Genetic Signatures

ASX Announcement 22 October 2020

Quarterly Activities Report and Appendix 4C

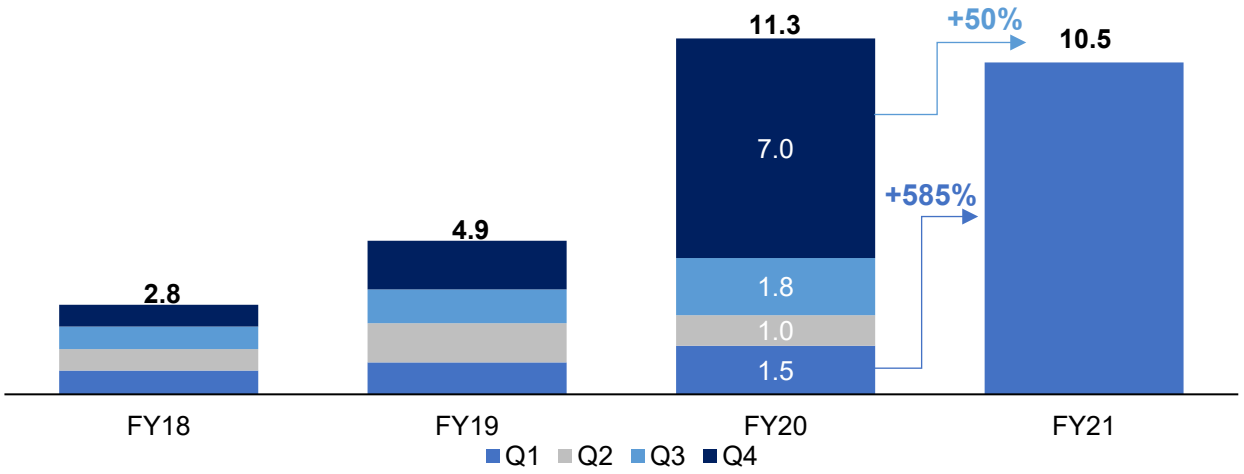
Highlights

- Record quarterly revenue of $10.5m, a 50% increase on the previous quarter of $7.0m and 585% increase on previous corresponding period of $1.5m
- Significant cashflow positive quarter, adding $3.4m in net cash from operating activities
- Receipts from customers were $11.4m during the quarter
- Sales from EMEA grew by more than 70% relative to the previous quarter, representing more than 15% of total quarterly revenue
- Permitted to supply *EasyScreen*™ SARS-CoV-2 Detection Kit to USA laboratories certified to perform high complexity testing under a Section IV.c exemption[1] following notification to FDA on the Company's intent to do so
- Clinical trial work has now recommenced for FDA clearance of the *EasyScreen*™ Enteric Protozoan Detection Kit
- Cash balance at 30 September 2020 of $33.2m 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 30 September 2020 ("1Q FY21").

Genetic Signatures achieved record revenue (unaudited) of $10.5m in 1Q FY21, a 50% increase on 4Q FY20 and a 585% increase on prior corresponding period, including instrument sales of $0.1m. Genetic Signatures was cashflow positive during the quarter, representing a significant milestone for the Company, adding $2.0m in total and $3.4m in net cash from operating activities.

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



[1] The FDA is permitting manufacturers that have or will submit an EUA for a SARS-CoV-2 test to supply their test prior to receiving the EUA. The FDA describes this marketing route in Section IV.C. of their Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)[2] Under the exemption the manufacturer must have validated the kit and is required to notify the FDA of their intent to supply the test. The use of the test is limited to laboratories that have been certified under CLIA (Clinical Laboratory Improvement Amendments) to perform high complexity testing and the laboratory is required to disclaim the status of the test on all results that are issued using the test. (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised)

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Genetic Signatures CEO, Dr John Melki commented:
"We are very pleased to report an exceptional quarter of revenue growth and positive cashflow. Strong demand from our customers following the second wave of COVID-19 infections, particularly in Victoria, contributed to the result. We are achieving good traction in EMEA, while our US sales team is actively pursuing COVID-19 opportunities under the recent FDA Emergency Use Authorisation (EUA) guidance.

As countries around the world battle to keep infection rates under control, extensive testing remains an essential tool for safely re-opening economies. We hope to see a successful reduction in the global number of active cases in the coming months, and we look forward to playing a role as governments encourage their populations to continue being tested to ensure further outbreaks are addressed early.

As Europe and North America approach the winter, the availability of respiratory pathogen tests will become increasingly important to ensure they are prepared for the potential outbreaks during the flu season."

