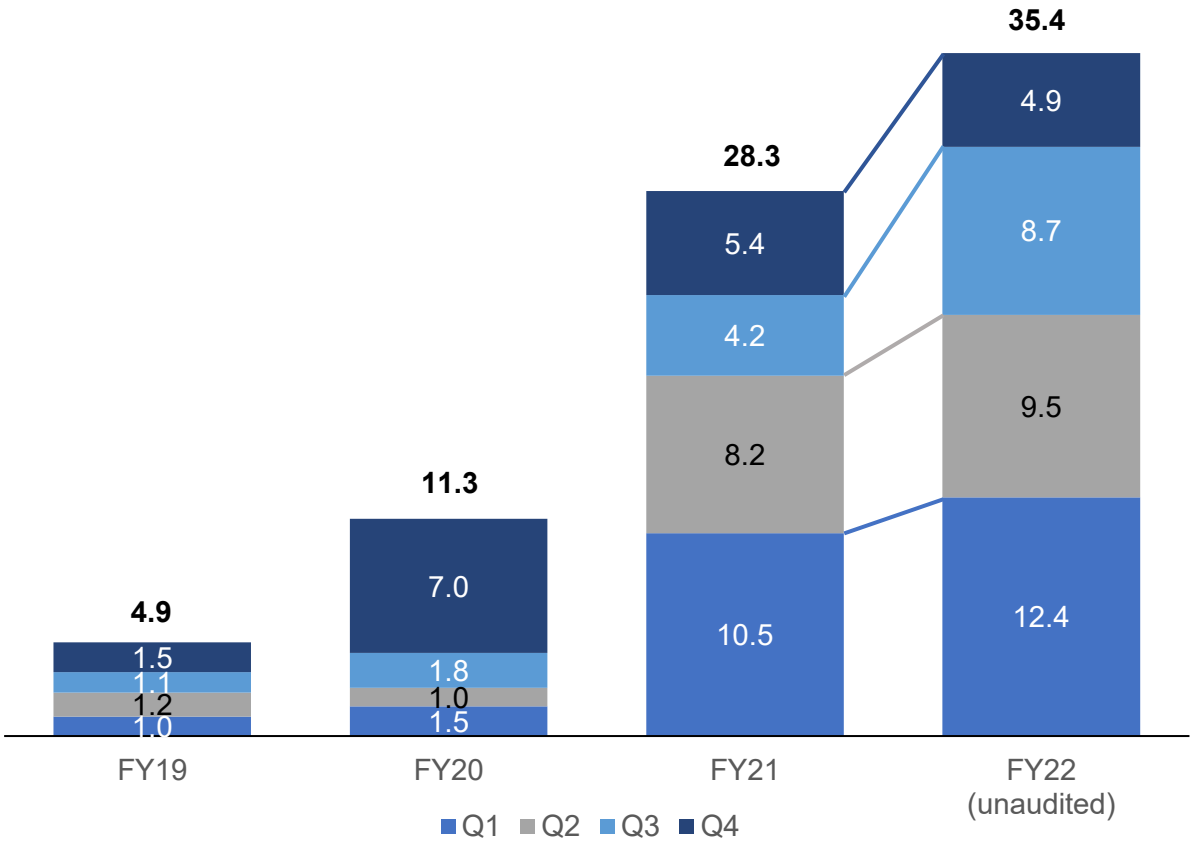
Quarterly Activities Report and Appendix 4C

Highlights

- Record $35.4 million FY2022 sales (unaudited), up 25% from FY2021 ($28.3 million);
- Quarterly sales of $4.9 million with increasing contribution from sale of non-SARS-CoV-2 kits;
- Cash receipts of $5.1 million during the quarter;
- Recruitment for *EasyScreen*™ Enteric Protozoan Detection Kit clinical trial completed, with submission of FDA 510(k) application expected in Q4 CY2022.

Genetic Signatures Limited (ASX: GSS) finished FY2022 with record sales of $35.4 million (unaudited), a 25% increase on FY2021. Q4 FY2022 sales were $4.9 million, a decline of 10% versus same period last year, reflecting the significant reduction in the use of molecular testing for SARS-CoV-2 in both the Australian and international markets.

