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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: 75 cents; **Shares on issue:** 266,571,206; **Market cap:** $199.9 million

Chief executive officer: Dr Neil Gunn (acting, permanent CEO Allison Rossiter starts in September 2024

Board: Dr Nick Samaras (chair), Dr Gunn, Dr Tony Radford, Michael Aicher, Caroline Waldron, Stephane Chatonsky

(Half year to December 31, 2023): revenue $3.6 million (down 65%), loss of $10.5 million ($6.48 million deficit previously)

Identifiable major holders: Christopher Abbott (Asia Union Investments) 23.5%, Perennial Value Management 12.4%, Fidelity Investments 9.7% (pre-capital raising).

Biotech investors need the patience of Job, but things are starting to happen for on a number of fronts.

This week, breast cancer diagnostics house Bcal Diagnostics launched a $10 million capital raise to support local and US market approval, while cancer drug developer Inoviq announced a breast cancer therapy breakthrough that sent the shares soaring.

After a four-year wait, parasitic diseases detector Genetic Signatures won US Food and Drug Administration (FDA) approval for its Easyscreen proprietary molecular test, which can detect eight tummy bugs (enteric protozoan pathogens) in the one assay.

The company also won approval for an associated automated workflow kit.

To support the rollout, Genetic Signatures has launched a $30 million capital raising through a placement and rights issue.

Genetic Signatures' acting CEO Dr Neil Gunn dubs the approval, the first in the US for the company, as a "momentous occasion" as it opens an addressable market of $500 million a year-plus. "This is a great moment and one to savor - it doesn't come along that often," he says.

The reason for the excitement is that the eight detectable nasties compare with three or four for the current US tests on market - so in simple terms it is at least twice as good. The eight tests also cover 90 percent of US gastro infections that afflict the US citizenry.

Dr Gunn adds that Genetic Signatures' 3base technology (see below) offers simpler workflows than the current polymerase chain reaction (PCR) DNA tests, which require a stool sample to be sent to a lab and analyzed under a microscope.

Genetic Signatures claims a reliability of 90 percent-plus, compared with around 55 percent for the standard assays.

Testing times

Genetic Signatures' smarts are based on its 3base platform, which enables syndromic (multiple) tests. These assays can detect up to 20 organisms at a time from the one patient, thus shortening the wait time from days to about five hours.

The tests replace the old 'sample on a slide' laboratory methods, enabling rapid screening of pathogens so that the right antibiotics can be swiftly administered.

Technically speaking, 3base converts the 4base microbial genome to three, with no additional steps required by the operator.

Genetic Signatures' current flagship test, Easyscreen, is approved and sold in dozens of countries but mainly in Australia, with more than five million patients tested to date.

Found in the gut of humans and other mammals, enteric protozoa are diarrhoea-inducing parasitic infections including giardia and cryptosporidium. They are hard to detect with traditional methods and can cause chronic illness.

Across the board Genetic Signatures' kits can detect more than 150 diseases across five broad categories: enteric (intestinal), respiratory, antimicrobial resistance, fungal and sexually transmitted infections. The tests can detect norovirus (the bane of cruise ships), salmonella, giardia and - lest we forget - Sars-Cov-2.

In late May this year, the company canned development of a respiratory (Covid) product for the US, citing lower testing rates and the emergence of more rival products.

Genetic Signatures' signature moves

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 Commonwealth Scientific and Industrial Research Organisation (CSIRO).

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

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

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, retained a 23 percent stake in the company ahead of the raising.

On April 30, this year, the company announced that CEO Dr John Melki would leave the building, having steered Genetic Signatures for 21 years.

His replacement, Allison Rossiter, will clock on in September. Dubbed by Dr Gunn as a "highly experienced commercially focused CEO who has sold into North America multiple times" Ms Rossiter had headed the Australian arm of Roche Diagnostics since 2019.

Dr Gunn will resume his non-executive director duties.

Sizing up the US opportunity …

In the US, an estimated 65 million parasitic infections occur each year, with 15 percent (9.7 million) resulting in a doctor's visit.

Typically, the doctor will say the cause of the infection is not clear and prescribe antibiotics.

"We estimate 5.5 million of these patients go forward for further testing," Dr Gunn says.

"Our initial target is this space and we believe we can approach a 40 percent market share over the next five years - 2.2 million tests - because we have the broadest coverage of any molecular test."

The company has been sprung like a steel trap in anticipation of the approval, with product ready and distribution channels primed.

