



# Biotech Daily

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*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: Genetic Signatures

**By TIM BOREHAM**

**ASX code:** GSS

**Share price:** \$1.20

**Shares on issue:** 142,907,246

**Market cap:** \$171.5 million

**Chief executive officer:** Dr John Melki

**Board:** Dr Nick Samaras (chair), Dr Melki, Dr Tony Radford, Michael Aicher (executive director), Dr Neil Gunn

**Financials (March quarter 2021):** revenue \$4.3m (Up 136%), net cash outflows \$3.43m, cash of \$32m

**Identifiable major holders:** Christopher Abbott (Asia Union Investments) 26%, Perennial Value Management 14.9%, Fidelity Investments 7.7%, Regal Funds Management 5.97%

“Cometh the hour, cometh the man” goes the saying variously attributed to William Shakespeare or The Bible.

In the coronavirus context, what better company to cometh at humanity's troubled juncture than a molecular diagnostics testing house with approved products on market?

When your columnist last appraised Genetic Signatures in November 2019, Covid-19 was but a distant bat (or pangolin) squeak in Wuhan.

As the ghastly extent of the virus became apparent, it didn't take Genetic Signatures too long to extend its testing capacity to Sars-Cov-2 (the bug that causes Covid-19).

But the Good Book\* also says: the Lord giveth and the Lord taketh away. Despite the company's undoubted progress, its stock price has retracted to close to pre-pandemic levels.

One concern held by investors is what the company's prospects look like when - not if - the pandemic recedes.

"We understand the pandemic won't be around forever - and that's a good thing," says Genetic Signatures CEO John Melki. "But testing isn't going to go away post vaccine."

Ultimately, Genetic Signatures wants to be known for its ability to use its core "3base" technology to detect a range of pathogens.

### **Assay, assay, what a great idea!**

Genetic Signatures was founded in 2001 by prominent fund manager Christopher Abbott and the late Dr Geoffrey Grigg, former head of microbiology at the esteemed CSIRO.

The company's original focus was on commercializing technology using a sodium bisulphite conversion method which, it was discovered, can be used to develop molecular assays for infectious pathogens.

Genetic Signatures sprung from CSIRO's laboratories in Sydney's North Ryde.

Dr Melki joined the company in 2003, having researched DNA and microarray technologies.

The company listed on the ASX in March 2015, raising \$7.5 million at 40 cents apiece.

The co-founder of boutique investment house Maple Brown Abbott, Christopher Abbott retains a 26 percent stake.

### **Aussie success story aces the world (no, not Ash Barty)**

Sold under the Easyscreen banner, Genetic Signatures' tests were developed (and made) in Australia and are sold in more than 30 countries.

The assays are based on the company's 3base technology, which can detect groups of organisms - up to 20 at a time - from the one patient. More than two million patients have undergone at least one 3base test.

The tests replacing the old 'sample on a slide' laboratory methods, enabling rapid screening of pathogens so that antibiotics can be swiftly dispensed (turnaround times are reduced from days to less than five hours).

## **The Covid story**

Following a regulatory submission in March 2020, a month later the company won consent to sell the tests in Europe and Australia - and wasted no time shipping them.

"We already had a pan-coronavirus test, including for 'flu and rhinovirus and we quickly modified the test to specifically pick up Covid," Dr Melki says.

"We worked incredibly hard to make sure we had stock in hand at a time of shipping disruptions and consumables shortages. We can proudly say we never let a customer down during the pandemic."

The tests also are able to detect that a patient not only does not have Covid-19, but does have a condition with the same symptoms. Dr Melki says pathology reports that 60 percent of suspected symptomatic Covid suspects had rhinovirus (that is, the common cold).

## **And the broader story...**

A feature of 3base is its ability to detect the disease regardless of the incidence of mutants. With minimal effort, labs can get five to 10 extra results by putting different assays in their work flows.

Dr Melki says testing for other infectious diseases has been overlooked during the pandemic and clients are making a big effort to catch up, especially in the US and Europe.

The Covid kits join a suite of Genetic Signatures' tests that cover 'flu and gastro enteric strains, flavivirus/alphavirus, antibiotic resistant bugs and sexually transmitted infections (STIs).

The gastro bugs tackled include the infamous norovirus, the bane of cruise operators - but not so much when so many of their vessels lie idle off the Florida coast.

Genetic Signatures' clients are hospital and commercial laboratories.

"The kits contain everything the lab needs to perform the test," Dr Melki says.

While the tests themselves are "platform agnostic", the company also provides Easyscreen-specific instrumentation to labs with higher input.

## **What's in the pipeline?**

The Covid test aside, the company has approved tests in Europe and Australia for enteric protozoan detection and antibiotic resistance.

