Genetic Signatures

Quarterly Activities Report - 31 December 2019

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 December 2019 ("2Q FY20").

Highlights

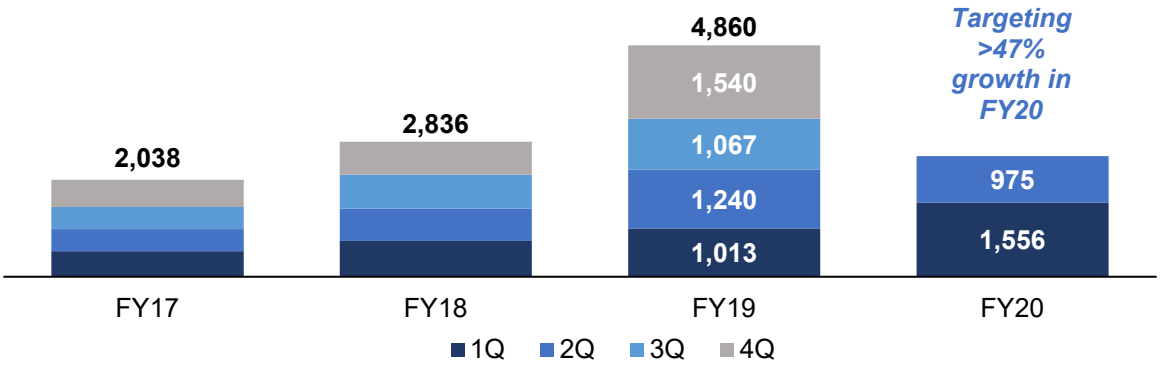
- **Quarterly net operating cash flows of $0.3m and half year net operating cash outflows of $0.9m (including the R&D tax refund).**
- **Quarterly revenue of A$1.0m (21% lower on pcp) and half year revenue of A$2.5m (up 12% on pcp)**
- **The Company remains optimistic that key accounts will convert in FY20 and drive strong revenue growth**
- **CE-IVD and TGA assessment and registration of EasyScreen™ STI / Genital Pathogen Detection Kit is on target for early 2020, followed by the Flavivirus / Alphavirus Detection Kit regulatory submission.**
- **FDA submission for the *EasyScreen™* Enteric Protozoan Detection Kit on track for mid-2020**
- **Received R&D tax incentive refund of A$2.1m**
- **Raised A$37.5m to accelerate global commercial expansion through to profitability, obtain further regulatory approvals and product development**
- **Cash balance at the close of the quarter of A$40.4m with no debt**
- **3base™ able to detect 2019-nCoV (Wuhan coronavirus)**

Genetic Signatures CEO, Dr. John Melki commented:

*"Genetic Signatures is well positioned to expand its customer base in FY20 with a number of trials nearing completion with potential customers and funding to execute its commercialisation strategy. This reporting quarter was lower than the prior corresponding period, though this was largely due to timing of orders. The interest and support received during the recent capital raising from new institutional investors, as well as the existing shareholders is an endorsement of Genetic Signatures' **3base™** technology and the global commercialisation strategy."*

Targeting new international customer wins in 2H FY20 to drive revenue growth

Figure 1: Genetic Signature's quarterly revenue (A$'000)



Genetic Signatures achieved 2Q FY20 revenue of A$1.0m, 21% lower than the prior corresponding period ("pcp") of A$1.2m (2Q FY19). Revenue for the 6 months ended 31 December 2019 ("1H FY20") was A$2.5m, which represents an increase of 12% on pcp (1H FY19). Sales performance between quarters can be impacted by timing of order receipt, and this has been the case with 2Q FY20, where orders have fallen either side of the reporting quarter. Despite this the Company has still reported growth over the half year compared to pcp.

Genetic Signatures is still forecasting growth for FY20 to exceed the 5-year historic CAGR of ~47%. This is derived from expectations that new contracts will be secured both overseas and locally in 2H FY20.

