Genetic Signatures

ASX: GSS

INVESTOR NEWSLETTER

MAY 2018

MESSAGE FROM THE CEO

JOHN MELKI

Dear Shareholders,

Operational activity so far in 2018 highlights our belief that 2018 is shaping up to be the most exciting year yet for Genetic Signatures.

Our operational focus continues to be on ramping up our US and EU sales efforts with a number of important milestones reached.

Never before has Genetic Signatures started a year in such a strong position, including:

- **Multiple product streams with approvals underway**
- **Expanding sales team across all markets**
- **12+ trials underway to build our customer pipeline**

We have initiated paid trials with offshore customers for new products, including maiden revenue for a new product to a large European healthcare entity.

We are excited about achieving EU registration (CE-IVD) for our 'antibiotic resistance' (ESBL & CPO) Detection Kit, with domestic registration to follow. Registration in Australia and Europe for our STI and Respiratory Detection Kits is also approaching, which will further strengthen our sales strategy.

We look forward to updating our shareholders with continued operational progress in the coming months.

First USA sales of ASRs

- **The sales order is an important step in Genetic Signatures' strategy to commercialise its products into the USA market**
- **The sales order also highlights the commercial potential for Analyte Specific Reagents (ASR), which provide early US revenue while FDA clearance for *EasyScreen*™ Detection Kits is pursued**

The customer is a well respected, mid-west pathology laboratory that performs millions of tests annually and offers extensive pathology services to its patients. The launch follows an extensive and successful trial period with Genetic Signatures and its ASRs.

The sale is also testament to the potential of Genetic Signatures' proprietary **3base**™ technology and the product solutions that have been developed.

KEY OPERATIONAL UPDATES

AUSTRALIA

- Nearing regulatory registration for 'antibiotic resistant' (ESBL & CPO) Detection Kits
- Customer orders continue to increase on prior corresponding periods

EUROPE

- European registration (CE-IVD) received for ESBL & CPO Kits
- Positive ESBL & CPO Detection Kit trial results presented at major European healthcare conference
- Recruiting currently underway to build larger European sales team
- Logistics being finalised with warehouse in final legal review
- Emerging traction with customers with paid trials underway across a number of products over the last few quarters

USA

- Several labs in the USA assessing the ASR products available for sale
- Trials reaching conclusion with local clinical labs
- Customer trial data being presented at upcoming conferences to highlight the substantial advantages of **3base**™
- Kits currently being sold to a US-based customer working in Kenya, who are leveraging the speed and accuracy of **3base**™ with repeat orders of the Alphavirus/Flavivirus and Respiratory Kits

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MARKET UPDATE

Demand outlook continues to strengthen

What are Molecular Diagnostics (MDx)?

MDx refers to a class of diagnostic tests that analyse nucleic acids or proteins at a molecular level. It is a developing technology which has the potential to disrupt the existing diagnostics market, and has become the fastest-growing segment of the in-vitro diagnostics market.

Which segment of the MDx market is the most attractive?

Genetic Signatures has focused on the development of its Enteric, ESBL & CPO, Respiratory and STI Detection Kits as the diagnosis of infectious diseases represents the largest application market for MDx, and accounts for more than 50% of the global market. This field is likely to experience strong growth in the near future due to the growing incidence of infectious diseases including HIV, HPV, bacterial infections, respiratory infections and the rising number of hospital-acquired infections.

Is the growing demand for testing sustainable at the status quo?

In addition to the growing demand for diagnostics, the industry is also moving towards testing with larger gene panels and the time and complexity of interpreting tests will grow exponentially. Traditional testing procedures face significant bottlenecks, particularly in regards to **scalability**, **time to result** and the **quality** of the interpretation. Genetic Signature's **3base™** technology is well positioned to satisfy the industry needs and meet the growing demand.

Sector M&A activity is increasing

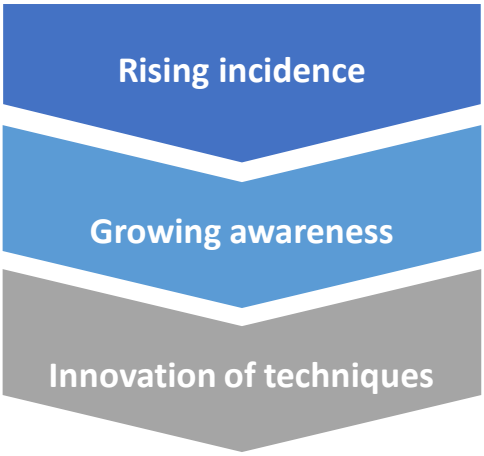
A number of recent transactions in MDx space highlight the rising interest in the sector, including the recent announcement (Jan-18) of the US$191m acquisition of STAT-Dx by Qiagen, a Molecular Diagnostics major.
STAT-Dx targets enteric and respiratory infections and is focused on lower throughput, near-patient MDx solutions (compared to GSS target of higher-throughput laboratories).

Genetic Signatures is at the the forefront of the growing MDx sector, with 12+ products in its portfolio and pipeline. The Company will continue to focus on development, while simultaneously driving commercialisation in Australia, USA and the EU.

