Lodge Partners Research
ABN: 25 053 432 769
AFSL: 246271

BUY	12 Month Price	65 cents
	Price	37.5 cents
	Implied Return	73%

Genetic Signatures

High throughput molecular diagnostics

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Company Details

ASX Code:	GSS
Price:	$0.375
Shares on Issue (at close):	72.9m
Market Capitalisation:	$27.3m
Volume (shares, April 15)	2.5m

Financials

Year ending Jun	**2014A**	**2015F**	**2016F**	**2017F**
Lodge adj profit	(1.7)	(3.5)	(2.1)	1.7
Reported profit (pre abn)	(1.7)	(3.5)	(2.1)	1.7
EPS pre goodwill (¢)	(3.5)	(5.7)	(2.8)	2.4
EPS growth	NA	**65.3%**	**-50.2%**	**-183.0%**
P/E ratio	(11.0)	**-6.6 x**	**-13.4 x**	**16.1 x**
EV / EBIT	-12.7 x	-7.6 x	-10.2 x	57.9 x
EV / EBITDA	-12.7 x	-7.6 x	-10.2 x	57.9 x
FCFPS (¢)	(3.5)	(5.6)	(3.5)	1.2
Price / FCFPS	-10.8 x	-6.8 x	-10.7 x	31.6 x
NTA per share	$0.05	$0.09	$0.06	$0.09
Pr / NTA	7.2 x	4.2 x	6.1 x	4.4 x

Directors & Chief Executive

Nick Samaras	Non-Executive Chairman
John Melki	Director & CEO
Philip Isaacs	Non-Executive Director
Pat Noland	Non-Executive Director
Robert Birrell	Director & CFO
Mike Aicher	Executive Director - US

Major Shareholders (Post-IPO)

Asia Union Investments (CM Abbott)	55%

Genetic Signatures is an Australian molecular diagnostics (MDx) company, with products in the Australian market, distributors appointed and initial sales in the European Union and plans to launch in the US, with first sales around end CY15.

Technology: The company's technology has significant advantages relative to traditional diagnostic methods and other MDx.

Relative to many traditional methods*, the company's tests are much quicker to yield a result (hours instead of days), more sensitive (few false negatives) and more specific (few false positives)*.

Relative to other MDx, Genetic Signatures tests use a technology termed 3Base™. It 'simplifies' the molecular structure of the targets MDx detect, allowing the development of tests *that detect a wider array of pathogens in a single reaction*.

Importantly, *the utility of the company's technology has been validated in a number of peer-reviewed studies*, demonstrating the company's technological advantages translate into real advantages in pathology laboratories.

Board & Management: The company's board and management reflect the needs of an MDx company (i.e. the appropriate spread of skills, experience). In particular, the team devoted to the US is proven and as exceptional as the company's technology. The US is the single most important MDx market.

Market: The worldwide MDx market was estimated at USD5.0b and is expected to grow at a rate of 9.7% (Research and Markets, 2013). This rate compares to a 7.0% expected for the broader diagnostic market. The US is, by far, the largest single MDx market and was worth USD3.0b in 2013 (Research and Markets, 2013).

Products: The company's initial focus is on infectious diseases and its first products are the *EasyScreen*™ enteric pathogen tests. They are designed to identify the cause of infectious gastroenteritis in patients. Infectious disease diagnosis plays to the company's technology strengths. *Enteric pathogen testing represents an attractive market, because traditional methods require days to yield a result and other MDx struggle to cope with the wide range of pathogens and their subtypes that cause the disease*. Five Australian hospitals are purchasing *EasyScreen*™ enteric tests, for FY14 revenues of $500k. Importantly, *we believe a major local listed company has recently signed an agreement with the company*, as well as one of Italy's larger pathology laboratories.

Genetic Signatures has two further tests, for respiratory tract infections and "golden staph", in beta testing to be launched this half (2H FY15). Tests for sexually transmitted infections, tuberculosis and meningitis are earlier in development. Many additional large opportunities exist (e.g. cardiology). *Infectious diseases is just the beginning of the applications for the company's technology*.

Competition: There are other MDx technologies for general use and diagnosing infectious diseases. The market, however, is not as competitive as might be thought, because of the number of niches within it and the inability of a single technology to satisfy all niches.

The *EasyScreen*™ tests are essentially a perfect fit for laboratories that test large volumes of samples, are interested in breadth of pathogen coverage and do not wish to purchase additional equipment.

This last point is important; *The EasyScreen™ tests are platform agnostic and can be run on existing equipment found in every relevant laboratory*. This is a significant advantage in attracting new customers, because there is no large capital outlay and no need to train-up staff to use the new equipment. Even the bench space required for new equipment can be a significant barrier to purchase.

Intellectual Property: Genetic Signatures has used *a classic intellectual property strategy* to protect its technology. Specific patents covering 3Base™ and improvements to the original method provide broad coverage. Individual patents on each of the tests provide specific protection. Currently, *the company's products are protected until 2031*. Further improvements should push this protection out further.

Valuation Methodology: We have a used a discounted cash flow (DCF) methodology with various assumptions to value Genetic Signatures. The valuation has not been probability adjusted, because of the very low amount of clinical trial and regulatory risk associated with the company's products. The derived valuation has been checked against market-based valuations of comparable companies.

Conclusion: We initiate coverage of Genetic Signatures with a **BUY** recommendation and a 12-month price target of **65 cents**.

Introduction

Genetic Signatures is an Australian-based platform molecular diagnostics (MDx) company. It has product in the market in Australia and approval to market in Europe. Entry to the largest single market, the US, is scheduled for this calendar year.

