Genetic Signatures

ASX Announcement 21 January 2022

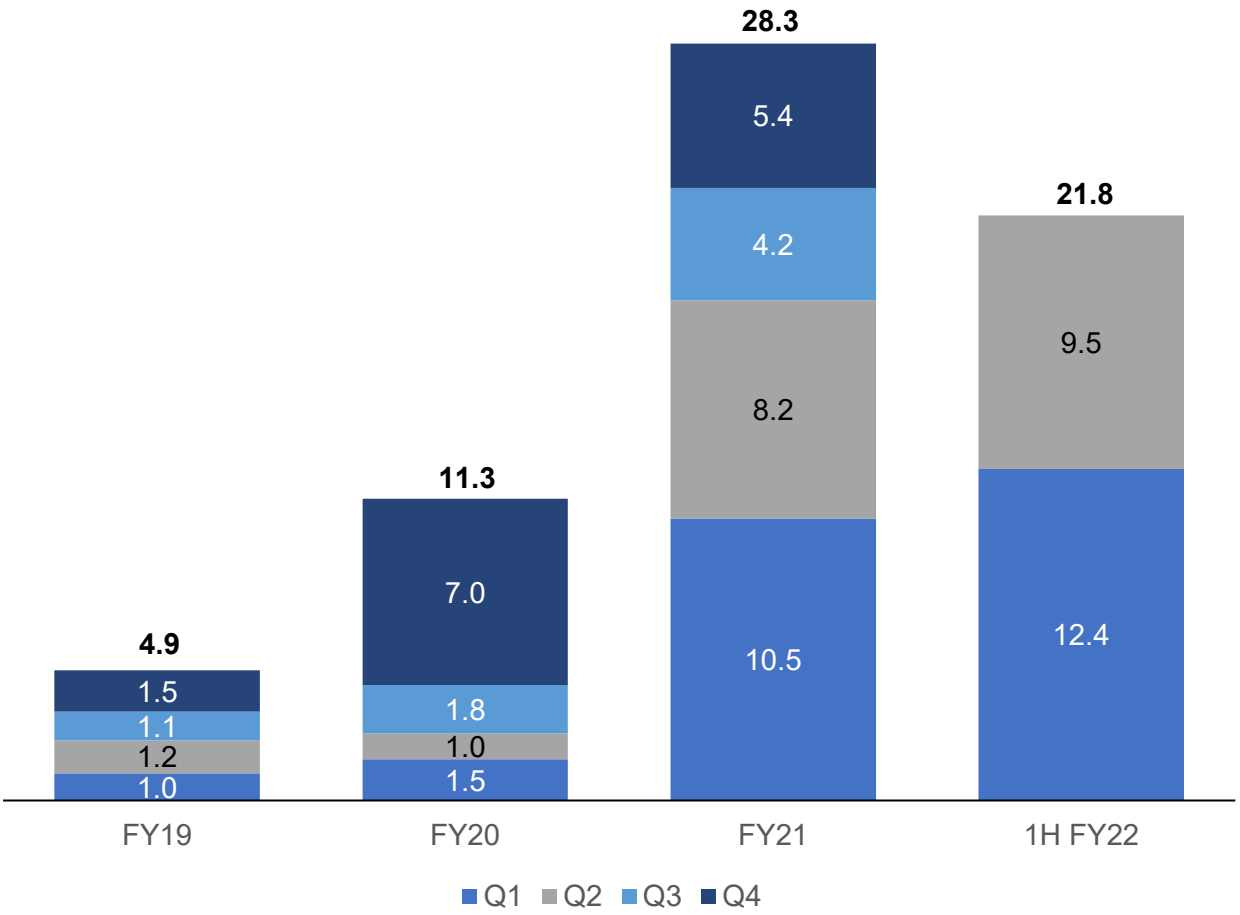
Quarterly Activities Report and Appendix 4C

Highlights

- Quarterly sales of $9.5 million, up 17% on pcp
- $21.8 million half year sales, 16% increase on pcp
- *EasyScreen*™ SARS-CoV-2 Detection Kit registered with TGA for saliva samples, and confirmed to be able to detect all variants of concern
- Growing global awareness of Genetic Signatures' **3base**® technology and full *EasyScreen*™ menu
- Clinical trials continue for the Enteric Protozoan Detection Kit FDA product clearance (510k) application
- $37.5 million cash and no debt

Genetic Signatures Limited (ASX: GSS) recorded strong quarterly sales of $9.5 million, a 17% increase on 2Q FY21. The total sales for 1H FY22 was $21.8 million (unaudited), 16% higher than 1H FY21. Receipts from customers of $12.1m was a quarterly record.

