Genetic Signatures

ASX Announcement 31 January 2024

Quarterly Activities Report and Appendix 4C

HIGHLIGHTS

- Successful $15.9 million capital raise completed in December and January by way of a Placement and Rights Issue
- Quarterly sales of $2.0 million which were impacted by reduced Australian sales *EasyScreen*™ Respiratory Pathogen Detection Kit while improvements are assessed by the TGA
- $6.9 million received under the Research and Development Tax Incentive in the quarter for expenditure incurred in the financial year ended 30 June 2023
- Cash receipts of $2.1 million during the quarter, closing cash balance $18.1 million with a further $8.0 million received from the Rights Issue in January 2024 resulting in pro-forma cash of $26.1 million.

Genetic Signatures Limited (ASX: GSS) recorded sales of $2.0 million (unaudited) for the second quarter of FY2024. Sales during the quarter were impacted by the previously reported temporary sales reduction of the *EasyScreen*™ Respiratory Pathogen Detection Kit. Non-COVID-only sales were $1.8 million for the quarter and approximately 11% of sales for this quarter were from international markets. Genetic Signatures ended the quarter with a cash balance of $18.1 million which includes a refund of $6.9 million received under the Research and Development Tax Incentive and proceeds from an $8 million placement (before expenses) to sophisticated and professional investors conducted in December 2023. The Company has subsequently received an additional $8 million (before expenses) from a fully underwritten, entitlement offer to shareholders which closed in January 2024.

Figure 1: GSS Quarterly revenue (A$m)

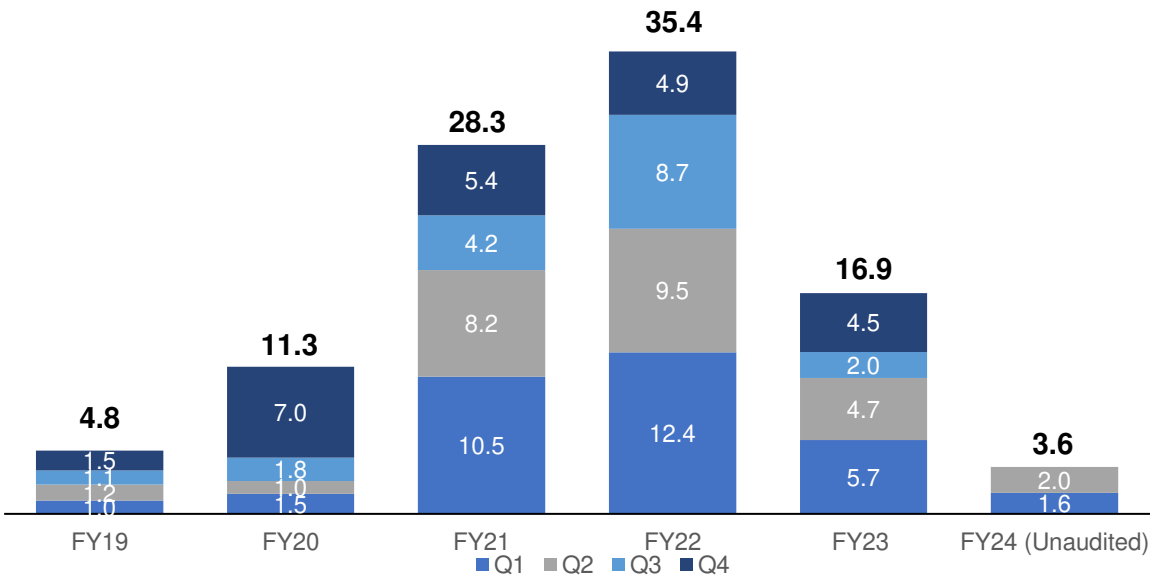
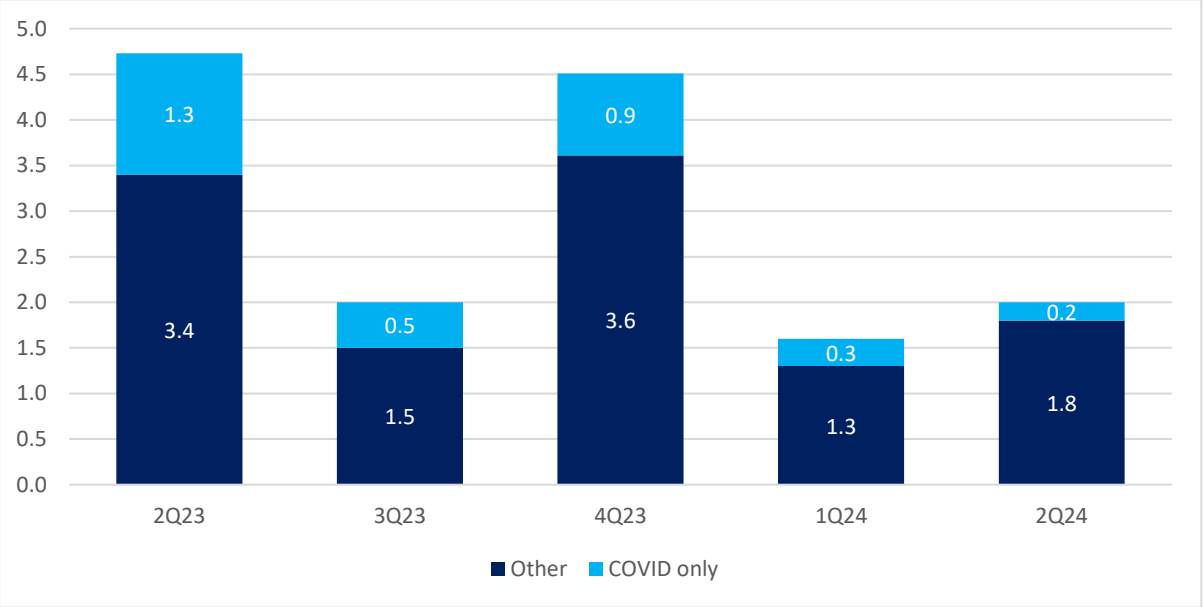


Figure 2: COVID only vs Syndromic test kit sales by quarter (A$m)



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.