MDx provide diagnoses on the basis of detecting DNA (deoxyribonucleic acid) sequences specific to a particular disease. MDx, including those of Genetic Signatures, can also detect RNA (ribonucleic acid), which is similar to and made from DNA. For simplicity, however, we will only discuss DNA in this report. DNA molecules define the type of organism (viruses through to humans) and, for complex organisms such as animals, it can essentially define an individual organism, as well. Because of this, MDx are capable of extreme precision and accuracy.

MDx are the fastest growing segment of IVDs

MDx is the fastest growing segment of in vitro diagnostics (IVD, IVDs are diagnostics that are performed in test tubes) market, with MDX continuing to replace 'traditional' IVDs everywhere they are found – microbiology, haematology, cardiology, etc. While precision and accuracy are hallmarks of MDx, they may have other advantages over traditional IVDs, including speed, cost, technical simplicity, etc.

3Base™ simplifies the variation seen at the DNA, while preserving clinical utility

Compared to similar MDx companies, the core advantage of Genetic Signatures technology is that, via a process the company terms 3Base™, it simplifies the variation seen at the DNA level, reducing the amount of variation that must be detected, while preserving clinical utility. This is important, because there are over a million possible combinations that could comprise even a short 10 unit strand of DNA. To put this complexity into perspective, humans have 46 chromosomes that are each composed of hundreds of millions of units of DNA. Scientists estimate that there are 4 billion DNA units in each human cell. The 3Base™ technology has profound implications in terms of the breadth of diseases and disease causing organisms it can detect in a small number of reactions.

EasyScreen™ enteric tests can influence a patient's treatment and enable the spread of the disease to other patients to be short-circuited

The company's first marketed product is the *EasyScreen*™ brand enteric pathogen tests. They are used by pathology laboratories to identify the organism which has caused a patient's gastroenteritis (inflammation of the gut, often associated with vomiting and/or diarrhoea). Gastroenteritis can be caused by three groups of microorganisms; viruses, protozoa and bacteria. MDx have been slow to replace traditional methods of identifying the microorganism causing a patient's gastroenteritis. This is despite the fact that an MDx can return a result in a few hours, compared to traditional methods, which can take days. In fact, by the time a traditional method has returned a result, it is often of academic interest only, while an *MDx can provide a result in time to influence a physician's treatment decision*. Infectious gastroenteritis is a huge cost to the healthcare system. If it can be identified quickly, measures to stop the disease spreading to other patients can be taken, such as placing a patient in isolation. Downstream disease costs, such as hospital ward closures, are then limited. Several studies have demonstrated the superiority of the *EasyScreen*™ enteric tests relative to traditional methods in detecting pathogens in real-world hospital settings.

Numerous products can be developed for the infectious disease and other markets

In terms of an investment thesis, it is important to understand that Genetic Signatures has numerous tests in development, including tests for methicillin-resistant staphylococcus aureus (MRSA or "golden staph" and the biggest single cause of hospital acquired infections (HAIs)), respiratory tract infections (RTIs) and sexually transmitted infections (STIs), with an almost limitless pipeline of tests in additional high-value areas that could be developed.

Genetic Signatures tests will run on standard laboratory equipment, which has a number of advantages

It is also important to understand that Genetic Signatures Technology is equipment agnostic. It will work on equipment found in any diagnostic laboratory. This is important from a commercialisation point of view, an addressable market point of view and a partnering point of view.

The company's board and management are as impressive as the company's technology

The board and senior management of Genetic Signatures is very strong, with a solid mix of experience and expertise across numerous functional areas supporting a core competency in MDx. Notable is the recent addition of several US-based executives and directors to the company, all with proven track records and relationships in the US IVD market. Of particular note is the company's Executive Director - US operations, Mike Aicher. Mr Aicher was founder and CEO of National Genetics Institute and engineered its sale to Laboratory Corporation of America Holdings (NYSE: LH) in 2000.

Valuation: Methodology & Assumptions

We have used a discounted cash flow method to value Genetic Signatures. From a regulatory approval point of view, CE marking of products to enter the European Union (EU) is not overly difficult to obtain and can be achieved based on information provided to the Australian Therapeutic Goods Administration and, largely, vice versa. The USA commercialisation pathway is well worn and does not involve the need to gain US Food and Drug Administration (FDA) approval for the foreseeable future. As a consequence, we have not probability adjusted for these events (or clinical trials that may be done). It is also important to note that Genetic Signatures expenses their inventories, so working capital remains low. Other assumptions include:

- No FOREX;
- Discount rate: 15%; terminal growth rate: 3%;
- Only three product categories (*EasyScreen™* enteric, respiratory and MRSA (methicillin resistant staphylococcus aureus, aka "golden staph");
- All three product categories on the market by end FY15;
- Sales in Australia commenced, EU commencing 2H FY15, US commencing 1H FY16;
- Average sales revenue of $600k/year per customer (260 work days/year);
- Pricing: Enteric panels (max 3), $13 per panel; Respiratory panels (max 2), $18; MRSA panel (max 1), $10.00);
- Average tests per day/hospital: 125; average revenue per test $12.36;
- Adoption by customer (% of average sales revenue): year 1, 35%; year 2, 75%; year 3, 100%;
- Number of laboratories (i.e. customers) at end of 10 year forecast period: Australia, 87 (penetration: ~20% of laboratories; US, 213 (~5.0%); EU 88 (~2%).
- Main Expenses: cost of goods sold (COGS), 25% of sales revenue; Employees, 30%; the latter fixed percentage commencing FY17.
- COGS currently includes inventories (Genetic Signatures does not breakout a traditional COGS in its financial statements.

