Genetic Signatures

ASX Announcement 28 July 2020

Quarterly Activities Report and Appendix 4C to 30 June 2020

Highlights

- Record quarterly revenue (unaudited) of $7.0m, a 351% increase on pcp
- Unaudited sales for FY20 of $11.3m, up 131% on pcp
- Strong revenue growth boosted by demand for our COVID-19 tests
- Australian and European registration for the *EasyScreen™* SARS-CoV-2 Detection Kit
- FDA Emergency Use Authorisation (EUA) request submitted
- Cash at 30 June 2020 was $31.2m and no debt
- Added to the S&P / ASX All Ordinaries Index

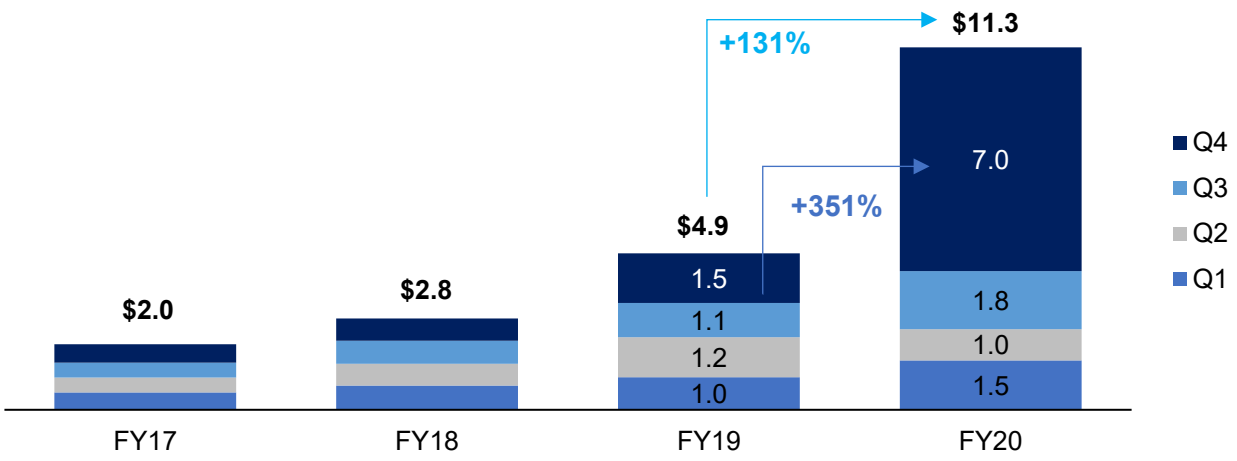
Genetic Signatures Limited (ASX: GSS) today provided an update on operating activities for the quarter ended 30 June 2020 as well as a summary of unaudited revenue for the quarter and the 12 months ended 30 June 2020.

The business achieved record revenue (unaudited) of $7.0m during 4Q FY20, a 351% increase on the prior corresponding period of $1.5m, and includes instrument sales of ~$1.0m.

Quarterly revenue growth was largely attributed to demand for the new *EasyScreen™* SARS-CoV-2 Detection Kit and increasing sales to customers in Australia and Europe. Unaudited revenue for the 12 months ended 30 June 2020 was $11.3m, which represents an increase of 131% on FY19.

Strong revenue growth driven by customer demand for *EasyScreen™* SARS-CoV-2 Detection Kits

Figure 1: GSS Quarterly revenue from FY17 to FY20 (A$m)



Commercialisation update and *EasyScreen™* SARS-CoV-2 launch

Australia and Europe

In April 2020, the Company received regulatory registrations for its *EasyScreen™* SARS-CoV-2 Detection Kit, allowing marketing of the test in Australia and Europe, as originally announced on April 1 and April 14.

Strong demand was evident from Genetic Signatures domestic customers, where it is being used both as a standalone test and in combination with the broader *EasyScreen™* Respiratory Pathogen Detection Kit, and this continues.

Orders have been received for both the kit and hardware from customers across Europe, with revenue from this region representing more than 13% of revenue in the quarter.