Executing global commercialisation strategy, targeting EMEA and North American markets

Genetic Signatures has made significant progress with prospective customers domestically and offshore, who are currently undertaking product trials. The sales teams have introduced new laboratories to the benefits of the **3base™** technology and planning is underway to commence new trials in 2H FY20.

Two new distributors were appointed in Spain and Benelux during the quarter with initial training underway. An additional salesperson has been recruited in the United Kingdom, and a replacement European Sales Director has also been hired (commencing February 2020) following the sad and unfortunate passing of the previous Head of Europe late last year.

A clinical trial is currently underway for the *EasyScreen™* STI / Genital Pathogen Detection Kit which will feed into the CE-IVD and TGA regulatory applications for this product. The European and Australian registration for the *EasyScreen™* STI / Genital Pathogen Detection Kit is expected within early 2020 pending regulatory agency processing time. This will be followed closely by submission of the *EasyScreen™* Flavivirus / Alphavirus Detection Kit, following results of a clinical evaluation scheduled for February.

The Company remains on track to lodge the FDA submission for the *EasyScreen™* Enteric Protozoan Detection Kit in mid-2020. Recruiting has started for extra sales personnel in USA in preparation for the launch of this product later in the year.

Genetic Signatures' *EasyScreen™* Respiratory Detection targets include an assay for pan-coronaviruses. The new strain that has originated from China, currently known as 2019-nCoV, can be identified without changes to the assay due to the unique capabilities of Genetic Signatures 3base™ technology. The Company is contacting various agencies to determine what interest may exist for the test.

The Company is also working towards expanding its product range through the development of new *EasyScreen*™ Detection Kits.

Focused on expanding industry awareness of its *EasyScreen™* brand

Genetic Signatures continued to focus on driving awareness of the benefits of its **3base™** technology, with an active presence at key global industry conferences. The Company attended two key global industry conferences in 2Q FY20:

- Exhibited at the Association for Molecular Pathology (AMP) 2019 Annual Meeting and Expo on 7-9 November 2019 in Baltimore MD, US. The event marked the 25th anniversary of AMP, representing a key event for global industry leaders in the molecular pathology industry.
- Exhibited at the Clinical Microbiological Infectious Symposium[1] on 5-7 December 2019 in Berlin, Germany. The event provided a valuable opportunity to showcase how **3base™** can improve laboratory workflow.

Scientific publications are an important means by which validation of new technologies, methodologies and discoveries are completed. This month, a journal article, *Validation of the Easyscreen™ flavivirus dengue alphavirus detection kit based on 3base amplification technology and its application to the 2016/17 Vanuatu dengue outbreak*[2] was published, and found that "the [3base] assays performed as well as, if not better than, other assays used in laboratories worldwide".

Corporate update

At 31 December 2019, the Company held A$40.4m in cash and cash equivalents, up from A$4.9m at 30 September 2019. Net operating cash inflows in 2Q FY20 were A$0.3m and included receipts from customers of A$1.3m and the research and development ("**R&D**") tax incentive of A$2.1m from the Australian Taxation Office, as disclosed in the attached Appendix 4C report. .

During the quarter, Genetic Signatures raised a total of A$37.5m, comprised of a A$35m placement ("Placement") to institutional and sophisticated investors across Australia and Asia and an oversubscribed A$2.5m share purchase plan ("SPP") from eligible shareholders on the same terms as the Placement. The funds raised enable Genetic Signatures to fund its global marketing and sales expansion in key international markets, obtain further regulatory product approvals, advance product development of new instrumentation and fund the Company through to profitability.

In November, Non-Executive Director, Mr. Phillip Isaacs retired from the Genetic Signatures Board, after more than 15 years of service. The Company thanks Mr. Isaacs for his service and significant contribution to Genetic Signatures. An international search for a new Non-Executive Director is currently underway.