Earlier this year, the Europeans approved a test for STIs and other genital pathogens, while local Therapeutic Goods Administration consent is pending.

One tends to overlook the 'old' diseases, but the global market for STI molecular diagnosis is worth a cool \$1.9 billion.

And they're not going away. According to an Australian Broadcasting Corp report this week, genomic sequencing has tracked syphilis outbreaks in Melbourne suburbs where the disease has not been prevalent.

Of course, the social distancing dictates of the Covid era - in theory - meant that STI rates should have declined, but we guess there's only so much Netflix you can watch.

Genetic Signatures's test, by the way, will detect not just the usual suspects of gonorrhoea and syphilis, but a broader suite of 12 organisms from the same sample.

## **Finances and performance**

The Covid test resulted in a 350 percent revenue boost in the June 2020 quarter, followed by 585 percent and 744 percent increases in the September and December quarters respectively.

Genetic Signatures then posted revenue of \$4.3 million in the March quarter of 2021, 136 percent higher than the March 2020 quarter.

And now the downbeat bit: having chalked up a maiden \$4.5 million profit in the half year to December 31, 2020, the March quarter showed cash outflows of \$3.43 million.

In late 2019, Genetic beat the capital raising rush by raising a meaty \$35 million in a placement and then \$2.5 million in an oversubscribed share purchase plan, both at 98 cents a share.

With a current cash balance of \$32 million, the company says it is well-placed to fund the intended new tests and chase US and European expansion.

International sales accounted for 24 percent of its turnover in the nine months to March 31, 2021, compared with nine percent in the 2019-'20 year.

The other way of viewing these numbers is that Australia, a relatively small market, still accounts for the lion's share of revenue.

“We were quite quick in getting regulatory approval [from the TGA] and that has underpinned the growth we have seen, not only for [Covid] but the entire respiratory portfolio such as ‘flu or rhinovirus,” Dr Melki says.

Conversely, the pandemic constrained US sales because of limited access to client sites, but kit sales are expected to “accelerate” in the current quarter.

Indeed, in December last year, Genetic Signatures announced its first US customer for the Covid (Sars-Cov-2) test followed by the second client a mere three weeks later.

Genetic Signatures shares have traded as low as 25 cents (March 2018) and as high as \$2.82 (July 27 last year).

### **Looking forward ...**

A key focus is a US Food and Drug Administration (510k) submission for the enteric protozoan kit, which can detect gastro infections.

Found in the gut of humans and other mammals, enteric protozoa are diarrhoea-inducing parasitic infections including giardia and cryptosporidium.

Like enteric bacteria and viruses, they can be found in water following direct or indirect contamination by faeces. They are hard to detect with traditional methods and can cause chronic illness.

“Our test will identify eight enteric parasites; others will do three to four of them but they might include non-parasite targets,” Dr Melki says.

The Covid curse meant the company was stymied in launching trials at three US sites to satisfy the FDA’s requirements, but the first one is now underway.

The company plans to carry out 1,500 tests across the three sites.

Dr Melki says the expected US enteric protozoan approval will be a significant moment, with the company targeting a 10 to 15 percent share of the 5.5 million of these tests done in the US annually.

As you could imagine, the need for gastro testing subsided during the Covid lockdowns but has now returned to pre-pandemic levels.

Dr Melki also reveals the company is working on a custom, next generation instrument for 3base assays.

“The pandemic has shown us that labs want to have tests that are easy to use with minimal hands-on time,” he says.

## **Dr Boreham's diagnosis:**

Dr Melki says even before the pandemic, the company's strategy centred on overseas expansion in the knowledge that Europe and the US account for 75 percent of the relevant world market (compared with one to two percent here).

"The pandemic gave us access to new customers, which fast-forwarded our sales efforts," he says.

Dr Melki attributes Genetic Signatures' share price weakness partially to some larger institutions rebalancing their holdings after the stock's strong run.

"They will do what they do and we will focus on winning global sales for our molecular diagnostics tests."

Dr Melki notes a recent spate of consolidation in the global molecular diagnostics industry, with larger companies buying smaller rivals on revenue multiples averaging 19 times.

For instance, the Nasdaq-listed women's health group Hologic in April acquired the private French-Finnish molecular diagnostics outfit Mobidiag Oy, for just over \$1 billion.

"We're frustrated [with the share price] because the company is really well-leveraged to reach our much larger customer base than 12 months ago," Dr Melki says.

"We really worked hard to increase customers base during pandemic. There's so much more to Genetic Signatures than Covid."

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort.***

***\* As an ecumenical scribe, he accepts the Good Book can also mean the Torah, the Koran, the Tripitaka or a John Grisham legal potboiler***

***Confession: the author owns Genetic Signatures shares.***