Commercialisation update

Strong demand from Genetic Signatures customers in Australia continued throughout the quarter. SARS-CoV-2 testing in Victoria remained high as the state faced a second wave of COVID-19 infections. While the number of active cases in New South Wales was controlled, customer demand continued throughout the period. Enteric testing numbers have started to increase as a result of restrictions being eased.

Kit sales to customers in EMEA grew by more than 70% relative to 4Q FY20 and represented more than 15% of 1Q FY21 revenue. The Company signed a new distributor in Greece, where the number of active cases and tests performed each day has rapidly increased since August 2020.

Genetic Signatures is anticipating CE-IVD and TGA registration for its *EasyScreen™* STI / Genital Pathogen Detection Kit within the current quarter following applications earlier in the year. Research and development work continues on a number of other projects which are at different stages in the development cycle. This work is essential to ensure Genetic Signatures has a broad suite of products for customers.

In the USA Genetic Signatures *EasyScreen*™ SARS-CoV-2 Detection Kit can now be marketed under the Section IV.c exemption[1] provided by the FDA while the previously lodged Emergency Use Authorisation (EUA) application is assessed. Genetic Signatures is now permitted to supply *EasyScreen*™ SARS-CoV-2 Detection Kit to USA laboratories certified to perform high complexity testing.

Genetic Signatures is well placed to assist the pandemic globally due to our **3base™** technology, and the US sales team is actively following a number of sales leads. North America represents the largest diagnostics market globally and the Company has continued to build inventory of its kits to ensure it can supply new North American customer contracts, which could represent a step change in revenue.

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Clinical trial work has now recommenced for Genetic Signatures application for FDA clearance of the *EasyScreen™* Enteric Protozoan Detection Kit following the gradual easing of COVID-19 restrictions. The Company is targeting FDA submission for the *EasyScreen™* Enteric Protozoan Detection Kit in the new year, conditional upon clinical sites' ability to complete the trials with COVID-restrictions in place. The Company has also recently appointed a distributor in Canada to support the commercialisation of Genetic Signatures products in that region.

COVID-19 testing volumes globally remains fluid and therefore the predictability of future revenue is difficult and dependent on measures imposed by various governments, including quarantine, travel restrictions, testing strategies and reimbursement rates.

Corporate update

Genetic Signatures had net operating cash inflows for 1Q FY21 of $3.4m, including receipts from customers of $11.4m. Achieving a robust positive operating cashflow is a significant milestone for the Company. Gross payments from operating activities was on aggregate 17% lower than in 4Q FY20, largely as a result of reduced inventory purchases. Payments include fees/salary to Directors and related parties of $252,000 for the quarter and are part of *1.2(e) – staff costs* in the Appendix 4C. As at 30 September 2020, Genetic Signatures held $33.2m in cash, with no debt. The business remains well capitalised to trade through this uncertain period and the Company is expecting to receive an R&D tax refund of approximately $2.5m in 2Q FY21.

– END –

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

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Name of entity

GENETIC SIGNATURES LIMITED

ABN	**Quarter ended ("current quarter")**
30 095 913 205	30 September 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	11,394	11,394
1.2	Payments for		
	(a) research and development	(587)	(587)
	(b) product manufacturing and operating costs	(4,911)	(4,911)
	(c) advertising and marketing	(3)	(3)
	(d) leased assets	(35)	(35)
	(e) staff costs	(2,031)	(2,031)
	(f) administration and corporate costs	(395)	(395)
1.3	Dividends received (see note 3)		
1.4	Interest received	25	25
1.5	Interest and other costs of finance paid	(8)	(8)
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**	**3,449**	**3,449**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(1,320)	(1,320)
	(d) investments		

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
	(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**	**(1,320)**	**(1,320)**

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	29	29
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(2)	(2)
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	(84)	(84)
3.10	**Net cash from / (used in) financing activities**	**(57)**	**(57)**

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Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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	31,176	31,176
4.2	Net cash from / (used in) operating activities (item 1.9 above)	3,449	3,449
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(1,320)	(1,320)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(57)	(57)
4.5	Effect of movement in exchange rates on cash held	(13)	(13)
4.6	**Cash and cash equivalents at end of period**	**33,235**	**33,235**

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	18,235	16,176
5.2	Call deposits	15,000	15,000
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)**	**33,235**	**31,176**

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	252
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)	3,449
8.2	Cash and cash equivalents at quarter end (Item 4.6)	33,235
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	33,235
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.

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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: 22 October 2020

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.