12-month price target: 65 cents/share

Based on the above methodology and assumptions, we have arrived at a **12-month price target for Genetic Signatures of 65 cents per share**.

Comparable companies support our valuation

The above price target was reality tested against the enterprise values (data not shown) of six comparable companies (CareDx, NASDAQ: CDNA; Trovagene, NASDAQ: TROV; Veracyte: NASDAQ: VCYT; Brain Resource Company, ASX: BRC; Genetic Technologies (ASX: GTG) and Impedimed, ASX: IPD). From those comparable companies we deduced an enterprise value of between $35m and $45m would be appropriate for **Genetic Signatures, which translates to a price target of between 65 cents and 83 cents per share**.

The *in vitro* Diagnostics Market

The IVD market can be split into several, often overlapping, segments, MDx being one of those. It can also be viewed in terms of where the test is actually performed, which is of relevance to Genetic Signatures products.

Market Segments

The IVD market can largely be split into two segments. Those markets are:

1) The laboratory market – this market refers to testing that is done within the confines of a laboratory, with patients' samples delivered to the laboratory for testing. In general, these are high volume tests (e.g. liver function tests) or tests that are too complex or inappropriate to be performed in other environments.

Tests designed for the laboratory market generally don't compete with those designed for the POC market

2) The point of care (POC) market – This market refers to testing that is done at or near where the patient is situated. It may include testing at a patient's bedside, in a doctor's office or in a home. These type of tests are, typically, only for one or a small number of analytes (analyte: the target of the test – e.g. blood glucose for diabetes), relatively expensive, not suited to large numbers of samples and, generally, aren't as accurate as laboratory-based tests). POC tests are, occasionally, used in the laboratory setting, if volumes of a particular test don't justify the use of a product designed for a laboratory.

Products designed for the laboratory market generally don't compete with those designed for

the POC market. In some cases, in fact, POC tests are later confirmed by subsequent laboratory testing.

Genetic Signatures products are solely designed for the laboratory setting, at this stage.

Diagnostic Characteristics
Unlike some aspects of healthcare (e.g. drug development, esoteric medical testing), high-throughput pathology is more of a volume game, than a margin game. Therefore, the cost-side of the equation is important and factors that affect cost will be carefully considered when a pathology laboratory is deciding which brand of diagnostic test it will buy, in addition to a test's purchase price. These factors include:

- Laboratory bench space and/or new equipment required
- Training time
- Level of automation (i.e. hands-on time)
- Reliability
- Work-flow (i.e. how does sample processing and testing fit with a laboratory's current protocols)
- Volume of samples

The demands on a diagnostic vary depending on the environment it is performed in, with each environment potentially representing a product niche

Factors related a test's impact on patient care will also be considered. These factors include:

- Sensitivity (the percentage of patients correctly identified by the test)
- specificity (the false positive rate)
- accuracy (a combination of sensitivity and specificity)
- turn-around-time (how fast it takes for the physician to get the result after ordering it)

Given there are so many parameters a pathology laboratory will assess before purchasing a diagnostic and a range of different requirements for each parameter depending on the buyer, it is not surprising to find that within the laboratory testing market*, there many niches even for tests that diagnose the same disease*.

From discussions with management, we are confident that Genetic Signatures has and continues to consider the above factors in the design of its tests for the various markets.

Market Size – *in vitro* Diagnostics & Molecular Diagnostics
The market size data provided in the following subsections is summarised in Table 1.

Overall Market Size
The global *in vitro* diagnostics market was estimated at USD$49.2 billion in 2012 by Research and Markets (2013). They expect this market to grow at a rate of 7% to hit USD69.1b in 2017. These figures agree well with those published, also in 2013, by Transparency Market Research. A forecast, prepared in 2014, by Markets and Markets indicates the global MDx market will reach USD8.0b in 2018, having grown from USD5.0b in 2013 at a rate of 9.7%. These figures are concordant with those from a 2014 report from Transparency Market Research, which put the global MDx market at USD4.3b in 2012. They expect it to grow at a rate of 11.1% to USD8.7b in 2019.

Overall markets are large

US and EU
The US IVD market was believed to be worth USD22.6b in 2013 and is forecast to grow at a rate of 4.0% to 2020, reaching a size of USD30.1b (Allied Market Research, 2014). The MDx segment of this market was worth USD3.0b (Kalorama, 2013). It is forecast to grow at a rate of 9.0% to USD4.6b in 2017.

The US is the largest market for IVDs and MDx

The data on the EU is older, with Frost and Sullivan estimating the IVD market to be worth USD8.5b in 2007 and forecast to grow to USD12.7b last year. EvaluateMedTech provides a figure of €10.8b (USD12.2b) for 2013, suggesting Frost & Sullivan's numbers were pretty accurate. In 2012, the EU market size for MDx was estimated at USD1.2b, being tipped to grow to USD1.6b by in 2017 (Kalorama, 2013).

Table 1. Summary of IVD and MDx Market Sizes. (sources: see text)

Market	Year	Size	Year	Size	Growth Rate
Global					
-IVD	2012	USD49.2b	2017	USD69.1b	7.0%
-MDx	2013	USD5.0b	2018	USD8.0b	9.7%
US					
-IVD	2013	USD22.6b	2020	USD30.1b	4.0%
-MDx	2013	USD3.0b	2017	USD4.6b	9.0%
EU					
-IVD	2007	USD8.5b	2014	USD12.7b	5.9%
-MDx	2012	USD1.2b	2017	USD1.6b	6.0%
Australia					
-IVD	2007	USD391m	2014	USD584m	5.9%
-MDx	2012	USD55m	2017	USD74m	6.0%

Australia

There is not a lot of publically available data on the Australian market.