Reimbursement-wise, Easyscreen is subject to an existing 'current procedural terminology (CPT) code, to the tune of around $US260 per test.

This means that the client labs will buy the material from Genetic Signatures and be reimbursed over and above what's on offer for current testing (microscopy tests attract reimbursement in the low teens).

The company cites an indicative selling price of $US60 test, which accrues fully to the company as it runs an in-house sales channel and thus does not have to share the spoils with other parties.

The figure is derived from a 'bottom up' assessment of what are likely to be willing to pay, combined with a 'top down' appraisal based on reimbursement levels.

… segment by segment

The company says the US market falls into four segments: the large commercial labs, the large hospital networks, specialty labs and independent hospitals.

While the mega lab chains such as Quest and Sonic will "drive the needle" on sales growth'; eventually, Genetic Signatures initially will focus on nine 'customer experience' sites: laboratories that have been working with the company but have not been able to buy the hitherto unapproved tests.

Seven of these labs are definitely on board, so the next step is for the company to negotiate volume-related contracts with them.

"We hope to convert these initial labs within 60 to 90 days of launch," Dr Gunn says, adding that a number of large hospital chains have also expressed interest.

Genetic Signatures is also eyeing the market for unapproved 'lab developed' tests, which involve the laboratory buying the separate components such as enzymes, buffers and probes and developing their own tests to run on a PCR instrument.

Laboratory developed tests are intended to be designed, manufactured, and used within a single laboratory that meets stipulated quality requirements.

"These have been known for years and have a very important place where there is no other test available," Dr Gunn says.

"However, the FDA has been pushing for additional enforcement and this year declared that lab-developed tests should transition to FDA-cleared tests if one is available."

In effect it will be just as easy for the labs to adopt an approved test - such as Easyscreen - rather than develop their own.

Currently, the company makes its tests at its Sydney North Ryde facility, which boasts high capacity "as was evidenced during the pandemic".

The company also has its own US warehouse and distribution capacity and is likely to open 'fill and finish' manufacturing facilities there.

Finances and performance

The capital raising is by way of a $6 million placement and a $24 million non-renounceable, accelerated rights issue, on the basis of one share for every 5.82 held.

The price is 75 cents, a shade (2.7%) above the 73 cents closing price before the shares went into trading halt on May 31.

The fully underwritten raising will take Genetic Signatures' cash kitty to $50.3 million – more than enough to fund the US rollout.

Dr Gunn expects the company to become cash-flow positive "in a couple of years".

Investors will be relieved to know the company has no plans for a further raising, having also pulled in $15.9 million in January this year by way of a rights issue at 37 cents a pop.

Genetic Signatures' March (third) quarter revenue of $1.7 million was 15 percent below the previous corresponding quarter, owing to reduced respiratory kit sales, here.

Of the total turnover, 84 percent derived from Australia.

This week, Dr Gunn said local respiratory sales are going well in a "difficult" season - difficult for the patients, that is, because respiratory infections are running at elevated levels.

In its record year to June 2022, the company posted revenue of $35 million.

Genetic Signatures shares were up as much as 10 cents or 13.3 percent to 85 cents after the trading halt was lifted on June 6.

Prior to that, the shares had traded in a 12-month range of 41 cents (January 2 this year) to 76 cents (May 22 this year).

The shares peaked at $2.59 in July 2020, when the company's Covid tests were walking off the shelves.

Dr Boreham's diagnosis

Dr Gunn dubs the company's US push as "ambitious and bold" because management decided on a never-before-attempted approval strategy based on the eight most clinically significant targets.

"They went with a very difficult study plan and achieved it, which was brave and bold and strategically very smart."

With the company on the verge of boosting its revenue fourfold and achieving profitability, the gamble certainly paid off.

While investor attention will focus on the rollout in the Land of the Free and Diseased, Dr Gunn says the company's ambitions don't stop there.

"I suspect with the FDA clearance, certain jurisdictions in Europe, the Middle East and Africa will pay [us] a lot of attention," he says.

"Beyond that, we are not stopping.

"We are investing in research and development and leveraging the 3base technology to bring on new detection kits."

In particular, the company plans to reactivate a 'next-generation' instrument, which was on hold to preserve cash.

The 'sample-to-result' gizmo is capable of running 400 samples per shift, even with mixed specimen types.

"We have a unique opportunity in a market that uses older technology," he says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He likes to think of himself as brave and bold and strategically very smart but others might not agree.