

# **Quarterly Activities Report - 30 June 2018**

Genetic Signatures Limited (ASX: GSS, "Genetic Signatures" or the "Company") is pleased to report on its activities for the guarter ended 30 June 2018 ("4Q FY18").

## **Highlights**

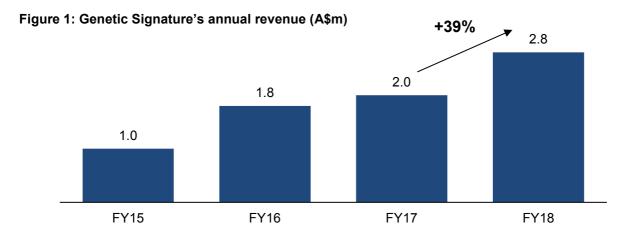
- +39% revenue growth to A\$2.8m for full year FY18
- +20% revenue growth on pcp to A\$691k in Q4 FY18
- Cash receipts of A\$510k in 4Q FY18
- First sales of ASR Kits in the USA, followed by repeat order in May 2018
- TGA registration received for EasyScreen<sup>™</sup> ESBL & CPO ('superbug')
   Detection Kit following CE-IVD registration in April 2018
- International expansion gaining momentum following recent regulatory approvals with advanced trials underway
- Late onset of domestic flu season expected to support 1Q FY19 revenue growth
- Strong balance sheet maintained with cash of A\$9.0m at 30 June 2018

#### Genetic Signatures CEO, Dr. John Melki commented:

"Progress over the last quarter has been especially pleasing, with strong revenue growth directly resulting from our targeted sales strategy and focus on product development. First sales in the USA and further regulatory approvals during the June quarter have paved the way for commercial expansion into international markets, with strong relationships maintained and repeat orders from existing customers."

"This quarter caps off a successful FY18 for Genetic Signatures and we are pleased to have achieved consistently strong revenue growth each quarter, ranging between 20-55% on pcp. Our focus for FY19 is to drive revenue growth through an increase in US and EU sales efforts, as well as support our domestic business which continues to deliver strong gains."

#### Sales update



# Genetic Signatures

Genetic Signatures achieved another year of strong revenue growth in FY18, with revenue of A\$2.8m, up +39% from FY17. Genetic Signatures is well positioned for continued revenue growth, with additional revenue streams expected following regulatory approval of the *EasyScreen*™ ESBL & CPO Detection Kit.

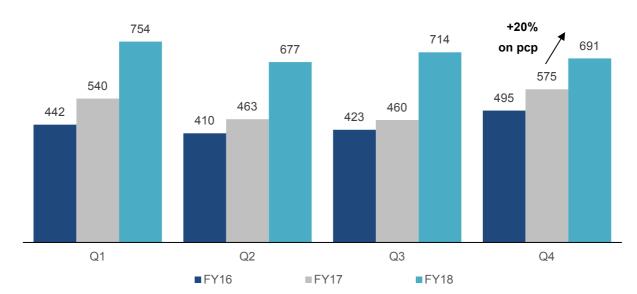


Figure 2: Genetic Signature's quarterly revenue (A\$m)

# International sales update

During the June quarter, Genetic Signatures continued to progress its international sales strategy with several achievements including:

- First sales order shipped to the USA of ASRs followed by a repeat order in May.
- Repeat orders to another US-based customer working in Kenya for the Respiratory and Flavivirus / Alphavirus Detection Kits
- European registration (CE-IVD) received for EasyScreen<sup>™</sup> ESBL & CPO Detection Kit
- Continued progress towards European and Australian submissions for regulatory approvals of EasyScreen<sup>TM</sup> Respiratory, STI / Genital and Flavivirus / Alphavirus Detection Kits, anticipated before the end of CY2018
- Validation of the ASR product with repeat orders out of the USA
- Patents granted for the 3base<sup>™</sup> Molecular Detection Assay in Canada, Israel and Malaysia throughout May and June in 2018



#### Conference and trial update

Trial results from a number of major Genetic Signatures trials were presented during the quarter. The trial results and conference participation continue to drive positive exposure of Genetic Signatures *EasyScreen<sup>TM</sup>* brand and the benefits of *3base<sup>TM</sup>* technology. The major presentations for the quarter included:

- "Evaluation of the EasyScreen<sup>TM</sup> CPO 3base real-time PCR assay for detection of carbapenemase genes directly from rectal swabs" presented at ECCMID (Spain, April 2018) with a summary of results presented at ASM 2018 (Brisbane, July 2018) and Molecular Microbiology Meeting (Sydney, April 2018)
- "Comparison of the performance of three different adenovirus quantitative PCR assays with ATCC reference strains and clinical samples" presented at the American Society for Microbiology (ASM) Clinical Virology Symposium on 6-9 May 2018 in Florida
- "Clinical Evaluation of the EasyScreen™ Enteric Viral Detection Kit" presented at 12th International Symposium on Molecular Diagnostics (ISMD2018) 31 May- 2 June 2018 in Graz, Austria

Attendance at key international industry conferences ensures Genetic Signatures is well positioned to capitalise on the growing MDx market, estimated to be worth US\$12bn by 2022.