Figure 1: GSS Quarterly revenue (A$m)



Genetic Signatures has continued to generate strong sales from its portfolio *EasyScreen*™ detection kits that simplify multi-pathogen molecular testing through the use of the Company's proprietary **3Base**® technology.

"*Genetic Signatures has continued to benefit from the recent strong demand for its* EasyScreen™ *SARS-CoV-2 Detection Kits. However, it is particularly pleasing to also see growing diversification of the EasyScreen™ product range and further expansion in key international markets, providing a robust foundation for long-term growth. The strong demand for our* EasyScreen™ *SARS-CoV-2 Detection Kits during the pandemic has significantly increased global awareness of Genetic Signatures and the unique benefits of **3base**® technology"* **said Genetic Signatures CEO, Dr John Melki.**

The use of molecular testing for monitoring and management of COVID-19 is very dynamic and is continually impacted by the ongoing emergence of new variants, changing guidelines and public health initiatives. Since the relaxing of lockdowns and travel restrictions, there has been a marked rebound in COVID-19, as demonstrated in the southern hemisphere's 2022 winter season. However, health authorities concurrently scaled back molecular testing programs for SAR-CoV-2, replaced with self-testing rapid antigen tests.

These policy changes resulted in an anticipated decline in the EasyScreen™ SARS-CoV-2 Detection Kits. However, despite lower immediate testing requirements, Genetic Signatures has the flexibility to scale up again to meet demand, when required. Indeed, the continued emergence of new Variants of Concern, for which Genetic Signature's **3base®** technology is ideally suited, may drive the resumption of wide-spread molecular testing as health authorities seek to improve variant surveillance and reporting.

Australia's winter has seen a significant increase in the number of other serious respiratory illnesses such as influenza, RSV and rhinovirus, and off-season spikes have also been recorded in the U.S. and Europe. The need for a syndromic solution to test for a range of different pathogens causing similar signs and symptoms is becoming the gold standard. Genetic Signatures is expecting increased testing requirements for this broader syndromic approach, of which the *EasyScreen*™ Respiratory Detection Kits are well placed to meet this demand.

Dr Melki added, *"For the first time since the start of the pandemic, we have seen a greater proportion of our revenue attributed to our other* EasyScreen™ *detection kits, a key strategic priority for the Company as we lay down the foundations for longer-term growth supported by increased sales across our syndromic product portfolio and key international markets. The strong sales growth we have seen in FY2022 has validated our strategy of targeting high volume customers such as hospitals, pathology laboratories and government users. In addition to providing volume sales, these customers typically provide broad-based diagnostic testing which provides the opportunity to expand the range of EasyScreen™ detection kits they use."*

"Customers can choose from an array of Genetic Signatures' uniquely configurable and fully registered syndromic tests for a broad range of pathogens causing gastrointestinal, respiratory, and sexually transmitted diseases. In addition, our EasyScreen™ *range of antimicrobial resistance products provide the most comprehensive detection of over 20 resistance gene targets*."

Genetic Signatures consolidated its presence in Europe and the UK during the quarter which accounted for 12% of revenue. The Company is expecting this region become a more important part of the revenue mix as non-SARS-CoV-2 detection kits start to make a greater contribution. To further enhance Genetic Signatures recognition in Europe a marketing campaign was launched in June in conjunction with a German customer, KH Labor, who has been using the *EasyScreen*™ SARS-CoV-2 detection kit for more than 12 months. A link to some of the materials is available here https://geneticsignatures.com/au/resource/partnership-with-kh-labor/

In the United States (US), the primary focus remains on progression of the FDA application for the *EasyScreen*™ Enteric Protozoan Detection Kit. Recruitment and sample collection at the three sites has been completed, and the samples will now be analysed for comparative purposes using commercially available tests where available, or with in-house developed validated comparative tests where no commercially available predicate exists. The Company anticipates filing the FDA application in Q4 CY2022. Once cleared, this will be the first **3base**® *EasyScreen*™ detection kit to secure marketing clearance in the U.S. and will support subsequent uptake of other *EasyScreen*™ detection kits.

