Genetic Signatures

ASX Announcement 28 April 2023

Quarterly Activities Report and Appendix 4C

HIGHLIGHTS

- Quarterly sales of $2 million; down 58% from preceding quarter, consistent with the decline in COVID diagnostic sales experienced across the industry
- Cash receipts of $3.9 million during the quarter, closing cash balance $21.6 million
- All studies for the Enteric Protozoan Detection Kit have now been completed with independent verification of the data currently being finalised prior to submission of the 510(k) application expected in the coming weeks
- Clinical testing of second product, the *EasyScreen™ Essentials Respiratory Detection Kit*, is 50% complete and is expected to conclude in 2H CY2023
- Initial working prototype of Next Generation, sample-to-result instrument performing well in first test runs

Genetic Signatures Limited (ASX: GSS) recorded sales of $2 million (unaudited) for the third quarter of FY2023, down 58% from the preceding quarter, reflecting the seasonally lower demand for syndromic respiratory testing during the Australian summer period, and in line with decline in COVID diagnostic sales experienced across the industry. Non-COVID-only sales were $1.5 million coming from syndromic testing for respiratory conditions in addition to gastroenteric infections and other tests within the **3base®** product portfolio. Approximately 22% of sales were from non-US international markets.

Figure 1: GSS Quarterly revenue (A$m)

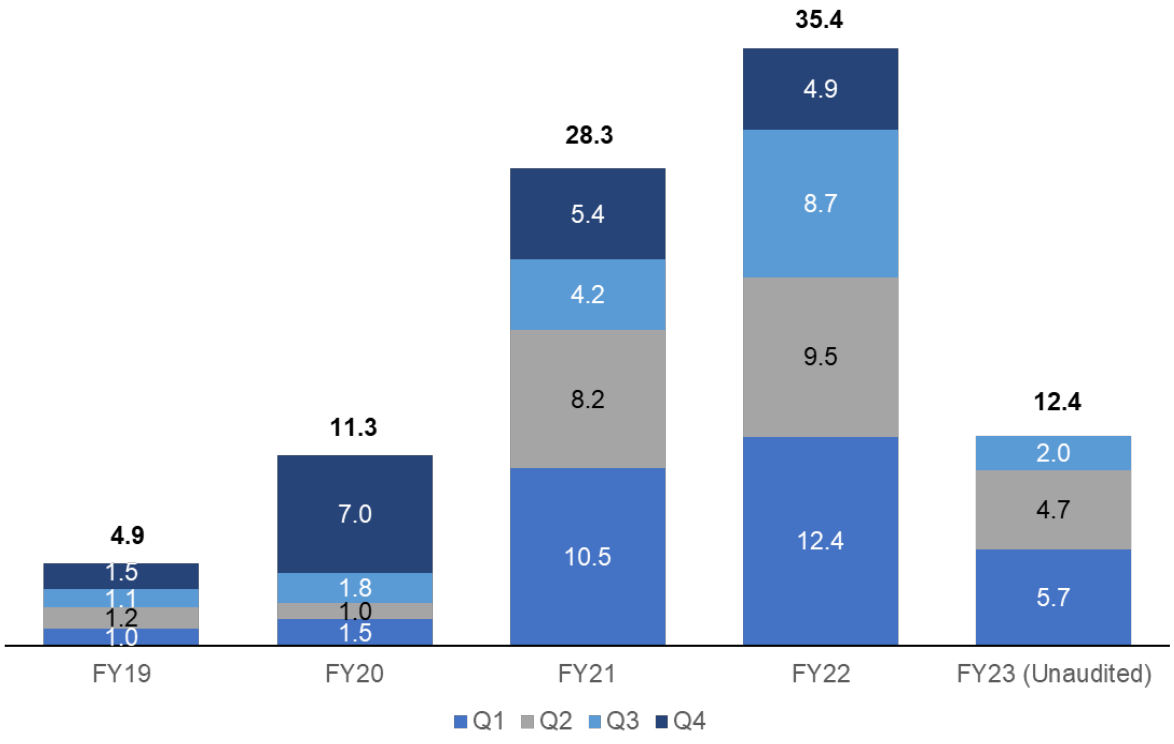
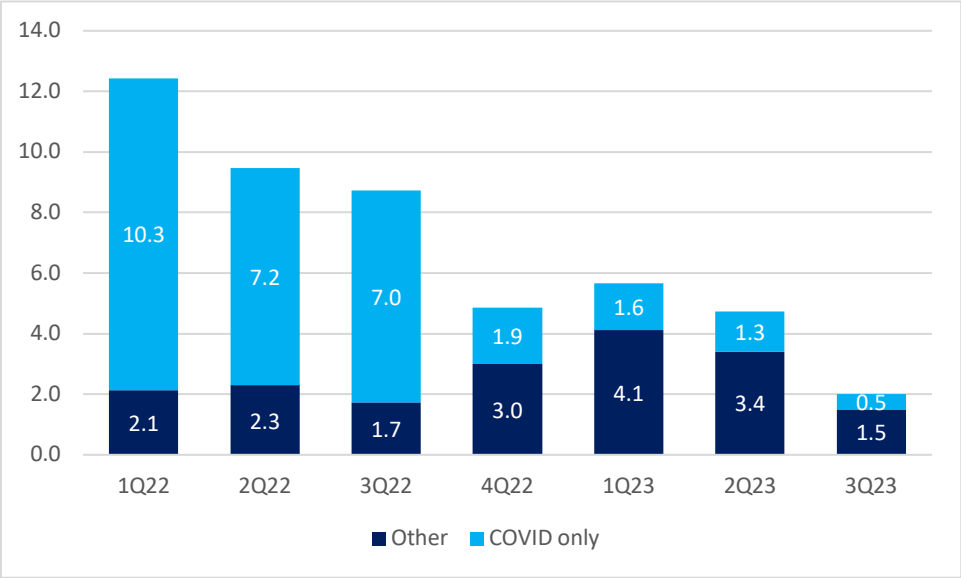


