Genetic Signatures

ASX Announcement 29 July 2021

Quarterly Activities Report and Appendix 4C

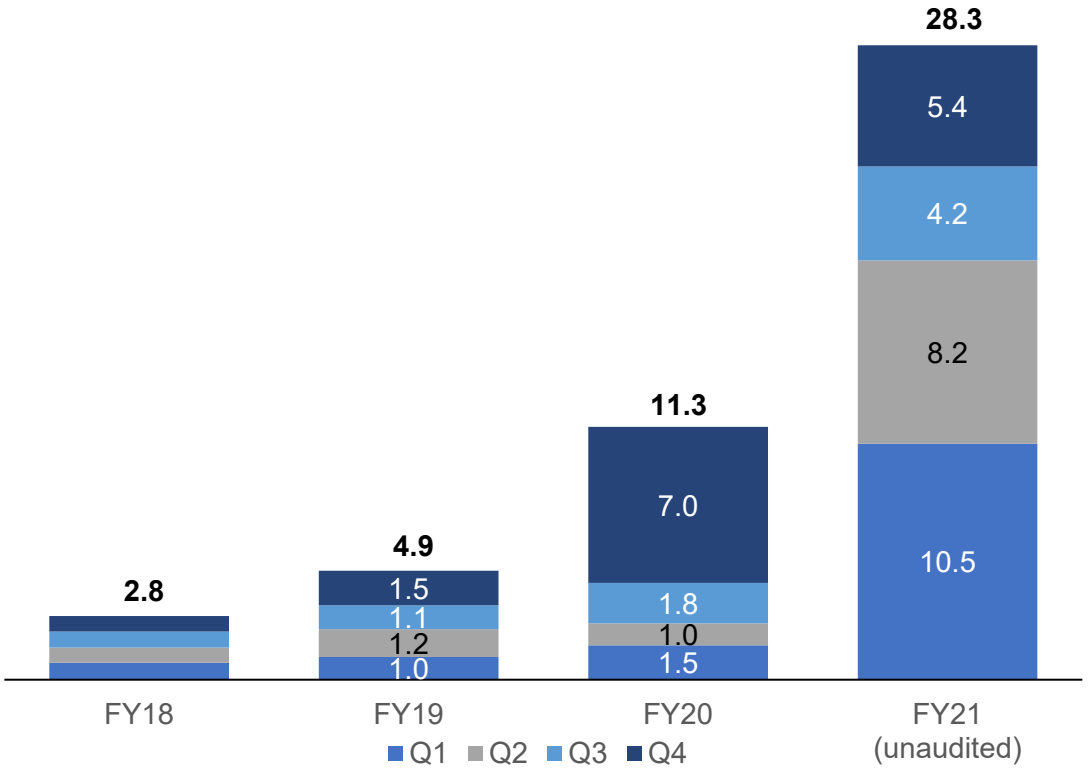
Highlights

- Sales revenue for June quarter of $5.4 million, up 27% on March 2021 quarter
- Full-year sales revenue (unaudited) of $28.3 million, up 151% on FY20
- International sales revenue a record 21% of total revenue in FY21, up from 10% of total revenue in FY20
- Receipts from customers in 4Q FY21 was $5.1 million
- Cash balance at 30 June $30.1 million and no debt
- Current quarter off to very strong start, with sales orders received in July exceeding $4.0 million to date

Genetic Signatures Limited (ASX: GSS) today provided an update on operating activities for the quarter ended 30 June 2021 as well as a summary of unaudited revenue for the quarter and the 12 months ended 30 June 2021.

The business achieved a record result in FY21 with sales of $28.3 million, a 151% increase over FY20. $5.4 million sales were booked during 4Q FY21, 27% higher than 3Q21. Receipts from customers increased to $5.1 million from the previous quarter's $4.6 million.

Figure 1: GSS Qtrly revenue (A$m)



Genetic Signatures CEO, Dr John Melki said, *"The pandemic and strong demand for our unique Australian diagnostic technology, continued to drive Genetic Signatures' revenue in the June quarter. This has necessitated a significant uplift in our company's capabilities base, as we have had to scale-up our manufacturing capacity substantially to meet the increase in customer demand worldwide.*

"As shareholders would expect, we continued in the quarter to leverage the market access we have gained through the pandemic in our key target markets in Europe and the US to increase customer knowledge of our unique platform and our capabilities across our suite of product groups.

