

ASX Announcement 31 July 2024

Quarterly Activities Report and Appendix 4C

HIGHLIGHTS

- Received FDA clearance to market and sell the EasyScreen[™] Gastrointestinal Parasite Detection Kit in the US
- Appointed Allison Rossiter, previous MD of Roche Diagnostics Australia, as CEO
- Completed \$30.0 million capital raise (before costs) comprising \$6.0 million institutional placement and fully underwritten \$24.0 million entitlement offer to shareholders
- Redesigned EasyScreen[™] Respiratory Detection Kit authorised for supply by Australian Therapeutic Goods Administration (TGA)
- Achieved quarterly sales of \$4.5 million with the resumption of Australian sales of EasyScreen™ Respiratory Pathogen Detection Kit as the Australian winter respiratory infection season commences

Genetic Signatures Limited (ASX: GSS) recorded sales of \$4.5 million (unaudited) for the fourth quarter of FY2024. Sales during the quarter were positively impacted by resumption of sales of the *EasyScreen*™ Respiratory Pathogen Detection Kit following authorisation of the revised kit by the Australian Therapeutic Goods Administration (TGA). Sales in international markets accounted for approximately 5% of sales during this quarter. Genetic Signatures ended the quarter with a cash balance of \$36.3 million. The proceeds from the Underwritten Retail Entitlement Offer, forming part of the \$30.0 million capital raise (before costs), was completed in July 2024, resulting in \$8.5m in proceeds (before costs).

Figure 1: GSS Quarterly revenue (A\$m)

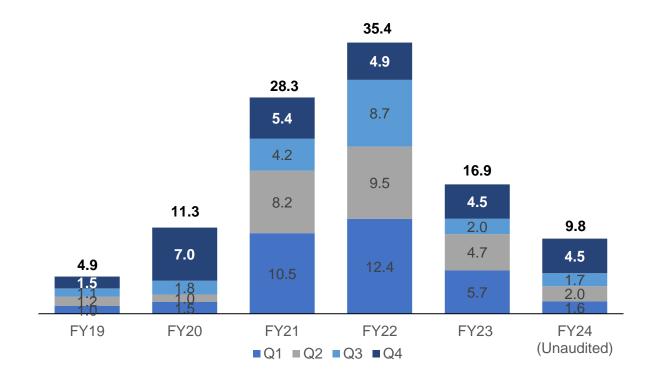
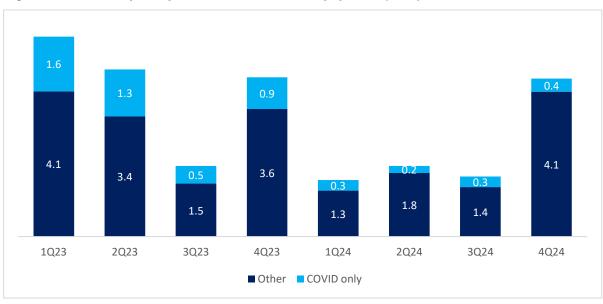


Figure 2: COVID only vs Syndromic test kit sales by quarter (A\$m)



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. With the World Health Organisation having officially declared that COVID-19 is no longer a global health emergency, molecular testing for only the SARS-CoV-2 virus has become less



common due to a great focus on testing for multiple acute respiratory infections. The relative contribution of COVID-only test products to Genetic Signature's overall revenue has declined and is expected to continue to decline following the US launch of the *EasyScreen™* Gastrointestinal Parasite Detection Kit. As a consequence, Genetic Signatures does not consider it relevant to continue to specifically break out the sales of COVID-only test products in future reporting periods.

In June 2024 US Food and Drug Administration (FDA) 510(k) cleared the *EasyScreen*™ Gastrointestinal Parasite Detection Kit and GS1 automated workflow for marketing and sale in the US. This kit has the broadest coverage of any FDA-cleared molecular test for this indication and is able to identify 8 of the most common and clinically relevant gastrointestinal parasites in a single test. These 8 pathogens are estimated to account for over 90% of all gastrointestinal parasitic infections in the US. Genetic Signatures' *EasyScreen*™ Gastrointestinal Parasite Detection Kit is highly automated and able to provide a result for all 8 targets within 5 hours.

The current practice for gastrointestinal parasite testing in the US is predominantly microscopic examination using O&P (ova and parasite) testing, which is time-consuming, labour intensive, slow to provide a result, of variable sensitivity, and frequently has poor patient compliance when using multi-sample protocols. It is estimated that there are 65 million cases of parasitic gastrointestinal infection in the US which require approximately 5.5 million O&P tests each year.

Genetic Signatures is well-advanced in its preparations for US commercial sales of the *EasyScreen*TM Gastrointestinal Parasite Detection Kit and workflow. The Company expects first commercial sales once the Company's pathology service provider customers have completed their internal technology evaluation and approval processes. During the FDA review process, Genetic Signatures installed instruments at nine customer-experience sites and completed training at these sites which span a range of customer groups including hospitals, health departments and corporate pathology providers. CPT codes have been identified which are relevant for providing reimbursement to end-users from both public and private payors.

