ASX Announcement 31 July 2023

Quarterly Activities Report and Appendix 4C

HIGHLIGHTS

- Quarterly sales of $4.5 million; up 125% from preceding quarter reflecting increased molecular testing for respiratory infections during the Australian autumn and winter seasons
- Sales of non-COVID only products were $3.6 million, up 140% from the preceding quarter and accounting for 80% of sales during Q4 FY23
- Completed data verification for 510(k) application for Genetic Signatures *EasyScreen™ Gastrointestinal Parasite Detection Kit* that will be submitted to the FDA in August 2023
- Clinical trial for *EasyScreen™ Essentials Respiratory Detection Kit* is 80% recruited and on track to complete in H2 CY2023 with regulatory application scheduled for 1H CY2024
- Two new distributors specialising in molecular diagnostic products appointed for Middle East and Israel markets
- Cash receipts of $3.5 million during the quarter, closing cash balance $16.3 million

Genetic Signatures Limited (ASX: GSS) recorded sales of $4.5 million (unaudited) for the fourth quarter of FY2023, up 125% from the preceding quarter reflecting the increased molecular testing for respiratory infections during the Australian autumn and winter season. Revenue for the full year FY2023 was $16.9 million (unaudited) down 52% reflecting the cessation of public health driven molecular testing for COVID-19 during the year. Non-COVID-only sales were $3.4 million for the quarter, up 140% from the preceding quarter and were generated from syndromic testing for respiratory conditions in addition to gastroenteric infections and other tests within the **3base®** product portfolio. Approximately 4% of sales for this quarter were from international markets, reflecting lower respiratory testing in the Northern hemisphere during the spring and summer months.

Figure 1: GSS Quarterly revenue (A$m)

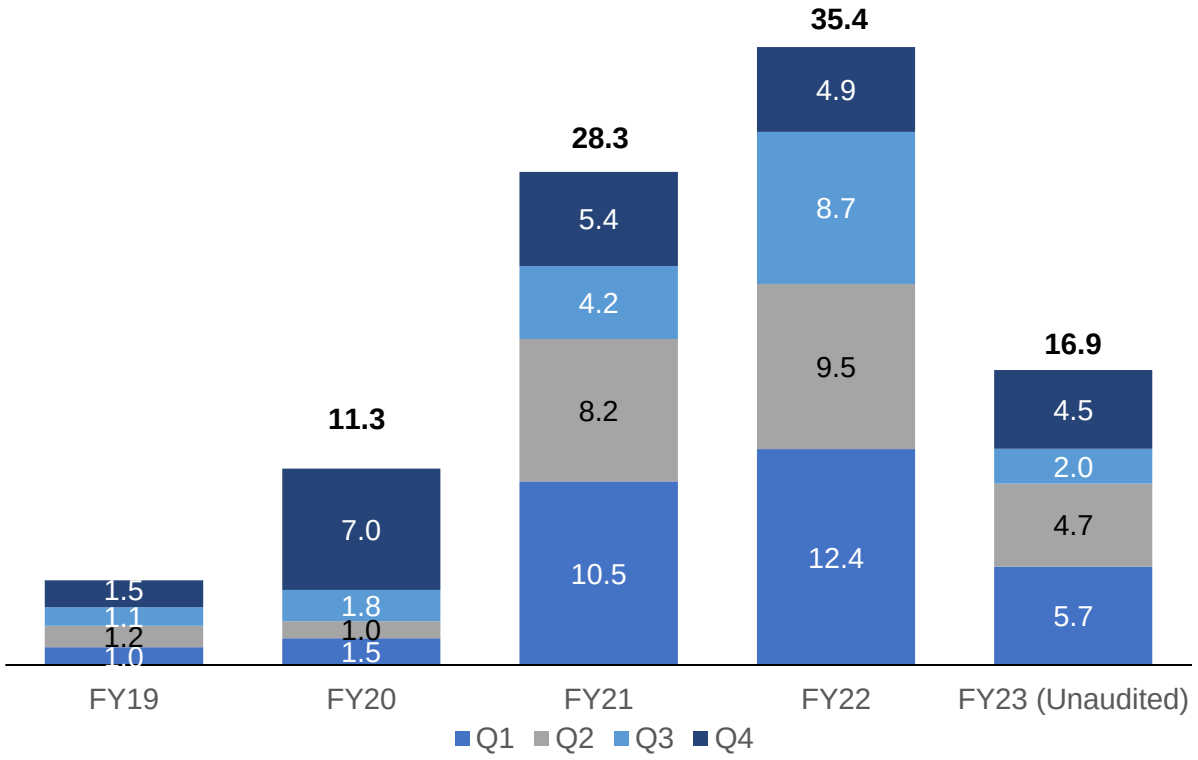
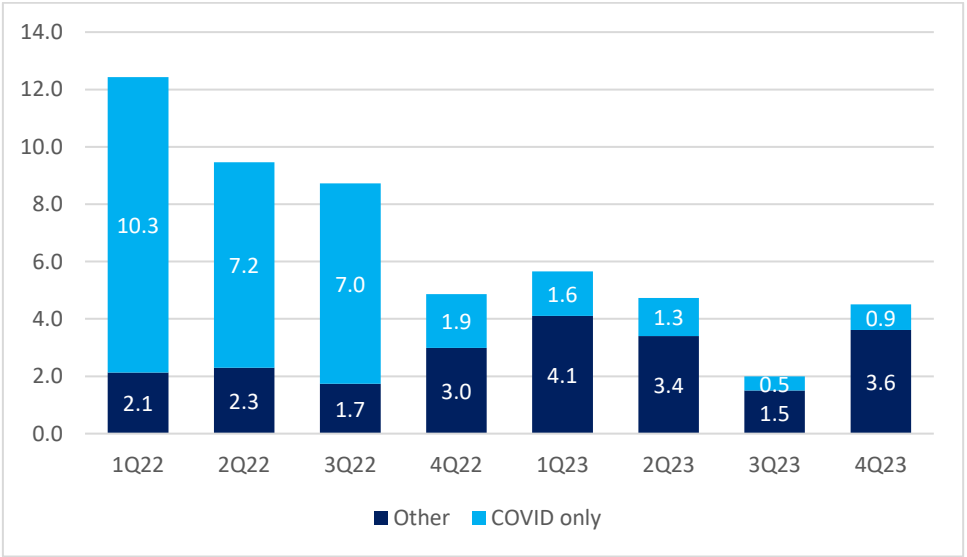