Initial marketing activities in the U.S. have already commenced with a series of live webinars featuring leading key opinion leaders highlighting the benefits of the molecular detection of gastrointestinal parasites. Genetic Signatures estimates the total addressable market to be 5.5 million tests per annum, and targets to win 40% of this market within 5 years. Preparatory work has also started for a second syndromic product to be put through the FDA process with trials to commence this half year.

Global marketing activity has increased, including attendance at leading medical and scientific conferences as travel restrictions have eased. Genetic Signatures was a sponsor for The European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) in April where there was considerable interest in **3base**® technology and Genetic Signatures' syndromic product range. The company also attended the American Society for Microbiology (ASM) during the quarter.

Genetic Signatures research and development (R&D) work continues. As previously disclosed, there are more than 5 new product groupings at various stages of development. These products will add to the Group's portfolio providing laboratories a broad range of tests to include in their offering to their customers.

Development of Genetic Signatures fully automated, high-throughput Next Generation Instrument is progressing well through the next development phase. This instrument has been designed to address the diagnostic laboratory's need for a fast, automated sample to result solution that retains high throughput capabilities and is simple to use. This new instrument will firmly position Genetic Signatures' unique products and instrumentation at the forefront of molecular testing of infectious diseases.

Corporate

As at 30 June 2022 the company has $36.9 million cash at bank. Genetic Signatures recorded cash outflows of $2.2 million in the quarter, of which $2.1 million was attributable to substantial investments in equipment for placement at customer sites plus capitalised costs associated with the development of the Next Generation Instrument. Operating cash outflows of $0.2 million included $5.1 million in receipts from customers; net operating inflows for FY2022 are $9.8 million. Payments of fees to Directors, including the CEO, were $223,000 for the quarter and are included in 1.2(e) – staff costs of the Appendix 4C.

Genetic Signatures was pleased to welcome Caroline Waldron as a new non-executive Director in May 2022. Ms Waldron is also a Director of Resimac Group Limited (ASX:RMC) and AMA Group Limited (ASX:AMA) Her experience in law, human resources, marketing and risk is already proving beneficial to the Board and the Genetic Signatures team.

– 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. Genetic Signatures is leveraging strong COVID-19 related sales of its *EasyScreen*™ respiratory kits and the growing interest in its gastroenteritis products to further commercialise its **3base®** technology to rapidly and cost effectively screen for a wide array of infectious pathogens including antibiotic resistant bacteria, sexually transmitted infections, meningitis and mosquito borne viral diseases.

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	30 June 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	5,148	39,405
1.2	Payments for		
	(a) research and development	(868)	(3,133)
	(b) product manufacturing and operating costs	(1,688)	(8,222)
	(c) advertising and marketing	(279)	(502)
	(d) leased assets	(73)	(264)
	(e) staff costs	(2,368)	(10,033)
	(f) administration, corporate and other costs	(53)	(7,552)
1.3	Dividends received (see note 3)		
1.4	Interest received	15	126
1.5	Interest and other costs of finance paid	(3)	(19)
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**	**(169)**	**9,806**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(1,380)	(1,714)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
	(d) investments		
	(e) intellectual property	(728)	(1,275)
	(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**	**(2,108)**	**(2,989)**

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	136	273
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(4)	(9)
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	(93)	(365)
3.10	**Net cash from / (used in) financing activities**	**39**	**(101)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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	39,051	30,121
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(169)	9,806
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2,108)	(2,989)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	39	(101)
4.5	Effect of movement in exchange rates on cash held	84	60
4.6	**Cash and cash equivalents at end of period**	**36,897**	**36,897**

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	11,897	13,865
5.2	Call deposits	25,000	25,186
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)**	**36,897**	**39,051**

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	223
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)	169
8.2	Cash and cash equivalents at quarter end (Item 4.6)	36,897
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	36,897
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	218

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: 27 July 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.