Genetic Signatures

ASX Announcement 27 October 2022

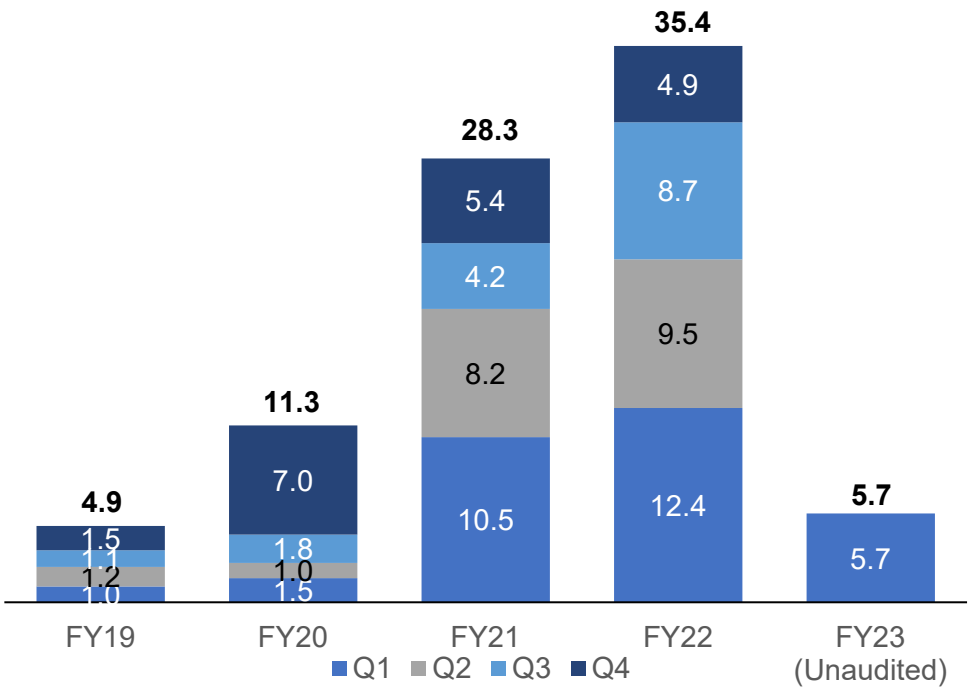
Quarterly Activities Report and Appendix 4C

Highlights

- Quarterly sales of $5.7 million; up 16% from preceding quarter
- Cash receipts of $7.8 million during the quarter, closing cash balance $32.4 million
- Completed recruitment for Enteric Protozoan Detection Kit pivotal clinical trial in the USA
- Independent study reporting high detection rate for Antimicrobial Resistance Detection Kit
- New sites in Australia including two pathology laboratories in Western Australia
- Health Canada licenses *EasyScreen*™ Enteric Protozoan Detection Kit

Genetic Signatures Limited (ASX: GSS) recorded sales of $5.7 million (unaudited) for the first quarter of FY2023. In line with expectations, sales were lower than the previous corresponding quarter as a result of health authorities significantly scaling back molecular testing programs for SARS-CoV-2. However, sales were up 16% from 4Q FY2022 with the majority of sales coming from **3base**® products for non-COVID applications. Approximately 11% of sales were from international markets, consistent with FY2022.

Figure 1: GSS Quarterly revenue (A$m)



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

"*Genetic Signatures benefited significantly from the strong demand for its* EasyScreen™ *SARS-CoV-2 Detection Kits during the pandemic. This resulted in an accelerated awareness of the advantages of our* **3base**® *technology in markets where Genetic Signatures has a presence and provided the company with a strong balance sheet sufficient to support its future growth . With the inevitable decline in testing for SARS-CoV-2, we are now leveraging this awareness and this is resulting in new and existing customers adopting our other* **3base**® *products for syndromic testing applications. This is reflected in the increasing proportion of our revenue that is coming from the sale of our non-COVID products. In addition, we expanded our Australian sales footprint to include two pathology providers in Western Australia and are continuing to gain traction with our international customer base"* **said Genetic Signatures CEO, Dr John Melki.**

In July, Genetic Signatures announced that recruitment and sample collection at the three sites participating in the pivotal trial of its *EasyScreen*™ Enteric Protozoan Detection Kit had been completed. These samples are currently being analysed using in-house developed comparative tests as required to support a 510(k) application to the US FDA. The Company is targeting filing this application in Q4 CY2022. If successful, this will be the first *EasyScreen*™ **3base**® detection kit to secure marketing clearance in the US and will lay the groundwork for Genetic Signatures' other **3base**® products. The Company has also lodged an application for registration of this product with Health Canada during the quarter and this registration was confirmed on 26 October. This is the 3rd *EasyScreen*™ Detection Kit to be registered in Canada. This product is also registered for sale in Europe (CE-IVD).