"Our 510(k) application that is currently with the US FDA for our EasyScreen™ *Gastrointestinal Parasite Detection Kit is progressing well"* **said Genetic Signatures CEO, Dr John Melki**. *"We are continuing to work closely with the FDA on this application and have already provided responses to the initial rounds of questions they have asked. We are currently preparing responses to address their most recent additional information request and expect to submit this before the end of April 2024. We remain on track for first US commercial sales of this product to commence in H1 FY2025 We are extremely grateful to our existing and new shareholders for their support in the capital raising activities that we conducted in December. This has provided Genetic Signatures with a much stronger balance sheet to launch these products into the US market as well as invest in new products and our sample to answer instrument that will provide long term growth for the Company."*

In September 2023, 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. Genetic Signatures is currently preparing responses to the most recent round of questions from the FDA in relation to this application. The Company intends to submit this additional information by the end of April and expects that the FDA will review and provide its response to the additional information soon after receiving it.

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 commenced work with several carefully selected, pre-qualified customer experience sites in the US to evaluate the *EasyScreen*™ Gastrointestinal Parasite Detection Kit and workflow. Genetic Signatures has installed instruments at six of its selected customer experience- sites and expects to install instruments at an additional three sites during the current quarter. Training has been completed at all the installed sites and will immediately follow the completion of installation at the remaining three sites. These sites span a range of customer groups which includes hospitals, health departments and some of the largest and most respected corporate pathology providers. The Company has received very positive feedback from these customer experience sites and consequently expects many of them 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. The Company has extended recruitment for this trial to include additional clinical samples collected during the US winter season

In August, Genetic Signatures advised the ASX that it had become aware of a sensitivity reduction for influenza B virus when employing the *EasyScreen*™ Respiratory Pathogen Detection Kit. The Company has made changes to the assay design which have restored detection in samples with low concentration of the influenza B virus. This has been confirmed through clinical testing of the new test design and the requisite analytical studies have been completed. An updated application for the *EasyScreen*™ Respiratory Pathogen Detection Kit was submitted to the Australian Therapeutic Goods Administration and the Company expects to receive a clearance for this application during the 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 have been temporarily deferred but are expected to recommence shortly after 510(k) clearance.

Corporate

As of 31 December 2023, Genetic Signatures ended the quarter with a cash balance of $18.1 million which includes a refund of $6.9 million received under the Research and Development Tax Incentive and proceeds from an $8.0 million placement (before expenses) to sophisticated and professional investors that the Company conducted in December 2023. Subsequently, Genetic Signatures has received an additional $8.0 million (before expenses) from a fully underwritten, entitlement offer to shareholders which closed in January 2024. Genetic Signatures recorded net operating cash inflows of $2.6 million during the quarter which included receipts from customers of $2.1 million and the refund of $6.9 million received under the Research and Development Tax Incentive. Net investing cash outflows of $2.4 million for the quarter included capitalised costs associated with the development of the Next Generation Instrument, other IP development, and investments in equipment for placement at customer or clinical trial sites. 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 $285,000 for the quarter and are included in 1.2(e) – staff costs of the Appendix 4C.

– END –

Genetic Signatures

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 December 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	2,069	5,585
1.2	Payments for		
	(a) research and development	(676)	(1,735)
	(b) product manufacturing and operating costs	(991)	(1,822)
	(c) advertising and marketing	(80)	(318)
	(d) leased assets	(160)	(317)
	(e) staff costs	(3,930)	(7,581)
	(f) administration, corporate and other costs	(629)	(3,353)
1.3	Dividends received (see note 3)		
1.4	Interest received	82	206
1.5	Interest and other costs of finance paid	-	(1)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	6,877	6,877
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**2,562**	**(2,459)**

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 (6 months) $A'000
	(d) investments		
	(e) intellectual property	(1,581)	(2,448)
	(f) other non-current assets		
2.2	Proceeds from disposal of:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(792)	(792)
	(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**	**(2,373)**	**(3,240)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	7,959	7,959
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	(480)	(480)
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**	**7,479**	**7,479**

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 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	10,463	16,349
4.2	Net cash from / (used in) operating activities (item 1.9 above)	2,562	(2,459)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2,373)	(3,240)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	7,479	7,479
4.5	Effect of movement in exchange rates on cash held	(7)	(5)
4.6	**Cash and cash equivalents at end of period**	**18,124**	**18,124**

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	18,010	7,349
5.2	Call deposits	114	3,114
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)**	**18,124**	**10,463**

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	285
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)	2,562
8.2	Cash and cash equivalents at quarter end (Item 4.6)	18,124
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	18,124
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: 31 January 2024

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.