Figure 2: COVID only vs Syndromic test kit sales by quarter (A$m)



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

"As we indicated at the beginning of the quarter, we have seen a lift in local sales with the commencement of the Australian 'flu season. As with previous years, we expect this momentum to continue into Q1 FY24. However, the key focus for Genetic Signatures this quarter has been on the completion and submission of the 510(k) application to the US FDA for our EasyScreen™ Gastrointestinal Parasite Detection Kit. This kit has been specifically designed to address a key clinical need in the US market. As a result, we are expecting it has the potential to secure a significant share of this market. The US is the largest, single market for molecular diagnostic testing and is estimated to represent approximately 40% of sales by value worldwide.

We have also continued clinical development work on our second product for the US market which provides a syndromic test for the most common respiratory pathogens. Our **3base®** *technology is particularly well suited to this application as it is inherently tolerant of the genetic changes that occur with emergence of new strains and variants each season. This trial is progressing well and remains on track for completion by the end of CY2023*" **said Genetic Signatures CEO, Dr John Melki**.

A key focus for this quarter has been the completion of our application to secure US clearance of Genetic Signatures' Gastrointestinal Parasite Detection Kit. The product is highly differentiated with a number of novel targets. The final data verification process has now been completed and the final reports finalised for an imminent submission.

Once the 510(k) application is submitted for the *EasyScreen*™ Gastrointestinal Parasite Detection Kit, Genetic Signatures will commence work with a limited number of carefully selected, pre-qualified customer experience sites in the US to begin evaluating the Kit. Once this application has been approved by the FDA, Genetic Signatures expects many of these customer experience sites will become initial customers for the *EasyScreen*™ Gastrointestinal Parasite Detection Kit. Reimbursement for the test will be covered by an existing CPT code, the Company expects to commence commercial sales shortly after FDA clearance.

