Genetic Signatures

ASX Announcement 30 October 2023

Quarterly Activities Report and Appendix 4C

HIGHLIGHTS

- 510(k) application for *EasyScreen*™ Gastrointestinal Parasite Kit submitted to the US FDA, questions received and answered, with preparations for anticipated US commercial launch well underway
- Quarterly sales of $1.6 million; down 64% due to the temporary impact of reported sensitivity loss in one test (FluB) of the fourteen pathogen *EasyScreen*™ Respiratory Pathogen Detection Kit
- Clinical trial for *EasyScreen*™ Essentials Respiratory Detection Kit expanded to include samples from US influenza season and scheduled to complete in Q1 CY2024
- Cash receipts of $3.6 million during the quarter, closing cash balance $10.5 million with $6.9 million under the Research and Development Tax Incentive expected in Q2 FY2024 resulting in pro-forma cash of $17.4 million.

Genetic Signatures Limited (ASX: GSS) recorded sales of $1.6 million (unaudited) for the first quarter of FY2024, down 64% from the preceding quarter due to a performance issue that has temporarily impacted sales of the *EasyScreen*™ Respiratory Pathogen Detection Kit during the peak of the Australian 'flu season. Non-COVID-only sales were $1.3 million for the quarter. Approximately 18% of sales for this quarter were from international markets. Genetic Signatures ended the quarter with a cash balance of $10.5 million and is eligible for $6.9 million under the Research and Development Tax Incentive, which it expects to receive in Q2 FY2024.

Figure 1: GSS Quarterly revenue (A$m)

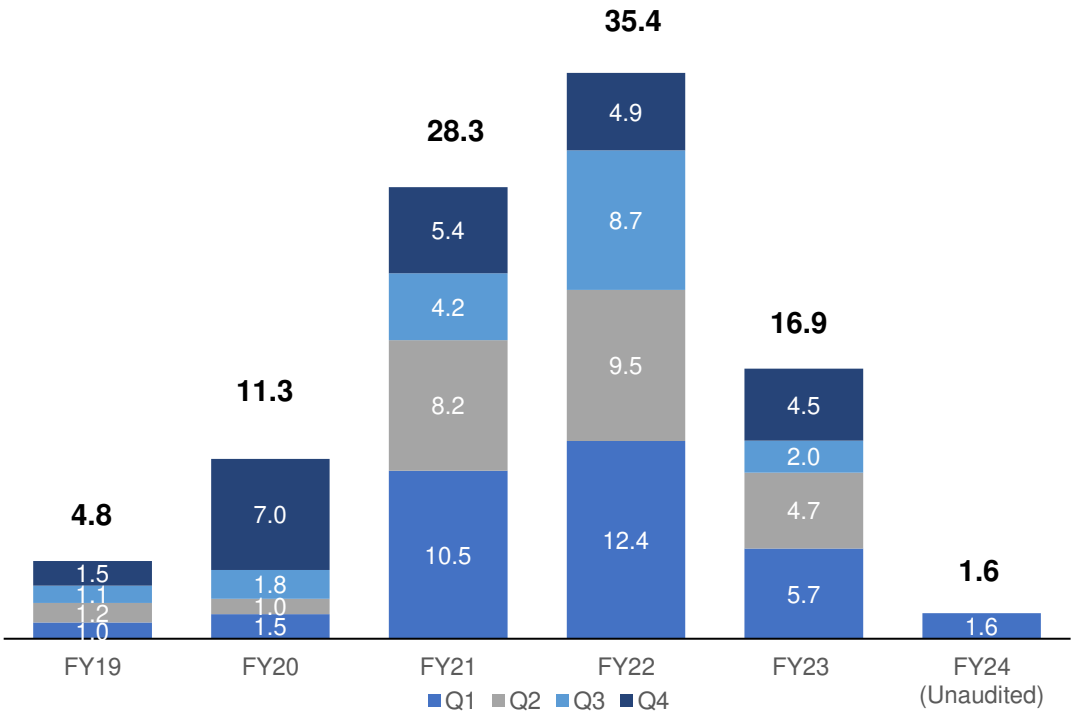
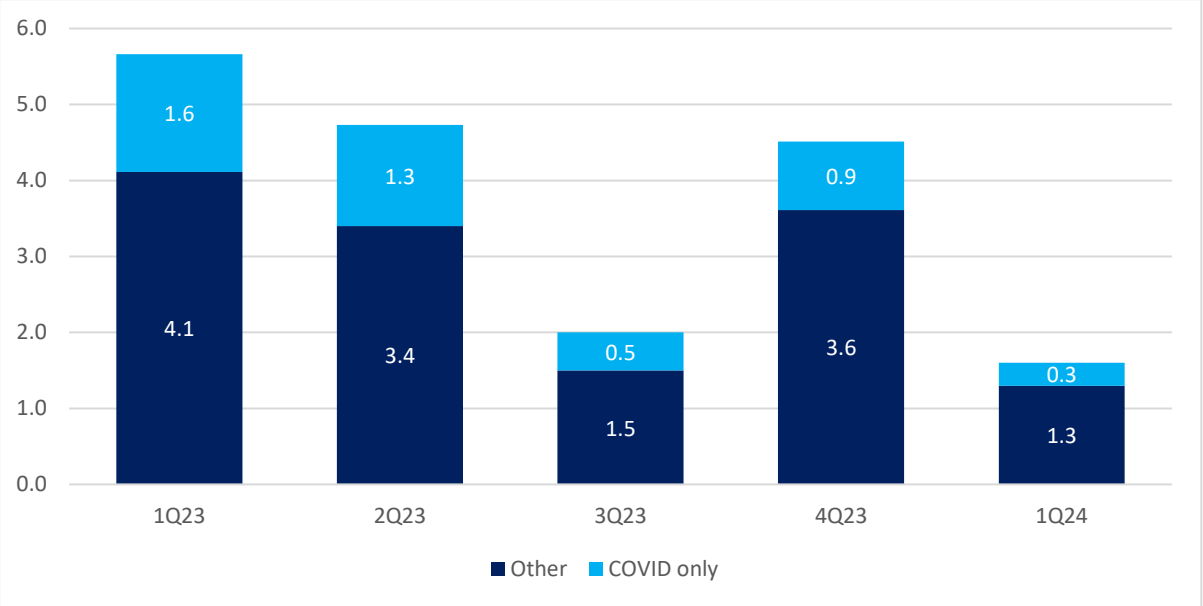