"Trading in the current quarter gives us a high level of confidence in how FY22 might pan out. To date, sales orders received in July exceed $4.0 million, though future revenue will be influenced by outbreaks and the various authorities' responses to them."

Quarterly revenue continued to be largely attributed to demand for the company's EasyScreen™ SARS-CoV-2 Detection Kit (the coronavirus that causes COVID-19). The appearance of new variants of SARS-CoV-2, particularly the Delta variant, has been an increasing focus of concern, and testing activity, in the recent quarter. While this is beneficial to GSS as our front-line assays can identify Delta (and all other known new variants of SARS-CoV-2), the context is a decline in the amount of COVID-19 testing in the developed world as vaccine rollouts gather pace.

Regional updates

Australia

Australia continues to represent the largest share of income for GSS. Sales were boosted by the unfortunate recurrence of outbreaks of COVID-19 in New South Wales and Victoria, which are our two largest markets; and the resultant lockdowns, which in turn have led to extensive testing for SARS-CoV-2. The Company was successful securing its first laboratory in Queensland during the quarter. The site has been initiated and placed their first order in July.

Europe, Middle East and Africa (EMEA)

Sales in the region were equivalent to the previous corresponding period excluding instrument sales, driven by the EasyScreen™ SARS-CoV-2 Detection Kit. Additionally, we have regulatory clearances already in place for our respiratory, enteric, sexually transmitted infection (STI) and antibiotic resistance detection kits in Europe. Encouragingly, discussions are underway with customers regarding adoption of some of these tests. Part of the transformative effect of FY21 is that the COVID-19 pandemic has led to GSS securing its first consistent customers in Europe, leading to sales levels that are almost 27 times what they were just two years ago.

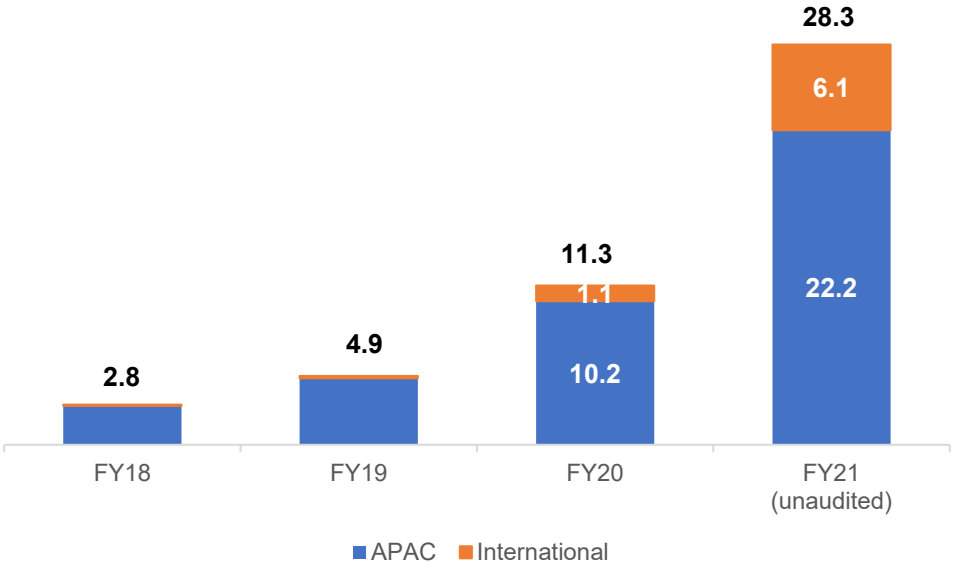
However, the seasonality factor of Europe being in summer during the June quarter also detracts from our business in this market at this time. To some extent this is offset by the fact that we now have consistent repeat purchases from European customers.

Americas

US sales for 4Q21 reflect the reduced COVID-19 testing volumes across the US and the focus by authorities on alternative solutions such as point-of-care tests.

The US and Europe together account for 75% of global testing for infectious diseases and we have an expanding footprint in these markets. We have increased our manufacturing capacity to meet demand through automation and increased staffing and have now sold kits in all our major target markets – US, Europe and Australia.