As mentioned in the activities statement for the December quarter, Genetic Signatures has commenced clinical testing of the second **3base®** product for the US market and is progressing as planned with over 80% of the patients recruited. This product is a syndromic test designed to detect the most common respiratory infections, including SARS-CoV-2. The **3base®** technology is particularly well-suited for the detection of seasonal viral pathogens as the tests are more resilient and efficient than traditional PCR at accommodating the genetic changes that occur with the emergence of new strains. The Company currently expects to complete the clinical testing of its *EasyScreen™ Essentials Respiratory Detection Kit* for the US market during H2 CY2023 with an application for clearance expected to be submitted in H1 CY2024.During the quarter, Genetic Signatures appointed two new distributors to market its **3base®** in the Middle East. Integrated Gulf Biosystems (IGB) has been appointed as exclusive distributor for United Arab Emirates, the Kingdom of Saudi Arabia, Bahrain and Qatar. IGB is a leading distributor of Life Science and Clinical Genomics Solutions in the Middle East where it distributes products for global life science companies including Thermofisher Scientific, Hamilton, Molecular Devices and others. For the Israel market, Genetic Signatures has appointed Almog Diagnostic where it has established relationships with the Diagnostics and Cell Therapy departments in all hospitals and community labs in Israel. *"In our continuous growth we always seek for the next 'big thing', cutting-edge technologies, that we can bring to the Israeli market. We strongly believe that our new collaboration with Genetic Signatures, the* ***3base®*** *syndromic multiplex testing solutions, and the coming sample-to-result automation, can make a change in the diagnostic market."* ***Nitsan Levi, VP New Technologies and Implementation.***

Both IGB and Almog have expertise in molecular diagnostic products, engineers and sales to support Genetic Signatures' products in these markets. By joining forces with experienced and well-connected partners like IGB and Almog Diagnostic, Genetic Signatures is better poised to make a significant impact in the diagnostic market in the region. This collaboration will bring Genetic Signatures' innovative **3base®**syndromic solutions for infectious diseases to the Middle East, resulting in increased brand visibility and sales in the region

Last quarter, Genetic Signatures reported that its initial prototype of the Next Generation sample to result instrument had completed a number of test runs which provided positive results, even with low levels of target material. During this quarter Genetic Signatures commenced work on the next phase of development and is on track to complete the construction of its alpha unit working prototype in February 2024 in line with the timeline for this project. The Next Generation sample to result instrument will automate laboratory processes to enable highly scalable testing involving different targets at the same time, reducing costs and laboratory space with a single testing instrument.

Research and development (R&D) work also 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.

Corporate

As at 30 June 2023 the company had $16.3 million cash at bank. Genetic Signatures recorded net operating cash outflows of $3.3 million during the quarter which included receipts from customers of $3.5 million. Net investing cash outflows of $1.9 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 the infrastructure to ensure the Company has a strong presence and capacity to meet demand once product registrations are completed. This has included hiring additional sales, marketing and support personnel, investing in new clinical trials, undertaking increased marketing activities in target jurisdictions, and continuing product development. Payments of fees to Directors, including the CEO, were $228,000 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 June 2023

Consolidated 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	3,466	19,098
1.2	Payments for		
	(a) research and development	(1,701)	(5,136)
	(b) product manufacturing and operating costs	(376)	(6,642)
	(c) advertising and marketing	(531)	(972)
	(d) leased assets	(215)	(697)
	(e) staff costs	(3,669)	(12,441)
	(f) administration, corporate and other costs	(454)	(5,845)
1.3	Dividends received (see note 3)		
1.4	Interest received	161	565
1.5	Interest and other costs of finance paid	-	(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**	**(3,319)**	**(12,071)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(692)	(2,313)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
	(d) investments		
	(e) intellectual property	(1,246)	(6,161)
	(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**	**(1,938)**	**(8,474)**

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	-	11
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	(1)
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	(1)	(33)
3.10	**Net cash from / (used in) financing activities**	**(1)**	**(23)**

Consolidated 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	21,627	36,897
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,319)	(12,071)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,938)	(8,474)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(1)	(23)
4.5	Effect of movement in exchange rates on cash held	(20)	20
4.6	**Cash and cash equivalents at end of period**	**16,349**	**16,349**

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	6,235	6,513
5.2	Call deposits	10,114	15,114
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)**	**16,349**	**21,627**

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	228
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)	(3,319)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	16,349
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	16,349
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	4.9

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 July 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.