The Australian healthcare system is much more like EU systems (i.e. heavily government funded), than it is the US (i.e. predominantly privately funded). Therefore, we have used the EU estimates/forecasts and simply adjusted by population size to derive Australian estimates. *This method suggests the Australian IVD market was worth USD391m (AUD495) in 2007 and USD584m (AUD740m) in 2014, while the MDx market was worth USD55m (AUD70m) in 2012 and is forecast to be USD74m (AUD94m) in 2017*.

Table 2. FY14 pathology revenues of Australian listed healthcare companies. (sources: annual reports)

Company	Revenues (AUD million)
Sonic Healthcare (SHL)	1,130
Primary Health Care (PRY)	887
Healthscope (HSO)	349
Total	**2,366**

Australia is a smaller, but not insubstantial, market

FY14 Australian pathology revenues for the Australian listed healthcare companies are given in table 2. The total, $2.4b for FY14, compares well to total Medicare Benefits Schedule (MBS) expenditure for FY13 of $2.5b provided by UBS Securities Australia. When looking at these figures, it must be remembered that pathology refers to all testing, not only IVDs. In addition, there must be room in the Medicare rebates to cover employees, occupancy, administration, etc. Nonetheless, the figures suggest that the values derived from the European markets are reasonable.

The Advantage of Molecular Diagnostics

As stated, above, there are many advantages that may be associated with MDx relative to traditional methods, particularly those used in infectious diseases (microbiology).

Numerous drawbacks to traditional testing methods

Traditional microbiological methods involve culturing a patient's sample under conditions that enable the microbe(s) in question to grow, ultimately, to the point where there is sufficient quantity for a definitive test to be performed. Typically, this process takes days, is time consuming from a technical point of view and may not be absolutely specific for the pathogen in question, among other things. Importantly, the time it takes to generate results by traditional methods means they may be of historical importance only in many cases by the time the result is known (i.e. a successful treatment course has/is already being administered).

MDx rely on a key attribute of DNA and a key laboratory technique. These keys are:

1) The large amount of information in the genetic code: The vast amount of differences between two organisms can be traced to their genetic code (the molecular sequence of DNA). Even two organisms which appear absolutely, completely, identical, will exhibit differences at the genetic level. This largely holds true even for the simplest

MDx out perform traditional IVDs due to the large amount of information in the genetic code and a laboratory technique called PCR

organisms, viruses. By designing the MDx appropriately, just about any level of discriminatory power can be incorporated in it.

2) A technique called polymerase chain reaction (PCR): This technique allows important (often termed target) segments of DNA to be amplified to detectable levels in hours, compared to waiting for the pathogen to replicate naturally, as do traditional methods.

By allowing results to be obtained so quickly, MDx *enable the physician to prescribe a course of treatment with much greater certainty*, because they know exactly what they are dealing with. It is also means that *further beneficial actions may be taken*. Again, using infectious diseases as an example, a patient with a highly infectious disease can be isolated quickly, but only when necessary. Infections acquired by patients from other patients in hospitals represent a huge cost to hospitals. Such hospital acquired infections (HAIs) have often been reported in the popular press. By isolating patients who present a risk quickly, a hospital will face lower costs in treating HAIs and avoid costly exercises, as mentioned earlier.

3Base™ - The Genetic Signatures Advantage

Due to the huge amount of information in the genetic code, the big **advantage** of MDx in a theoretical sense, is also the big *disadvantage* of MDx in a practical sense.

The huge amount of genetic information has created the opportunity for 3Base™

DNA is made up of two strands of four bases (cytosine, guanine, adenine and thymine; often abbreviated to C, G, A and T), with each strand binding the other (forming the classic double-helix structure). Each base binds a specific base in the other strand (C binds G, A binds T), such that by knowing the sequence of bases in one strand, the sequence of the other strand can be predicted.

The example we used in the introduction of over a million variants for a 10 base segment is simply the calculation 4^{10} (meaning that there are 4 possible bases in each of the 10 positions). When one considers you need a specific means (termed a probe in MDx) of detecting each variant, the task is, obviously, a big one.

The nature of the variation further enhances 3Base™ usefulness

In reality, the variation actually observed in DNA sequences is not random due to the nature of evolution. In other words, the different strains of influenza are similar to each other, as they are all influenza; however there is still the variation that exists between the strains which defines specific properties (such as the difference between bird flu and swine flu). This subtle variation, may be only one or two bases in that ten base segment. Because MDx require the separation and re-annealing of the DNA strands and primers (short pieces of DNA used in PCR), unless the conditions are just right, you can get closely related, but not perfectly complementary binding occurring. This can lead to erroneous results or failure of the test and is all the more likely because the variation that exists is often subtle.