Figure 2: GSS FY revenue from operations by region (A$m)



Commercialisation update

Progress continued during the quarter on the FDA submission for the EasyScreen™ Enteric Protozoan Detection Kit, with the first clinical trial site nearing completion of their data collection. The second site is underway, and the third site is nearing initiation. The FDA requires data from three independent sites.

As mentioned in the Shareholder Newsletter, released on 30 June 2021, the Enteric Protozoan Detection Kit is a major plank in our strategy to expand the company's markets. Our product is a significant advance on the capability of current molecular tests, which are limited in the number of enteric protozoan pathogens they can detect. In contrast, our EasyScreen™ Enteric Protozoan Detection Kit can detect eight of the most common protozoa in a single sample without a loss of accuracy or processing speed. Once we attain FDA clearance, we feel justified in aiming to win up to 40% of the enteric protozoan testing market within five years.

The Shareholder Newsletter also referenced the many R&D projects at various stages. Of particular note is the development of our new next-generation "sample-to-result" instrument, specifically designed for 3base™. We have conducted initial project scoping and design work with the assistance of external consultants, and this work is progressing.

Likewise, development work continued in the quarter on the three new product groups in our product pipeline, namely the rapid multiplexed measles, mumps and rubella assay; the Tick-borne disease (pathogen) assay; and the test for the presence of Dermatophytes, which cause infections of the skin, hair and nails. All three programs are at different stages of the development process. All three represent new approaches to unmet needs; we are heartened by the progress in each; and we see very good market opportunities for them.

Corporate update

As at 30 June 2021, the company held $30.1 million in cash, with no debt. For the quarter, the operating cash outflow improved to $502,000, compared to $3.4 million outflow in 3Q21. Cumulatively, operating cash flow for FY21 was a positive $3.7 million offset by purchases of instrumentation both for customer sites and to expand manufacturing capabilities, resulting in a cash outflow of $1.0 million.

Research and development costs for the quarter were higher than previous quarters due to US clinical trials. However, product manufacturing and operating costs decreased considerably. This reflects a reduction in the inventory balance, which peaked in the March quarter: GSS had stocked-up to meet customers' needs and are now using that stock to supply customers. Payments of fees to directors, including the CEO, were $208,000 for the quarter and are included in 1.2(e) – staff costs of the Appendix 4C.

The business remains well-capitalised to trade through this uncertain period, while assessing any opportunities to add value.

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For further information, see our website (www.geneticsignatures.com) or contact us:

Dr John Melki
Chief Executive Officer
john.melki@geneticsignatures.com

Peter Manley
Chief Financial Officer
peter.manley@geneticsignatures.com

T: +61 (0)2 9870 7580

Announcement authorised by Genetic Signatures' Board of Directors

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 2021

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	5,116	30,030
1.2	Payments for		
	(a) research and development	(1,034)	(2,761)
	(b) product manufacturing and operating costs	(405)	(14,504)
	(c) advertising and marketing	(60)	(100)
	(d) leased assets	(65)	(189)
	(e) staff costs	(2,514)	(8,595)
	(f) administration, corporate and other costs	(1,543)	(2,977)
1.3	Dividends received (see note 3)		
1.4	Interest received	10	326
1.5	Interest and other costs of finance paid	(7)	(36)
1.6	Income taxes paid	-	
1.7	Government grants and tax incentives	-	2,554
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(502)**	**3,748**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(1,154)	(4,531)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
	(d) investments		
	(e) intellectual property		
	(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**	**(1,154)**	**(4,531)**

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	24	163
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(4)	(11)
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	(87)	(342)
3.10	**Net cash from / (used in) financing activities**	**(67)**	**(190)**

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	31,862	31,176
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(502)	3,748
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,154)	(4,531)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(67)	(190)
4.5	Effect of movement in exchange rates on cash held	(18)	(82)
4.6	**Cash and cash equivalents at end of period**	**30,121**	**30,121**

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	5,019	6,760
5.2	Call deposits	25,102	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)**	**30,121**	**31,862**

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	208
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)	(502)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	30,121
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	30,121
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	60

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: 29 July 2021

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.