Genetic Signatures

ASX Announcement 27 April 2021

Quarterly Activities Report and Appendix 4C

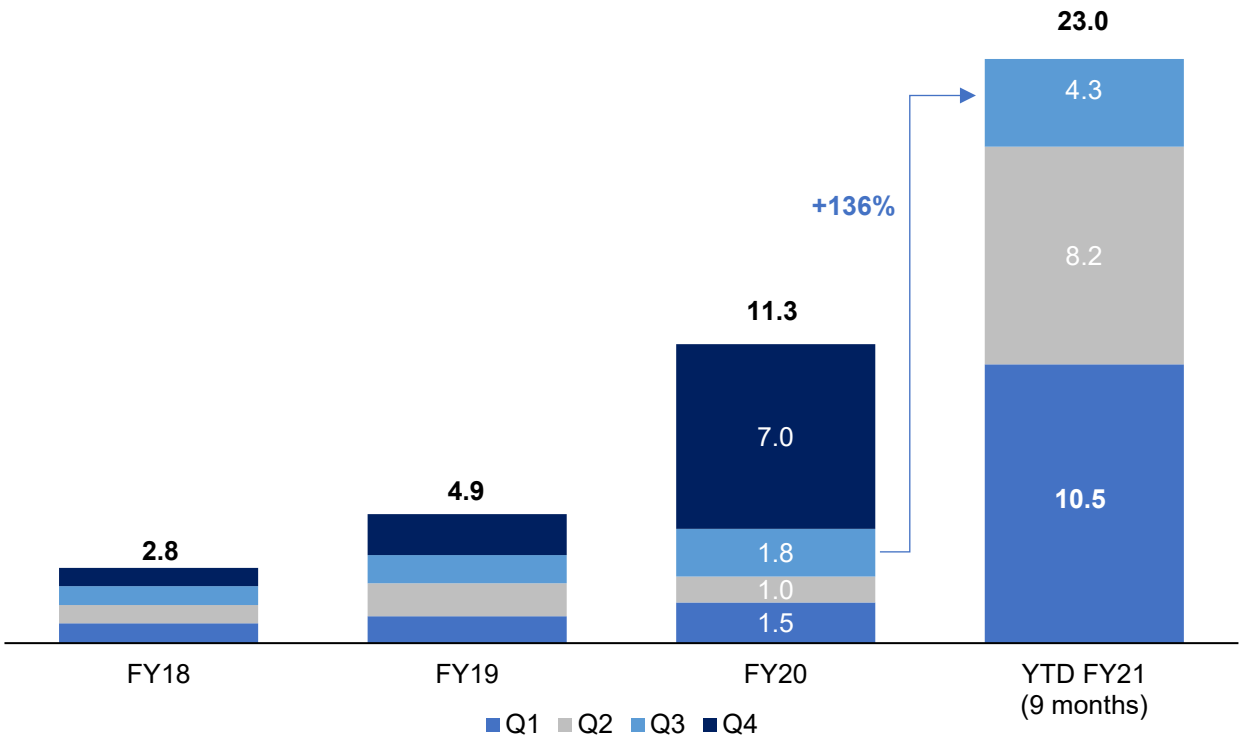
Highlights

- Year to date revenue now A$23.0m more than double FY2020 full year revenue, and quarterly revenue of $4.3m (increasing 136% on 3Q FY20)
- Receipts from customers were $4.6m during the quarter
- Continued growth in international sales representing 43% of total quarterly revenue, increasing from 24% in 2Q FY21
- CE-IVD registration for *EasyScreen™* STI / Genital Pathogen Detection Kit
- Application for FDA clearance of the EasyScreenTM Enteric Protozoan Detection Kit progressing
- Dr Neil Gunn appointed as non-executive Director – ex-Roche executive
- Cash balance at 31 March 2021 of $31.9m and no debt

Genetic Signatures Limited (ASX: GSS, "**Genetic Signatures**" or the "**Company**") is pleased to report on its activities for the quarter and provide a summary of unaudited revenue for the period ending 31 March 2021 ("3Q FY21").

