Genetic Signatures

ASX Announcement 21 December 2021

Investor Update

- Revenue projection for 1H 2022 – $21m+
- New SARS-CoV-2 Variant Detection Kit developed – specifically differentiates Delta and Omicron variants
- Europe update
- FDA clinical trial progress

Genetic Signatures Limited (ASX: GSS) is pleased to provide an update to shareholders.

Half Year Sales

Genetic Signatures has had a strong year to date and expects sales of at least $21m for the half year. First quarter sales were a company record $12.4m supported by a surge in SARS-CoV-2 testing in Australia. The recent emergence of the Omicron variant has seen testing volumes increase dramatically in the past two weeks. This increased testing will likely continue into 2022.

SARS-CoV-2 Update

At the beginning of December a new, highly transmissible SARS-CoV-2 Omicron variant was identified and classified as a variant of concern by the WHO. Genetic Signatures determined via *in silico* analysis that the current *EasyScreen*™ SARS-CoV-2 Detection Kit was able to detect all known variants, including the Omicron variant and has advised its customers.

Since then, a new detection kit has been developed, the *EasyScreen*™ SARS-CoV-2 Variant Detection Kit. This was designed in collaboration with customers to differentiate the Omicron and Delta variants prior to sequencing. Performance of the new kit has been confirmed in-house against more than 300 clinical patient samples. The new kit is being offered initially as Research Use Only and can identify mutations specific to Delta or Omicron in SARS-CoV-2 positive samples. The test can be used either in parallel with, or as a reflex test to the primary screen.

Customers have already expressed interest in using this test as an adjunct to Genetic Signatures' standard test that will allow for the prioritisation of suspected Omicron positive patient samples for genomic sequencing and epidemiological studies.

European Update

The European sales team has engaged with current and potential customers to promote the broader suite of *EasyScreen*™ products, particularly the enteric range of kits. In the September quarter the first order for enteric tests was received and GSS now has two other sites close to concluding trials of these tests with a view to adopting them. SARS-CoV-2 testing has continued, though at a slower rate, continuing the trend from 1Q FY22. This may increase in the new year as infection rates have increased in northern Europe.

Genetic Signatures seeks feedback from customers at regular intervals regarding the products, workflow and support. This exercise was undertaken in December with clients in Europe with pleasing results. The comments below from senior scientific staff in UK sites help explain why customers, once acquired, tend to remain long term customers that adopt additional tests over time.

"[What was most appealing about Genetic Signatures] for enterics was very much the platform, throughput and repertoire. This is a system which offers a flexible and comprehensive panel in a format we can adapt to a number of skill mixes and still provide results to a challenging timetable. The flexibility of the panels and the limited hands-on time have been major bonuses."

"Using the GS1-HT for our Covid -19 PCR test has allowed us to test large volumes of samples in a short time. Having a low minimum sample number requisite for a run has enabled us to prioritise certain patient pathways to ensure results are reported in a timely manner. GS-call software has made analysing and reporting results quicker. Looking through the data and studies done by Genetic Signatures, the significant drop in numbers of total mismatches after a 3base® conversion is very promising. The drop is consistent with several SARS-CoV-2 variants."

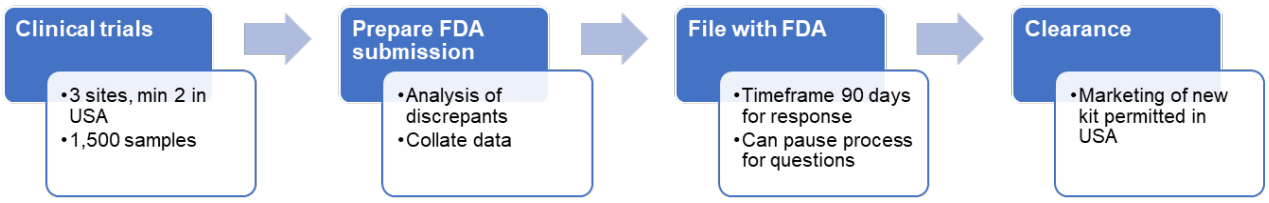
"I would recommend [Genetic Signatures] as they are a good company to work with and are always looking for ways to improve current methods to facilitate laboratory needs."

Enteric Protozoan – FDA progress

Clinical trials are a key component of any application for US FDA product clearance (510k). Genetic Signatures is required to supply data from three different clinical sites and a minimum 1,500 patient samples with the application. GSS had hoped that these trials would be completed by year end but sample collection has been hampered by laboratories being unable to source adequate numbers of samples or not having the capacity to process samples due to COVID-19 demands. The expectation is that these trials will be completed before the end of the March quarter.

The graphic below shows the remaining steps in the clearance process after which GSS can market its *EasyScreen*™ Enteric Protozoan Detection Kit.

Once clearance is achieved GSS is targeting 40% of the available market within five years of launch.



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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.