In April, Genetic Signatures was advised that the Australian Therapeutic Goods Administration (TGA) had completed its review of the redesigned *EasyScreen*™ Respiratory Pathogen Detection Kit and included the updated device in the Australian Register of Therapeutic Goods (ARTG), allowing its supply to Australian customers. The updated product provides improved detection of the Influenza B virus in samples with low concentrations of the virus. With the commencement of the Australian winter acute respiratory infection season, sales of this product to customers commenced during the quarter and are in line with historical sales indicating that previous customers have resumed their purchase of the product following its temporary withdrawal from the market during mid-2024.

The Company has a solid R&D program which includes over 5 new product groupings at various stages of development, workflow enhancements and analytical software. The development of its Next Generation sample-to-answer instrument is expected to resume after further analysis of the markets. Considering the reduced cash inflows during this financial year, non-critical expenditure on these R&D programs had been deferred but are expected to resume once sales of the *EasyScreen*™ Gastrointestinal Parasite Detection Kit commence.

Corporate

As of 30 June 2024, Genetic Signatures ended the quarter with a cash balance of \$36.3 million which includes the proceeds from a \$30 million capital raise that comprised an institutional placement and a fully-underwritten, entitlement offer to shareholders which was completed in July. Genetic Signatures



recorded net operating cash outflows of \$3.3 million during the quarter which included receipts from customers of \$2.1 million. Net investing cash outflows of \$0.8 million for the quarter included capitalised costs associated with 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 \$274k for the quarter and are included in 1.2(e) – staff costs of the Appendix 4C.

In April, Genetic Signatures announced that Dr John Melki had stepped down from the role of CEO and that Director Dr Neil Gunn had assumed the role of Interim CEO pending the appointment of a new CEO. In June, the Company announced that Allison Rossiter, Managing Director of Roche Diagnostics Australia, was appointed as CEO and would commence in that role by September 2024. On commencement of Ms Rossiter's appointment, Dr Neil Gunn will conclude his role as Interim CEO but will continue as Non-Executive Director

In June, Genetic Signatures announced a \$30 million equity raising (before costs) through a placement to institutional investors and a fully-underwritten pro rata accelerated non-renounceable entitlement offer to all shareholders. The Institutional Offer raised \$21.5 million at \$0.75 per share through the placement of 8.0 million shares under the Placement Offer and 20.6 million shares under the Institutional Entitlement Offer. In July, the Company announced completion of the fully-underwritten Retail Entitlement Offer which raised \$8.5 million at \$0.75 per share.

- END -

Announcement authorised by Genetic Signatures' Board of Directors

For further information, see our website (<u>www.geneticsignatures.com</u>) 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*TM 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 June 2024

Con	solidated 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	2,155	9,895
1.2	Payments for		
	(a) research and development	(1,032)	(3,376)
	(b) product manufacturing and operating costs	(235)	(3,283)
	(c) advertising and marketing	(574)	(1,303)
	(d) leased assets	-	(529)
	(e) staff costs	(3,661)	(14,745)
	(f) administration, corporate and other costs	(196)	(4,102)
1.3	Dividends received (see note 3)		
1.4	Interest received	243	484
1.5	Interest and other costs of finance paid	(26)	(36)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	6,877
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(3,326)	(10,118)

2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(599)	(1,979)

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Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
	(d) investments		
	(e) intellectual property	(206)	(2,812)
	(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	(805)	(4,791)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	21,584	37,522
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	(1,447)	(2,530)
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	(104)	(180)
3.10	Net cash from / (used in) financing activities	20,033	34,812

Con	solidated 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	20,355	16,349
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,326)	(10,118)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(805)	(4,791)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	20,033	34,812
4.5	Effect of movement in exchange rates on cash held	(5)	-
4.6	Cash and cash equivalents at end of period	36,252	36,252

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	3,852	5,341
5.2	Call deposits	32,400	15,014
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)	36,252	20,355

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	274
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 qu	arter end		
7.6	Include in the box below a description of each rate, maturity date and whether it is secured facilities have been entered into or are proposinclude a note providing details of those facilities.	or unsecured. If any add sed to be entered into af	itional financing	
8.	Estimated cash available for future operating activities \$A'000			
8.1	Net cash from / (used in) operating activities	Net cash from / (used in) operating activities (Item 1.9) (3,326)		
8.2	Cash and cash equivalents at quarter end (It	em 4.6)	36,252	
8.3	Unused finance facilities available at quarter end (Item 7.5)		-	
8.4	Total available funding (Item 8.2 + Item 8.3) 36,25		36,252	
8.5	Estimated quarters of funding available (It Item 8.1)	tem 8.4 divided by	10.9	
	Note: if the entity has reported positive net operating ca- figure for the estimated quarters of funding available mu		m 8.5 as "N/A". Otherwise, a	
8.6	If Item 8.5 is less than 2 quarters, please pro	If Item 8.5 is less than 2 quarters, please provide answers to the following questions:		
	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 quest	tions 8.6.1, 8.6.2 and 8.6.3 abo	ve must be answered	

Compliance statement

- 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 July 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".
- 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.