Market development activities have already commenced in the US with a series of live webinars highlighting the benefits of **3base**® molecular testing for the identification of a broad spectrum of protozoan infections. Once cleared by the FDA, Genetic Signatures will be able to market its *EasyScreen*™ Enteric Protozoan Detection Kit in the US. The company estimates the US market comprises approximately 5.5 million tests per annum, with Genetic Signatures aiming to secure 40% of this market within 5 years of launch. Preparatory work for a second product for the US market has already begun with trials to expected to start before year end.

In September, Genetic Signatures announced that results from an independently conducted study evaluating Genetic Signatures' *EasyScreen*™ ESPL/CPO Detection Kit had been published in a peer-reviewed journal. This study demonstrated that Genetic Signatures' *EasyScreen*™ ESPL/CPO Detection Kit has excellent sensitivity and specificity for detection of the genes that are responsible for the majority of antibiotic resistance in microbial strains. The authors of this study concluded that "irrespective of the host bacteria, the *EasyScreen*™ ESBL/CPO Detection Kit showed excellent biological performance (sensitivity and specificity) for the five most common carbapenemases (enzymes responsible for antimicrobial drug resistance)". Furthermore, the kit was very effective at identifying other antimicrobial resistance genes that are not well detected by most other molecular assays. The authors commented that the kit's "short turnaround time and simplicity makes it suitable for routine use in most clinical microbiology laboratories".

Genetic Signatures expanded its Australian footprint to include two pathology laboratories in Western Australia. These customers are intending to adopt a range of different *EasyScreen*™ kits into their pathology workflow. They have already installed Genetic Signatures' instruments to improve the throughput and efficiency of testing using the company's proprietary **3base**® technology and have completed the purchase of their initial kits. Genetic Signatures has Australian TGA registrations in place for **3base**® *EasyScreen*™ syndromic test kits for the evaluation of respiratory infections, enteric gastrointestinal pathogens and antimicrobial drug resistance (AMR). While the company has generated

material sales of these products in Australia over the past four years, these have primarily been to high-volume customer groups based in New South Wales, Victoria and Queensland.

Research and development (R&D) work continued to progress during the quarter. 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. In addition, the company is developing a fully automated, high-throughput Next Generation Instrument specifically designed for use with its **3base®** technology. 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 September 2022 the company had $32.4 million cash at bank. Genetic Signatures recorded cash outflows of $4.5 million in the quarter, of which $2.1 million was attributable to continued investments in equipment for placement at customer sites plus capitalised costs associated with the development of the Next Generation Instrument. As anticipated, there was an increase in net operating cash outflows reflecting increased investment in people, marketing, R&D and new product development. Net operating outflows for the quarter were $2.4 million and included collections from customers of $7.8m. Payments of fees to Directors, including the CEO, were $276,000 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	30 September 2022

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	7,848	7,848
1.2	Payments for		
	(a) research and development	(1,078)	(1,078)
	(b) product manufacturing and operating costs	(1,976)	(1,976)
	(c) advertising and marketing	(173)	(173)
	(d) leased assets	(149)	(149)
	(e) staff costs	(3,193)	(3,193)
	(f) administration, corporate and other costs	(3,652)	(3,652)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	6	6
1.5	Interest and other costs of finance paid	(1)	(1)
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**	**(2,368)**	**(2,368)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(840)	(840)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
	(d) investments		
	(e) intellectual property	(1,246)	(1,246)
	(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**	**(2,086)**	**(2,086)**

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		
3.4	Transaction costs related to issues of equity securities or convertible debt securities		
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	(32)	(32)
3.10	**Net cash from / (used in) financing activities**	**(32)**	**(32)**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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	36,897	36,897
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,368)	(2,368)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2,086)	(2,086)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(32)	(32)
4.5	Effect of movement in exchange rates on cash held	8	8
4.6	**Cash and cash equivalents at end of period**	**32,419**	**32,419**

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	7,419	11,897
5.2	Call deposits	25,000	25,000
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)**	**32,419**	**36,897**

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	276
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)	2,368
8.2	Cash and cash equivalents at quarter end (Item 4.6)	32,419
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	32,419
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	13.7

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 October 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.