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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: $1.025

Shares on issue*: 119,648,477

Market cap: $122.6 million

Chief executive officer: Dr John Melki

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

Financials: (September quarter): revenue $1.53 million, loss of $1.27 million, cash balance $4.93 million***, estimated December quarter outflows $3.5 million.

Identifiable Major Holders**:** Christopher Abbott (Asia Union Investments) 31%, Karst Peak Capital 16%, Perennial Value Management, Regal Funds Management.

***** Shares on issue include 15,589,040 shares issued on November 4 as tranche one of the $35 million placement. A further 20,125,246 shares are due to be issued on December 12
****** Phillip Isaacs resigned from the board as of the November 22 AGM. A search for a replacement is underway
******* Ahead of $37 million placement and share purchase plan
******** The Perennial and Regal stakes are not known until the second tranche of the raising is completed.

As the saying goes, if you can make it in New York you can make it anywhere. But for the home-grown molecular diagnostics house, cracking it in Australia has been the acid test of its greater abilities.

“The Australian diagnostic market is the hardest in the world,” says Genetic Signatures chief Dr John Melki.

“It is highly competitive. Rebates are the lowest in the world and pricing is similar to that in Vietnam.”

What’s more, the big three local pathology providers account for 60 to 70 percent of the market - a concentration you do not see elsewhere.

A provider of all-in-one testing for range of bugs, Genetic Signatures is further frustrated by the Medicare reimbursement coding system. That’s because the current rules only allow funding for three tests, but the company might test for 20 diseases in one go.

Despite these trips and traps, Genetic Signatures has gleaned a 10 to 25 percent share of the local market, which in the 2018-’19 year accounted for 97 percent of its revenue.

“We are incredibly proud of what we have done in Australia,” Dr Melki says. “But we are only one or two percent of the world market while the US and Europe account for 75 percent.”

To achieve its offshore ambitions, the company has just raised a meaty $35 million in a share placement that saw Perennial Value Management come on as a cornerstone holder.

The raising was also supported by existing holder Regal Funds Management and an unnamed offshore institution.

Genetic Signatures retail holders have now been invited to fill their boots for up to 30,000 shares ($29,400 worth) at the 98 cents a share offer price (the same as the placement price).

The story to date

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.

Dr Melki joined the company in 2003, having researched DNA and microarray technologies. He was awarded the Sydney University Peter Bancroft Prize in 2001.

Genetic Signatures 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 has a 31.7 percent stake.

He is also not on the board and lets management get on with the job, much to the envy of certain other biotechs with pesky major shareholders.

Bug off!

In short, Genetic Signatures tests for rapid screening of pathogens so that the appropriate antibiotic or treatment can be swiftly dispensed.

The tests replace old lab methods such as the ‘stool on a slide’ under a microscope and can be done in hours rather than days.

Dr Melki says the 3-base test can be used with urine samples or swabs for STIs, throat swab for respiratory disease or stools for gut problems and the test reads out the presence of target pathogens. This is especially appealing to hospitals as they grapple to control antibiotic-resistant bugs.

The company’s Easyscreen tests are based on the company’s 3-base technology, which allows for faster and more accurate diagnosis of a number of ailments.

The existing tests cover ‘flu and gastro enteric strains, flavivirus and alphavirus, antibiotic resistant bugs and sexually transmitted infections (STIs).

The most advanced product Easyscreen Enteric tests for 20 tummy bugs including norovirus, the bane of many a cruise ship.

How the tests work

Glad you asked.

The tests take the genetic information of the targeted organism and change the genetic sequence to make it easier to detect.

As the name implies, 3-base converts the original four-base microbial genome to three, which reduces the variables from more than one million to a mere 60,000 or so.

All readers really need to know is that it reduces pathology turnaround times from five days to less than five hours.

“We can do what no-one else can,” Dr Melki says. “For example, we can look for 20 causes of gastro and do 200 tests at a time.”

Seal of approval

The company’s kits are approved in Australia and Europe and are sold in 30 countries, with more than 500,000 patients treated to date.

The current tests are for a range of gastroenteric and respiratory bugs (notably the ’flu) and antibiotic resistant superbugs.

The company expects to lodge applications for STIs and other genital pathogens and flavovirus and alphavirus in Australia and Europe, with a view to selling in 2020.

A submission to the US Food and Drug Administration for enteric protozoan testing is also imminent, also with a view to launching the tests there in 2020.

Found in the gut of human 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. Sydneysiders may recall the water contamination crisis in 1998 when they were forced to boil their drinking water.

“Essentially they can be hard to detect with traditional methods and can cause chronic illness,” Dr Melki says.

Genetic Signatures is targeting a 10 to 15 percent share of the 5.5 million enteric protozoan tests done in the US annually.

In the US, the company is already allowed to sell analytical spectrum re-agents, in effect ingredients to be incorporated in tests that are self-developed by the labs.

In Europe, the company has assembled a small sales force for a concerted push into that market, targeting path labs with mid to high throughout.

Dr Melki says Europe is moving to a higher standard of testing, which raises the bar in terms of registration requirements.

Given Genetic Signatures products are grandfathered from the new requirements, this should work in the company’s favor.

Finances and performance

Dr Melki says he is “absolutely delighted” by the $35 million raised, with the prospect of another $2 million to come.

Of this amount, $10 million will be used to expand the company’s sales force from 13 staff to 36, with $6 million earmarked for clinical trials.

A further $5 million will be spent on new customer installations.

Genetic Signatures recorded record third (September) quarter revenue of $1.53 million, 54 percent better than a year previously. The company also made a $1.27 million loss.

In the year to June 2019, Genetic Signatures generated revenue of $4.9 million, 75 percent higher and with a $3.5 million deficit.

Genetic Signatures revenues derive from a mix of capital equipment and consumables, a.k.a the 'printer and cartridge' model.

Customers can use their own diagnostics or buy their own hardware and in some cases it's worthwhile for Genetic Signatures to fund this capital equipment.

Dr Boreham's (non-molecular) diagnosis:

Genetic Signatures revenue has grown steadily from a standing start in 2014. But as this business is almost entirely derived locally, the European push should boost turnover, meaningfully.

The company doesn't exactly have the field to itself, in that it competes with other molecular diagnostics outfits as well as the traditional lab assays.

Dr Melki says the nearest rival is the South Korean molecular diagnostics testing house Seegene, which is active in the Europe but not the US. Listed on the South Korean exchange, Seegene is valued at around $700 million.

Genetic Signatures revenues are influenced by the severity or otherwise of the influenza season, which was a good one this year as it started early.

(Not good for the sufferers of course).

The beauty of a Northern Hemisphere business is that the 'flu seasons don't align with Australia's which smoothes out revenues over the year.

With a cabal of deep-pocketed backers and a strong record of customer retention, there's no reason why Genetic Signatures shouldn't prevail in the battle of the bugs on the global stage.

Let's not forget the Australian market accounts for a little more than one percent of the world's $US7.6 billion molecular diagnostics market.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He would also be "absolutely delighted" to diagnose $35 million if anyone is offering.