



Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: Proteomics International Labs

By **TIM BOREHAM**

ASX code: PIQ

Share price: \$1.02; **Shares on issue:** 130,892,616; **Market cap:** \$133.5 million

Managing director: Dr Richard Lipscombe (co-founder)

Board: Neville Gardiner (chair), Dr Lipscombe, Roger Moore, Paul House, Dr Robyn Elliott

Financials (March quarter 2024): receipts \$173,000, operating cash outflows \$1.975 million, cash on hand \$9.04 million, quarters of available funding: 4.6

Major identifiable holders: Dr Lipscombe 12.54%, FIL Ltd (Fidelity) 6%, Dunlop family 2.95%

Having served as Proteomics chief since he-co founded the company in 2001, Dr Richard Lipscombe is used to setbacks and delays.

On March 18, Proteomics said it would not be able to meet the June 2024 timeline for the US launch of its Promarker D test, to detect likely onset of the debilitating diabetic kidney disease (DKD).

"The complexities involved in bringing a new test into broad clinical use have meant the process is taking longer than expected," the company intoned.

The shares tumbled 30 cents, or 24 percent, but a sanguine Dr Lipscombe is happy to play the long game and not rush and release a substandard test.

“It’s taken a bit longer than our initial three-to-five-year plan [to bring the test to market],” he says. “In the scheme of things a few months won’t matter.”

Strictly speaking, it’s up to the company’s US distribution partner, Sonic Healthcare US, to iron out the glitches. Given the US arm of the ASX-listed Sonic Healthcare is the third-biggest US pathology chain, one would expect the company to find a way.

Ultimately, investors decided the product launch was a postponement - not a Qantas ‘ghost’ flight that would never arrive - and the shares partially recovered.

About Proteomics (the science)

Proteomics refers to mapping the structure and function of proteins that, unlike genes, differ from cell to cell and change levels over time.

Promarker D is about identifying “biological fingerprint” protein biomarkers via a simple blood test. The objective is to find a fingerprint to distinguish one individual with the disease from one who isn’t afflicted.

One in three adults with diabetes already have diabetic kidney disease (DKD) and about 10 percent of ‘healthy’ diabetics will go on to develop the disease in the next four years.

The trouble is, the existing tests, eGFR and ACR, can only detect chronic kidney disease once it is present. Patients face the choice of a kidney transplant (if they’re lucky) or a shortened life on dialysis.

eGFR is the estimated glomerular filtration rate, a simple blood test based on levels of creatinine (a waste product), age and sex.

ACR stand for albumin creatinine ratio and detects elevated levels of the protein albumin in urine (a marker of kidney damage).

“Over their lifetime a majority of diabetics will progress to DKD, it’s a question of when,” Dr Lipscombe says. “The purpose of Promarker D is to test the broad-based diabetes population and catch these people before they progress.”

About Proteomics (the company)

Proteomics International was established in 2001 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, and boasts the first laboratory in the world to receive international standard 17025 accreditation for proteomics services.

Dr Lipscombe and fellow company founder, the late Dr Bill Parker, previously worked together on protein analysis at the University of Western Australia (UWA).

The duo formed the company with rented space at Murdoch University and UWA.

Promarker D is running as a lab-developed assay in the US, the idea being the test can be integrated into the standard panels of the commercial labs.

The test is also registered under the Conformité Européenne (CE) mark regimen and with the UK Medicines and Healthcare Products Regulatory Agency. In the UK, it has a distribution licence with Apacor Ltd.

Under the five-year Sonic deal announced in May 2023, Sonic pays for marketing and development costs and Proteomics receives royalties.

Proteomics also has a compact with Omics Global Solutions, covering Puerto Rico, the Dominion Republic and Chile.

In January this year, the company announced the test had won crucial US Medicare/Medicaid reimbursement of \$US390.75 (\$A590) per test (to be exact). Based on early market assessments, management had expected a price of \$US150 to \$US200.

The company hasn't been so lucky on its home turf: in September 2023, the Therapeutic Goods Administration knocked back approval "primarily due to changes to manufacturing".

Canvas-ing some pleasing results

The company's key claim is that Promarker D can predict diabetic kidney disease up to four years earlier than the standard-of-care, thus enabling doctors to prescribe therapies earlier.

This is based on samples across 5,000 patients, in multiple four-year studies.

The initial work was with the University of Western Australia's medical school, which has been carrying out one of the world's biggest diabetes trials (the Fremantle study).

Covering almost 800 patients, the four-year validation study showed Promarker D was able to predict - with 86 percent accuracy - the incidence of disease-free candidates going on to develop the ailment.

The results were confirmed in the 'Canvas' multi-centre, retrospective study, which assayed 3,568 participants in a collaboration with Janssen J&J Clinical (an arm of Johnson + Johnson).

The results also showed that 98 percent of patients in the 'green zone' - those with a low risk of developing DKD - indeed did not progress to the disease. This raises the prospects of them not being put on drugs unnecessarily.

