

ASX Announcement 26 April 2024

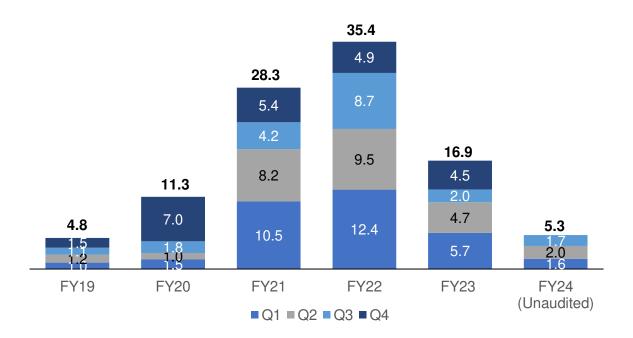
Quarterly Activities Report and Appendix 4C

HIGHLIGHTS

- Australian Therapeutic Goods Administration (TGA) authorises supply of the redesigned EasyScreen™ Respiratory Detection Kit
- Closed underwritten \$8.0 million Entitlement Issue completing Capital Raising of approximately \$15.9 million in proceeds before costs
- Quarterly sales of \$1.7 million which were impacted by reduced Australian sales EasyScreen™ Respiratory Pathogen Detection Kit
- Cash receipts of \$2.2 million during the quarter, closing cash balance \$20.3 million

Genetic Signatures Limited (ASX: GSS) recorded sales of \$1.7 million (unaudited) for the third quarter of FY2024. Sales during the quarter were impacted by seasonally reduced sales of the *EasyScreen*™ Respiratory Pathogen Detection Kit and reduced shipping while modifications to the kit were under review by the Australian Therapeutic Goods Administration (TGA). Non-COVID-only sales were \$1.4m million for the quarter and approximately 16% of sales for this quarter were from international markets. Genetic Signatures ended the quarter with a cash balance of \$20.3 million which includes proceeds from the \$15.9 million capital raise (before costs) that was completed in January 2024.

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



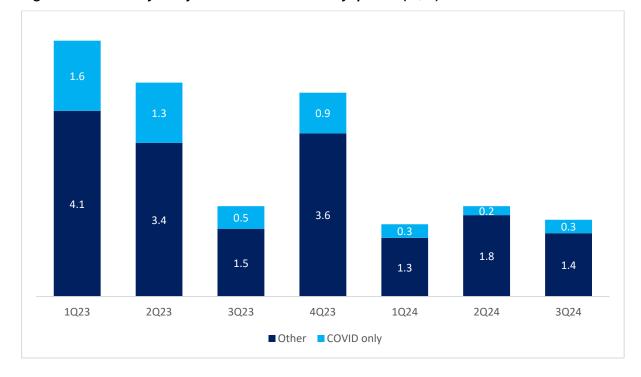


Figure 2: COVID only vs Syndromic test kit sales by quarter (A\$m)

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.

"We were very pleased to be advised that the Australian TGA has approved the changes to the design of our EasyScreen™ Respiratory Pathogen Detection Kit. We are now able to ship this redesigned kit immediately to our customers as they prepare for the Australian influenza season." said Genetic Signatures CEO, Dr John Melki. "We have also been working on a comprehensive response to the latest submission to the US FDA in relation to the 510(k) application for our EasyScreen'™ Gastrointestinal Parasite Detection Kit and we continue our preparations for launching this in the US in the second half of this calendar year."

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. 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 has been addressing the most recent round of questions from the FDA in relation to the application. The Company is expecting that the FDA will review and provide its response to the additional information provided soon after receiving it.

Genetic Signatures is well-advanced in its preparations for the anticipated commercial launch once it is cleared by the FDA. The Company has established local warehousing and demonstration laboratory



facilities and commenced work with several carefully selected, pre-qualified customer experience sites in the US to evaluate the *EasyScreen*TM Gastrointestinal Parasite Detection Kit and workflow. Genetic Signatures has installed instruments at nine customer-experience sites and has completed training at the majority of sites. These span a range of customer groups which includes hospitals, health departments and corporate pathology providers. The Company has received very positive feedback from these customer experience sites and expects many of them will become initial commercial customers once the *EasyScreen*TM Gastrointestinal Parasite Detection Kit is cleared for sale by the FDA.

In August 2023, 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. The Australian TGA has reviewed and has authorised the supply of the updated EasyScreen™ Respiratory Pathogen Detection Kit. The Company has maintained regular contact with its customers regarding these changes and is expecting sales of its respiratory products will return to historical levels as the Australian influenza season commences.

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. Considering the reduced cash inflows during this financial year to date, 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 March 2024, Genetic Signatures ended the quarter with a cash balance of \$20.3 million which includes the proceeds from a capital raise that comprised a placement and a fully underwritten, entitlement offer to shareholders which was completed in January 2024. Genetic Signatures recorded net operating cash outflows of \$4.3 million during the quarter which included receipts from customers of \$2.2 million. Net investing cash outflows of \$0.7 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 \$281k 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 (<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

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	GENETIC SIGNATURES LIMITED	
	GENETIC SIGNATURES LIMITED	
- 1		

ABN

Quarter ended ("current quarter")

30 095 913 205 31 March 2024

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	2,155	7,740
1.2	Payments for		
	(a) research and development	(609)	(2,344)
	(b) product manufacturing and operating costs	(1,226)	(3,048)
	(c) advertising and marketing	(411)	(729)
	(d) leased assets	(212)	(529)
	(e) staff costs	(3,503)	(11,084)
	(f) administration, corporate and other costs	(553)	(3,906)
1.3	Dividends received (see note 3)		
1.4	Interest received	35	241
1.5	Interest and other costs of finance paid	(9)	(10)
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	(4,333)	(6,792)

2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(588)	(1,380)

ASX Listing Rules Appendix 4C (17/07/20)

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Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
	(d) investments		
	(e) intellectual property	(158)	(2,606)
	(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		(746)	(3,986)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	7,979	15,938
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	(603)	(1,083)
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	(76)	(76)
3.10 Net cash from / (used in) financing activities		7,300	14,779

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Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (9 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	18,124 16,349	
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,333)	(6,792)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(746)	(3,986)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	7,300	14,779
4.5	Effect of movement in exchange rates on cash held	10	5
4.6	Cash and cash equivalents at end of period	20,355	20,355

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	5,341	18,010
5.2	Call deposits	15,014	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)	20,355	18,124

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	281
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.	Note: the arranger Add note	cing facilities e term "facility' includes all forms of financing ments available to the entity. es as necessary for an understanding of the of finance available to the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000	
7.1	Loan fa	acilities			
7.2	Credit	standby arrangements			
7.3	Other (please specify)			
7.4	Total f	inancing facilities			
7.5	Unuse	d financing facilities available at qu	arter 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) (4,33			(4,333)	
8.2	Cash and cash equivalents at quarter end (Item 4.6)			20,355	
8.3	Unused finance facilities available at quarter end (Item 7.5)				
8.4	Total available funding (Item 8.2 + Item 8.3) 20,355				
8.5	.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)			4.7	
	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

- 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: 26 April 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.