Year to date sales revenue (unaudited) is $23.0m for the 9 months ended 31 March and is more than double full year revenue for FY2020. Sales for the 3Q FY21 was $4.3m, an increase of 136% on pcp (3Q FY20) and equivalent to all sales in the 9 months to 31 March 2020. Instrument sales contributed $0.3m to 3Q FY21 revenue.

Figure 1: GSS Quarterly revenue from FY18 to FY21 (A$m)



Genetic Signatures CEO, Dr John Melki commented:
"It is an exciting time for Genetic Signatures as SARS-CoV-2 has given our Company access to a number of new customers in the USA, Europe and Australia. These new customers, and other potential customers, are recognising that testing is now transitioning from SARS-CoV-2 only to screening for a broader range of respiratory pathogens, and this is where the true benefits of our 3base™ technology become apparent. Genetic Signatures is well positioned to take advantage of this opportunity with regulatory approvals already in place for Respiratory, Enteric, STI and antibiotic resistance detection kits in Europe and Australia, and SARS-CoV-2 kit along with ASR's available in the USA."

Commercialisation update

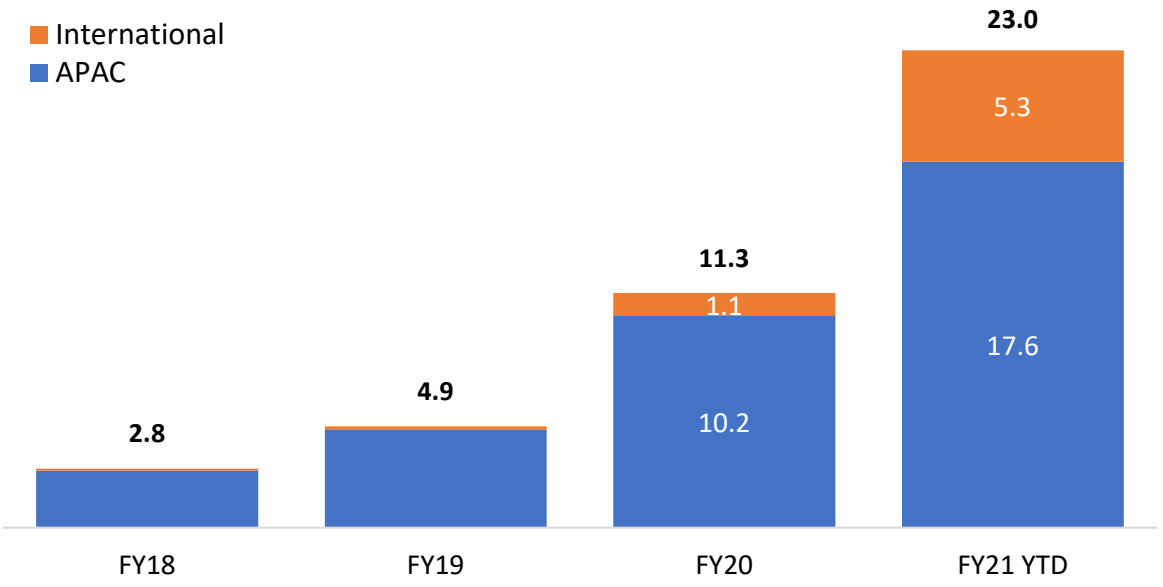
In the USA, Genetic Signatures continued to supply *EasyScreen™* SARS-CoV-2 Detection Kits to its customers. While some sites have taken longer than expected to increase their throughput, volumes are now starting to increase, and kits sales are expected to accelerate in 4Q FY21. Encouragingly, discussions are underway regarding expanding the testing menu to include extra targets such as Influenza and RSV which is beneficial to Genetic Signatures. *EasyScreen™* diagnostic tests use a syndromic approach to testing that allows throughput and accuracy to be maintained while many different pathogens are detected.

Kit sales to customers in Europe were consistent quarter to quarter. New customers who signed supply agreements in late December and through January faced installation delays beyond Genetic Signatures' control that has impacted timing of orders. These have now been resolved, with new sites validating our test kits, increased kit sales are expected in 4Q FY21. As with USA there is interest in expanding the testing menu for each sample.

Overall, international sales continue to represent a growing share of Genetic Signatures' revenue with sales in Europe and North America contributing 43% of 3Q FY21 revenue up from 24% in 2Q FY21.