Figure 2: COVID only vs Syndromic test kit sales by quarter (A$m)



Genetic Signatures has continued to generate sales from its portfolio of *EasyScreen*™ kits that simplify multi-pathogen syndromic molecular testing through the use of the company's proprietary **3base**® technology." *In line with our expectations, sales declined this quarter reflecting the seasonally lower demand for syndromic respiratory testing during the Australian summer period and prior to the commencement of sales of our first product in the US market. While it is still early, we have seen a lift in local sales as we enter the Australian 'flu season with over $1 million in sales already recorded in the first month of Q4 FY23. This is a particularly exciting time for Genetic Signatures as we are on the cusp of achieving a significant milestone with the submission our first application for the regulatory clearance of a product using* **3base**® *technology for the US market. The US is the largest, single market for molecular diagnostic testing and is estimated to represent approximately 40% of sales by value worldwide. Our* EasyScreen™ Enteric Protozoan Diagnostic 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.*

We have also commenced 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 much more tolerant of the genetic changes that occur with emergence of new strains and variants each season. Many of the molecular tests for SARS-CoV-2 are provided under the Emergency Use Authorisation linked to the Public Health Emergency in the US, which is set to conclude in May 2023. The design of the panel used in our* EasyScreen™ Essentials Respiratory Detection Kit *has been guided by input from key US clinicians and will provide one of the few molecular syndromic testing panels that can detect multiple strains of SAR-CoV-2. Having syndromic respiratory products cleared in both Australia and the US will also reduce our exposure to seasonality in the sales of these products*" **said Genetic Signatures CEO, Dr John Melki**.

A key focus for this quarter was completion of the studies to support US clearance of Genetic Signature's Enteric Protozoan Diagnostic Kit and we are now awaiting final, independent verification of the data from the 1,500 sample clinical trial which is required for the 510(k) application to the FDA. These studies were successfully completed during April and the final data, once verified, will be incorporated into the 510(k) application that is currently being prepared. Genetic Signatures expects to submit this application to the FDA in the next few weeks. In addition to being the first **3base**® product

being reviewed for clearance by the FDA, for this application the Company had to develop in-house tests for tests in the Enteric Protozoan Diagnostic Kit where existing predicate tests were not available.

In preparation for the anticipated commercial launch of Genetic Signatures' **3base®** technology in the US, which is expected to be spearheaded by the EasyScreen™ Enteric Protozoan Diagnostic Kit, the Company held a focus group with seven Key Opinion Leaders (KOLs) in the US. The KOLs provided valuable feedback on the **3base®** technology including the attractiveness of having common PCR test conditions, suggestions around future test offerings, and the format and user interface of Genetic Signatures Next Generation sample-to-result instrument. The Company is also starting to work with a limited number of carefully selected, pre-qualified sites which may be initial adopters of the Enteric Protozoan Diagnostic Kit once it is cleared by the FDA.

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 50% of the patient samples already recruited. This product is a syndromic test designed to detect the most common respiratory infections, including the SARS-CoV-2 virus. The **3base®** technology is particularly well-suited for the detection of seasonal viral pathogens as the tests are more resilient in that they are better able than traditional PCR to accommodate the genetic changes that occur with the emergence of new strains than traditional PCR. Currently there is only one multi-pathogen molecular respiratory product that has been cleared by the FDA that includes SAR-CoV-2 (the BioFire® Repiratory 2.1 Panel). A recent meta-analysis of over 17,000 subjects across 27 different studies was published in a peer-reviewed journal and reported that use of syndromic PCR tests for respiratory viruses can reduce the time to result by 24 hours leading to shorter hospital stays and improvements in infection control management. 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.

A milestone was achieved in the development of the Next Generation, sample-to-result instrument last quarter which provided a working prototype to test **3base™** chemistry on all integrated sub-systems. During this quarter and in preparation for commencing the next phase of development, a number of test runs were performed on the working prototype which provided positive results, even with low levels of target material.

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 31 March 2023 the company had $21.6 million cash at bank. Genetic Signatures recorded net operating cash outflows of $3.4 million during the quarter which included receipts from customers of $3.9 million. Net investing cash outflows of $1.8 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 $236,000 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	31 March 2023

Consolidated 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	3,867	15,632
1.2	Payments for		
	(a) research and development	(1,337)	(3,435)
	(b) product manufacturing and operating costs	(2,329)	(6,266)
	(c) advertising and marketing	(100)	(441)
	(d) leased assets	(144)	(482)
	(e) staff costs	(3,037)	(8,772)
	(f) administration, corporate and other costs	(478)	(5,391)
1.3	Dividends received (see note 3)		
1.4	Interest received	152	404
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**	**(3,406)**	**(8,752)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	149	(1,621)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
	(d) investments		
	(e) intellectual property	(1,957)	(4,915)
	(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**	**(1,808)**	**(6,536)**

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	-	(32)
3.10	**Net cash from / (used in) financing activities**	**-**	**(22)**

Consolidated 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	26,810	36,897
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,406)	(8,752)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,808)	(6,536)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	(22)
4.5	Effect of movement in exchange rates on cash held	31	40
4.6	**Cash and cash equivalents at end of period**	**21,627**	**21,627**

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	6,513	11,495
5.2	Call deposits	15,114	15,315
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)**	**21,627**	**26,810**

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	239
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)	(3,406)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	21,627
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	21,627
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	6

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: 28 April 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.