Figure 2: COVID only vs Syndromic test kit sales by quarter (A$m)



Genetic Signatures generates sales globally from its portfolio of *EasyScreen*™ detection kits that simplify multi-pathogen syndromic molecular testing through the use of the company's proprietary **3base®** technology.

"During the quarter, Genetic Signatures achieved a significant milestone with the submission of our 510(k) application for the EasyScreen™ Gastrointestinal Parasite Detection Kit to the US FDA. This is the first US regulatory submission for a product that uses our **3base®** *technology,"* **said Genetic Signatures CEO, Dr John Melki**. *"With our preparations for the anticipated launch of this product well underway, we look forward to bringing our* **3base®** *technology to the largest molecular diagnostics market in the world. The clinical trial of our second product for the US market is progressing very well and we remain on track to submit an application for this product next year. As reported during this quarter the performance inconsistencies from the EasyScreen™ Respiratory Pathogen Detection Kit materially impacted our sales of this product during this quarter. However, believe that we will be in a position to inform the TGA that we have resolved this issue during this current quarter and recommence normal shipment of these kits."*

In September, Genetic Signatures submitted a 510(k) application to the FDA for regulatory clearance to market its *EasyScreen*™ Gastrointestinal Parasite Detection Kit and automated workflow in the US. The US represents a significant commercial opportunity for this syndromic solution, with an estimated Total Addressable Market (TAM) of 5.5 million tests per annum. Currently in the US, the diagnosis of gastrointestinal (GI) protozoan infections primarily relies on sample culture and microscopy, supported by antigen detection and pathogen-specific molecular tests. This approach is well recognised as being time-consuming, of variable reliability, labour-intensive and can take several days to provide a result. The extensive clinical trial data shows that Genetic Signatures' *EasyScreen*™ Gastrointestinal Parasite Detection Kit provides an effective, rapid molecular test that covers the eight most common and clinically

relevant GI parasites. The FDA are currently reviewing the application and multiple rounds of questions have been responded to during this period.