3Base™ turns a four base code into one with only three bases

Genetic Signatures 3Base™ technology essentially simplifies the genetic code by converting cytosine residues to thymine residues, effectively, creating a three base code (now with only G, A and T bases). Again, using the above 10 base example, what was over a million possibilities becomes just under 60 thousand (3^{10}) possibilities with the 3Base™ technology. In technical terms, 3Base™ makes it much easier to design an MDx that works well (i.e. where DNA strands bind perfectly)**.**

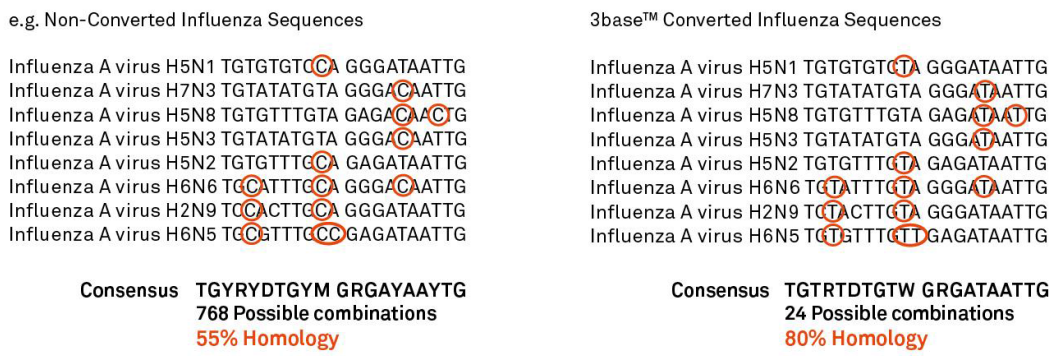
Variation that is lost is not important to test performance

While 3Base™ does reduce the amount of information contained in a sample, this can be ameliorated by choosing the targets/probes the MDx relies on carefully, such that the benefits of the reduced variation are achieved and only irrelevant information is lost.

Figure 1 provides a real world example of 3Base™ when it is applied to detecting the influenza virus. Obviously, detecting all strains of influenza is important and is the goal of any test. As can be seen, 3Base™ reduces the number of sequences associated with influenza from 768 to 24. The reduction by percentage, 97%, is bigger than in our general example, 94%, due to appropriate sequence selection. The net result is that it is much easier to design an MDx where accurate binding between complementary bases consistently occurs and all subtypes of influenza are more easily identified.

It is important to note that no competing technology to 3Base™ exists.

Figure 1. The effect of 3Base™ on influenza virus sequences. (course: company presentation)



Products On Market & In Development

Genetic Signatures has chosen to focus on infectious disease MDx in the first instance, because it is a large market opportunity to which the 3Base™ technology lends itself extraordinarily well, given the wide range of pathogens, the often many subtypes of those pathogens and the clinical significance of the subtypes.

Infectious diseases is an area where Genetic Signatures technology truly outperforms

On Market - *EasyScreen*™ Enteric Screening Kits

Genetic Signatures first products are a set of kits designed to detect the cause of infectious gastroenteritis. Gastroenteritis is the inflammation of the stomach and intestines, typically resulting from bacterial toxins or viral infections, which causes vomiting and diarrhoea. Nearly everyone has experienced this disease at one time or another.

The company sells four kits in this product segment, they are:

- Enteric Bacteria Screening
- Enteric Viral Screening
- Enteric Protozoan Screening
- *C. difficile* Detection and Reflex Kits

The kits (or panels) are based on the general type of pathogen to allow a pathology laboratory to choose what it tests for. Depending on the laboratory and the setting, a laboratory may choose any or all panels. *C. difficile* is a major HIA and, consequently, its detection can be very important. The reflex kit allows the specific subtype of *C. difficile* to be determined, which is important because the strains vary in the severity of gastroenteritis they cause.

MDx have been slow to replace traditional methods in enteric screening, largely for reasons which Genetic Signatures technology addresses

It is difficult to find good estimates of the size of the enteric MDx screening market. This can be attributed to two facts. The first is that the MDx testing that is occurring can be classified under numerous headings (HAIs, organism identification, other). The second is that it has been a somewhat neglected market, probably because testing for the very wide range of pathogens that can cause gastroenteritis has, prior to 3Base™, been considered too difficult to do with an MDx. *This makes enteric screening an ideal first product for Genetic Signatures, because it has clear clinical utility and limited competition from other MDx.* This, in turn, *means Genetic Signatures faces an easier time of getting its technology into the hands of users making it more likely that they will pick up additional tests once they are available*.

In effect, enteric MDx screening is growing at the expense of traditional methods, hence estimating market size on current data is difficult

Kalorama has estimated the worldwide market for microbiology/virology MDx at USD2.8b in 2012, growing to $4.0b in 2017. It seems reasonable to assume that enteric testing could represent a USD100 million to USD200 million opportunity based on these figures. This figure could be substantially higher, however, because the Kalorama figures don't capture the large amount of testing that still occurs via traditional methods.

In Development

Genetic Signatures has MDx for several other infectious diseases in development.

Two additional tests to be launched this half (2H FY15)

The two primary diagnostics are those for *respiratory tract infections (RTIs)* and *methicillin-resistant staphylococcus aureus (MRSA, golden staph)*. These products are in the beta-

testing stage and should be ready for market release during the course of this half (2H FY15).

RTIs are difficult to diagnose and even the fastest of traditional methods takes 30 hours to return a result. They are also a very significant health concern, with the World Health Organisation placing them among the top four causes of death and disease.

Both tests are entering large and growing markets

MRSA is the most notorious of the HIAs, accounting for about 10% of cases. According to the U.S. Association for Professionals in Infection Control and Epidemiology, a 2012 survey found that more than 75% of healthcare facilities in the United States now conduct active surveillance testing to detect patients with MRSA. The HAI MDx market was believed to be worth USD390m in 2012 and is forecast to grow to USD880m in 2017 (Kalorama Information, 2013).

Further tests earlier in development

Behind RTIs and MRSA, the company has several other tests in development, most notably an MDx for sexually transmitted infections (STIs). The STI market was thought to be worth around USD480m in 2012, with a forecast of USD550m in 2017 (Kalorama Information, 2013).