During the quarter, the Company also submitted formal applications to regulators in Europe and Australia for its *EasyScreen™* STI / Genital Pathogen Detection Kit. As previously announced, work is set to recommence on the *EasyScreen™* Flavivirus / Alphavirus Detection Kit applications for TGA and CE-IVD registrations when COVID-19 restrictions are lifted.

North America

In April 2020, Genetic Signatures submitted an Emergency Use Authorisation (EUA) application to the US Food and Drug Administration (FDA) for the *EasyScreen™* SARS-CoV-2 Detection Kit. The FDA has been overwhelmed with a high volume of applications while also dealing with restrictions on staffing due to the pandemic, which has led to delays in application clearances.

Receipt of the FDA EUA will allow Genetic Signatures to pursue direct sales to approved US laboratories in North America -- the largest molecular diagnostic market in the world.

Additionally, clinical trials are starting for the *EasyScreen™* Enteric Protozoan Detection Kit FDA submission.

Corporate update

Genetic Signatures had net operating cash outflows for 4Q FY20 of $4.8m, including receipts from customers of $4.8m. The difference between customer receipts and sales revenue reflects the timing of invoicing which occurred later in the quarter.

To meet current and anticipated customer demand, the business has dramatically increased its inventory holdings in comparison to prior periods including a considerable increase in automation instrumentation. This is reflected in cash usage. Payments of fees to directors, including the CEO, were $0.2m for the quarter and are included in *1.2(e) – staff costs* of the Appendix 4C. As at 30 June 2020, the Company held $31.2m in cash, with no debt. The business remains well capitalised to trade through this uncertain period, while assessing value-accretive opportunities.

During the reporting period, increased trading volumes and the rise in our market capitalization saw Genetic Signatures added to the S&P / ASX All Ordinaries Index following the quarterly rebalancing.

Genetic Signatures CEO, Dr John Melki said, “The pandemic and strong demand for our unique Australian diagnostic technology has helped drive a step change in revenue and accelerated the commercial rollout.

“Despite the challenging operating environment, the business has leveraged its internal capabilities and moved to successfully scale manufacturing capacity to meet the significant increase in customer demand worldwide.

“We continue to invest in building our distribution and customer networks to support future growth and to deliver shareholder value.

“Inclusion in the S&P / ASX All Ordinaries Index has helped bring our business and its global potential to the attention of a new wider group of investors and we look to the coming year with great confidence.”

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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	30 June 2020

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	4,751	8,816
1.2	Payments for		
	(a) research and development	(632)	(1,769)
	(b) product manufacturing and operating costs	(2,141)	(4,307)
	(c) advertising and marketing	(89)	(186)
	(d) leased assets	(9)	(33)
	(e) staff costs	(1,800)	(6,188)
	(f) other costs	(4,917)	(6,355)
1.3	Dividends received (see note 3)		
1.4	Interest received	32	129
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid		
1.7	Government grants and tax incentives	-	2,147
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(4,805)**	**(7,746)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) entities		
	(b) businesses		
	(c) property, plant and equipment	(3,175)	(4,098)

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**	**(3,175)**	**(4,098)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	38,718
3.2	Proceeds from issue of convertible debt securities		
3.3	Proceeds from exercise of options	48	158
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(4)	(1,892)
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	(107)	(298)
3.10	**Net cash from / (used in) financing activities**	**(63)**	**36,686**

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	39,163	6,312
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,805)	(7,746)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(3,175)	(4,098)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(63)	36,686
4.5	Effect of movement in exchange rates on cash held	56	22
4.6	**Cash and cash equivalents at end of period**	**31,176**	**31,176**

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	16,176	20,163
5.2	Term deposits	15,000	19,000
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)**	**31,176**	**39,163**

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	171
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

Directors fees & CEO salary are included under 1.2(e) – staff costs

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)	(4,805)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	31,176
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	31,176
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	6.5

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:

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: 28 July 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.