Genetic Signatures is well advanced in its preparations for the anticipated commercial launch of its *EasyScreen*™ Gastrointestinal Parasite Detection Kit once it is cleared by the FDA. This has included the investment in local warehousing and demonstration laboratory facilities. The Company has also commenced work with a number of carefully selected, pre-qualified customer experience sites in the US to evaluate the *EasyScreen*™ Gastrointestinal Parasite Detection Kit and workflow. Genetic Signatures has commenced installation of instruments in these sites and is training site staff who are conducting pilot testing using the *EasyScreen*™ Gastrointestinal Parasite Detection Kit to familiarise themselves with the technology and the automated workflow that it provides. The Company expects many of these customer experience sites will become initial customers for this syndromic solution, once it is cleared for sale by the FDA.

Genetic Signatures is also conducting a clinical trial to support a 510(k) application for its second product in the US, the *EasyScreen*™ Essentials Respiratory Detection Kit. This trial is progressing well with over 80% of the initially planned patients recruited to date. In order to ensure robust sample recruitment for each pathogen target, the Company has extended recruitment for this trial to include additional clinical samples collected during the US winter season. As a result, the Company expects recruitment for this trial to be completed by Q1 CY2024, with the submission of regulatory application to the US FDA scheduled for 2H CY2024.

In August, Genetic Signatures advised the ASX that it had become aware of a sensitivity reduction for influenza B virus when employing the *EasyScreen*™ eleven Respiratory Pathogen Detection Kit. These losses affected only a small proportion of samples with a low concentration of the virus, and were specific to the influenza B virus. Detection of influenza A virus was not affected. Usually, FluB is only present at small numbers compared to FluA, but this year it has been a frequent pathogen. As a result, there was a significant reduction in the number of kits that were shipped during the quarter which, historically, has been a strong revenue quarter for the Company. Minor changes to the assay design have restored detection in samples with low concentration of the influenza B virus which has been confirmed through clinical testing of the new test design. The Company is now undertaking the requisite analytical studies before informing the Therapeutic Goods Administration (TGA) of the resolution during this current quarter.

The Company has a solid R&D program which includes over 5 new product groupings at various stages of development, and the development its Next Generation sample-to-answer instrument. In light of the reduced cash inflows during this quarter, non-critical expenditure on these R&D programs has been temporarily deferred until sales of the *EasyScreen*™ Respiratory Pathogen Detection Kit have been restored.

Corporate

As of 30 September 2023, the Company had $10.5 million cash in the bank. In addition, the Company estimates it is entitled to receive $6.9 million under the Federal Government's Research and Development Tax Incentive scheme in relation to eligible R&D expenditures incurred during the FY2023 financial year. Genetic Signatures recorded net operating cash outflows of $5.0 million during the quarter which included receipts from customers of $3.5 million. Net investing cash outflows of $0.9 million for the quarter included capitalised costs associated with the development of the Next Generation Instrument and other IP development. Genetic Signatures has continued to invest in building infrastructure to ensure the Company has a strong presence and capacity to meet demand once

international product registrations are completed. Payments of fees to Directors, including the CEO, were $253,000 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:

Dr John Melki
Chief Executive Officer
john.melki@geneticsignatures.com
T: +61 (0)2 9870 7580

Karl Pechmann
Chief Financial Officer
karl.pechmann@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.

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 2023

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	3,516	3,516
1.2	Payments for		
	(a) research and development	(1,059)	(1,059)
	(b) product manufacturing and operating costs	(831)	(831)
	(c) advertising and marketing	(238)	(238)
	(d) leased assets	(157)	(157)
	(e) staff costs	(3,651)	(3,651)
	(f) administration, corporate and other costs	(2,724)	(2,724)
1.3	Dividends received (see note 3)		
1.4	Interest received	124	124
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**	**(5,021)**	**(5,021)**

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

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
	(d) investments		
	(e) intellectual property	(867)	(867)
	(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**	**(867)**	**(867)**

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	-	-
3.10	**Net cash from / (used in) financing activities**	**-**	**-**

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	16,349	16,349
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(5,021)	(5,021)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(867)	(867)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	2	20
4.6	**Cash and cash equivalents at end of period**	**10,463**	**10,463**

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	7,349	6,235
5.2	Call deposits	3,114	10,114
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)**	**10,463**	**16,349**

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	253
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)	(5,021)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	10,463
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	10,463
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	2.1

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: 30 October 2023

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.