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[1] English translation of conference titled 'Klinisch Mikrobiologisch Infektiologische Symposium' (KMIS)

[2] Garae C, Kalo K, Pakoa GJ, Baker R, Isaacs P, Millar DS (2020) Validation of the easyscreen flavivirus dengue alphavirus detection kit based on 3base amplification technology and its application to the 2016/17 Vanuatu dengue outbreak. PLoS ONE 15(1): e0227550. https://doi.org/10.1371/journal.pone.0227550

Upcoming activities

- Genetic Signatures has set itself a milestone to sign announcement worthy contracts in both EMEA and North American markets to underpin FY20 revenue growth
- CE-IVD submission and registration of *EasyScreen™* STI / Genital Pathogen Detection kits in Australia and Europe – targeting early 2020
- TGA submission of *EasyScreen™* STI / Genital and Flavivirus / Alphavirus Detection kits in Australia – targeting early 2020
- FDA submission for *EasyScreen™* Enteric Protozoan Detection Kit expected in mid-2020 with clearance anticipated approximately 90 days post submission
- Develop new kits to expand product portfolio

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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.

+Rule 4.7B

Appendix 4C

Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

Name of entity

GENETIC SIGNATURES LIMITED

ABN	**Quarter ended ("current quarter")**
30 095 913 205	31 December 2019

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	1,336	2,871
1.2	Payments for		
	(a) research and development	(458)	(707)
	(b) product manufacturing and operating costs	(574)	(907)
	(c) advertising and marketing	(18)	(137)
	(d) leased assets	(10)	(43)
	(e) staff costs	(1,423)	(2,741)
	(f) administration and corporate costs	(683)	(1,426)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	23	53
1.5	Interest and other costs of finance paid	(11)	(15)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	2,147	2,147
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**329**	**(905)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(393)	(512)
	(b) businesses (see item 10)		
	(c) investments		

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
	(d) intellectual property		
	(e) other non-current assets		
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment		
	(b) businesses (see item 10)		
	(c) investments		
	(d) intellectual property		
	(e) other non-current assets		
2.3	Cash flows from loans to other entities		
2.4	Dividends received (see note 3)		
2.5	Other (Security Deposit)		
2.6	**Net cash from / (used in) investing activities**	**(393)**	**(512)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of shares	37,500	37,513
3.2	Proceeds from issue of convertible notes		
3.3	Proceeds from exercise of share options		
3.4	Transaction costs related to issues of shares, convertible notes or options	(1,855)	(1,857)
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	Other (lease principal)	(63)	(105)
3.10	**Net cash from / (used in) financing activities**	**35,582**	**35,551**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of quarter/year to date	4,930	6,312
4.2	Net cash from / (used in) operating activities (item 1.9 above)	329	(905)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(393)	(512)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	35,582	35,551

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
4.5	Effect of movement in exchange rates on cash held	(7)	(5)
4.6	**Cash and cash equivalents at end of quarter**	**40,441**	**40,441**

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	21,624	1,130
5.2	Term deposits	18,817	3,800
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)**	**40,441**	**4,930**

6.	**Payments to directors of the entity and their associates**	**Current quarter $A'000**
6.1	Aggregate amount of payments to these parties included in item 1.2	224
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

Directors' fees and CEO salary

7.	**Payments to related entities of the entity and their associates**	**Current quarter $A'000**
7.1	Aggregate amount of payments to these parties included in item 1.2	
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	

7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

8.	**Financing facilities available** *Add notes as necessary for an understanding of the position*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
8.1	Loan facilities		
8.2	Credit standby arrangements		
8.3	Other (please specify)		

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

9.	**Estimated cash outflows for next quarter**	**$A'000**
9.1	Research and development	666
9.2	Product manufacturing and operating costs	689
9.3	Advertising and marketing	50
9.4	Leased assets	100
9.5	Staff costs	1,549
9.6	Administration and corporate costs	365
9.7	Other (provide details if material)	-
9.8	**Total estimated cash outflows**	**3,419**

10.	**Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)**	**Acquisitions**	**Disposals**
10.1	Name of entity	Not applicable	Not applicable
10.2	Place of incorporation or registration		
10.3	Consideration for acquisition or disposal		
10.4	Total net assets		
10.5	Nature of business		

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.

Sign here:  Date: 30 January 2020
Company Secretary

Print name: Peter Manley

Notes

1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
2. If this quarterly 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 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.