Figure 1: GSS Qtrly revenue (A$m)



Genetic Signatures CEO, Dr John Melki said, *"The discovery of the Omicron variant saw a surge in PCR testing, which has led to continued and strong demand for our **3base**® EasyScreen™ SARS-CoV-2 Detection Kits. With the substantial scale-up of the company's manufacturing capacity and uplift in our company's capabilities, Genetic Signatures is well placed to meet present and ongoing global customer demand, and to date we have been able to fulfil all purchase orders.*

The company continues to place value on collaborating closely with customers to obtain feedback on our products, workflows, and support. The development of our SARS-CoV-2 Variant Detection Kit, as well as the development of a Saliva-based protocol, is a testament to this collaborative approach and the Genetic Signatures team in acting quickly to meet new challenges and demands.

*The pandemic has stressed the need to adopt fast and accurate diagnostic techniques, and molecular PCR technologies have now proven their superiority. We are confident Genetic Signatures' **3Base**® technology will see increasing demand in laboratories globally far beyond COVID-19 testing."*

Sales in Australia for the quarter were strong again with SARS-CoV-2 testing continuing to be a driver of volume. Testing numbers contracted early in the quarter after a stellar performance in 1Q FY22 but picked up dramatically again in December after infection rates rose with the Omicron variant outbreak. This has continued into the new year. Enteric test kit sales are tracking at pre-pandemic levels.

There was a trend of slower rates of SARS-CoV-2 testing in the first quarter of FY22 in Europe, however testing volumes increased in the 2nd quarter and this may continue as Omicron cases rise, and we are already seeing evidence of this from our testing sites. European contribution to sales was 10% of the total in 2Q FY22.

The European sales team is actively engaged with current and potential customers to promote the broader range of **3base®** *EasyScreen*™ detection kits, and the first order from a second European customer of the Enteric Protozoan Detection Kits was received during the quarter. Other sites are concluding internal trials with the view of adopting the enteric tests also.

The US region was disappointing with no revenue recorded in the quarter. This is attributed largely to both reductions in testing numbers in the USA coupled with easing of supply chain constraints from the customers' primary suppliers. This meant that secondary testing methodologies implemented to supplement or ensure capacity was no longer required. Genetic Signatures has enhanced its sales team over the last 6 months and the team has been charged with establishing a ready market for the **3base®** *EasyScreen*™ Enteric Protozoan product once it clears FDA, building relationships with KOL's, and identifying other revenue opportunities.

As awareness of Genetic Signatures and its **3base**® technology continues to grow globally alongside its SARS-CoV-2 Detection Kit, interest continues to extend to other *EasyScreen*™ products. Laboratories in Europe, and by extension the USA, which were previously slow to adopt new technologies, represent promising new avenues of revenue for the company beyond COVID-19.

SARS-CoV-2 Update

Following detection of the new highly transmissible SARS-CoV-2 Omicron variant at the beginning of December, Genetic Signatures announced that its **3base®** *EasyScreen*™ SARS-CoV-2 Variant Detection Kit could detect the new strain and all known variants. The surge in local SARS-CoV-2 strongly contributed to revenue for the quarter, and the demand has continued into the current quarter.

Emergence of the new variant presented an opportunity for laboratories to differentiate Omicron and Delta variants prior to sequencing to prioritise suspected Omicron patient samples for genomic sequencing and epidemiological studies. The company collaborated with customers to develop the **3base®** *EasyScreen*™ SARS-CoV-2 Variant Detection Kit, which is being offered for research use.