In Australia, customers responded to the pre-Christmas outbreaks in both Sydney's Northern Beaches and in Victoria by pre-ordering large quantities of test kits in December in anticipation of continued high testing volumes. The combination of timing of purchases and reduced SARS-CoV-2 testing resulted in Australian sales being lower in 3Q FY21 vs. the previous two quarters. 4th quarter is traditionally the start of flu season in Australia, so broader respiratory testing would be expected to increase. Encouragingly testing for other pathogens, particularly gastroenteritis has increased demand for *EasyScreen™* Enteric Detection Kits.

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



Clinical trial work is continuing for the Genetic Signatures' application for US FDA clearance of the *EasyScreen™* Enteric Protozoan Detection Kit. The chosen US clinical sites' ability to complete the trials during the pandemic has improved and the Company is hopeful initial data collection will be completed from the first site and ready for analysis by the end of this quarter. The second site is being initiated and the third site is currently being prepared. The FDA require data from 3 independent sites.

CE-IVD registration was received during the quarter for the *EasyScreen™* STI / Genital Pathogen Detection Kit. This is the fourth product line that can be marketed in Europe and UK. An application was also submitted to TGA in late 2020 and the Company is awaiting final review. The global market for STI molecular testing is estimated at A$1.9bn per annum. Research and development work has not paused during the pandemic and a number of other projects are at different stages of the development cycle.

During the quarter Genetic Signatures commenced work on its own custom sample to result instrument which will uniquely run **3base™** assays. This will be a next generation product that will retain high throughput capacity and accuracy while significantly reducing user input. The project is expected to take 24 months to complete, and further updates will be provided in the near future.

Corporate update

Genetic Signatures had net operating cash outflows for 3Q FY21 of $3.4m, including receipts from customers of $4.6m. Gross payments from operating activities were slightly higher than 2Q FY21, and include further increases in inventory to ensure supplies to customers while global shortages in some areas still exist. Payments include fees/salary to Directors and related parties of $172,000 for the quarter and are part of *1.2(e) – staff costs* in the Appendix 4C. As at 31 March 2021, Genetic Signatures held $31.9m in cash, with no debt, and remains well capitalised.

Earlier this month Genetic Signatures welcomed Dr. Neil Gunn as a new non-executive Director. Dr. Gunn brings more than 30 years' experience and was until recently the President of Roche Sequencing Solutions. Prior to this he was the Vice President of Roche's Molecular Diagnostics global business.

Industry update

Since the beginning of the year M&A activity in the diagnostics sector has become very active, with six transaction being announced since March. Interest and understanding of molecular diagnostics has increased markedly as a result of SARS-CoV-2 testing.

Acquirer	Target	Date announced	Value (US$M)
Hologic	Diagenode SA	1-Mar	159
Thermo-Fisher	Mesa-BioTech	2-Mar	550
Bio-Techne	Asuragen	3-Mar	320
Roche	GenMark Diagnostics	15-Mar	1,800
Hologic	Mobidiag	8-Apr	795
DiaSorin	Luminex	13-Apr	1,800

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

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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	31 March 2021

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	4,580	24,913
1.2	Payments for		
	(a) research and development	(442)	(1,727)
	(b) product manufacturing and operating costs	(4,583)	(13,947)
	(c) advertising and marketing	11	(41)
	(d) leased assets	(32)	(124)
	(e) staff costs	(2,081)	(6,081)
	(f) administration, corporate and other costs	(889)	(1,461)
1.3	Dividends received (see note 3)		
1.4	Interest received	13	317
1.5	Interest and other costs of finance paid	(8)	(28)
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**	**(3,431)**	**4,375**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(968)	(3,526)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 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**	**(968)**	**(3,526)**

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	5	139
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(2)	(8)
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	(86)	(255)
3.10	**Net cash from / (used in) financing activities**	**(83)**	**(124)**

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	36,273	31,176
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,431)	4,375
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(968)	(3,526)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(83)	(124)
4.5	Effect of movement in exchange rates on cash held	71	(39)
4.6	**Cash and cash equivalents at end of period**	**31,862**	**31,862**

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	6,760	11,171
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)**	**31,862**	**36,273**

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	172
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)	(3,431)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	31,862
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	31,862
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	9.3

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: 27 April 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.