



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Proteomics International Laboratories

By TIM BOREHAM

ASX code: PIQ

Share price: 52 cents

Shares on issue: 92,405,875

Market cap: \$48.05 million

Chief executive: Dr Richard Lipscombe

Board: Terry Sweet (chairman), Dr Lipscombe, Roger Moore, Paul House

Financials (12 months to June 30, 2020): revenue \$1.9 million, loss of \$1.74 million, cash on hand \$2.36 million, quarters of available funding: three

Major identifiable holders: Dr Lipscombe 19.54%, John Dunlop 4.17%, Xylo Pty Ltd (The Parker Family) 3.25%, Sparrow Holdings (Sweet super fund) 2.53%.

Proteomics chief executive Richard Lipscombe adheres to a simple but elegant dictum: "If you can predict earlier, you can intervene earlier."

With earlier detection, patients can go on a drug earlier at a lower, safer dosage or perhaps be treated with something more novel.

In the case of the Perth-based diagnostics house, the key aim is to prevent millions of cases of diabetes turning into diabetic kidney disease (DKD).

Sufferers face two outcomes and neither is attractive: an organ transplant or a (shortened) life on dialysis.

After years of development Proteomics key product Promarker D is now “revenue ready”, having been simplified into a product that client labs can use more easily.

A blood test, Promarker D also has Conformité Européenne (CE) mark approval for diabetic kidney disease prediction and the company is also eyeing assent from the US Food and Drug Administration.

“We had a viable test some years ago, but discovered it was too complex for everyday lab use,” Dr Lipscombe says. “We took a decision to re-engineer it and we have done that without any loss of performance.”

Proteomics explained

Proteomics is the art of mapping the structure and function of proteins that, unlike genes, differ from cell to cell. Promarker D is about identifying “biological fingerprints”. The objective is to find a fingerprint to distinguish one individual with the disease from one who isn’t afflicted.

While diabetic kidney disease remains the company’s key focus, Promarker D is based on a platform technology and can be used in other life sciences, veterinary health and agriculture applications.

Proteomics currently earns its revenue from analytic services to support clinical trials.

For example, Proteomics is engaged by A2 Milk to check that all of its cow juice sold in Western Australia contains the A2 protein and is not tainted by the A1 variety.

Proteomics was spawned from the University of Western Australia (UWA) and then listed in April 2015, having raised \$3.1 million at 20 cents apiece.

Proteomics activities are based at Perth’s Harry Perkins Institute of Medical Research, which boasts the first laboratory in the world to receive international standards accreditation for proteomics services.

Dr Lipscombe and fellow company founder, the late Dr Bill Parker, worked on protein analysis at UWA.

Dr Lipscombe says choosing diabetes was a no-brainer: it’s a widespread disease, with 260 million folk affected today and 700 million likely to be affected within 20 years if the trends endure.

While diabetes doesn't kill anyone, the knock-on effects certainly do, including loss of eyesight, cardiovascular disease and amputations ... and kidney damage.

One in three diabetics will develop diabetic kidney disease, but the existing urine-based tests are not effective.

It doesn't help that kidney disease is a silent killer: you can lose 20 percent of kidney function and feel a bit lethargic, but with no other prior symptoms.

Paradoxically, healthy people can give 50 percent of their kidney function away by donating one of the organs (such as Kerry Packer's generous helicopter pilot).

But once a kidney is 15 to 20 percent damaged it's not repairable and there's only one path: dialysis or a transplant and with the former you can expect to live another five years - even if you are a billionaire.

3,000 patients can't be wrong

Proteomics has long partnered with the University of WA's medical school, which has been carrying out one of the world's biggest diabetes trial (the Fremantle study).

A four-year validation study of 792 patients showed Promarker D was able to predict, with 86 percent accuracy, the incidence of disease-free candidates going on to develop the ailment.

These results have now been vindicated by a global study carried out in collaboration with Janssen Research and Development, an arm of Johnson & Johnson.

The study showed the patients predicted by Promarker D to be at high risk of diabetic kidney disease were 13.5 times more likely to develop it than patients classed as low risk.

"Importantly, the [data] confirms previous findings that Promarker D is able to correctly predict a clinically significant decline in kidney function up to four years in advance," Dr Lipscombe says.

Janssen is testing the efficacy of its drug Invokana (canagliflozin) to treat diabetic kidney disease (DKD). In 2018 the FDA approved the drug to reduce the risk of cardiovascular events among type two diabetes sufferers.

"It's an exciting area. There are a lot of drugs on trial for DKD and it's fantastic from the point of view of what we can do with DKD," Dr Lipscombe says.

But he adds: "It's one thing to be diagnosed, but it's good to know there's a treatment."

