Genetic Signatures

ASX Announcement 30 January 2023

Quarterly Activities Report and Appendix 4C

Highlights

- Quarterly sales of $4.7 million; down 12% from preceding quarter
- Non-COVID sales up 49% on pcp, up 350% from same quarter pre-covid (Q2FY20), reflecting growth of underlying business
- Cash receipts of $3.9 million during the quarter, closing cash balance $26.8 million
- Clinical trial for intended second US **3base®** product started
- Completed work on Phase 1 of the development program for high throughput instrument
- Established subsidiary in Germany to provide support for European sales and marketing effort

Genetic Signatures Limited (ASX: GSS) recorded sales of $4.7 million (unaudited) for the second quarter of FY2023. In line with expectations, sales were lower than the previous corresponding quarter (pcp) as a result of health authorities significantly scaling back molecular testing programs for SARS-CoV-2. Encouragingly though, non-COVID related sales were $3.4 million, up 49% from the pcp as customers transition from COVID only testing to broader syndromic testing for respiratory conditions, gastroenteric infections or other tests within the **3base®** product portfolio. Non-COVID specific sales are also up 350% from same quarter pre-covid (Q2FY20), reflecting the greater number of active customer sites and increased testing volumes at these laboratories. Approximately 7% of sales were from international markets.

Figure 1: GSS Quarterly revenue (A$m)

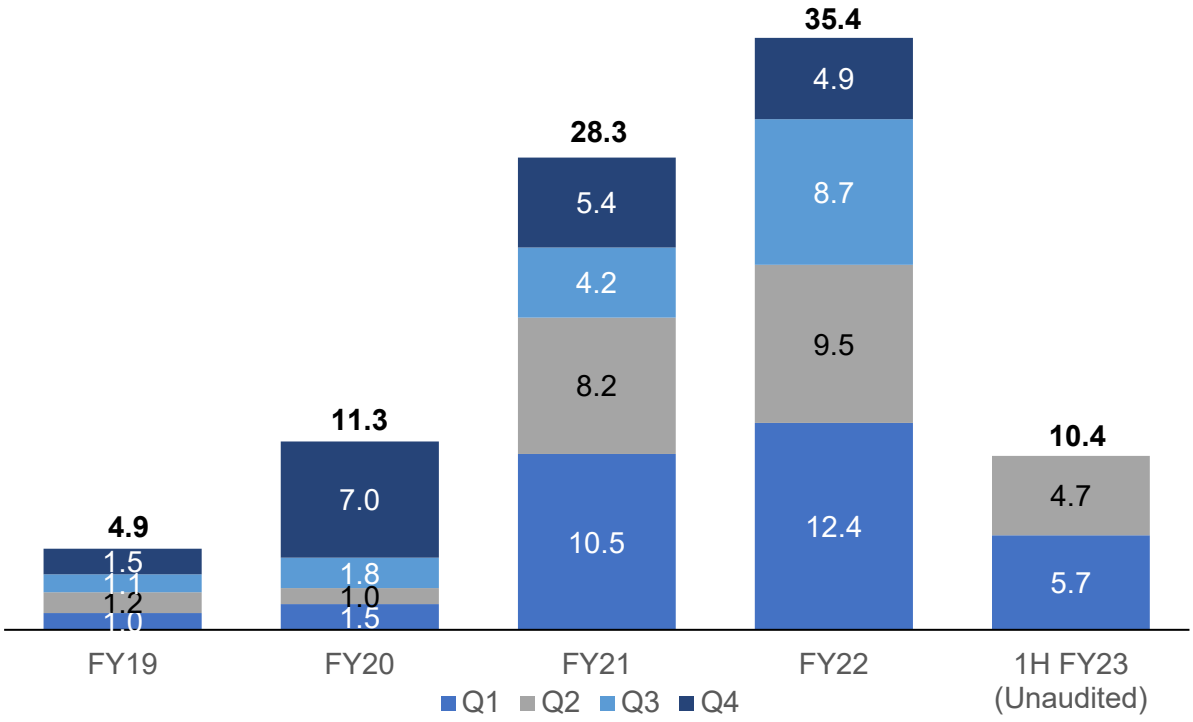
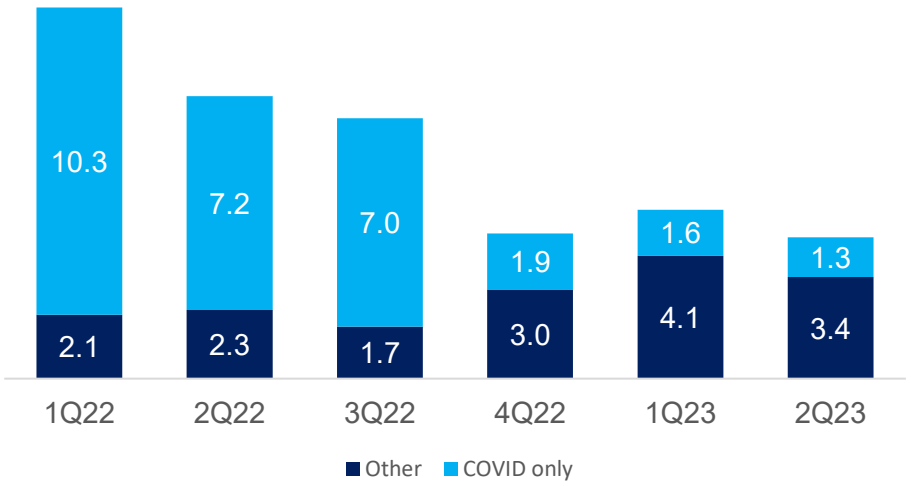