Other diagnostic fields may also be entered

MDx also have application in haematology, cardiology, histology, cytology and a range of other areas. *Success in infectious diseases is likely to lead to Genetic Signatures developing MDx in one or more of these other areas.*

Sales – The Current State of Play

***EasyScreen*™ enteric products generated approximately $500k in FY14 for Genetic Signatures**

Genetic Signatures currently sells its MDx in Australia. It has also commenced marketing in Europe. In terms of the US, the company hopes to launch its products this calendar year. Genetic Signatures recorded revenue of $684k in FY14, which is believed to include about $500k in enteric product revenues.

Post GSS's IPO, company announcements state that the company has started to receive revenues from Europe (Italy specifically) and that the company has expanded its customer footprint in Australia outside of New South Wales.

Australia

A dedicated sales representative was only recently added

Genetic Signatures has been marketing its enteric tests in Australia for the last 18 months, although it only put on its first dedicated sales representative in mid-2014. We believe the company has approximately five large public hospital pathology laboratories using its tests, with trials planned in others.

Targeting public hospitals first in Australia is a sound strategy

Public hospital pathology laboratories are the appropriate segment to target first in our opinion, primarily for two reasons. The first is that they tend to take a more academic approach than private laboratories and, consequently, they provide the company with marketing material in the form of publications and conference presentations. The second is that the choice of diagnostic in a public laboratory is not as pure an economic decision as it is in a private pathology laboratory. It is much better to be able to market on performance, as Genetic Signatures can do, rather than price, because it is easier to maintain margins and, ultimately, profits in that scenario.

One of the listed health care has agreed to use *EasyScreen*™

Importantly, in terms of the local event mentioned above, *logic suggests that the new Australian customer is likely to be one of the three listed players in the space (Sonic Healthcare, Primary Health Care or Healthscope)*. This would indicate that cost conscientious pathology laboratories see value in the company's tests beyond maximising profit margin and, overall, it would be a very big tick for the company, its technology and, given the pathology revenues of these businesses (table 2), Genetic Signatures' bottom line.

European Union

Regulatory approval to market the *EasyScreen*™ tests was gained in 2012 for the *C. difficile* kit with the other kits gaining approvals in 2013/14. A general manager of EU operations was appointed in 2013. Since then, distributors have been appointed for Italy and Israel, both in 2014. Genetic Signatures is currently assessing potential distributors for other Member States. The Italian and Israeli distributors are currently believed to be in active negotiations with several potential large scale customers. The news regarding first product revenues from Italy indicates that these appointments are starting to bear fruit.

New Italian customer likely significant size

O*ur belief is that the new Italian customer is of a material size*, definitive confirmation of which

may appear in Genetic Signatures June quarterly report and/or their FY15 annual report.

United States
The United Sates is the largest single market for MDx by far and, consequently, is very important for the company.

The company intends to launch its products in the US this calendar year (2015) and record its first revenues in the second half of this year (1H FY16). To this end, *it has appointed a group of top-flight US-based directors and managers to enable this to happen*. From a market entry point of view, the US is more complex than the EU. Many Australian companies with good products have failed in the US due to a lack of management expertise. Clearly, Genetic Signatures is not making that mistake.

The RUO to LDT pathway is common one used by smaller entrants to the US diagnostics market

The products launched in the US will be different to those launched in Australia and the EU due to the regulatory complexity of the US. While complete kits are sold elsewhere, in the US the components of the kits will be sold to pathology laboratories in a research use only (RUO) form. Pathology laboratories can then use the components to create a laboratory developed test (LDT). The RUO to LDT pathway is common in the US, particularly for emerging companies. The pathway avoids the immediate requirement for approval by the US FDA and provides near term cash flows for the company, while it tackles gaining FDA approval.

While there is potential that the RUO to LDT pathway could be made more difficult to traverse due to regulation, if this does occur *it will not be in a timeframe relevant to Genetic Signatures*.

Competition Relative to Other Molecular Diagnostics
The broad advantages of Genetic Signatures' technology relative to traditional methods were described earlier, with the major ones being sensitivity, specificity and uniformity across tests. Time to result is also a key advantage in certain areas, most notably infectious diseases.

There are competing MDx technologies in general and specific to the area of enteric testing. These technologies, with specific reference to enteric testing products, are compared in figure 2.

As can be seen, all of these MDx technologies have a rapid turnaround time. The main points of difference are *EasyScreen*™'s:

EasyScreen™ competitive advantages come down to pathogen coverage, throughput, choice and its equipment agnosticism

- Pathogen coverage - largely enabled by the 3Base™ technology;
- Open platform nature – *EasyScreen*™ tests/reagents are not limited by hardware broadening the applicable market and easing adoption by laboratories;
- Throughput – compatibility with 384-well format means up to 384 tests can be performed at the same time; and
- Viral, bacterial and protozoan coverage – related to pathogen coverage, but allows customers to focus on a particular pathogen type.

The inclusion of separate endogenous extraction and inhibition controls, while probably not a decision maker on its own in the minds' of customers, is a real advantage, particularly for laboratories with a strong emphasis on quality.

Even among infectious disease MDx, there is little head-to-head competition

It needs to be understood, that although we talk about high-throughput laboratories as a group, there is considerable variation between laboratories, as mentioned earlier, and, as a consequence, numerous niches. Correspondingly, the MDx listed in the figure 2 vary, generally, based on a perceived market niche. The Biofire FlimArray assay, for example, does detect a wide variety of pathogen's and very quickly, but its throughput is highly limited (one specimen at a time) and it requires a devoted piece of specialist equipment. Consequently, it is, in reality, unlikely to compete to a great extent with the *EasyScreen*™ enteric tests.

