

Quarterly Activities Report - 31 December 2018

Genetic Signatures Limited (ASX: GSS, "Genetic Signatures" or the "Company") is pleased to report on its activities for the quarter ended 31 December 2018 ("2Q FY19").

Highlights

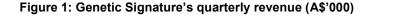
- Strong revenue growth of +83% on pcp to \$1.2m in 2Q FY19
- Cash receipts for the quarter of \$1.2m
- EasyScreen[™] Respiratory Pathogen Detection Kit received European (CE-IVD) registration and Australian (TGA) application submitted
- International expansion progressing with additional appointments of key European sales executives
- Appointment of highly experienced CFO in October 2018
- Strong balance sheet with cash of \$8.8m at 31 December 2018 with no debt

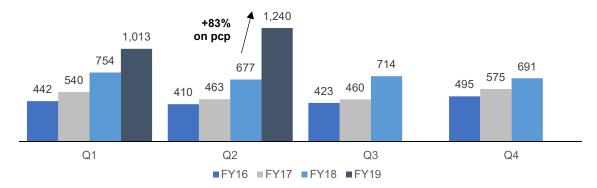
Genetic Signatures CEO, Dr. John Melki commented:

"2018 has been a year of significant progress for Genetic Signatures. Sales traction is building with continued strong quarterly revenue growth.

We are seeing increased interest in our EasyScreenTM products and are bolstering our international sales teams with recent additional European appointments. During the quarter we submitted both domestic and European approvals for our Respiratory Kit and were successful in having this kit CE/IVD-marked in December.

Sales update







Genetic Signatures again recorded impressive growth in 2Q FY19, with sales revenue of A\$1.2m, an increase of +83% over 2Q FY18. The Company is well positioned to continue executing its international commercialisation strategy leveraging the strong momentum of our domestic business.

Genetic Signatures continued to achieve quarterly revenue growth throughout 2018 and anticipates this trend will continue into 2019 as the Company progresses regulatory submissions of its pathogen detection kits, including those intended to detect sexually transmitted infections (STI) and Alphavirus / Flavivirus, in key regions.

International and Domestic sales update

Prior to the quarter, the Company announced a major new contract with a large Australian pathology service provider and launched two new products, the second generation $EasyScreen^{TM}$ Respiratory Pathogen Detection Kit and the Genetic Signatures Automation System (GS1-HT). Orders from this new customer have steadily increased, reflecting customer satisfaction and product validation.

Genetic Signatures' has also made significant operational progress internally and is continuing to bolster its European efforts with its expanding sales force in Europe. Recent appointments are expected to help drive increased European customer interest in the near-term.

Regulatory update

In December 2018, the Company achieved European registration (CE-IVD) for the *EasyScreenTM* Respiratory Pathogen Detection Kit, permitting sales across Europe. Australian registration (TGA) was submitted during the quarter and is expected to follow in the coming months. These regulatory approvals, in conjunction with the August 2018 signing of a large domestic customer of the Respiratory Kit positions the Company well to generate further interest in the kit both domestically and internationally.

During the quarter, Genetic Signatures continued to progress European and Australian applications for the *EasyScreenTM* STI / Genital and Flavivirus / Alphavirus Detection Kits with submissions anticipated in 1H CY19. Further, the Company is also in the early stages of developing additional kits to broaden the Company's portfolio.

Genetic Signatures' also continued the regulatory activity for its *EasyScreenTM* Enteric Protozoan Kit in the US, with FDA clearance anticipated in 2019. The US represents a significant market opportunity for the Company as it looks to continue executing on its US commercialisation strategy and focus on the ASR offering.



Conference update

Medical and industry conferences are an important means to drive positive exposure of Genetic Signatures $EasyScreen^{TM}$ brand and the benefits of **3baseTM** technology. Key events the Company exhibited and presented during the quarter include:

- NRL Molecular Diagnostic Workshop on 15-16 October 2018 in Melbourne
- Association for Molecular Pathology (AMP) Annual meeting on 1-3 November 2018 in San Antonio, Texas

Corporate update

An appointment of a highly experienced CFO, Peter Manley, was made in October 2018. Peter has extensive experience as a finance professional in the life sciences industry having served as CFO and company secretary for both AtCor Medical Holdings Limited (now Cardiex) and Sirtex Medical Ltd.

At 31 December 2018, the Company held \$8.8m in cash and cash equivalents which represents an increase of \$1.4m since 30 September. It includes receipts from customers in the September quarter of \$1.2m and a refund from the Australian Tax Office (ATO) under the R&D tax incentive program of \$2.6m, as disclosed in the attached Appendix 4C report.

Upcoming Activities

- Primary focus remains sales growth in both international and domestic markets
- Commencement of new product trials with customers in the US and EU in addition to progression of trials already underway
- Potential receipt of regulatory registration for *EasyScreen[™]* Respiratory Detection Kit in Australia
- Potential receipt of regulatory registration for *EasyScreen[™]* STI / Genital Pathogen and Flavivirus / Alphavirus Detection Kits in Australia and Europe
- Increasing presence in US market through additional sales of extended ASR range and participation at industry events
- Continue progress towards FDA listing with scientific validation and further clinical trials

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For further information, see our website (<u>www.geneticsignatures.com</u>) or contact us as below:

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Chief Executive Officer

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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**TM. 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*TM brand. Genetic Signatures' proprietary MDx **3base**TM 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

30 095 913 205

Quarter ended ("current quarter")

31 December 2018

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	1,236	2,302
1.2	Payments for		
	(a) research and development	(406)	(648)
	 (b) product manufacturing and operating costs 	(463)	(789)
	(c) advertising and marketing	(25)	(160)
	(d) leased assets	(51)	(139)
	(e) staff costs	(1,151)	(2,213)
	(f) administration and corporate costs	(312)	(907)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	88	92
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	2,561	2,561
1.8	Other (provide details if material)	-	
1.9	Net cash from / (used in) operating activities	1,476	99

2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(94)	(276)
	(b) businesses (see item 10)	-	-
	(c) investments	-	-

Appendix 4C Quarterly report for entities subject to Listing Rule 4.7B

Con	solidated 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	(94)	(276)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	-	-
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	52	52
3.4	Transaction costs related to issues of shares, convertible notes or options	(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	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	50	50

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	7,392	8,955
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,477	99
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(94)	(276)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	50	50

Appendix 40	С
Quarterly report for entities subject to Listing Rule 4.78	3

Con	solidated 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	(4)	(7)
4.6	Cash and cash equivalents at end of quarter	8,821	8,821

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	3,321	1,313
5.2	Call deposits	5,500	6,079
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)	8,821	7,392

6. Payments to directors of the entity and their associates

- 6.1 Aggregate amount of payments to these parties included in item 1.2
- 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

- 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

Current quarter \$A'000	
194	
-	

Current quarter \$A'000	
-	
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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)	_	-
0.4	Include below a description of each facil	ity above including the lander	interest rate and

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	(350)
9.2	Product manufacturing and operating costs	(308)
9.3	Advertising and marketing	(120)
9.4	Leased assets	(59)
9.5	Staff costs	(1,252)
9.6	Administration and corporate costs	(400)
9.7	Other (provide details if material)	-
9.8	Total estimated cash outflows	(2,489)

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.

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Company secretary

Date: 29 January 2019

Print name: Anna Sandham

Notes

- 1. The guarterly 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.
- Dividends received may be classified either as cash flows from operating 3. activities or cash flows from investing activities, depending on the accounting policy of the entity.