Figure 2: COVID vs Non-COVID revenue



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

"*With the expected decline in pathogen-specific molecular testing for SARS-CoV-2, it is very pleasing to see the strong momentum that is building across our product portfolio. We believe this will continue to provide long-term, durable growth for the Company. For respiratory infections, the market has increasingly shifted to multi-pathogen syndromic testing and this has certainly been reflected in the composition of our sales mix. Our* **3base®** *technology is highly relevant for syndromic testing approaches as it is less impacted by the emergence of new strains which is becoming a recognised limitation for most molecular test formats. In addition to ongoing work on the development of new* **3base®** *syndromic test products, two key elements of our growth strategy are the expansion of our international sales base and the development of a high-throughput, sample-to-result instrument. During the quarter, we made good progress on both of these with the establishment of a subsidiary in Germany to provide sales and marketing support for our European customers, commencement of work on the clinical trial for our second US product, and completion of the first phase of development of our dedicated* ***3base®*** *instruments for use in high-volume molecular pathology settings*" **said Genetic Signatures CEO, Dr John Melki.**

Following completion of recruitment for the clinical trial to support the 510(k) application for Genetic Signature's Enteric Protozoan Diagnostic Kit, Genetic Signatures has to independently confirm the results for the 1,500 clinical samples collected using commercially available tests or with in-house developed tests where commercially available predicate tests are not available. A final study shall commence shortly (following Institutional Review Board (IRB) approval) after which all studies will be complete. Genetic Signatures can then finish its 510(k) application and submit to the FDA, which is expected before the end of April 2023. The Company also initiated its first clinical trial site to support an application for regulatory clearance for a second **3base®** product for the US market.

During the quarter, Genetic Signatures registered a European subsidiary in Germany which will provide support for its European sales and marketing effort. A number of European sites initially adopted the **3base®** technology to assist with testing for SARS-CoV-2 during the pandemic. Following this experience, many of these customers are now either evaluating or have started to purchase **3base®** syndromic kits for other indications. The European subsidiary has been established to provide sales, marketing and technical support for these customers.

Genetic Signatures has now completed the first of four phases of its program to develop a fully-automated, high-throughput, sample-to-result instrument specifically designed for **3base®** technology. This program will now move into the development of a working prototype prior to building the commercial instrument. The design, requirements, and specifications for this instrument has been informed by extensive customer research which highlighted the attractiveness of a fully-automated, high-throughput, sample-to-result instrument for high-volume sites wanting to routinely adopt **3base®** technology as part of their molecular testing offering.

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 December 2022 the company had $26.8 million cash at bank. Genetic Signatures recorded cash outflows of $5.6 million in the quarter, including receipts from customers of $3.9 million. $2.6 million was attributable to capitalised costs associated with the development of the Next Generation Instrument ($1.4 million), other IP development and investments in equipment for placement at customer or clinical trial sites. Genetic Signatures 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 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 December 2022

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	3,917	11,764
1.2	Payments for		
	(a) research and development	(1,019)	(2,098)
	(b) product manufacturing and operating costs	(1,961)	(3,937)
	(c) advertising and marketing	(168)	(340)
	(d) leased assets	(189)	(338)
	(e) staff costs	(2,542)	(5,735)
	(f) administration, corporate and other costs	(1,261)	(4,913)
1.3	Dividends received (see note 3)		
1.4	Interest received	246	252
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**	**(2,977)**	**(5,346)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(929)	(1,769)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(d) investments		
	(e) intellectual property	(1,713)	(2,959)
	(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**	**(2,642)**	**(4,728)**

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	11
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1)	(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**	**10**	**(22)**

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	32,419	36,897
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,977)	(5,346)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(2,642)	(4,728)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	10	(22)
4.5	Effect of movement in exchange rates on cash held	-	9
4.6	**Cash and cash equivalents at end of period**	**26,810**	**26,810**

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	11,495	7,419
5.2	Call deposits	15,315	25,000
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)**	**26,810**	**32,419**

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	236
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)	(2,977)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	26,810
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	26,810
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	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: 30 January 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.