EasyScreen™ tests are cost competitive with an appropriate gross margin

Similarly, pricing varies depending on the product offering and other factors. We believe that Genetic Signatures is likely to charge around $15 per panel for its enteric tests (i.e. bacterial, viral or protozoan). The company expects it will be able to charge this price whether the buyer is a distributor or end-user. The cost of goods sold (COGS) is likely to run eventually at 20% and is in line with other diagnostics. These sorts of metrics will make *EasyScreen*™ cost competitive relative to competing tests, with the ability to negotiate for volume. Since the

enteric test is split into panels that can be purchased separately, the customer does have the ability to control their spend based on what they need to do to get paid (e.g. by Medicare), how much they get paid (e.g. by Medicare), other cost considerations and any externalities (i.e. infection control in hospitals).

Intellectual Property

Genetic Signatures' products are protected by a classic IP strategy

Genetic Signatures technology is covered by 6 patent families comprising 9 patents. The key patents are those that cover the base conversion of G's to C's, a method that dramatically reduces the amount of time required to convert the bases and individual patents on each specific MDx. All up the existing patent portfolio should provide the company with strong protection out to 2031.

Figure 2. A comparison of enteric screening products. (source: company presentation)

	Genetic Signatures Products for Enteric Screening	Competing Products for Enteric Screening							
	Genetic Signatures (*EasyScreen*™)	Biofire FilmArray	Hologic/ Gen-Probe	BD (BD Max)	Tib Molbiol[1]	Fast Track Diagnos-tics	AusDiag-nostics	Luminex	Seegene[2]
Probe based PCR	●	●	●	●	●	●	●	●	●
Combined extraction and PCR set-up platform provided by supplier of IVD kits[3]	●	●	●*	●	●	●	●	●	●
Rapid Time to Result (<5 hours)	●	●	●	●	●	●	●	●**	●
Thorough Coverage of Common Enteric Pathogens (20 or more targets in a run)	●	●	●	●	●	●	●***	●	●
Separate endogenous extraction and inhibition Controls	●	N/A	●	●	●	N/A	●	N/A	●
Open Platform (Extraction and PCR) from multiple suppliers	●	●	●	●	●	●	●****	●	●
Viral, bacterial and Protozoan coverage	●	●	●	●	●	●	●	●	●
Manufactured in Australia	●	●	●	N/A	●	●	●	●	●

● – Yes; ● – No; N/A – Information not available from company website

[1] Distributed in Australia by Roche Diagnostics
[2] On a single integrated platform
[3] Seeplex End point PCR range
* This test is not compatible with Hologic automated instrumentation
** Does not include pre-treatment time
*** Requires the use of multiple assays with redundant targets under current menu
**** May be compatible with some 3rd party 384-well PCR instrumentation

Management

The board and management are an accurate reflection of the needs of an MDx company

Genetic Signatures board and senior management exhibit a solid mix of experience and skills relevant to the company. Chairman, **Dr Nick Samaras**, was previously Managing Director of Applied Biosystems, a large laboratory instrumentation and reagent company, and before that he held senior roles at Perkin Elmer and AMRAD Corporation. Chief Executive Officer, **Dr John Melki**, has held previous roles within the company and has a very strong understanding of the company's technology, its applications and markets. He has previously built a business and effected its successful sale. Executive Director – US Operations, **Mr Mike Aicher**, has spent a significant proportion of his career with the American pathology company, Laboratory

Corporation of America, Inc (LabCorp), where he managed businesses with revenues in excess of USD1 billion. Mr Aicher came to LabCorp, after selling the National Genetics Institute to it; a company he founded and led. Non-Executive Director, **Mr Pat Noland**, is a former Senior Vice President of LabCorp and is currently the CEO of an anatomic pathology company, StrataDx. Director and Chief Financial Officer **Mr Robert Birrell** has had a varied and successful career, having held senior positions in Macquarie Bank, Industrial Equity Limited and Austar United Communications. Non-Executive Director, **Mr. Phillip Isaacs**, a biochemist by training, has had a long career, primarily in the area of laboratory instrumentation and has worked for companies such as Technicon Equipment's Australian subsidiary (Managing Director) and Beckman Instruments (Managing Director, Area Director).

Genetic Signatures Limited (GSS: $0.375)

Mkt Cap: $27m

Valuation data

Year ending Jun	2014A	2015F	2016F	2017F	2018F
Lodge adj profit	**(1.7)**	**(3.5)**	**(2.1)**	**1.7**	**4.5**
Reported profit (pre sig)	(1.7)	(3.5)	(2.1)	1.7	4.5
EPS$_{adj}$ (¢)	**(3.5)**	**(5.7)**	**(2.8)**	**2.4**	**6.2**
EPS$_{adj}$ grow th	NA	(65.3%)	50.2%	183.0%	162.9%
P/E ratio	-10.8 x	-6.6 x	-13.2 x	15.9 x	6.0 x
EV / EBIT	-12.5 x	-7.5 x	-10.0 x	57.2 x	11.5 x
EV / EBITDA	-12.5 x	-7.5 x	-10.0 x	57.2 x	11.5 x
FCFPS (¢)	(3.5)	(5.6)	(3.5)	1.2	5.0
Price / FCFPS	-10.7 x	-6.7 x	-10.6 x	31.1 x	7.5 x
NTA per share	$0.05	$0.09	$0.06	$0.09	$0.15
Pr / NTA	7.1 x	4.1 x	6.0 x	4.4 x	2.5 x

Balance sheet ($M)