## Regulatory update

During the June quarter, Genetic Signatures accelerated the *EasyScreen<sup>TM</sup>* ESBL & CPO Detection Kit clinical program due to increasing customer demand for rapid detection of hospital 'superbugs' or 'antibiotic resistant' pathogens. European regulatory registration (CE-IVD) of the *EasyScreen<sup>TM</sup>* ESBL & CPO Detection Kit was achieved in April 2018, with domestic registration (TGA) following shortly after in May 2018.

ESBL & CPO organisms have proven challenging to detect and are a significant global concern. Commercial release of the EasyScreenTM ESBL & CPO Detection Kit is expected to deliver more rapid results to assist clinicians in providing faster treatment to patients and ultimately saving lives.

Approval was accelerated due to increasing customer demand for rapid detection of hospital superbugs, demonstrating Genetic Signatures ability to recognize and effectively respond to customer demands.

In addition to achieving regulatory registration for the  $EasyScreen^{TM}$  ESBL & CPO Detection Kit, Genetic Signatures is working on securing regulatory registration for the  $EasyScreen^{TM}$  Respiratory, STI / Genital and Flavivirus / Alphavirus Kits in Australia and Europe.

The Company also have trials for the  $EasyScreen^{TM}$  Enteric range underway in the US and is anticipating FDA listing in 2019. Trials are continuing across a number of new products including ESBL & CPO in Q1 FY19.



#### Corporate update

Receipts from customers in the June quarter was A\$510k, as disclosed in the attached Appendix 4C report, was slightly lower than revenue for the same period (A\$691k) due to the timing of payment terms and several large orders being received late in the quarter.

At 30 June 2018, the Company held A\$9.0m in cash and cash equivalents, down from A\$10.6m at 31 March 2018.

#### **Upcoming Activities**

- Primary focus remains sales growth in domestic and international markets
- Commencement of new product trials with customers in the US and EU
- Potential receipt of regulatory registration for EasyScreen<sup>TM</sup> STI / Genital, Respiratory and Flavivirus / Alphavirus Detection Kits in Australia and Europe
- FDA listing progress with scientific validation and further clinical trials

- END -

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

Dr John Melki Chief Executive Officer john@geneticsignatures.com T: +61 (0)2 9870 7580

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**<sup>™</sup>. 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*<sup>™</sup> brand. Genetic Signatures' proprietary MDx **3base**<sup>™</sup> 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 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	30 June 2018

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	510	3,199
1.2	Payments for		
	(a) research and development	(373)	(2,143)
	(b) product manufacturing and operating costs	(269)	(940)
	(c) advertising and marketing	(92)	(354)
	(d) leased assets	(68)	(289)
	(e) staff costs	(1,001)	(3,597)
	(f) administration and corporate costs	(256)	(1,360)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	93	269
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	1,598
1.8	Other (provide details if material)	-	
1.9	Net cash from / (used in) operating activities	(1,456)	(3,617)

<sup>+</sup> See chapter 19 for defined terms

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(169)	(519)
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(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)	(8)	(63)
2.6	Net cash from / (used in) investing activities	(177)	(582)

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	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	-	-
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	-	-

+ See chapter 19 for defined terms

Con	solidated 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 quarter/year to date	10,610	13,193
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,456)	(3,617)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(177)	(582)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(7)	(24)
4.6	Cash and cash equivalents at end of quarter	8,970	8,970

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	962	605
5.2	Call deposits	8,008	10,005
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)	8,970	10,610

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	123
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-
6.3	6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2	

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		

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	(336)	
9.2	Product manufacturing and operating costs	(347)	
9.3	Advertising and marketing	(174)	
9.4	Leased assets	(136)	
9.5	Staff costs	(1,165)	
9.6	Administration and corporate costs	(151)	
9.7	Other (provide details if material)	-	
9.8	Total estimated cash outflows	(2,309)	

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**

- 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: Ama Sandla Date: 27 July 2018

Company Secretary

Print name: Anna Sandham

#### **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.