“These are long term studies run over several years so we have a lot of data to back up our statements,” Dr Lipscombe says.

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

Speaking of the latter, this month the company disclosed a collaboration with Curtin University’s Crop and Disease Management Centre to improve understanding about how die-back affects plants.

A better diagnosis for endometriosis

Proteomics’ progress on a test for endometriosis is not far behind the Promarker D program, with hopes for commercialization sooner rather than later.

The assay, called Promarker Endo, would be the world’s first diagnostic blood test for the painful condition, caused by uterus tissue growing into another organ.

Globally, endometriosis affects about 10 to 20 percent of women. Diagnosis takes an average 7.5 years and requires a laparoscopy, costing \$US2,000 to \$US3,000, which involves a camera inserted in a cut in the abdominal wall and a biopsy obtained.

A prototype test identified 90 percent of patients with the disease. Working with Melbourne’s Royal Women’s Hospital and the University of Melbourne, the company has analyzed about 1,000 samples.

Dr Lipscombe says diagnosis takes so long because doctors are unwilling to recommend risky laparoscopies or – shamefully - patients are not believed (especially teenage girls).

“The data we have is as good as we have seen from anyone who claims to detect endometriosis,” Dr Lipscombe says.

Oesophageal cancer

Also in advanced development, the Promarker Eso test targets oesophageal adenocarcinoma and the non-malignant cancer precursor Barrett’s oesophagus.

Named for Australian thoracic surgeon Dr Norman Barrett, the conditions affect one to two percent of Western populations and is often caused by severe gastric reflux.

These cancers account for one in 20 of cancer mortalities globally and sufferers have a five-year average survival rate of only 20 percent.

Promarker Eso identified 90 percent of people with - or without - the disease. “We have nice data on several hundred patients,” Dr Lipscombe says.

Currently, diagnosis requires a specialist endoscopy at a cost of around \$US2,700.

The size of the DKD prize

There are about 32 million diabetes sufferers in the US, of whom 20 million know they have diabetes and are - or should be - regularly tested. More than 90 percent are type 2.

Sonic accounts for about 10 percent of the US market, which implies two million tests reimbursed at \$US390 per test or \$US780 million in total.

The company has guided to royalties being in the five to 15 percent range, which at the mid-point implies annual royalties of \$US78 million.

Bear in mind, the test is not a 'one-off' and at-risk diabetics should be tested every one to two years.

Dr Lipscombe adds a similar number of pre diabetics who will move into the type 2 diabetes 'club' in the next two decades.

Finances and performance

In January 2024, Proteomics went to the well for \$6.5 million, in an institutional placement struck at 76 cents per share, a 16.5 percent on the last closing price.

The company's largest holder, Dr Lipscombe agreed to sell down \$2 million of shares to minimise the dilutionary impact of issuing shares.

The receipts from customers for the three months to March 31, 2024, of \$173,000 were gleaned from analytical services, such as pharmacokinetic testing for drug companies.

Dr Lipscombe still accounts for about 12 percent of the register, with other directors holding a further 14 percent. Fundie Fidelity holds six percent, having joined via the entitlement offer.

Over the last 12 months, Proteomics shares have traded between 73 cents (August 2023) and \$1.34 (March 2024). Since listing the shares have traded between 15c (May 2017) and \$1.34 (February 2024).

Drug optimism

While the diabetes trends are ominous, at least the drugs to treat diabetes and chronic kidney disease have improved.

In September last year, the FDA approved the SGLT2 inhibitor empagliflozin, sold by Boehringer Ingelheim under the Jardiance brand.

This was for the new indication of adults with chronic kidney disease, at risk of progression without necessarily having type 2 diabetes or heart failure.

About 50 to 60 percent of kidney disease is caused by diabetes.

Semaglutides such as the diabetes-turned-weight-loss drug Ozempic show great promise as a treatment for advanced diabetes-related kidney damage.

Ozempic's manufacturer, Novo Nordisk launched a 3,500-patient trial in 2019. The blinded study was meant to have gone for five years, but it was so effective it was stopped (continuing the trial would have been unfair on those in the placebo arm).

"It's highly likely that drug will get indicated for DKD," Dr Lipscombe says.

Dr Boreham's diagnosis:

Globally, diabetes affects 260 million people today and 700 million likely to be affected within 20 years as Western diets (a.k.a. Big Macs) replace healthier traditional fare.

In Australia, there are about 1.5 million diabetics - about five percent of the population.

Sadly, even if the test wins TGA approval it is unlikely to be sold here because Medicare reimbursement would pale in comparison with the US rate.

"It is frustrating, given the test was developed here and will be available in other markets well before Australia," Dr Lipscombe says.

The company faces similar issues with the socialised European health systems, although the bigger markets of Germany, France and Spain remain promising.

Still, if the crucial US foray succeeds, more Proteomics tests will flow across broader geographies.

"The platform is very versatile and there will be more [products] coming," Dr Lipscombe says."

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