The second stage of the testing involves using the diagnostic to gauge the actual efficacy of the drug.

The path to commercialization

Dr Lipscombe dubs the company “revenue ready”, with some initial licencing deals in test markets.

The company initially will focus on commercial laboratory clients, especially in the US, with the test integrated into the labs’ standard panels.

“Having got the tech into a simple-to-use immune assay format, we are in dialogue with a number of groups about getting that test available,” he says.

“In parallel with that, we would look at FDA approval for the kit version.”

He says there’s also the opportunity to provide the “platform agnostic” tech to diagnostic device makers such as Siemens or Roche.

“We are exploring and engaging in a number of avenues, from the manufacturers of the instruments for the pathology labs to the labs themselves.”

Geographically, the company is targeting the US, Europe and Japan. While the US leads the way with 30 million type 2 diabetes sufferers, Japan has 10 million despite the nation’s famed healthier, fish-based diet.

“We are looking at these markets from an informed perspective in terms of where we want to go and why,” Dr Lipscombe says.

Covid-19 and other catastrophes

The company’s prospective pipeline includes tests for endometriosis, giardia, cancers and perhaps even Covid-19.

Endometriosis is abnormal growth of the uterine lining outside the uterus. It’s very hard to diagnose, via laparoscopy (minimally invasive surgery).

A proof-of-concept study yielded “significant results” and the company is eyeing a larger study.

Some cancers lend themselves to protein-based testing, others to genetic based (such as prostate and breast).

“We are looking at applying the newer technologies and have moved to the point of maturity where they can be successfully applied to a range of diseases,” Dr Lipscombe said.

And yes, the platform could potentially be applied to detecting and/or predicting the presence of Sars-Cov-2.

Armed with a \$200,000 grant from the Western Australian Covid-19 grants program, the company is mulling a saliva-based test to replace the current method that involves a sadistic* nurse and a deep nasal swab.

These tests are also complex for laboratories to handle.

The second leg of the Covid-19 work involves isolating a protein “fingerprint” biomarker that may explain why some sufferers breeze through the disease with nary a symptom, while others are far less fortunate.

“There must be a difference in their biological makeup that’s responsible for that,” Dr Lipscombe says.

The research is being carried out in alliance with the University of Western Australia’s respiratory physicians. To date, the work has been stymied by a lack of subjects in the Western Australia bubble - but “developments in Melbourne have made the projects more achievable”.

Finances and performance

The reality of the health system is that a diagnostic tool will only gain traction if the proponent can demonstrate a bottom-line benefit to the health funders.

In the US the company is eyeing a minimum price of \$US55 (\$A76) per test, based on existing reimbursement codes.

But the company is pushing for its own more generous CPT (current procedural terminology or reimbursement) code, in which case a much higher per-test price is possible.

Health insurers are acutely aware that dialysis costs an average \$US72,000 per patient per year.

“The benefits to the patients and benefits to the healthcare system are going to be massive,” Dr Lipscombe enthuses.

Meanwhile, Proteomics has a modest cash balance of \$2.37 million as of June 30, having raised \$3 million late last year.

The company spent \$3 million on research and development in the 2019-20 year, with revenue of \$1.5 million. “We are on a similar trajectory this year,” Dr Lipscombe says.

He says the company is fully-funded for the next 12 months and will only raise more for “strategic” reasons.

Mind you, the market’s amenable to life science companies passing the hat around.

“There seems to be quite a few pennies thrown around. I won’t pass comment on the wisdom of that in some cases,” Dr Lipscombe says.

Proteomics has a tightly held register, with Dr Lipscombe accounting for just under 20 percent and his fellow directors a further four percent or so.

Proteomics shares have traded between 15 cents (June 1, 2017) and 68.5 cents (August 5, 2020).

Dr Boreham’s diagnosis:

An obvious question is why no-one has developed an effective predictive test for diabetic kidney disease until now.

“The reality is, it's not simple to find out what's going on,” Dr Lipscombe says. “Diabetes is a complex condition and there are a lot of confounding variables.”

Large studies are required to screen out markers for other diabetes complications such as cardio vascular disease.

The recent on-market performance of Volpara Health Technologies, Genetic Signatures and the freshly listed Atomo Diagnostics shows what can happen when a company gets a diagnostic product to market.

In another comparison, kidney diagnosis house Renalytix recently raised \$US80 million to list on the Nasdaq and now has a \$US1.02 billion market valuation. The company has no approved products.

In short, now’s the time for Proteomics to get a wriggle on.

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

* Rest assured, 99 out of 100 nurses are lovely caring people, but your columnist got Nurse Ratched on a bad day