Year ending Jun	2014A	2015F	2016F	2017F	2018F
Cash	1.9	5.3	2.7	3.6	7.2
Receivables	0.1	0.2	0.4	1.6	2.9
Inventories	0.0	0.0	0.0	0.0	0.0
Current Tax Assets	0.6	0.3	0.3	0.3	0.3
Current assets	**2.6**	**5.7**	**3.4**	**5.5**	**10.4**
Net PPE	0.4	0.8	1.2	1.6	2.0
Investments	0.0	0.0	0.0	0.0	0.0
Intangibles	0.0	0.0	0.0	0.0	0.0
FITB	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Non-current assets	**0.4**	**0.8**	**1.3**	**1.6**	**2.0**
Total assets	**3.0**	**6.6**	**4.7**	**7.1**	**12.4**
Debt	0.2	0.1	0.2	1.0	1.7
Provisions	0.2	0.2	0.2	0.2	0.2
Other	0.0	0.0	0.0	0.0	0.0
Total liabilities	**0.4**	**0.3**	**0.4**	**1.1**	**1.9**
Equity / reserves	25.5	33.0	33.0	33.0	33.0
Retained profits	(22.9)	(26.4)	(28.5)	(26.8)	(22.2)
Total s/h funds	**2.6**	**6.6**	**4.5**	**6.3**	**10.8**
Minorities	0.0	0.0	0.0	0.0	0.0
Total funds emp.	**0.9**	**1.4**	**2.1**	**3.7**	**5.3**

Ratio analysis

Year ending Jun	2014A	2015F	2016F	2017F	2018F
EBITDA / sales	-326%	-539%	-135%	12%	26%
EBITAg / sales	-341%	-559%	-149%	7%	21%
EBIT / sales	**-341%**	**-559%**	**-149%**	**7%**	**21%**
Return on assets	-208%	-335%	-153%	15%	59%
Return on equity	**-65%**	**-53%**	**-46%**	**27%**	**42%**

Profit and loss ($M)

Year ending Jun	2014A	2015F	2016F	2017F	2018F
Sales revenue	0.7	0.8	2.0	8.0	14.3
growth over pcp	*211%*	*13%*	*158%*	*301%*	*77%*
EBITDA	(2.2)	(4.2)	(2.7)	1.0	3.6
Dep'n and amort'n	(0.1)	(0.2)	(0.3)	(0.4)	(0.6)
EBITAg	**(2.3)**	**(4.3)**	**(3.0)**	**0.5**	**3.0**
Goodw ill amortisation	0.0	0.0	0.0	0.0	0.0
EBIT	**(2.3)**	**(4.3)**	**(3.0)**	**0.5**	**3.0**
growth over pcp		*86%*	*31%*	*118%*	*458%*
Net interest expense	0.0	0.1	0.1	0.3	0.5
Pre-tax profit	(2.3)	(4.2)	(2.9)	0.8	3.5
Tax	1	1	1	1	1
Effective tax rate	*0%*	*0%*	*0%*	*0%*	*0%*
Preference dividends	0.0	0.0	0.0	0.0	0.0
Minorities	0.0	0.0	0.0	0.0	0.0
Lodge adjustments	0.0	0.0	0.0	0.0	0.0
Lodge adj profit	**(1.7)**	**(3.5)**	**(2.1)**	**1.7**	**4.5**
Reported Net Profit pre-adj.	(1.7)	(3.5)	(2.1)	1.7	4.5
Adjustment	0.0	0.0	0.0	0.0	0.0
Reported net profit	(1.7)	(3.5)	(2.1)	1.7	4.5

Cashflow ($M)

Year ending Jun	2014A	2015F	2016F	2017F	2018F
EBIT	(2.3)	(4.3)	(3.0)	0.5	3.0
Net interest paid	0.0	0.1	0.1	0.3	0.5
Dep'n and amort'n	0.1	0.2	0.3	0.4	0.6
Tax paid	0.6	0.7	0.8	0.9	1.0
Gross cash from op'ns	**(1.6)**	**(3.3)**	**(1.8)**	**2.2**	**5.1**
(Inc) / dec in w k'g cap	0.0	(0.1)	(0.1)	(0.5)	(0.5)
Inc / (dec) in Other Liab.	0.0	0.0	0.0	0.0	0.0
Other	0.3	0.0	0.0	0.0	0.0
Operating cashflow	**(1.4)**	**(3.5)**	**(1.9)**	**1.7**	**4.7**
growth over pcp	*0.0*	*0.7*	*(0.5)*	*(0.1)*	*1.8*
Investing cashflows					
Capital expenditure	(0.4)	(0.6)	(0.7)	(0.8)	(1.0)
Asset sales	0.0	0.0	0.0	0.0	0.0
Investments	0.0	0.0	0.0	0.0	0.0
Divestments	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0
Financing cashflows					
Gross equity raised	3.4	7.5	0.0	0.0	0.0
Dividends paid	0.0	0.0	0.0	0.0	0.0
Chg in loans	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Other non-op flow s	0.0	0.0	0.0	0.0	0.0
Net chg in cash	**1.7**	**3.4**	**(2.6)**	**0.9**	**3.7**

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Expected total Return is measured as (capital gain (or loss) + dividend)/purchase price

We have divided our recommendations into three main categories:

Buy: Expected Total Return in excess of 15% over a 1 year period.

Hold: Expected Total Return between 0% and 15% over a 1 year period.

Sell: Expected Total Return less than 0% over a 1 year period.

Analyst Verification

I verify that I Marc Sinatra, have prepared this research report accurately and that any financial forecasts and recommendations that are expressed are solely my own personal opinions. In addition, I certify that no part of my compensation is or will be directly or indirectly tied to the specific recommendation or financial forecasts expressed in this report.

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