At the National Reference Laboratory conference in October 2021 Genetic Signatures' Senior Principal Research Scientist, Dr Rohan Baker, presented results that showed the use of saliva swabs for COVID-19 testing were as good as, if not better than, nasopharyngeal swabs when using the **3base**® methodology. In December a South Africa study[1] demonstrated that Omicron could be more effectively

detected via saliva swabs than nasal swabs in PCR tests. This was due to the higher viral RNA load in saliva as compared to nasal samples. This was different to previous variants, which were more reliably detected by nasal swabs. At the beginning of January, the company announced that the Therapeutic Goods Administration (TGA) registered its *EasyScreen*™ SARS-CoV-2 Detection Kit for saliva samples. Some of Genetic Signatures' local customers have already adopted the new protocol and further laboratories are expected to follow.

As PCR testing will likely continue to play a major role in pandemic control policies, Genetic Signatures will continue to work in collaboration with its customers to develop and improve its products to provide the most effective and highest quality tests.

Enteric Protozoan FDA Progress

Clinical trials continue for the company's US FDA product clearance (510k) application, which requires Genetic Signatures to submit data from three clinical sites and a minimum of 1,500 patient samples. The completion of the trials was unfortunately delayed as laboratories had trouble sourcing adequate numbers of samples or lacked capacity to process samples due to COVID-19. Expectations are for these trials to complete recruitment by the end of the current quarter.

Genetic Signatures is targeting 40% of the available Enteric Protozoan testing market within five years of launch, with potential for up to US$88 million revenue per annum from the US.

Corporate

As at 30 December 2021, the company has $37.5 million cash at bank. The Group recorded cash inflows of $4.5 million during the quarter, and $7.4 million for 1H FY22. This is the fourth quarter in the last six that Genetic Signatures has reported positive cashflows. Payments of fees to directors, including the CEO, were $213,000 for the quarter and are included in 1.2(e) – staff costs of the Appendix 4C.

Capital Management Plan

Over the next two years, COVID-19 permitting, Genetic Signatures will invest its cash in various high value additive projects that will see increased expenditure offsetting positive cashflows. GSS has embarked on development of a next generation sample to result instrument which has progressed through the initial concept and design phases and is ready to transition to the next phase. The project is expected to cost $10-$12m over this period.

The USA represents the largest molecular diagnostics market in the world, but there are strict criteria governed by US FDA to meet before products may be sold. Costs can be significant to satisfy these criteria including engaging consultants and undertaking clinical trials in the USA. Genetic Signatures estimates an expenditure of up to $2.0m per product and is aiming to advance three or more of its current products through this process commencing this year.

Additionally, the Group has been increasing its headcount and will continue to employ more people, particularly overseas in sales, field support, regulatory and clinical roles. R&D activity will continue on current and new, as yet undisclosed, products and technologies. The launch of the new platform and products will also make demands on working capital.

– 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 2021

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	12,084	22,424
1.2	Payments for		
	(a) research and development	(1,054)	(1,903)
	(b) product manufacturing and operating costs	(1,423)	(2,880)
	(c) advertising and marketing	(50)	(92)
	(d) leased assets	(61)	(120)
	(e) staff costs	(2,362)	(4,754)
	(f) administration, corporate and other costs	(2,375)	(4,877)
1.3	Dividends received (see note 3)		
1.4	Interest received	80	88
1.5	Interest and other costs of finance paid	(4)	(9)
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**	**4,835**	**7,877**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(252)	(280)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
	(d) investments		
	(e) intellectual property	(93)	(157)
	(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**	**(345)**	**(437)**

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	65	116
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1)	(3)
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	(91)	(180)
3.10	**Net cash from / (used in) financing activities**	**(27)**	**(67)**

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	33,038	30,121
4.2	Net cash from / (used in) operating activities (item 1.9 above)	4,835	7,877
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(345)	(437)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(27)	(67)
4.5	Effect of movement in exchange rates on cash held	(5)	2
4.6	**Cash and cash equivalents at end of period**	**37,496**	**37,496**

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	12,323	7,936
5.2	Call deposits	25,173	25,102
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)**	**37,496**	**33,038**

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	213
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)	4,835
8.2	Cash and cash equivalents at quarter end (Item 4.6)	37,496
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	37,496
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	N/a

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: 21 January 2022

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.