QIAGEN

STAT Dx
Closer to Care

GROWTH DRIVERS FOR MOLECULAR DIAGNOSTICS



The rising incidence of cancer and infectious diseases due to an aging population in many countries

A growing awareness and acceptance of advanced diagnostic choices and preference for MDx

The development of proteomics and genomics techniques are creating new demand for MDx products

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SUCCESSFUL TRIAL RESULTS PRESENTED AT KEY EUROPEAN CONFERENCE

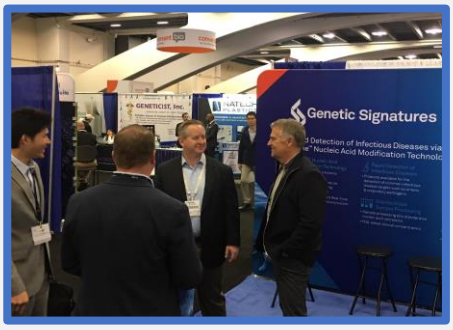
Following the CE-IVD registration of Genetic Signatures' *EasyScreen*™ ESBL & CPO Detection Kit in April 2018, Ireland's National CPE Reference Laboratory presented successful trial results of the kit to an audience of potential customers at the 28th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) in Madrid.

The results illustrate that **3base™** technology provides a specific and rapid (less than 3 hours) method for detecting hospital 'superbugs' or 'antibiotic resistant' pathogens, relative to traditional culturing methods (require several days).

No.	Sample Type	Culture Result	Direct Detection	Additional Molecular Findings
1	Liquid	OXA-48 *Citrobacter species*	OXA-48	TEM, CTX-M, SHV, DHA
2	Liquid	OXA-48 *K. pneumoniae*	OXA-48	TEM
3	Liquid	No Growth	IMP	TEM
4	Liquid	OXA-48 *Citrobacter species*	OXA-48	TEM, SHV
5	Liquid	OXA-48 *E.coli* & OXA-48 *K.pneumoniae*	OXA-48	TEM, CTX-M, SHV
6	Liquid	OXA-48 *E.coli*	OXA-48	TEM, CTX-M, SHV
7	Liquid	OXA-48 *Citrobacter species*	OXA-48	TEM, SHV
8	Liquid	OXA-48 *K.oxytoca* & OXA-48 *Citrobacter species*	OXA-48	SHV
9	Liquid	OXA-48 *Citrobacter species*	OXA-48	TEM
10	Liquid	OXA-48 *E.coli*	OXA-48	TEM, CTX-M
11	Liquid	KPC *Citrobacter species*	KPC	TEM, DHA
12	Liquid	OXA-48 *E.coli*	OXA-48	TEM, CTX-M, SHV, MCR-1
13	Liquid	OXA-48 *E.cloacae complex*	OXA-48	TEM, CTX-M
14	Charcoal	*OXA-48 K. variicola*	OXA-48	TEM
15	Liquid	OXA-48 *E.cloacae complex*	OXA-48	TEM, CTX-M
16	Liquid	OXA-48 *Citrobacter species*	OXA-48	TEM, SHV, DHA
17	Liquid	OXA-48 *E.coli* & OXA-48 *K.pneumoniae*	OXA-48	TEM, DHA
18	Liquid	IMP *E.cloacae complex*	IMP	TEM, SHV
19	Liquid	OXA-48 *E.coli* & OXA-48 *K.pneumoniae*	OXA-48	TEM, CTX-M, SHV, CMY
20	Liquid	KPC *Citrobacter species*	KPC	TEM, SHV, DHA
21	Charcoal	OXA-48 *E.coli*	OXA-48	TEM
22	Liquid	OXA-48 *E.coli*	OXA-48	CTX-M

DRIVING COMMERCIALISATION – AT THE 25TH INTERNATIONAL MMTC

For a second year, Genetic Signatures proudly exhibited at the 25th Molecular Medicine Tri-conference (MMTC) in San Francisco on 12-14 February 2018.



Genetic Signatures generated significant interest from experts in the MDx field while exhibiting its growing number of *EasyScreen™* viral and infectious disease reagents.

It was a great opportunity to demonstrate how **3base™** fosters more efficient detection of infectious microorganisms, within a streamlined workflow solution.

Genetic Signatures will also host an exhibit at the upcoming Clinical Virology Symposium in West Palm Beach, Florida in May 2018. A key highlight for Genetic Signatures is expected to be the publication of new trial data from recently completed tests supporting the advantages of **3base™** technology.

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BSP MEETING IN ABERYSTWYTH – UNITED KINGDOM

In April 2018, Prof John Ellis, an international expert in medical and veterinary protozoology, presented highly positive findings of its *D.fragilis* testing using *EasyScreen™* Enteric Parasite Detection Kits.

"The results show that the *EasyScreen™* assay should be considered the gold standard for real time PCR detection of *D.fragilis* and other gastrointestinal parasites" – Prof John Ellis

CORPORATE SUMMARY AND RECENT EVENTS

- Cash receipts for the first 3 quarters in FY18 has exceeded the total for FY17
- At 31 March 2018, the Company held A$10.6m in cash and cash equivalents, down from A$11.7m at 31 December 2017

UPCOMING ACTIVITIES

- Primary focus remains sales growth in international markets
- Commencement of new product trials with customers in the US and EU
- Potential receipt of regulatory registration for STI and Respiratory products in Europe, and domestic registration of ESBL & CPO

REGULATORY APPROVAL UPDATE

	AU	EU	USA
EasyScreen™ **Enteric**	◉	◉	◎ ✓
EasyScreen™ **Respiratory**	◎	◎	✓
EasyScreen™ **STI / Genital**	◎	◎	✓
EasyScreen™ **Flavivirus / Alphavirus**	◎	◎	✓
EasyScreen™ **ESBL & CPO**	◎	◉	✓
EasyScreen™ **Meningitis**	●		✓
EasyScreen™ **Atypical Respiratory**			

Trials underway ●

Approval process underway ◎

Fully approved ◉

ASRs available for sale ✓

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